

SYNLOGIC, INC.

FORM 8-K/A (Amended Current report filing)

Filed 09/26/17 for the Period Ending 08/25/17

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

FORM 8-K
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 25, 2017

SYNOLOGIC, INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37566
(Commission File No.)

26-1824804
(IRS Employer Identification No.)

Synlogic, Inc.
200 Sidney St., Suite 320
Cambridge, MA 02139
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (617) 401-9947

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Explanatory Note

On August 28, 2017, Mirna Therapeutics, Inc., a Delaware corporation now known as Synlogic, Inc. (the “Company”) completed its merger with privately-held Synlogic, Inc. (“Private Synlogic”) in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated May 15, 2017, whereby one of the Company’s wholly owned subsidiaries merged with and into Private Synlogic, with Private Synlogic surviving as the Company’s wholly owned subsidiary (the “Merger”). In connection with the Merger, the Company changed its name from Mirna Therapeutics, Inc. to Synlogic, Inc.

On August 28, 2017, the Company filed a Current Report on Form 8-K (the “Original Form 8-K”) reporting, among other items, the consummation of the Merger. This Amendment No. 1 to Current Report on Form 8-K amends the Original Form 8-K to include the historical audited and unaudited financial statements of Private Synlogic and the pro forma condensed combined financial information required by Items 9.01(a) and 9.01(b) of Current Report on Form 8-K that were excluded from the Original Form 8-K in reliance on the instructions to such Items.

Item 8.01 Other Events

For the general information of investors, the Company is filing herewith information that was previously disclosed as part of the prospectus contained in the Form S-4 registration statement (File No. 333-218885) relating to the Merger, as declared effective by the SEC on July 13, 2017. Specifically, filed herewith as Exhibits 99.1 and 99.2, respectively, are excerpts of the “Synlogic Business” and “Risk Factors” sections thereof, which are incorporated by reference herein. Such information is as of July 13, 2017 (unless an earlier date is indicated).

Item 9.01. Financial Statements and Exhibits.

(a) Financial statements of business acquired.

The audited financial statements of Private Synlogic as of and for the years ended December 31, 2016 and 2015, are filed herewith as Exhibit 99.3. The unaudited financial statements of Private Synlogic as of June 30, 2017 and for the three and six months ended June 30, 2017 and 2016, are filed herewith as Exhibit 99.4. The consent of KPMG LLP, Private Synlogic’s independent registered public accounting firm, is attached as Exhibit 23.1 to this Amendment No. 1 to Current Report on Form 8-K.

(b) Pro forma financial information.

The unaudited pro forma condensed combined financial information of the Company and Private Synlogic as of and for the year ended December 31, 2016 and as of and for the six months ended June 30, 2017 are filed herewith as Exhibit 99.5.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
23.1	Consent of KPMG LLP, Private Synlogic’s independent registered public accounting firm
99.1	“ Synlogic Business ” section excerpt from Registration Statement
99.2	“ Risk Factors ” section excerpt from Registration Statement
99.3	Audited financial statements of Private Synlogic as of and for the years ended December 31, 2016 and 2015
99.4	Unaudited financial statements of Private Synlogic as of June 30, 2017 and for the three and six months ended June 30, 2017 and 2016
99.5	Unaudited pro forma condensed combined financial information of the Company and Private Synlogic as of and for the year ended December 31, 2016 and as of and for the six months ended June 30, 2017

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 hereunto duly authorized.

SYNLOGIC, INC.

By: /s/ Todd Shegog

Name: Todd Shegog

Title: Chief Financial Officer and Secretary

Dated: September 26, 2017

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Synlogic, Inc.

We consent to the incorporation by reference in the registration statements (Nos. 333-207299 and 333-210466) on Form S-8 of Synlogic, Inc. (formerly known as Mirna Therapeutics, Inc.) of our report dated June 19, 2017, with respect to the consolidated balance sheets of Synlogic, LLC as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, contingently redeemable preferred units and equity, and cash flows for the years then ended, which report appears in the Form 8-K/A of Synlogic, Inc. dated September 26, 2017.

/s/ KPMG LLP
Cambridge, Massachusetts

September 26, 2017

The following is an excerpt of portions of the prospectus contained in the Form S-4 registration statement (File No. 333-218885) as declared effective by the Securities and Exchange Commission on July 13, 2017. Such information is as of July 13, 2017 (unless an earlier date is indicated).

SYNOLOGIC BUSINESS

Overview

Synlogic™ is pioneering the development of Synthetic Biotic™ medicines: a novel class of living medicines intended to treat a broad range of human diseases, ranging from genetic and acquired metabolic disorders to inflammation and cancer. Synthetic Biotic medicines are generated from Synlogic's proprietary drug discovery and development platform. Synlogic applies the principles and tools of synthetic biology to engineer beneficial probiotic bacteria to perform or deliver critical therapeutic functions, compensating for missing or damaged pathways in patients with these serious diseases. As living medicines, Synthetic Biotic medicines are designed to sense a local disease context within a patient's body and to respond by metabolizing toxic substances or delivering combinations of therapeutic factors.

Synlogic's initial focus is on metabolic diseases with potential to be corrected following oral delivery of a living medicine to the gut. This includes a group of rare genetic diseases called inborn errors of metabolism ("IEMs"), as well as acquired metabolic diseases caused by organ dysfunction:

- Patients with certain IEMs are born with faulty genes that block the transformation of food into energy or prevent the elimination of toxic byproducts of metabolism.
- Patients with acquired metabolic diseases have similar defects in the metabolism of food, but these defects arise due to the impaired function of organs responsible for food metabolism, such as the liver.

In patients with these diseases, byproducts of failed metabolism can accumulate to toxic levels and cause serious health consequences throughout the body. Synthetic Biotic medicines are designed as oral therapies to act in the gut to convert toxic metabolites into non-toxic byproducts and, as a result, reduce toxic metabolite levels in the systemic circulation and tissues. Synthetic Biotic medicines are engineered to clear toxic metabolites specific to each metabolic disease and have the potential to provide meaningful benefits to patients suffering from these debilitating conditions.

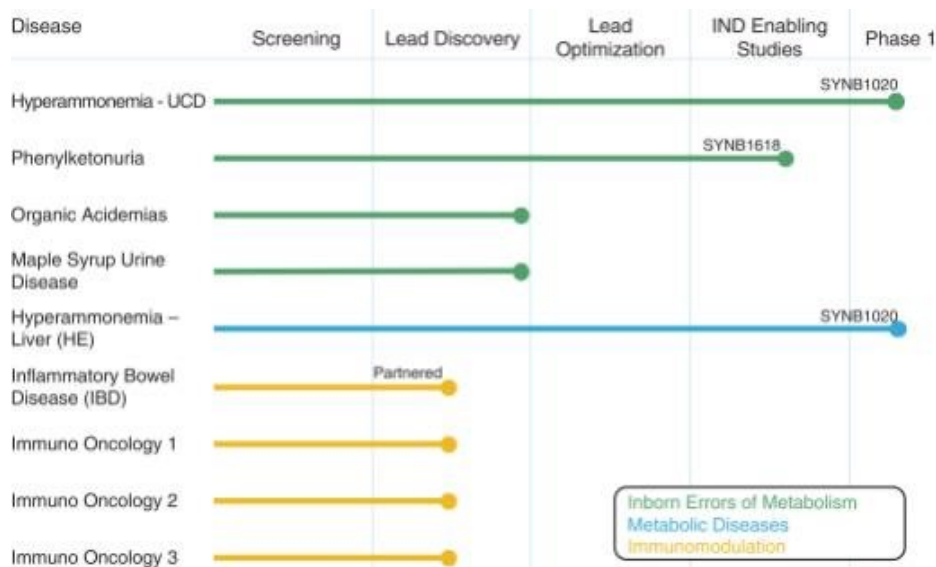
Synlogic initiated a Phase 1 clinical trial for its lead Synthetic Biotic program, SYN1020, in June 2017. SYN1020 is in development as an oral treatment for patients with hyperammonemia. In patients with hyperammonemia, ammonia accumulates in the body and becomes toxic leading to neurocognitive crisis and risk of long-term cognitive or behavioral impairment, coma, or death. Hyperammonemic conditions include a group of IEMs known as Urea Cycle Disorders ("UCD"), and hepatic encephalopathy ("HE") in liver disease patients. SYN1020 is designed to remove excess ammonia from the gut by converting it into the beneficial amino acid arginine, with potential to result in lowered ammonia levels in the blood. Synlogic's second program, SYN1618, is an oral therapy intended for the treatment of phenylketonuria ("PKU"), an IEM in which the amino acid phenylalanine accumulates as a result of genetic defects, becoming toxic to the brain and leading to neurological dysfunction. SYN1618 is designed to have activity in the gut of patients to reduce excess phenylalanine to result in normalization of levels in the blood and tissues. Synlogic is planning to initiate a Phase 1 clinical trial for SYN1618 in the first half of 2018. Synlogic's earlier metabolic disease pipeline includes discovery-stage product candidates for additional IEMs, such as maple syrup urine disease ("MSUD"), isovaleric acidemia ("IVA") and organic acidemias.

Synlogic's platform also has the potential to generate clinically meaningful therapies for patients affected by immune-mediated diseases and cancer. Synthetic Biotic medicines are designed to locally deliver combinations of complementary therapeutics to treat these complex disease states. Synlogic's portfolio of immuno-oncology programs is designed to deliver a combination of activities to modify the tumor microenvironment, activate the immune system and result in tumor reduction. In addition, Synlogic has established a strategic collaboration with the integrated pharmaceutical company AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease ("IBD") such as Crohn's disease and ulcerative colitis. While Synlogic intends to develop and commercialize therapeutic candidates for the treatment of IEMs on its own, Synlogic may consider entering additional strategic partnerships in the future to maximize the value of Synlogic's programs and its Synthetic Biotic platform.

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

Synlogic has assembled a management team of seasoned biopharmaceutical executives with extensive, relevant experience at leading pharmaceutical companies such as Pfizer Inc. ("Pfizer"), GlaxoSmithKline, Biogen, Inc. ("Biogen"), AstraZeneca, Millennium Pharmaceuticals, Inc. ("Millennium Pharmaceuticals") (now Takeda Pharmaceutical Company Limited) and MedImmune, as well as the National Institute of Health. Synlogic is supported by the Synlogic Board of Directors and the Synlogic scientific advisory board, each of which offer complementary experience in drug discovery and development, as well as expertise in building public companies, management, and business development. Synlogic's founding science came from the labs of Professors James Collins and Timothy Lu from the Massachusetts Institute of Technology ("MIT"), who remain highly engaged in guiding development and application of Synlogic's platform.

Synlogic's pipeline of programs is shown below.



As Synlogic advances its lead programs, Synlogic continues to learn and improve the flexibility, manufacturability and translatability of its Synthetic Biotic platform, which will inform all future portfolio programs. Consequently, Synlogic believes it has a robust engine for building a sustainable pipeline of novel, living medicines across a range of diseases. Through the strength of Synlogic's internal team and network of partners, Synlogic believes it can deliver on the promise of Synthetic Biotic medicines to improve the lives of patients with significant unmet medical needs.

Synlogic's Strategy

Synlogic's goal is to use its Synthetic Biotic platform to design, develop and commercialize living medicines to transform the lives of patients for whom conventional treatment approaches are either not available or have limited efficacy and safety. To achieve its goal, Synlogic is pursuing the following key strategies:

Rapidly Advance Clinical Development of the SYNBI020 Hyperammonemia Program . Synlogic's lead Synthetic Biotic program is for the treatment of hyperammonemic conditions such as UCD and HE. SYNBI020 is an oral therapy designed to deliver a complementary metabolic pathway in the gut with the intended consequence of removing excess ammonia in the blood. SYNBI020 has received orphan drug designation and in June 2017 was granted Fast Track designation for UCD from the FDA. Synlogic initiated its first Phase 1 clinical trial to assess safety, tolerability and pharmacokinetics in healthy volunteers in June 2017. Assuming success in the Phase 1 clinical trial, Synlogic plans to initiate an HE study to better understand safety, tolerability and therapeutic potential of SYNBI020. Synlogic expects to start the study in the first half of 2018 and to have topline data by the end of 2018. Similarly, based on the results of the Phase 1 clinical trial, Synlogic expects to begin a clinical trial in UCD by mid-2018 with data expected in the first half of 2019.

Complete IND-Enabling Activities to Advance SYNBI1618 into Clinical Development . Synlogic's second IEM program is an oral therapy for PKU. SYNBI1618 is designed to act from the gut to convert excess phenylalanine to non-toxic metabolites and thereby prevent phenylalanine from accumulating in the blood, becoming toxic and leading to neurological dysfunction. Synlogic expects to initiate a Phase 1 trial for this candidate in the first half of 2018. The Phase 1 design will include healthy volunteers, as well as an adult patient cohort, to assess safety, tolerability and pharmacodynamics. Synlogic expects to have final results from the healthy volunteer study, including insights from a mechanistic biomarker, by the end of 2018 and insights regarding therapeutic potential by the first half of 2019.

Expand Synlogic's Pipeline by Targeting Additional Rare Genetic Metabolic Diseases . Synlogic plans to continue to leverage its expertise from its lead programs to accelerate development of Synlogic's pipeline of clinical candidates for IEMs. For example, Synlogic's portfolio includes two additional discovery-stage Synthetic Biotic programs in lead optimization, including one for MSUD/IVA and the other for propionic acidemia ("PA")/methylmalonic acidemia ("MMA"), organic acidemias with high unmet need for which there are biomarkers that Synlogic believes can guide efficient product development programs.

Maximize the Value of the Synthetic Biotic Platform in Broader Metabolic and Inflammatory Diseases and in Immuno-Oncology Leveraging Strategic Partnerships . Synlogic's Synthetic Biotic platform and product discovery and development capabilities offer the potential to generate multiple clinically meaningful treatments for a broad set of metabolic and inflammatory diseases as well as cancer. For these indications, there is opportunity to reset a metabolic or immune dysfunction with a lower risk of systemic toxicity than other modalities. To achieve this, oral Synthetic Biotic medicines may be designed to deliver a combination of mechanisms following oral administration for activity in the gut or intra-tumoral injection. For example, Synlogic is establishing a discovery-stage immuno-oncology portfolio.

Synlogic expects to continue to explore strategic partnerships that would leverage the complementary capabilities of its partners to develop Synthetic Biotic medicines for these broader groups of patients in need. Synlogic's current partnership with AbbVie is focused on the discovery and development of Synthetic Biotic-based therapies for the treatment of IBD, and in June 2017 Synlogic announced its first milestone for this program. While Synlogic intends to develop and commercialize its programs for IEMs, Synlogic may consider entering into additional strategic partnerships to maximize the value of its Synthetic Biotic platform in these more common indications.

Expand the Synthetic Biotic Platform to Lead in the Discovery and Development of Additional Living Medicines and Enabling Technologies . Synlogic intends to advance in the field of living medicines by continuing to innovate and broaden the potential of its Synthetic Biotic platform to deliver clinically meaningful benefits for patients. Synlogic plans to build on its expertise in design, optimization and manufacturing to further develop the Synthetic Biotic platform as a reproducible and scalable engine for generating a pipeline of product candidates that address a broad range of diseases.

Protect and Leverage Synlogic's Intellectual Property Portfolio and Patents . Synlogic believes that it has a broad intellectual property portfolio that includes patents and patent applications relevant to the engineering, development, manufacturing and formulation of human therapeutic products based on synthetic biology and the metabolic engineering of probiotics. Synlogic intends to continue to protect and leverage its intellectual property assets by maintenance and expansion of its worldwide portfolio of intellectual property, including through the pursuit of composition of matter and other intellectual property directed to its Synthetic Biotic programs and its technology platform.

Synlogic's Focus: Living Medicines

Synlogic is developing and advancing a novel approach to creating living medicines—therapeutics designed to sense a local disease context within a patient's body and to respond by metabolizing toxic substances or delivering combinations of therapeutic factors. Synlogic applies the tools and principles of synthetic biology to engineer beneficial probiotic bacteria to perform or deliver critical therapeutic functions, compensating for missing or damaged pathways in patients with metabolic diseases, inflammation and cancer.

Synlogic believes living medicines have unique advantages as potential therapeutics. Living biologic cells can carry out functions that cannot be performed by many conventional drug treatments, such as small molecules or antibodies. While many conventional treatments can address one molecular dysfunction, living medicines can compensate for the dysfunction of entire processes or pathways missing in disease and required for health. By contrast to conventional therapeutics that engage a single target, living medicines can be designed to dynamically sense diseased environments and respond with a programmed and combinatorial effect. Moreover, a living medicine can also function "catalytically," as a single living cell can carry out multiple cycles of the intended therapeutic activity during its time in the patient.

There is opportunity to expand the impact that previous cell therapies have had by applying the well-established tools of synthetic biology to probiotic bacteria, converting them into efficient therapeutic engines. Probiotic bacteria are non-pathogenic bacteria isolated from the human microbiota widely used as supplements believed to provide health benefits. To confer a therapeutic effect, Synlogic leverages basic biological properties of bacteria to develop engineered probiotics. Bacteria have evolved over several billion years to adapt, survive, and carry out active metabolism in many different environments. They are also amenable to genetic manipulation. Synlogic's intention is to lead in the discovery and development of Synthetic Biotic therapies as safe living medicines capable of robust and precise pathway complementation and therapeutic benefit.

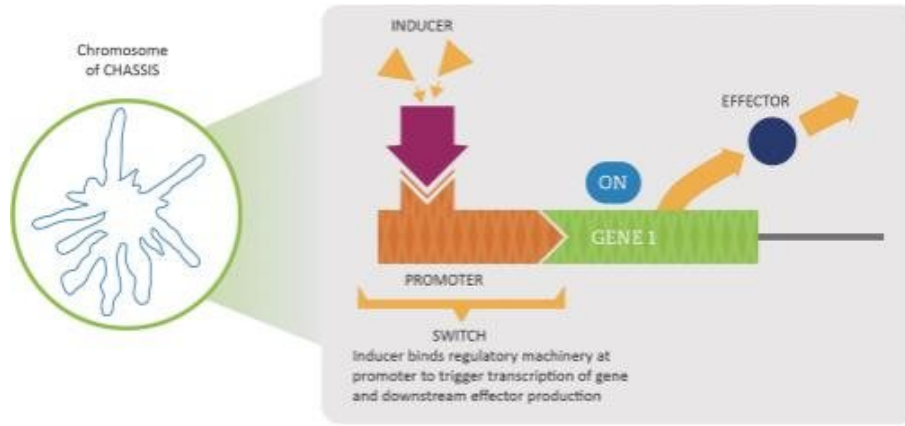
Leveraging Synthetic Biology and Metabolic Engineering of Probiotic Bacteria to Produce Living Medicines

Synlogic's proprietary Synthetic Biotic discovery and development platform combines synthetic biology and metabolic engineering to re-design the genetic circuitry of beneficial probiotic bacteria and generate living medicines.

Synthetic Biology

Synthetic biology is an emerging and rapidly-evolving discipline that applies engineering principles to biological systems to enable rational, design-based control of cellular function for a specific purpose. Biological systems are governed by DNA sequences, or genes, that code for the production and regulation of proteins, metabolites and other molecules. The regulation of the function of proteins occurs via complex biochemical and cellular reactions working through intricate signaling pathways. Synthetic biology allows manipulation of these pathways to direct a desired therapeutic outcome. While efforts have been made to apply these principles across industries, Synlogic believes it is a leader in deploying synthetic biology for the treatment of human disease.

Synlogic scientists genetically engineer a beneficial probiotic bacterium with "wiring" or biological circuits to direct cellular biological processes in a manner analogous to designing electrical circuits. The critical parts of an engineered Synthetic Biotic medicine include (1) the chassis, or probiotic bacterium, (2) the effector module, which is a gene or pathway encoding the core biological activity that provides the therapeutic function, and (3) tunable switches to precisely determine the circumstances under which the effector module will be activated, as well as the strength, performance and output of the effectors themselves. Synlogic aims to precisely control the amount, location and activity of its Synthetic Biotic medicines to address a broad range of disease.



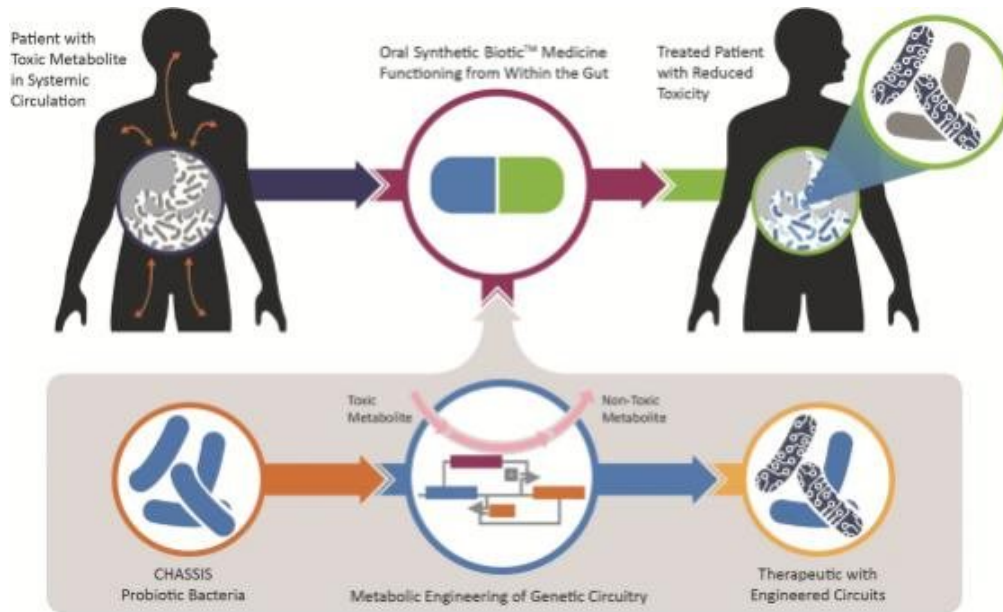
Metabolic Engineering of Probiotic Bacteria

(1) *The Chassis*: Synlogic’s Synthetic Biotic platform employs well-characterized bacteria used as probiotics to serve as the chassis upon which Synlogic builds its living medicines. Synlogic’s initial programs use *E. coli* Nissle, which is one of many non—pathogenic strains isolated from the human microbiota. *E. coli* Nissle has been used as a probiotic bacterial supplement for the last 20 years to promote gut health. *E. coli* Nissle is a non-colonizing probiotic in that it has recently been shown in the clinic to be rapidly cleared from most individuals with no significant safety issues. Synlogic believes *E. coli* Nissle’s widespread use as a probiotic is evidence of its utility as a safe background chassis to apply synthetic biology to confer a therapeutic effect.

(2) *Building the Effector Module*: *E. coli* Nissle’s metabolic systems are well-understood and extremely adaptable, making it an excellent organism for introducing new or enhanced activities to treat human disease. The highly flexible nature of its genetic and metabolic machinery provides a robust cellular context into which genetic information encoding proteins and pathways to correct for disease can be introduced with high efficiency and little or no damage to the fitness of the bacterium. This provides the potential for excellent reproducibility, stability, and activity during manufacturing. Moreover, the advanced nature of the synthetic biology toolkit available for *E. coli* Nissle enables the rapid iterative design, assembly, and testing of prototype product candidates and remains unique among other bacterial and cellular engineering approaches. Synlogic has leveraged proprietary tools, know how and intellectual property to build multiple Synthetic Biotic lead strains that produce a therapeutically relevant effect in laboratory experiments. Progression of these strains as product candidates in diseases with high unmet need is based on prioritizing those with feasible drug development paths in terms of availability of informative animal models and existence of biomarkers to guide efficient clinical development.

(3) *Tunable Switches*: Synlogic also designs and engineers proprietary switches to mediate the activity of the new pathways it introduces, with the aim of controlling the therapeutic output, or effector, of Synthetic Biotic medicines. To optimize the fitness of a Synthetic Biotic strain, it is critical that the effector is activated only at the proper time and place. The switches Synlogic has developed are based on engineering DNA elements call “inducible promoters” to sense and respond to disease states, specific environmental signals, or exogenously added inducing molecules. The goal is to discover and develop Synthetic Biotic medicines programmed with switches to produce its therapeutic effect at precisely the right time and location such as the anaerobic environment of the gut, in the context of local inflammation, and in response to other pathogenic factors.

While applicable across metabolic, inflammatory and immuno-oncology indications, Synlogic’s initial Synthetic Biotic programs are designed for rare metabolic diseases in which a toxic metabolite accumulates in the body and causes systemic toxicity. Synlogic believes that the Synthetic Biotic platform can be leveraged to engineer a safe probiotic with enhanced genetic circuitry and the capability to transform a toxic metabolite into one that is non-toxic or even beneficial. The resulting Synthetic Biotic medicines are built to be taken orally and function from within the gut. Metabolites produced by both a person’s organs and by our endogenous flora circulate or flux between the human gastrointestinal (“GI”) tract and blood circulation and vice versa. As Synlogic’s Synthetic Biotic medicines transit through the GI tract, they are designed to have activity in the gut and to take advantage of this flux, ultimately reducing the systemic levels of toxic metabolites in the blood to treat rare metabolic diseases.



Advantages of Synlogic’s Synthetic Biotic Living Medicines

Synlogic believes its platform has the potential to provide safe and effective therapies for patients given several attributes of Synlogic’s Synthetic Biotic approach:

Unique Mechanisms to Treat Systemic Metabolic and Immune Dysfunction: Local Pathway Complementation or Therapeutic Delivery

Synlogic’s Synthetic Biotic platform allows it to engineer living medicines that act as engines capable of metabolic pathway compensation and essentially replace what a patient cannot do with his or her somatic organs, such as the liver. Unlike traditional small molecule and biologic therapeutics, Synthetic Biotic medicines can be designed with multiple pathway components optimized to consume or transform unwanted metabolites or produce those that are medically beneficial. This approach is well suited to regulate the amount of a metabolic byproduct in a patient’s body, particularly when there is unconstrained metabolite flux between the systemic circulation. Synlogic’s Synthetic Biotic programs for rare metabolic diseases are designed to be dosed orally, to act locally while transiting through the gut and, as a consequence, to decrease toxic metabolite levels in the blood, thereby providing a systemic therapeutic benefit to the patient.

In addition, Synlogic is developing Synthetic Biotic medicines with the potential to normalize function of a dysregulated immune system. In inflammatory and autoimmune indications, this may be achieved by producing anti-inflammatory metabolites and proteins particularly for diseases of the GI tract. Synthetic Biotic medicines can also be designed to consume or produce metabolites or secrete and display proteins that may shift the tumor microenvironment of the immune system towards anti-tumor activity.

Combination and Local Delivery of Multiple Mechanisms in One Therapy for Greater Efficacy and Enhanced Safety

Currently, many complex diseases, such as inflammatory and autoimmune indications and oncology, require that patients be treated with a combination of therapeutic agents, often resulting in poor tolerability, multiple adverse events and increased cost of therapy. Synlogic’s approach is to leverage the adaptability of *E. coli* Nissle to enable the combination of multiple activities into one therapy, which therefore could have greater efficacy while avoiding the impact of multiple separate systemic therapies.

Moreover, Synlogic’s Synthetic Biotic medicines are based on beneficial probiotic bacteria derived from the natural human gut. A chassis such as *E. coli* Nissle is suited for local delivery, either orally or through intra-tumoral injection. Synlogic believes that, when delivered locally, Synthetic Biotic medicines have the potential to avoid the risks of dose-limiting side effects often associated with systemic therapies, especially when combinations of systemic therapies are required.

Ability to Tune and Enhance Efficacy in Context of Disease

Synlogic’s Synthetic Biotic platform includes a suite of switches to permit precise control of the timing and amount of therapeutic effect produced. Synthetic Biotic therapies may be designed such that they are activated to produce the desired effect in a particular disease environment, such as sites of inflammation. This tuning has the potential to increase the therapeutic window by increasing the margin between the level of medicine needed for efficacy relative to the risk of systemic toxic side effects.

Advantages of Synlogic's Synthetic Biotic Drug Development Platform

The Synthetic Biotic platform employs a well-characterized probiotic bacterium with a proven safety record that is readily modified using state-of-the-art synthetic biology tools. This unique combination of features allows Synlogic to rapidly develop prototypes for the treatment of human diseases with unmet medical need. Advantages to discovery, development, manufacturing and commercialization, include unique mechanisms of action enabling a broad range of therapeutic applications and rational design to achieve predictable drug-like properties:

Unique Mechanisms of Action Enabling a Broad Range of Therapeutic Applications

Synlogic's approach allows it to engineer two types of mechanistic activities into Synlogic's Synthetic Biotic medicines. These activities may be further improved for therapeutic effect when combined or when under the control of tunable switches that determine when the mechanisms should be activated.

- *Metabolic Pathway Complementation* : Synthetic Biotic medicines may be programmed with entire pathways to degrade unwanted molecules or produce those that are beneficial. Synlogic believes metabolic pathway complementation is advantageous as compared to gene, RNA or enzyme replacement therapies that are limited to targeting a single gene or protein defect and may require several unique drug products to address genetically heterogeneous patient populations. By compensating with an entire pathway, Synthetic Biotic medicines may provide a therapeutic solution to broader disease populations as a single engineered therapeutic. Moreover, in the IEMs space Synlogic believes its approach has advantages versus these other modalities that may be limited by delivery, transduction efficiency, duration of therapeutic expression and unclear potential for long-term dosing. Given the potential for chronic oral dosing, Synthetic Biotic medicines may have benefits in terms of prediction of dose, reversibility of activity and more traditional pricing strategies.
- *Production of One or More Protein Effectors at the Site of Disease* : Combinations of cytokine, antibody and protein therapies have potential for great effect, but can be restricted by dose-limiting side effects when administered systemically. The potential to program the control of expression of one or more proteins at the local disease site represents a unique approach to targeted therapy. Synlogic has developed proprietary integration systems to direct stable insertion of multiple genetic circuits and pathways into optimal chromosomal locations, or "landing pads," of *E. coli* Nissle. This enables efficient expression of multiple genes encoding desired enzymes and other proteins. Synlogic has also developed approaches to enhance the secretion of protein effectors to the extracellular environment. For example, in the case of inflammatory conditions, Synthetic Biotic medicines may be programmed to detect inflammation and respond with the production of one or more anti-inflammatory molecules. In oncology, Synlogic's programs are being designed to secrete effectors to promote immune system activity against a tumor. These activities may further be combined with metabolic complementation pathways. By incorporating multiple actions, Synthetic Biotic medicines have the potential to address complex diseases while avoiding the risk of systemic toxicity and reducing development costs associated with combining systemic therapies.

Rational Design to Achieve Predictable Drug-like Properties

Synlogic has demonstrated the ability to move a program from concept to clinical development in as little as three years for its lead program. Features of Synlogic's Synthetic Biotic platform enable a highly efficient drug discovery and development process and have the potential to advance product candidates more rapidly and efficiently than is typically possible with other novel or emerging modalities. These include:

- *Single Strain as Safe Chassis* . There are several benefits of employing a single, safe and well-characterized probiotic bacterium such as *E. coli* Nissle as the background chassis. First, because Synlogic's lead programs are based on *E. coli* Nissle, experience can be leveraged broadly across the portfolio, further optimizing the efficiency and reproducibility of discovery, development and manufacturing efforts. Next, the non-colonizing nature of *E. coli* Nissle can be combined with engineering approaches to optimize safety in terms of impact on the patient and the environment. *E. coli* Nissle can be engineered to require a specific exogenous nutrient supplement for growth, which limits the ability to replicate in the human body and environment. By controlling replication, Synlogic can control the number of cells being administered to a patient. Also, dependence on an essential nutritional supplement not available in the environment reduces biocontainment risk. Moreover, the risk of Synthetic Biotic medicines to the environment is further limited given that it is disadvantaged in terms of fitness due to its modifications.
- *Predictive Pharmacology and Biomarkers* . Synthetic Biotic programs are designed to achieve a target activity, and the platform supports an iterative design-build-test cycle to improve performance for achieving this target. For example, Synthetic Biotic programs can be optimized by including multiple copies or regulated control of certain genes, by adding transporters for particular substrates or by optimizing enzymes for basic bacterial metabolism. These tools enable rational and iterative engineering cycles in the discovery phase.

Biomarkers as indicators of mechanistic and clinical activity may also be engineered into Synthetic Biotic medicines from the beginning to drive optimization and decision-making. By assessing the activities of Synlogic's Synthetic Biotic programs in *in vitro* and *in vivo* pre-clinical models, Synlogic can model activity in humans. As Synlogic progresses into clinical studies, Synlogic expects its predictive pharmacology models will be further refined to inform dosing and development decisions for its additional programs.

- *Stability and Manufacturing* . Synlogic's lead Synthetic Biotic programs have advanced the platform by defining manufacturing processes that can be deployed against the entire portfolio. Manufacturing efforts have demonstrated reproducibility, yield and stability during small, medium and Phase 1 clinical-scale manufacturing efforts. Moreover, Synlogic's use of synthetic biology switches permits the precise control of engineered metabolic pathway activation. This can be used to suppress effector activity during manufacturing, enabling generation of biomass and robust, cost-efficient scale up of product candidates.

Synlogic's Product Pipeline

Synlogic's approach to selecting its initial programs is based on the potential of the Synthetic Biotic platform to uniquely address conditions in which there is (1) unmet medical need with (2) well understood biology that is (3) based on an imbalance of a metabolite and (4) where that metabolite is available within or originates from the gut lumen. Additional considerations include the availability of animal models, relevant biomarkers and feasible clinical development paths. Synlogic's initial clinical and pre-clinical programs are focused on certain IEMs that share these characteristics. When delivered orally, Synthetic Biotic medicines are designed to act from the gut to compensate for the dysfunctional metabolic pathway with the intended consequence of reducing the levels of the toxic metabolites systemically. Synlogic believes success in IEMs will enable it to demonstrate the potential of its oral Synthetic Biotic medicines to address metabolic dysfunction, while bringing meaningful change to lives of patients suffering from these debilitating conditions.

Synlogic's two lead therapeutic programs are being developed for the treatment of IEMs; UCD and PKU. There is unmet need for both indications, as well as an opportunity to reduce toxic metabolites that originate from the gut. Both also inform the potential of the Synthetic Biotic platform in unique ways. Synlogic's lead product candidate, SYNBI020, is designed as an oral therapy to remove excess ammonia from the blood by accessing ammonia in the lower GI tract and converting it into arginine, a natural amino acid used in normal growth and metabolism. The conversion of ammonia into arginine is based on enhancing an enzyme pathway endogenous to *E. coli* Nissle. The program has clinical application in that multiple disease indications involve toxic ammonia levels. In addition to UCD, Synlogic is exploring SYNBI020 to treat patients with HE secondary to chronic liver disease to stave off episodes of cognitive dysfunction. SYNBI020 has also received orphan drug designation and in June 2017 was granted Fast Track designation for UCD from the FDA. Synlogic initiated a Phase 1 clinical trial of SYNBI020 in healthy volunteers in June 2017.

Synlogic's second IEM program, SYNBI618 for PKU, is designed to act in the upper GI tract to reduce excess phenylalanine in the blood. Unlike SYNBI020, the engineering of SYNBI618 is based on leveraging enzymes from other bacterial species to optimize the conversion of phenylalanine to non-toxic metabolites. SYNBI618 has demonstrated activity in a rodent model of PKU. Synlogic expects to initiate a Phase 1 clinical trial for this program in the first half of 2018. Synlogic's research-stage IEM portfolio includes Synthetic Biotic programs for (1) MSUD and IVA and (2) PA/MMA. These are rare metabolic deficiencies with no approved therapies in which the toxic accumulation of leucine and organic acids, respectively, can lead to neurological decline and death.

For more common metabolic, inflammatory and immuno-oncology indications with more complex biology, clinical and commercial paths, Synlogic will explore strategic partnerships to exploit the potential of the Synthetic Biotic platform. Synlogic's collaboration with AbbVie for the discovery and development of Synthetic Biotic therapies for the treatment of IBD is one such example. Synlogic is also developing a portfolio of immuno-oncology programs using a rational approach to select combinations of relevant mechanisms to address specific tumor types. Synlogic's strategy is to alter the state of the tumor microenvironment to one that is "anti-tumor" through Synthetic Biotic medicines that consume or combine effectors that promote immune system activation, reverse immunosuppression, expand tumor antigen-specific T cells and/or remodel the tumor protective stroma to tip the balance toward an anti-tumor effect. Synlogic is currently working on three discovery-stage programs, which are diversified in terms of indications, combinations of mechanisms and routes of administration.

Synlogic's Initial Programs: Overview of IEMs

Patients with IEMs are born with faulty genes that result in the loss of a necessary enzyme function in an essential metabolic pathway and prevent the body from metabolizing commonly occurring byproducts of digestion. In patients with IEMs, these byproducts can accumulate to toxic levels in the gut and systemically throughout the body to cause serious health consequences, including irreversible neurological dysfunction. Although in some cases diet modification can be beneficial, unmet medical need remains as there are few current treatments for IEMs.

While there are hundreds of genetic conditions grouped as IEMs, individual IEMs are considered orphan diseases, with each disease affecting fewer than 200,000 patients in the United States and fewer than five per 10,000 people in the European Union. IEMs include diseases of the urea cycle, amino acid metabolism and organic acid accumulation, among others. Many IEMs are thought to be underdiagnosed given the rarity of the conditions, potential for infant death, lack of available diagnostics and limited therapies.

SYNBI020 for Hyperammonemia: Urea Cycle Disorder and Hepatic Encephalopathy

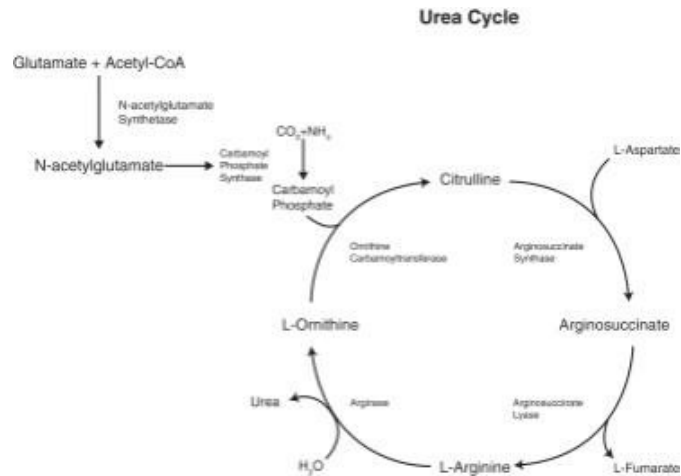
Hyperammonemia is a metabolic condition characterized by an excess of ammonia in the blood. In healthy individuals, ammonia is primarily produced in the intestine as a byproduct of protein metabolism and microbial degradation of nitrogenous-containing compounds. Ammonia itself is then converted to urea in the liver and is excreted in urine. However, if the liver's ability to convert ammonia to urea is compromised, either due to a genetic defect or acquired liver disease, ammonia accumulates in the blood. Elevated blood ammonia levels are toxic to the brain and can have severe consequences including neurologic crises requiring hospitalization, irreversible cognitive damage and death.

SYNBI020, Synlogic's lead Synthetic Biotic program, is a genetically engineered strain of *E. coli* Nissle designed to deliver a complementary metabolic pathway to the gut to reduce excess ammonia in the blood in individuals with disease. The SYNBI020 program offers potential in treating multiple indications associated with toxic ammonia levels, including UCD and HE, and has demonstrated reduction in blood ammonia levels in rodent models of hyperammonemia. SYNBI020 has received orphan drug designation and in June 2017 was granted Fast Track designation for UCD from the FDA. Synlogic initiated a Phase 1 clinical trial of SYNBI020 in healthy volunteers in June 2017. Assuming success in this study, Synlogic plans to initiate two studies in UCD and HE to better understand the safety and tolerability of SYNBI020 in patients. Synlogic intends to clinically explore ammonia lowering in these patients to drive design of confirmatory studies for SYNBI020.

Overview of UCD

UCDs are a group of rare but serious and potentially fatal, genetic diseases. The urea cycle is an enzymatic pathway in which waste nitrogen, produced as a byproduct of protein metabolism, is converted into urea by the liver and eliminated from the body through urine. Patients with a UCD carry a deficiency in one of the six enzymes necessary for completion of the urea cycle, resulting in accumulation of waste nitrogen throughout the body in the form of ammonia, a substance that is highly toxic even in small amounts.

Functional Urea Cycle



UCD patients have intermittent periods of hyperammonemia, the symptoms of which can range from mild (loss of appetite, vomiting, and lethargy) to a severe hyperammonemic crisis associated with long-term cognitive or behavioral impairment, toxic encephalopathy, and even death. Symptoms often depend on the severity of the enzyme deficiency, and patients with the most severe disease present shortly after birth. Hyperammonemia in newborn infants due to UCD could be catastrophic and is associated with 24% mortality. Patients with later onset disease could suffer from a period of hyperammonemia that is often triggered by stress or illness (surgery, trauma, or drugs) resulting in severe neurological symptoms and associated with a high risk of mortality.

While it is difficult to estimate the exact incidence and prevalence of UCD, as it is thought that many patients go undiagnosed, it is estimated that UCD occurs in approximately one in 35,000 births in the United States. Based on analysis of the newborn screening data and demographic data from the UCD Longitudinal Registry Study sponsored by the NIH, Synlogic believes the size of the diagnosed prevalent population in the United States to be approximately 2,000 patients and that approximately two-thirds of these patients are under 18 years of age.

The mainstay of management of UCD is dietary protein restriction. Patients must carefully balance their protein intake to ensure the body receives adequate nutrients for growth and development, while avoiding triggering hyperammonemia. However, varying protein requirements and variable growth and activity levels often elicit episodes of hyperammonemia that can result in irreversible neurological damage. To supplement for the lower protein intake, patients may incorporate amino acid dietary formulations, such as L-citrulline or L-arginine, into their diet. However, dietary management remains challenging, especially in infants and children.

The only available drugs, sodium phenylbutyrate (Buphenyl®) and glycerol phenylbutyrate (Ravicti®), are approved for the chronic management of patients with UCD and create an alternate pathway for nitrogen/ammonia elimination from the body, but patients maintain protein restricted diets. Use of sodium phenylbutyrate is limited by pill burden, taste, and tolerability issues that can make compliance challenging. These therapies are mechanistically similar treatment options with limitations on maximal effect due to dose-related neurological safety issues (e.g., vomiting, nausea, headache, somnolence, confusion, or sleepiness) and enzymatic saturation and, therefore, the unmet need remains high.

When these management approaches fail to control chronic UCD-induced hyperammonemia, patients may be candidates for liver transplantation, which is potentially curative as it may correct the enzyme deficiency that causes UCD. However, aside from being very costly, transplants are limited by availability of donor organs and are associated with potentially life-threatening risks and require life-long suppression of the immune system. Ultimately, morbidity and mortality remain high in UCD, and patients continue to suffer hyperammonemic crises. Synlogic believes that a truly transformative therapy for UCD would be an effective oral medicine without systemic toxicity that will maintain blood ammonia concentration at a safe level while allowing patients to eat a normal or only moderately restricted diet.

Overview of HE

The primary function of the liver is to filter out toxins, particularly ammonia, that are harmful if not sufficiently metabolized. In patients whose liver function is impaired, these toxins can accumulate in the blood stream and cause organ damage, particularly in the brain, which leads to a decline in brain function that is referred to as HE. Ammonia, a highly toxic substance produced in the body as a byproduct of protein metabolism, plays a key role in the development and prognosis of HE. While ammonia can be minimally metabolized by the brain in patients whose liver function is impaired, excessive ammonia levels can overwhelm the capacity of brain tissue and lead to a greater chance of developing brain swelling, coma and death for patients with HE. It is estimated that 30-45% of patients with chronic liver disease are affected by episodes of HE, and while many HE symptoms can be reversed with appropriate treatment, persistent impairment of memory and learning can occur.

HE severity is typically classified as covert or overt based largely on a patient's mental state. Covert HE is difficult to diagnose and is often observed in patients with cirrhosis who appear to have no obvious disorientation, but who display mild to moderate symptoms, such as difficulty concentrating, forgetfulness, changes in personality or behavior, and poor sleep. Patients with covert disease are at a higher risk of developing the more severe overt HE and have increasingly been recognized as a cause of morbidity linked with increased risk of traffic accidents and unemployment. Overt HE is associated with obvious mental disorientation and physical symptoms such as lethargy, seizures, tremors, organ failure, or brain swelling, that arise suddenly and may induce a coma or even death, particularly if not adequately treated. Overt HE is associated with a poor prognosis, with one-year survival estimates of 20% to 55%.

The current standard of care for overt HE includes lactulose, a non-absorbable disaccharide that prevents the absorption of ammonia in the gut. Lactulose is associated with GI side effects including both painful abdominal cramping and diarrhea. Non-absorbable antibiotics are also used to treat HE, often concurrently with lactulose. Rifaximin (Xifaxan®), a broad-spectrum antibiotic used to reduce growth of bacteria that produce ammonia in the colon, was approved for HE based on improvements in the duration of remission, reduced hospitalizations over six months, and improved quality of life in patients with HE. Although rifaximin and lactulose are used therapeutically for overt HE, there are no approved treatments for covert HE.

Morbidity and mortality associated with overt HE remains high and hospitalizations for HE impose a high burden on community resources. When current therapies fail to control overt HE, patients may be candidates for a potentially curative liver transplantation. However, aside from being costly, transplants are limited by availability of donor organs and are associated with potentially life-threatening risks and require life-long suppression of the immune system. There is a need for an effective therapy for patients with HE to stave off episodes of cognitive dysfunction and hospitalizations.

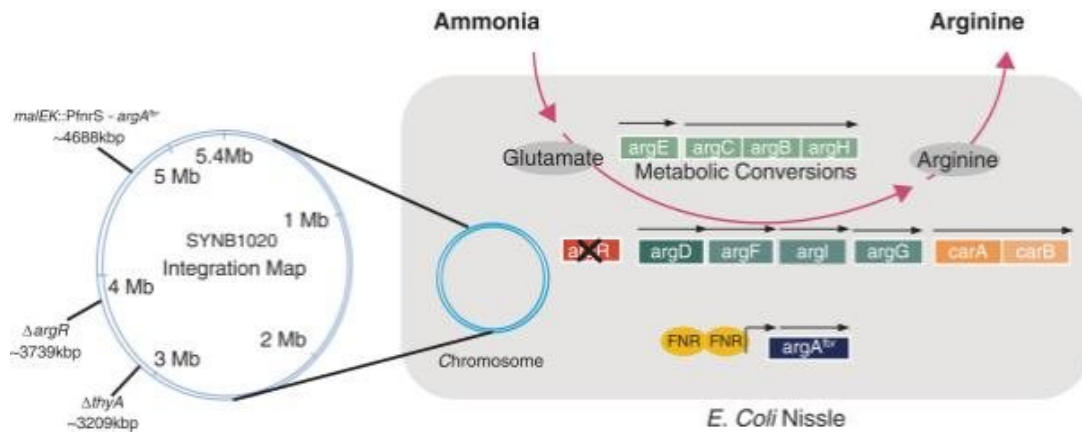
Synlogic believes that because ammonia is produced in the GI tract, a Synthetic Biotic medicine could be an effective therapeutic to reduce the levels of excess ammonia in the blood of patients with UCD and HE without the need for severe protein restriction and risk of systemic toxicities.

SYNB1020 Design

SYNB1020, Synlogic's lead Synthetic Biotic program, is an orally administered, engineered strain of *E. coli* Nissle. SYNB1020 was designed to complement the missing enzyme functions in patients with UCD with an enhanced pathway to consume ammonia, thus having the potential to treat the spectrum of enzyme deficiencies that underlie UCD. This mechanism also has applicability in liver disease where there is a need to reduce excess ammonia in the colon before it can be absorbed into the blood and cause HE episodes.

Synlogic's approach was to create a Synthetic Biotic medicine that would continuously consume excess ammonia where it is naturally produced in the colon, before it can be absorbed into the blood, and produce arginine. Arginine production is deficient in UCD patients due to a defect in the urea cycle, and patients are often treated with arginine supplements. *E. coli* Nissle has an endogenous arginine production pathway that uses four molecules of ammonia for every new molecule of arginine produced. Synlogic modified this pathway to significantly enhance arginine production function through two key modifications: (1) deletion of a gene that represses the production of the arginine biosynthetic enzymes (*argR*) and (2) insertion of a gene that encodes a feedback-resistant enzyme in the arginine biosynthesis pathway ("*argA^{fbr}*"). To enhance activity, *argA^{fbr}* is placed under the control of an inducible promoter, FNR, to allow expression of the gene when the cell experiences micro-aerobic or anaerobic environments, such as the mammalian gut.

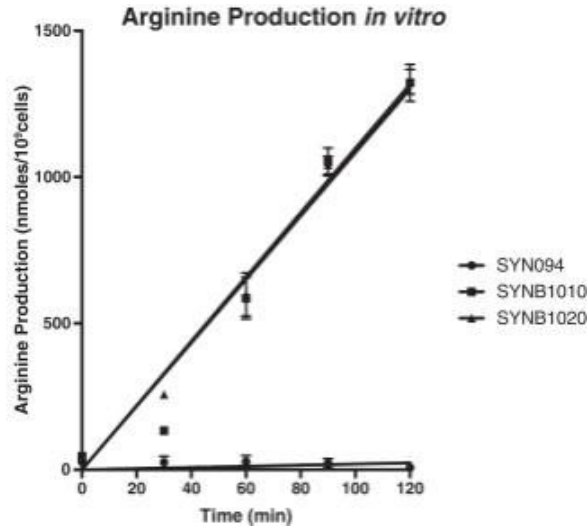
Schematic of SYNB1020



Abbreviations: argA = N-acetylglutamate synthase gene; argA fbr = feedback resistant N-acetylglutamate synthase; ArgB = acetylglutamate kinase; ArgC = N-acetyl glutamylphosphate reductase; ArgD = N-acetylornithine aminotransferase; ArgE = acetylornithine deacetylase; ArgFI = ornithine carbamoyltransferase; ArgG = arginosuccinate synthase; ArgH = arginosuccinate lyase; argR = arginine repressor gene; CarAB = carbamoylphosphate synthetase; FNR = fumarate and nitrate reductase; P fnrS = fumarate and nitrate reductase regulator sensor promoter; Δ thyA = thymidylate synthase such that the strain can only grow in thymidine-rich environments. Arrows denote operons.

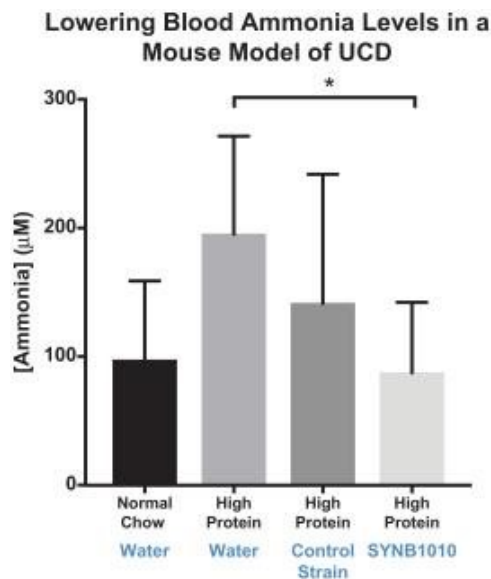
SYNB1020 Nonclinical Program

In an *in vitro* study, SYNB1020 and a related research strain SYNB1010 (identical to SYNB1020 except designed to grow in the presence of kanamycin for selection and use in pre-clinical studies) consumed ammonia and produced arginine at substantially higher rates compared with a control strain of *E. coli* Nissle that had not been engineered (“SYN94”). Arginine production was 650.1 and 658.7 nmol/10⁹ cells/hour for SYNB1010 and SYNB1020, respectively, and only 11.8 nmol/10⁹ cells/hour for the control strain. Similarly, conversion of ammonia to arginine was 2545 and 2570 nmol/10⁹ cells/hour for SYNB1010 and SYNB1020, respectively, and 46 nmol/10⁹ cells/hour for the control strain.



Pre-Clinical Efficacy Study

To test the *in vivo* activity in a setting of hyperammonemia, the spf-ash/F1 mouse was adapted from a published model based on a mutation in the gene for ornithine transcarbamylase (“OTC”), a common deficiency in human UCDs. The activity of the research strain SYNB1010 was compared to a non-arginine producing control strain of *E. coli* Nissle, and to water as an additional control. All mice were dosed orally, twice daily beginning on Day 1. Hyperammonemia was induced on Day 3 by switching animals to a high-protein diet. SYNB1010 reduced Day 5 blood ammonia levels in comparison with water and the non-arginine producing control strain of *E. coli* Nissle. This reduction in blood ammonia resulted in improved survival of animals dosed with SYNB1010 compared to animals given water or the non-arginine producing control strain.



Statistically significant difference: * = p-value 0.019 (two-tailed t test)

In a GLP 28-day mouse toxicology study, SYNBI020 was safe and well tolerated. No toxicity was detected at the highest feasible dose, and there was no evidence of distribution of SYNBI020 outside the GI tract. Consequently, the no observed effect level was equal to the maximum feasible dose that could be administered, a threshold defined by volume limitations permitted in animals. This represents a greater than 1,000-fold safety margin over the starting dose planned in the Phase 1 study.

SYNBI020 Clinical Development Plan

Synlogic initiated a Phase 1, randomized, double-blinded, placebo-controlled study in June 2017 to evaluate the safety, tolerability, and gastrointestinal clearance of single and multiple doses of SYNBI020 in healthy volunteers. Synlogic expects approximately 50 subjects will be enrolled. The starting oral dose and subsequent range for dose escalation were selected based on the nonclinical toxicology and efficacy experiments and are expected to span the projected efficacious dose range in humans. The primary outcome measures will evaluate the safety and tolerability of SYNBI020 by assessing the nature and frequency of adverse events, laboratory assessments and electrocardiogram. Secondary measures will investigate the gastrointestinal tolerability and the kinetics of SYNBI020. In addition, blood, urine, and fecal samples will be collected and evaluated for exploratory biomarkers to gain mechanistic insights regarding ammonia consumption. If SYNBI020 appears well tolerated and safe in healthy subjects, Synlogic plans to evaluate SYNBI020 for the management of hyperammonemic patients, such as UCD and HE.

SYNBI1618 for PKU

PKU is a rare IEM caused by a genetic defect in the gene phenylalanine hydroxylase (“PAH”) leading to phenylalanine (“Phe”) accumulation in the blood and brain, where it is neurotoxic and can lead to neurological deficits and even death. Current disease management of PKU involves dietary protein restriction with the consumption of phenylalanine-free protein supplements. The only approved medication, Kuvan® (sapropterin dihydrochloride) is indicated for a subgroup of patients and does not eliminate the need for ongoing dietary management. Despite recommendations supporting life-long control of phenylalanine levels, compliance is challenging due to the highly restrictive nature of the diet, putting patients at risk for cognitive and psychiatric disease and supporting the need for novel treatment approaches.

Synlogic’s Synthetic Biology platform is well-suited to complement the missing enzyme function in PKU patients by providing alternative metabolic pathways to consume Phe. Synlogic’s second IEM program, SYNBI1618 for PKU, is designed to remove excess phenylalanine from the blood by transforming it into non-toxic metabolites. SYNBI1618 has demonstrated activity in a rodent model of PKU. Synlogic expects to initiate a Phase 1 clinical trial for SYNBI1618 in the first half of 2018.

Overview of PKU

Phenylalanine is an essential amino acid that enters the body primarily through dietary protein, and can be toxic if not sufficiently broken down and eliminated. The metabolism of phenylalanine by the liver is dependent on adequate function of the liver enzyme PAH and the cofactor tetrahydrobiopterin (“BH4”) necessary for its activity. When the PAH gene is mutated and/or the production of BH4 is blocked, phenylalanine cannot be sufficiently broken down and accumulates to toxic levels (i.e., hyperphenylalaninemia), which can cause irreversible brain damage. PKU is an inherited metabolic disease that presents as a severe form of hyperphenylalaninemia.

The disease course of PKU typically involves worsening neurological function that begins in infancy or early childhood. The clinical manifestations vary depending on severity of the enzyme mutation, the time of diagnosis and treatment initiation, and compliance. Symptoms may be extensive, such as severe mental retardation, or they may reflect more moderate neurocognitive or physical issues, such as below average intelligence, behavioral or mood disorders, memory loss, difficulty concentrating, decreased motor function, eczema, body odor, and tremors or seizures. A woman with PKU who becomes pregnant could develop maternal PKU if her diet is not strictly controlled, and there is a risk that the baby will be born with one or more birth defects such as mental retardation, microcephaly or congenital heart disease.

Based on the success of newborn screening efforts that began in developed countries in the 1960s, it is believed that nearly all PKU patients under the age of 40 have been diagnosed at birth. The National PKU Alliance estimates that in the United States there are currently 16,500 people living with PKU.

Currently, management of PKU requires a heavily modified diet that restricts protein intake, in order to minimize consumption, combined with essential amino acid and vitamin supplementation. Special medical foods, including phenylalanine-free protein formula, provide patients with dietary protein and fulfill other nutrient needs. However, it is challenging for most PKU patients, even with the efforts of supportive family and social networks, to adhere to the restricted diet to the level that provides the necessary control of phenylalanine levels. Patients often have trouble adhering to the diet from a young age, with particular challenges arising during times of increasing independence during adolescence. Furthermore, access to low protein foods can be challenging, as they are costlier and less nutritious than their higher protein, non-modified counterparts.

Kuvan® (sapropterin dihydrochloride) was the first drug approved for the treatment of PKU in 2007. It is indicated for the reduction of blood phenylalanine in patients with hyperphenylalaninemia with residual PAH activity as it is a synthetic form of the BH4 cofactor. Oral administration of Kuvan, along with protein restriction, has lowered phenylalanine levels in patients who have residual PAH activity and/or mild forms of the disease, which accounts for approximately 20-50% of the PKU population. However, Kuvan does not eliminate the need for ongoing dietary management in all patients. Large neutral amino acids have also demonstrated activity in blocking absorption of excess phenylalanine by the intestines and brain, but are currently only administered in adolescents and adults.

A pegylated form of recombinant phenylalanine ammonia lyase (“PAL”), called Pegvaliase, an enzyme that metabolizes phenylalanine but does not require cofactor activity, is in clinical development for PKU and is not yet approved. While Pegvaliase injections one to two times daily have been proven to lower phenylalanine levels regardless of whether patients are following a low protein diet or not, patients may experience injection site reactions and/or develop antibodies to the enzyme, which limits its effectiveness.

Despite recent improvements in PKU therapy, patients continue to suffer from poor outcomes. Even patients who are diagnosed and treated early have increased risk of neurocognitive abnormalities and psychiatric complications and are burdened by the life-long struggle to comply with strict dietary modifications. Available drug therapies demonstrate limited effectiveness, are accompanied by immunologic and other toxicities, and may still require patients to maintain a heavily restricted diet. Synlogic believes a truly transformative therapy would be orally-dosed and provide sustained, safe concentrations of phenylalanine while allowing for a normal or only moderately restricted diet. Synlogic believes that a Synthetic Biotic medicine could be an effective oral therapeutic that acts from the gut to transform excess phenylalanine with the consequent effect of reducing levels in the blood without the need for severe phenylalanine restriction or risk of systemic toxicities.

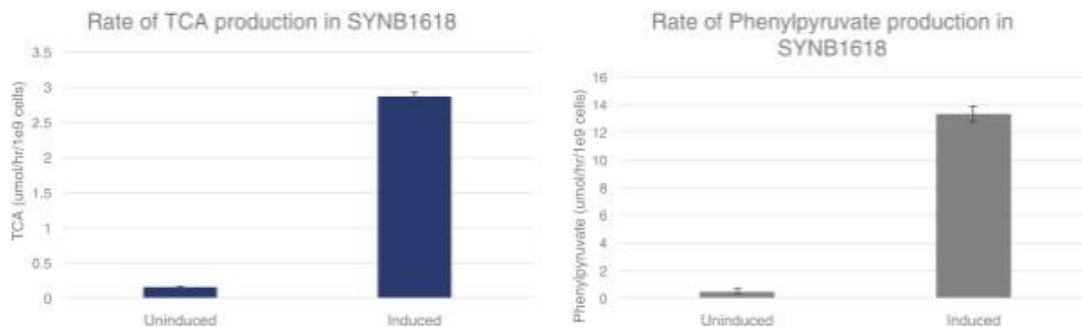
SYNB1618 Design

SYNB1618 is a genetically-modified strain of *E. coli* Nissle engineered to express a synthetic pathway for transporting and metabolizing phenylalanine in patients with PKU following oral administration. SYNB1618 was designed to overcome the missing enzyme function in patients with PKU with an alternative pathway to reduce phenylalanine levels.

In designing SYNB1618, Synlogic integrated genes encoding the phenylalanine transporter (“PheP”), PAL derived from *Photorhabdus luminescens* and L-amino acid deaminase (“LAAD”) derived from the organism *Proteus mirabilis* into the *E. coli* Nissle genome. PheP transports phenylalanine into the Synthetic Biotic bacterial cell with high efficiency, while within the cell PAL converts phenylalanine to the non-toxic byproduct *trans*-cinnamate (“TCA”). The inclusion of multiple copies of these genes further enhanced activity. Similar to PAL, LAAD converts phenylalanine to a non-toxic byproduct, phenylpyruvate.

SYNB1618 Nonclinical Program

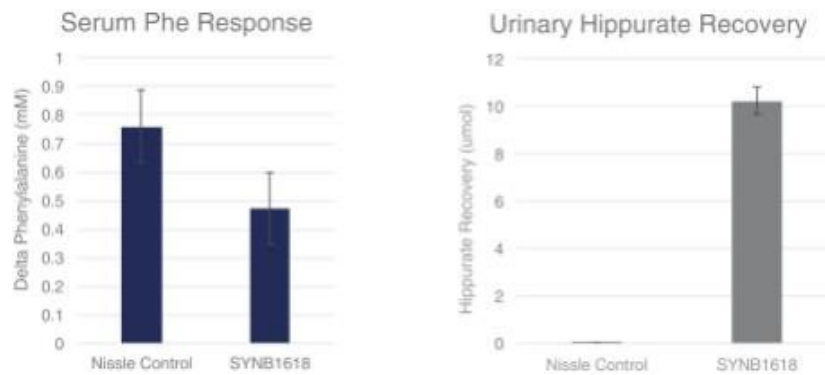
Synlogic has demonstrated that SYNB1618 can metabolize phenylalanine *in vitro* using both the PAL and LAAD enzymes by measuring their respective non-toxic byproducts. Synlogic compared the activity of SYNB1618 under conditions in which the Synthetic Biotic strain is induced (in the “ON” state) versus when uninduced when metabolic activity is suppressed. As shown in the graphs below, *in vitro* activation of PAL led to an 18.5-fold increase in production of the TCA metabolite over uninduced levels, and *in vitro* activation of LAAD led to production of phenylpyruvate levels at 26.7-fold over uninduced levels.



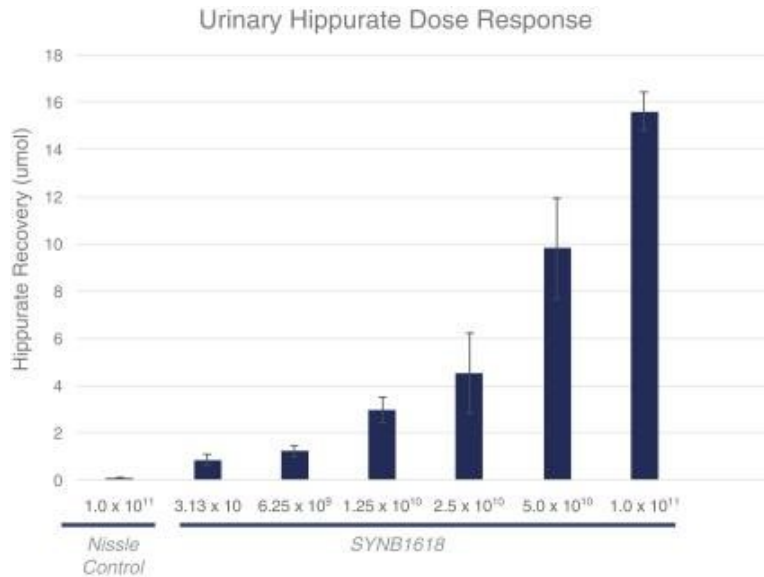
Pre-Clinical Efficacy Studies

In vivo studies have focused on the *enu2*^{-/-} mouse model that contains a mutation in the gene coding for phenylalanine hydroxylase, the same enzyme that is deficient in PKU patients. Mice with this genetic defect maintained on normal chow accumulate phenylalanine in their blood at concentrations greater than 2000 μM , which is similar to blood concentrations found in humans with PKU. On a phenylalanine-restricted diet, blood phenylalanine levels can be maintained at the healthier range of 100-200 μM . Subcutaneous injection of phenylalanine-restricted mice with phenylalanine (0.1 mg/g body weight) results in a rapid increase in blood phenylalanine concentrations. As shown in the graph below, this increase associated with this phenylalanine challenge was significantly blunted (as reported as the delta, or reduction, from peak phenylalanine levels) upon oral administration of SYNB1618, compared to administration of the non-engineered control strain that did not have the phenylalanine degradation pathway (39% blunting of serum phenylalanine, $p = 0.0002$).

To further support the development of SYNB1618, hippuric acid was followed as a urinary biomarker of phenylalanine degradation. One product of phenylalanine degradation by SYNB1618, TCA, is converted to hippurate by liver enzymes and excreted in the urine. Following treatment of *enu2*^{-/-} mice with SYNB1618, urinary hippurate concentration increased 270-fold compared to mice treated with unengineered *E. coli* Nissle controls. Taken together, these data show that SYNB1618 has activity in the GI tract, and that degradation of recirculating phenylalanine is effective in decreasing the levels found in blood, independent of dietary intake.



Synlogic has also demonstrated a dose response in the same animal model with its clinical candidate strain SYN1618. With increasing oral doses of this single strain, Synlogic observes increasing levels of urinary hippurate in mice.



Moreover, in preliminary primate studies, administration of SYN1618 to cynomolgus monkeys following an oral high protein challenge resulted in elevated levels of urinary hippurate recovery compared to the protein challenge alone. These data indicate that SYN1618 is functional in the environment of the primate gut.

SYNB1618 Clinical Development Plan

Synlogic is currently conducting IND-enabling studies and scaling up manufacturing to support initiation of clinical studies of SYN1618. Synlogic is planning a Phase 1, randomized, double-blinded, placebo-controlled study to evaluate the safety, tolerability, and gastrointestinal clearance of SYN1618. In such study, healthy adult volunteers would be treated with single- or multiple-ascending doses of SYN1618. Synlogic expects approximately 50 subjects will be enrolled.

Upon determination of the maximum tolerated dose, Synlogic expects an expansion cohort of up to 16 adult subjects with PKU will be treated. In addition to the primary endpoint of safety and tolerability, this study will evaluate the change from baseline in several pharmacodynamic parameters compared to placebo in order to characterize the kinetics of SYN1618 in humans, and provide mechanistic and clinical insights regarding urinary hippurate production and phenylalanine reduction. Synlogic expects to initiate this Phase 1 trial in the first half of 2018.

Synthetic Biotic Medicines for Additional IEMs

Learnings from the design, pre-clinical research, clinical planning and scalable manufacturing of the lead programs have already informed development of future clinical candidates. Synlogic's initial programs were selected based on applicability of the Synthetic Biotic platform to provide pathway complementation in IEMs in which the toxic metabolite was known to be associated with the relevant clinical endpoint and to be accessible in the GI tract. Additional examples in which there is opportunity to expand the potential of Synthetic Biotic medicines include discovery-stage programs for (1) MSUD and IVA and (2) PA and MMA. These are

rare metabolic deficiencies in which a toxic metabolite can accumulate and lead to neurological decline and death. There is no approved therapy for either disease and these patients are managed with dietary modifications, supportive care, and liver transplant when available.

A Synthetic Biotic Program for Maple Syrup Urine Disease and Isovaleric Acidemia

MSUD is an IEM that was first described in the 1950s as an inherited progressive neurological degenerative disorder. Patients with this disease have mutations in one of the protein subunits of the mitochondrial multi-enzyme complex called branched-chain alpha-ketoacid dehydrogenase. These mutations cause the patients to accumulate high levels of the branched chain amino acids (“BCAA”) leucine, isoleucine or valine that are neurotoxic and cause severe neurological pathologies characterized by brain edema, seizure, spasticity and respiratory irregularities that can lead to death. The MSUD name derives from the strong maple syrup odor in the urine of these patients. Similarly, IVA can result from a genetic defect leading to leucine accumulation. It is difficult to estimate the prevalence of these rare indications given few longitudinal studies. Based on estimates of the live birth rate of MSUD of 1:185,000 and IVA of 1:250,000, respectively, and applying assumptions to account for mortality and survival rates, it is estimated that there may be approximately 2,500 MSUD or IVA patients in the United States.

Currently-available treatments for disorders involving the catabolism of BCAA are inadequate for the long-term management of the disorders and have severe limitations. A low protein/BCAA-restricted diet, with micronutrient and vitamin supplementation as necessary, is the widely-accepted long-term disease management strategy. However, BCAA-intake restrictions can be problematic since these amino acids are also essential nutrients that can only be acquired through diet and are necessary for metabolic activities such as protein synthesis. Even with proper monitoring and patient compliance, branched chain amino acid dietary restrictions result in a high incidence of mental retardation and mortality. MSUD is cured by liver transplantation; however, limited availability of donor organs, costs, and the need to rely on life-long immunosuppressant therapy are limiting. Therefore, there is significant unmet need for an effective, reliable, and/or long-term treatment for disorders involving the catabolism of branched chain amino acids.

Synlogic has built a Synthetic Biotic discovery program to modulate the expression of two BCAA transporters and three BCAA-degrading enzymes. Results *in vitro* demonstrate the efficient degradation of BCAAs into non-toxic branched-chain alcohols that can then be further metabolized and eliminated from the body. In preliminary studies in a mouse model of MSUD, the oral delivery of the Synthetic Biotic strain suppresses the increase in blood BCAA levels induced by a high-protein diet and prevents the associated waning, or moribund, phenotype as measured by improved locomotor activity. Based on the *in vivo* therapeutic effects observed, Synlogic continues to improve this approach as a potential promising therapy for MSUD and IVA patients.

Synlogic’s Synthetic Biotic Program for Propionic Acidemia and Methylmalonic Acidemia

Organic acidemias are a group of rare IEMs in which amino acid metabolism is disrupted, causing an accumulation of toxins. Normally, the human body converts certain amino acids, such as isoleucine, valine, threonine, and methionine, into a derivative of propionic acid to create energy. Patients with PA and MMA have enzyme deficiencies caused by mutations in the pathway for propionate catabolism that lead to the toxic accumulation of propionic acid or methylmalonic acid-related metabolites in the blood stream, leading to damage of the brain, heart, and liver. Clinical manifestations of the disease vary depending on the degree of enzyme deficiency and include seizures, vomiting, lethargy, hypotonia, encephalopathy, developmental delay, failure to thrive, and secondary hyperammonemia. It is difficult to estimate the prevalence of these indications given few longitudinal studies. The live birth rates are estimated as 1:105,000-1:130,000 for PA and 1:50,000-100,000 for MMA. Applying assumptions to account for mortality and survival rates, it is estimated that there may be 2,000-3,000 PA or MMA patients in the United States.

Currently available treatments for disorders involving propionate catabolism are inadequate and have severe limitations. Patients may present acutely at birth with metabolic acidosis and hyperammonemia, or later in life with more heterogeneous clinical symptoms, and run the risk of early death or severe neurologic damage. Mental outcomes tend to be worse in PA, and patients who can also experience late complications like cardiomyopathy. Late complications for MMA patients include chronic kidney disease. Except for MMA patients who are responsive to vitamin B12, there is significant unmet need for effective, reliable and/or long-term treatment for disorders involving the catabolism of propionate.

Propionate is produced naturally in the gut by bacterial metabolism, and therefore a Synthetic Biotic medicine that consumes propionate in that environment could be an attractive approach to treating these disorders. Synlogic has constructed two discovery-stage Synthetic Biotic strains that have each demonstrated degradation of propionate into non-toxic metabolites *in vitro*. In a preliminary experiment in a mouse model of propionic acidemia, the oral delivery of both Synthetic Biotic strains independently suppressed the plasma concentration of disease-related toxic metabolites. Synlogic is planning to continue assessing these strains in animal models and improving them as potential promising therapies for PA and MMA patients.

Synthetic Biotic Medicines for Broader Metabolic Disease

Synlogic’s Synthetic Biotic platform combined with its product discovery and development capabilities drive the potential for multiple clinically meaningful opportunities for patients affected by a broad set of metabolic diseases such as Nonalcoholic Steatohepatitis (“NASH”). For these indications, there is need for a safe, oral therapy with local activity in the gut to reset a metabolic dysfunction. Synlogic’s approach is amenable to enabling combination therapy, which is increasingly recognized as a necessary component of effective treatment. Synlogic continues to explore strategic partnerships that would leverage the complementary capabilities of partners in order to develop Synthetic Biotic medicines for these broader groups of patients in need.

Synthetic Biotic Medicines for Immunomodulation

Synlogic's Synthetic Biotic platform has the potential to generate clinically meaningful therapies for patients affected by immune-mediated diseases. Among these conditions, IBD is particularly attractive, as it allows Synlogic to leverage knowledge and expertise gleaned from Synlogic's metabolic programs to develop living medicines that can act locally at the site of disease in the gut. Because Synlogic's approach is based on local delivery to the site of inflammation and not on systemic administration, Synlogic anticipates that its Synthetic Biotic medicines may offer an attractive safety profile in this setting. In 2015, Synlogic entered into a multi-year global collaboration with AbbVie focused on the discovery and development of a Synthetic Biotic medicines for the treatment of IBD.

Synlogic's Synthetic Biotic Medicines for Inflammatory Bowel Disease

IBD is a group of diseases characterized by significant local inflammation in the GI tract typically driven by T cells, activated macrophages and compromised function of the epithelial barrier. IBD pathogenesis is linked to both genetic and environmental factors and may be caused by altered interactions between gut microbes and the intestinal immune system. Current approaches to treat IBD are focused on therapeutics that modulate the immune system and suppress inflammation. These therapies include steroids, such as prednisone, and tumor necrosis factor inhibitors, such as Humira®. Drawbacks from these approaches are associated with systemic immunosuppression, which includes greater susceptibility to infectious diseases and cancer. It is estimated that between 1.0-1.3M patients have IBD in the United States.

Compromised gut barrier function also plays a central role in autoimmune diseases pathogenesis. A single layer of epithelial cells separates the luminal contents of the gut from the host circulatory system and the immune cells in the body. Disrupting the epithelial layer can lead to pathological exposure of foreign antigens from the lumen resulting in increased susceptibility to autoimmune disorders. The interplay between the gut microbiota and the host is thought to play key roles in both the maintenance of the epithelial barrier as well as homeostatic immunity. Thus, enhancing barrier function and reducing inflammation in the gastrointestinal tract are potential therapeutic mechanisms for the treatment or prevention of autoimmune disorders. Synlogic's Synthetic Biotic platform allows for the effective programming of *E. coli* Nissle to execute these functions, including the metabolic production of factors such short chain fatty acids to enhance barrier function and secreting proteins, such as immunomodulatory cytokines.

Synlogic's Synthetic Biotic Medicines for Immuno-Oncology

Synlogic believes boosting the body's immune response against tumor cells is one of the most promising advances in the treatment of cancer. The so-called "hot tumors", those with robust immune cell infiltration, specifically by T cells, respond well to immunotherapies such as the PD-1 and CTLA-4 checkpoint inhibitors. Checkpoint inhibitors work by blocking pathways that inhibit T cells thus enabling them to recognize and destroy the tumor. Checkpoint inhibitors have significantly extended the lives of patients with several cancer types and, in some cases, have resulted in complete clinical responses. However, a large proportion of tumors are "cold" (i.e., they lack T cells), and respond poorly to immunotherapy.

Synlogic's goal is to leverage its Synthetic Biotic platform to design living medicines that can modify the tumor microenvironment to convert "cold" tumors into "hot." Synlogic believes that this transition will dramatically expand the patient population amenable to clinical benefit by immunotherapy. Synlogic's approach is designed to deliver robust therapeutic combinations to the tumors, without significant systemic exposure. Synthetic Biotic medicines are being developed to be administered by an intra-tumor injection or, in the case of GI cancers, by oral administration and can be engineered to perform three types of functions: metabolic conversions, secretions of proteins or bacterial surface display of specific single chain antibody domains, known as scFvs.

Synlogic's Synthetic Biotic platform allows it to approach "cold" tumors in a rational, mechanistic way, and can deliver multiple validated mechanisms to elicit specific immune responses in the tumor microenvironment. Synlogic's main mechanistic areas of focus in the context of tumor immunology include:

- ***Immune activation and priming***: Synlogic's bacterial Synthetic Biotic chassis is predicted to engage innate immune cells in the tumor microenvironment, thereby initiating an immune cascade to activate and direct T cells to the tumor. Lack of effective presentation of tumor-specific antigens to T cells is recognized as a significant limitation to the initiation of immune responses in tumors. Synlogic is building and optimizing Synthetic Biotics medicines with the potential of addressing this issue.
- ***Immune augmentation/Reversal of immunosuppression***: Synlogic has developed strains that actively consume and transform immunosuppressive metabolites in the tumor microenvironment, with the goal of setting up a milieu conducive to immune activation and tumor destruction.
- ***T cell expansion***: Tumor antigen-specific T cell expansion and prevention of exhaustion are recognized as key objectives for successful cancer immunotherapy. Synlogic is developing Synthetic Biotic medicines programs to secrete specific cytokines to promote T cell survival and expansion.
- ***Stromal modulation***: The physical structure of tumors is receiving increasing attention as emerging data demonstrate its importance in orchestrating tumor growth, immune evasion and resistance to chemotherapy, such as in pancreatic ductal adenocarcinoma. Tumor-derived extracellular matrix proteins can limit the perfusion of drugs or antibodies, contributing to the remarkable resistance of this tumor type to therapy. Synlogic has developed strains that secrete active enzymes with the capacity to remodel extracellular matrix proteins to make the tumor more permeable.

Synlogic's product vision for immuno-oncology is to use a rational approach to selecting and combining relevant mechanisms of action for the microenvironment of specific tumor types. Synlogic will focus on tumor types with high unmet medical need, including colorectal and hepatocellular carcinomas, pancreatic cancer and melanomas refractory to current immunotherapies. Currently three programs are in the early pipeline and are diversified in terms of indication, combinations of mechanisms, and route of administration.

Collaboration Agreements

To accelerate the development and commercialization of Synthetic Biotic medicines to patients in therapeutic areas outside of IEMs, Synlogic has formed, and intends to seek other opportunities to form, strategic alliances with collaborators that can expand Synlogic's pipeline of therapeutic development and product candidates. Synlogic also works, and intends to seek additional opportunities to work, with multiple academic, research and translational medicine organizations and entities to deepen its understanding and development of living medicines with the potential to treat disease and disorders.

AbbVie

In July 2015, Synlogic entered into a license agreement with its subsidiary Synlogic IBDCo, Inc. ("IBDCo") and an Agreement and Plan of Merger with AbbVie (together, the "AbbVie Agreements") to collaborate on the discovery and development of Synthetic Biotic medicines for the treatment of IBD. The AbbVie Agreements provide AbbVie with an exclusive option to acquire IBDCo, which would then have an exclusive worldwide license to develop and commercialize up to three specified Synthetic Biotic medicines for the treatment of IBD.

Under the terms of the collaboration with AbbVie, Synlogic has the responsibility to discover, characterize and optimize one lead Synthetic Biotic product candidate to the point of a IND-enabling package, together with two backup product candidates, through a research and development program covering a limited number of effectors that modulate the IBD pathophysiology. The multi-year collaboration combines AbbVie's expertise in inflammatory diseases with Synlogic's expertise in synthetic biology and metabolic engineering. AbbVie agreed to pay IBDCo an upfront payment of \$2.0 million, received in December 2015, and up to \$16.5 million upon the achievement of certain research and development milestones. In May 2017, IBDCo achieved one of these research and development milestones under the AbbVie Agreement for which it will receive \$2.0 million.

If AbbVie accepts Synlogic's IND-enabling package covering the lead Synthetic Biotic product candidate, AbbVie may exercise its exclusive option to acquire IBDCo, which would house the lead and two backup product candidates. If this option is exercised, AbbVie would pay Synlogic an option exercise fee upon the closing of the IBDCo merger and Synlogic would be eligible to receive future development, regulatory and commercial milestone payments, and low single digit royalties on sales of the Synthetic Biotic medicines. In addition, AbbVie would then assume full control of all further clinical development and commercial activity, including responsibility for all expenses and decisions.

Potential Future Collaborations

Synlogic views strategic partnerships as important drivers for helping accelerate its goal of effectively treating patients, and Synlogic will continue to seek strategic alliances with collaborators who can help fund, develop and commercialize its novel therapeutic development and product candidates, particularly in large metabolic indications and immune-oncology. As the potential application of its Synthetic Biotics platform is extremely broad, Synlogic also plans to continue to identify academic, research and translational medicine organizations and entities that can contribute expertise and resources to its programs, to allow it to more rapidly expand Synlogic's impact to broader patient populations.

Intellectual Property

Synlogic strives to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to its business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from Synlogic's collaborators or other third parties. Synlogic's policy is to seek to protect Synlogic's proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to Synlogic's proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of Synlogic's business. Synlogic also relies on trade secrets and know-how relating to its proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain its proprietary position in the field of synthetic biology. Synlogic additionally relies on data exclusivity, market exclusivity, and patent term extensions when available, and plans to seek and rely on regulatory protection afforded through orphan drug designations. Synlogic's commercial success may depend in part on its ability to obtain and maintain patent and other proprietary protection for its technology, inventions, and improvements; to preserve the confidentiality of its trade secrets; to maintain Synlogic's licenses to use intellectual property owned by third parties; to defend and enforce Synlogic's proprietary rights, including its patents; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

Synlogic believes it is well positioned in terms of intellectual property because Synlogic:

- has built and expanded, and intends to continue expansion in, a broad worldwide portfolio of intellectual property, including patents and patent applications, in areas relevant to the development, manufacturing and formulation of human therapeutic products using live biotherapeutics based on synthetic biology;

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- intends to take additional steps, where appropriate, to further protect Synlogic's intellectual property rights, including, for example, through the use of copyright and trademark protection, as well as regulatory protection available via orphan drug designations, data exclusivity, market exclusivity and patent term extensions.

Synlogic believes its intellectual property portfolio provides broad coverage of its Synthetic Biotic platform and applicable disease-related technologies, which are directed to diseases and conditions associated with hyperammonemia, hyperphenylalanemia, other IEMs and acquired metabolic disorders, autoimmune and other inflammatory disorders and oncology. As of June 2017, Synlogic's intellectual property portfolio consists of 193 Synlogic-owned and in-licensed patents and patent applications in U.S. and foreign jurisdictions, including 11 issued patents.

Disease-related applications.

The disease-related applications in Synlogic's intellectual property portfolio relate to certain pathological conditions and provide coverage for engineered bacteria having genetic circuitry designed to specifically address those conditions and the associated disease states. Disease related applications relate to pathological conditions and include:

Hyperammonemia

- Synlogic's lead program addresses conditions associated with hyperammonemia, for which it has developed engineered bacterial strains containing genetic circuitry specifically designed to metabolize ammonia.
- The intellectual property portfolio provides robust coverage for compositions directed to engineered bacterial strains, methods of making the bacterial strains and methods for treating diseases that involve accumulation of ammonia (e.g., UCD, HE). Synlogic's intellectual property provides coverage for the lead product candidate SYNBI020 and methods of its manufacture and use. In addition to UCD, SYNBI020 could be useful for the treatment of hyperammonemia in HE patients with cirrhosis of the liver, which indication is also covered by Synlogic's intellectual property.
- Currently, intellectual property relating to this technology includes ten pending applications in U.S. and foreign jurisdictions, as well as one issued and one allowed U.S. patent directed to composition of matter and pharmaceutical composition claims covering Synlogic's clinical candidate. The patent term for this IP will expire in December 2035, excluding any patent term adjustments or extensions.

Hyperphenylalanemia

- Synlogic's program addresses conditions associated with hyperphenylalanemia, for which it has developed engineered bacterial strains containing genetic circuitry specifically designed to metabolize phenylalanine.
- Synlogic's intellectual property portfolio provides coverage for compositions directed to engineered bacterial strains, methods of making the bacterial strains and methods for treating diseases that involve accumulation of phenylalanine. Synlogic's intellectual property provides coverage for the lead product candidate SYNBI1618 and methods of its manufacture and use.
- Currently, intellectual property relating to this technology includes three pending U.S. patent applications and two international patent applications directed to composition of matter and pharmaceutical compositions covering Synlogic's lead product candidate. The patent term for this intellectual property will expire in May 2036, excluding any patent term adjustments or extensions.

Other Inborn Errors of Metabolism

- Additional disease-related intellectual property includes patent applications directed to Synlogic's Synthetic Biotic technology for use in treating diseases and conditions arising from IEMs.
- Synlogic's intellectual property provides coverage of compositions of engineered bacteria, methods of making the bacterial strains and methods of treating diseases associated with accumulation of BCAA (e.g., leucine, isoleucine and valine), including MSUD. Synlogic currently has one U.S. application and one PCT application directed to diseases involving accumulation of BCAA. The patent term for this intellectual property will expire in June 2036, excluding any patent term adjustments or extensions.
- Additional Synlogic intellectual property covers compositions of engineered bacteria, methods of making the bacterial strains and methods of treating organic acidemias, including those associated with accumulation of propionic acid and related toxic metabolites, such as PA and MMA. Synlogic currently has one U.S. application and one PCT application directed to diseases involving accumulation of organic acid metabolites. The patent term for this intellectual property will expire in July 2036, excluding any patent term adjustments or extensions.

Metabolic Disorders

- In addition to IEMs, other disease-related intellectual property includes patent applications directed to Synlogic's Synthetic Biotic technology for use in treating diseases and conditions associated with acquired metabolic disorders, including, but not limited to NASH.

- Synlogic’s intellectual property provides broad coverage of compositions of engineered bacteria, methods of making the bacterial strains and methods of treating various metabolic diseases. Synlogic’s current intellectual property consists of two PCT applications relating to this technology. The patent term for this intellectual property has expiration dates ranging from June 2036 to December 2036, excluding any patent term adjustments or extensions.

Inflammatory and Autoimmune Diseases

- Additional disease-related intellectual property includes numerous patent applications directed to Synlogic’s Synthetic Biotic technology for use in treating diseases and conditions associated with an inflammatory state, including, but not limited to, diseases associated with gut inflammation, compromised gut mucosal barrier (leaky gut), and various autoimmune disorders.
- Synlogic’s intellectual property provides broad coverage of compositions of engineered bacteria, methods of making the bacterial strains and methods of treating diseases associated with gut inflammation, leaky gut, and autoimmune disorders, such as Inflammatory Bowel Disease, including Crohn’s Disease, ulcerative colitis, and other diseases. Synlogic’s current intellectual property consists of three U.S. applications and three PCT applications relating to this technology, which is being developed in collaboration with AbbVie and which intellectual property is Synlogic-owned. The patent term for this intellectual property has expiration dates ranging from December 2035 to March 2036, excluding any patent term adjustments or extensions. In addition, Synlogic has one PCT application relating to this technology which is jointly owned by Synlogic and MIT, which expires in December 2035, excluding any patent term adjustments or extensions.

Immuno-Oncology

- In addition, Synlogic has disease-related intellectual property directed to its Synthetic Biotic technology for use in immuno-oncology, which intellectual property covers bacterial strains engineered to metabolize and/or produce biomolecules that modify the tumor microenvironment and immune response, resulting in an array of mechanistic functions, including immune activation and priming, immune augmentation and/or reversal of immunosuppression, T-cell expansion, and tumor stromal modulation.
- Synlogic’s intellectual property provides broad coverage of compositions of engineered bacteria, methods of making the bacterial strains and methods of treating various cancers. Synlogic’s current intellectual property consists of two PCT applications with expiration dates ranging from January 2037 to February 2037, excluding any patent term adjustments or extensions.

Platform Technology Applications.

In addition to the disease-related technology, Synlogic’s intellectual property portfolio also includes applications directed to platform technologies developed internally by Synlogic. Exemplary platform technologies include bacterial chassis-related and genetic circuitry-related technological developments, including, for example, improvements in inducible gene regulation, control of bacterial cell growth, including auto-regulation thereof, and systems for importing metabolites, as well as secreting therapeutic effectors. These platform technologies, and Synlogic’s intellectual property coverage thereof, are broadly applicable to Synlogic’s therapeutic Synthetic Biotic medicines.

In addition to Synlogic’s own patent applications, Synlogic has licensed patents and patent applications from MIT and Trustees of Boston University (“BU”) to access intellectual property covering synthetic biology circuitry that Synlogic is exploring and developing. The intellectual property licensed from MIT and BU relates to genetic circuitry (designed to be modular components for integration into biological systems), cells containing the genetic circuitry, and methods and systems for gene regulation using the genetic circuitry.

The intellectual property licensed from MIT includes applications related to genome editing systems used to target specific genes for recombination and methods for delivering a gene editing system to endogenous bacteria. It also includes applications directed to genetic circuits and biological systems for regulating gene expression using various recombinase-based and other promoter systems, including promoter systems that respond to different levels of an input signal. The MIT intellectual property also covers methods for identifying mutant promoters that have an altered level of response to an input signal and methods of controlling gene expression in certain bacteria. In addition, the MIT intellectual property includes a PCT application jointly owned by Synlogic and MIT, directed to engineered bacteria and methods for treating inflammatory bowel disease. The licensed patents and applications from the MIT have expiration dates ranging from 2033 to 2037, excluding any patent term adjustments or extensions.

The intellectual property licensed from BU includes patents and applications relates to genetic circuitry and biological systems for controlling gene expression employing the genetic circuits, detecting the production of a target gene product, and delivering genetic circuits to endogenous bacteria. The various genetic circuits are designed to respond to external cues and also designed to tighten control of gene expression regulated by inducible and constitutive promoter systems using a variety of genetic components, for example, sensors, inducers, repressors, antisense, stem-loop sequences, recombinases, RNAi, inverted sequences, and ribosome-binding site sequences, to generate various promoter toggle switches, adjustable threshold switches, and oscillator switches, among others. In addition, the BU intellectual property covers biocontainment systems that couple environmental sensing with circuit-based control of cell viability. The licensed patents and applications from BU have expiration dates ranging from 2019 to 2036, excluding any patent term adjustments or extensions.

Massachusetts Institute of Technology (“MIT”) License

Synlogic entered into a license agreement with MIT, effective November 2015 and amended as of July 2016. Under this license agreement, MIT granted Synlogic a worldwide license under certain patents and patent applications that is exclusive in the therapeutics and theranostics fields and non-exclusive in the internal research field. The license grants Synlogic rights to develop, make, have made, use, import, sell, and offer to sell licensed products and processes. Synlogic does not have the right to control prosecution of these licensed patents and patent applications and its rights to enforce the in-licensed patent rights are subject to certain limitations.

Under the terms of the MIT license agreement, as consideration for the license, Synlogic paid to MIT an upfront license fee and is eligible to receive an annual maintenance fee, milestone fees, sublicense fees if Synlogic should ever grant a sublicense to the licensed patents or patent applications and low single-digit royalty percentages on net sales of licensed products. MIT also receives reimbursement from Synlogic for patent prosecution expenses. Synlogic is subject to diligence requirements to develop licensed products in accordance with certain development milestones.

BU and MIT License

Synlogic entered into a license agreement with BU and MIT effective October 2015 and signed April 2017. Howard Hughes Medical Institute (“HHMI”) has an ownership interest in certain patent rights licensed to Synlogic under this license, which interest HHMI assigned to BU. HHMI is not a party to the license agreement, but receives the benefit of certain terms. Under this license agreement, BU and MIT granted Synlogic a worldwide license under certain patents and patent applications that is exclusive in the therapeutics and theranostics fields and non-exclusive in the diagnostic and internal research field. The license grants Synlogic rights to make, have made, use, lease, import, sell, and offer to sell licensed products and processes. Synlogic does not have the right to control prosecution of the licensed patents and patent applications, and Synlogic’s rights to enforce the licensed patent rights are subject to certain limitations. Under the terms of this license agreement, as partial consideration for the license, BU, MIT and MIT’s agent Omega Cambridge SPV, L.P. were issued an aggregate of 325,377 shares of Synlogic Common Stock. In addition, Synlogic paid an upfront fee, and reimbursed past patent prosecution costs, and the licensors are eligible to receive from Synlogic an annual maintenance fee, milestone fees, sublicense fees if Synlogic should ever grant a sublicense to the licensed patents and patent applications and low single-digit royalty percentages on net sales of licensed products. BU also receives reimbursement from Synlogic for patent prosecution expenses. Synlogic is subject to diligence requirements to develop licensed products in accordance with certain development milestones.

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to account for delays in prosecution at the U.S. Patent and Trademark Office and/or to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. For regulatory delays, the restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

The patent positions of companies like Synlogic are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of synthetic biology has emerged in the United States. The patent situation outside of the United States is even more uncertain. With respect to both licensed and company-owned intellectual property, Synlogic cannot be sure that patents will be granted with respect to any of Synlogic’s pending patent applications or with respect to any patent applications filed by it in the future, nor can Synlogic be sure that any of its existing patents or any patents that may be granted to in the future will be commercially useful in protecting Synlogic’s products and the methods used to manufacture those products. For additional risks, please see the section entitled “*Risk Factors—Risks Related to Intellectual Property*” in this proxy statement/prospectus/information statement.

Trademarks

Synlogic’s registered trademark portfolio currently contains 31 registered trademark applications, consisting of seven (7) pending trademark applications in the United States and 24 pending trademark applications in Australia, Canada, China, Europe, India, Japan, Mexico and New Zealand and under the Madrid Protocol. Synlogic may also rely, in some circumstances, on trade secrets to protect its technology.

Other

Generally, Synlogic seeks to protect its technology and product candidates, in part, by entering into confidentiality agreements with those who have access to Synlogic’s confidential information, including employees, contractors, consultants, collaborators, and advisors. In some circumstances, Synlogic may rely on trade secrets to protect its technology. Synlogic seeks to preserve the integrity and confidentiality of its proprietary technology, trade secrets and processes by maintaining physical security of Synlogic’s premises and physical and electronic security of its information technology systems. Although Synlogic has confidence in these individuals, organizations, and systems, agreements or security measures may be breached and Synlogic may not have adequate remedies for any breach. In addition, Synlogic’s trade secrets may otherwise become known or may be independently discovered by competitors. To the extent that company employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for Synlogic, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more

comprehensive risks related to Synlogic's proprietary technology, inventions, improvements and products, please see the section entitled "*Risk Factors—Risks Related to Intellectual Property*," in this proxy statement/prospectus/information statement.

Regulatory Matters

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record keeping, promotion, advertising, distribution, marketing and export and import of products such as those Synlogic is developing. A new drug must be approved by the FDA through the NDA process and a new biologic must be approved by the FDA through the biologics license application ("BLA"), process before it may be legally marketed in the United States

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug and Cosmetic Act ("FDCA") and in the case of biologics, also under the Public Health Service Act ("PHSA"), and implementing regulations. Synlogic's product candidates will be regulated by the FDA as biologics. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on Synlogic. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies according to cGLP other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well controlled human clinical trials according to cGCP to establish the safety and efficacy of the proposed drug for its intended use;
- development and approval of a companion diagnostic device if the FDA or the sponsor believes that its use is essential for the safe and effective use of a corresponding product;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the BLA.

Once a pharmaceutical candidate is identified for development, it enters the pre-clinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. In June 2016, the FDA issued an updated guidance for the industry entitled "Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing and Control Information," which included recommendations from the FDA regarding the chemistry, manufacturing and control information that should be included in an IND for early clinical trials with live biotherapeutic products. Guidances such as this one reflect the FDA's thinking on a topic at the time that they are issued and although this guidance is not binding on the FDA or a sponsor, it provided Synlogic with additional information about what should be included in Synlogic's IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with cGCP regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board ("IRB") at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. Phase 1, Phase 2, and Phase 3 testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug. If this type of discussion occurs, a sponsor may be able to request a Special Protocol Assessment ("SPA"), the purpose of which is to reach agreement with the FDA on the design of the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to FDA guidance for industry on the SPA process, a sponsor that meets the prerequisites may make a specific request for a special protocol assessment and provide information regarding the design and size of the proposed clinical trial. The FDA is required to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began. If the sponsor makes any unilateral changes to the approved protocol, the agreement will be invalidated.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of all trial related information, and it is possible that data and other information from trials involving drugs that never garner approval could require disclosure in the future.

U.S. Review and Approval Processes

The results of product development, pre-clinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product. The submission of a BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The user fee for FY 2017 is \$2,038,100 for an application containing clinical data. The FDA reviews all BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a BLA for filing. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in depth substantive review. FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than Synlogic interprets the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the BLA, or an approved letter following satisfactory completion of all aspects of the review process. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving a BLA, the FDA will inspect the facility or facilities where the product is manufactured.

BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. Priority review for an original BLA will be six months from the date that the BLA is filed. In addition, products studied for their safety and effectiveness in treating serious or life threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well controlled Phase 4 clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

After the FDA evaluates a BLA, it will issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS"), to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

The Pediatric Research Equity Act ("PREA"), requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. Orphan indications are exempt from PREA. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of Synlogic's drugs, some of Synlogic's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (referred to as the "Hatch Waxman Amendments"). The Hatch Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term

restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND, and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, Synlogic intends to apply for restorations of patent term for some of its currently-owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the filing of the relevant NDA.

Pediatric exclusivity is a type of marketing exclusivity available in the United States. Under the Best Pharmaceuticals for Children Act (the "BPCA"), an additional six months of marketing exclusivity may be available if a sponsor conducts clinical trials in children in response to a written request from the FDA. If a written request does not include clinical trials in neonates, the FDA is required to include its rationale for not requesting those clinical trials. The FDA may request studies on approved or unapproved indications in separate written requests. The issuance of a written request does not require the sponsor to undertake the described clinical trials. To date, Synlogic has not received any written requests.

Biologics Price Competition and Innovation Act of 2009

The ACA, which included the BPCIA, amended the PHSA to create an abbreviated approval pathway for two types of "generic" biologics, biosimilars and interchangeable biologic products, and provides for a 12-year data exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric clinical trials are performed and accepted by the FDA, the 12-year data exclusivity period will be extended for an additional six months. Because Synlogic's product candidates will be regulated as biologics, if they are approved they may be subject to competition from biosimilars. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically-inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical trials to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

The FDA has issued several final and draft guidance documents that provide FDA's current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. The FDA intends to issue additional guidance documents in the future. Nonetheless, the absence of final guidance documents covering all biosimilars issues does not prevent a sponsor from seeking licensure of a biosimilar under the BPCIA, and the FDA has already approved a few biosimilar applications in the United States.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether a drug is no longer designated as an orphan drug. More than one product candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity, except in very limited circumstances. The FDA issued a final rule, effective August 12, 2013, intended to clarify several regulatory provisions, among which was a clarification of some of those limited circumstances. One of the provisions makes clear that the FDA will not recognize orphan drug exclusive approval if a sponsor fails to demonstrate upon approval that the drug is clinically superior to a previously approved drug, regardless of whether or not the approved drug was designated an orphan drug or had orphan drug exclusivity. Thus orphan drug exclusivity could also block the approval of one of Synlogic's products for seven years if a competitor obtains approval of the same drug as defined by the FDA and Synlogic is not able to show the clinical superiority of its drug or if Synlogic's product candidate is determined to be contained within the competitor's product for the same indication or disease.

In August 2016, the FDA granted Synlogic orphan drug designation for its lead product candidate *E. coli* Nissle bacterium modified to metabolize ammonia for the treatment of urea cycle disorders. Orphan drug designation will provide Synlogic with seven years of market exclusivity that begins when the BLA for the drug receives FDA marketing approval for the use for which the orphan drug status was granted.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The request may be made at the time of IND submission and generally no later than the pre-BLA meeting. The FDA will respond within 60 calendar days of receipt of the request. Priority review, which is requested at the time of BLA submission, is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs that treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. Discussions with the FDA about the feasibility of an accelerated approval typically begin early in the development of the drug in order to identify, among other things, an appropriate endpoint. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing clinical trials to confirm the appropriateness of the surrogate marker trial.

In the Food and Drug Administration Safety and Improvement Act (“FDASIA”), Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law’s enactment and also promulgate confirming regulatory changes. The FDA published a final guidance on May 30, 2014, entitled “Expedited Programs for Serious Conditions—Drugs and Biologics.” One of the expedited programs added by FDASIA is that for Breakthrough Therapy. A Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. A sponsor may request Breakthrough Therapy designation at the time that the IND is submitted, or no later than at the end of Phase 2 meeting. The FDA will respond to a Breakthrough Therapy designation request within 60 days of receipt of the request. A drug that receives Breakthrough Therapy designation is eligible for all Fast Track designation features, intensive guidance on an efficient drug development program, beginning as early as Phase 1 and commitment from the FDA involving senior managers. FDA has already granted this designation to several new biologics and two have received approval as of the end of March 2017.

In June 2017, the FDA granted Synlogic Fast Track designation for the use of a genetically modified strain of *E. coli* Nissle, SYNBI020, for the treatment of urea cycle disorders.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws and regulations. Synlogic relies, and expects to continue to rely, on third parties for the production of clinical and commercial quantities of its products. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of Synlogic’s contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by Synlogic or Synlogic’s partners pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time-to-time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, Synlogic will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of its products. Whether or not Synlogic obtains FDA approval for a product, Synlogic must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before it may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more “concerned” member states based on an assessment of an application performed by one member state, known as the “reference” member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

As in the United States, Synlogic may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of third party reimbursement. Third party payors include government healthcare programs such as Medicare, managed care providers, private health insurers and other organizations. Synlogic anticipates third party payors will provide reimbursement for its products. However, these third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly-approved healthcare products. Synlogic may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of its products. Synlogic’s product candidates may not be considered cost effective. It is time consuming and expensive for Synlogic to seek reimbursement from third party payors. Reimbursement may not be available or sufficient to allow Synlogic to sell its products on a competitive and profitable basis.

Medicare is a federal healthcare program administered by the federal government that covers individuals age 65 and over as well as individuals with certain disabilities. Drugs may be covered under one or more sections of Medicare depending on the nature of the drug and the conditions associated with and site of administration. For example, under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage for outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level.

Medicare Part B covers most injectable drugs given in an in-patient setting and some drugs administered by a licensed medical provider in hospital outpatient departments and doctors’ offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for a Part B-covered drug based on a percentage of manufacturer-reported average sales price, which is regularly updated. Synlogic believes that its product candidates that are intended to be administered intratumorally will be subject to the Medicare Part B rules.

Synlogic expects that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, “ACA”) enacted in March 2010, was expected to have a significant impact on the health care industry. ACA resulted in expanded coverage for the previously uninsured, however, President Trump ran for office on a platform that supported the repeal of the ACA and one of his first actions after his inauguration was to sign an Executive Order commanding federal agencies to try to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health care industry and others. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the ACA. The U.S. Senate is currently considering its own legislation, and while Synlogic believes that the Senate is unlikely to adopt the American Health Care Act as passed by the House of Representatives, Synlogic cannot predict whether the Senate will ever introduce its own bill, what a Senate bill will contain if it does, or whether the House of Representatives and the Senate will ultimately agree on a joint bill.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of Synlogic placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Synlogic’s products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other Regulatory Matters

Synlogic is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. These operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Synlogic's operations may also produce hazardous waste products. Synlogic contracts with third parties for the disposal of these materials and wastes.

Manufacturing

Synlogic has made and continues to make significant investments to develop manufacturing processes designed to allow it to reproducibly manufacture high quality living medicines at clinical scale and, later, at commercial scale to enable approval of its product candidates. Synlogic has a small-scale internal development group to support discovery and pre-clinical research and is building the organization to support scale-up and development towards commercialization. Synlogic currently works with contract manufacturing organizations ("CMOs") for clinical material and formulation development work.

Synlogic has successfully transferred its manufacturing process for its lead hyperammonemia program to a CMO where it was used to manufacture Phase 1 clinical material pursuant to FDA's cGMP requirements. Synlogic is similarly undertaking manufacturing technology transfer for its PKU program to supply material for its IND-enabling studies and subsequently for Phase 1 clinical trials.

These first clinical materials use a liquid formulation. Synlogic is investing in formulation development in parallel with Phase 1 clinical trial progress with the goal of providing a solid dose oral formulation (tablets or capsules) for later stage clinical development and commercial presentation, likely with a sachet formulation for pediatric use.

To enable the production of high levels of cells, or biomass, that can be administered as activated living medicines to perform metabolic functions, Synlogic can engineer its Synthetic Biotic medicines with switches. These switches are comprised of transcription factor and promoter pairs that allow for controlled expression of the therapeutic effectors produced by its Synthetic Biotic medicines. To ensure the metabolic capacity of the cells is allotted to the production of a high level of biomass during manufacturing, the effector circuits in the Synthetic Biotic programs are not expressed during this growth phase. At the end of the manufacturing process, the circuits are then induced, or activated. This two-step approach was designed to enable a high level of biomass production as well as to deliver the required activity necessary at the time of administration.

As Synlogic progresses in clinical development, it will need to scale up from Phase 1 clinical-scale to commercial-scale manufacturing. Synlogic is in the process of assessing CMOs who meet its criteria to supply its later-stage clinical development and commercial supply. Synlogic plans to compare the merits of working with one or more CMOs who meet its criteria with the possibility of building cGMP manufacturing capacity and capabilities internally.

Competition

The biotechnology industry is extremely competitive in the race to develop new products. While Synlogic believes it has significant competitive advantages with its industry-leading expertise in synthetic biology and metabolic engineering of probiotic bacteria, its clinical development expertise, and dominant intellectual property position, Synlogic currently faces and will continue to face competition for its development programs from companies that use synthetic biology or cell therapy development platforms and from companies focused on more conventional therapeutic modalities such as small molecules and antibodies. The competition is likely to come from multiple sources, including larger pharmaceutical companies, biotechnology companies and academia. Many of these competitors may have access to greater capital and resources than Synlogic. These competitors also compete with Synlogic in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in accessing technologies to enable Synlogic's programs. For any products that Synlogic may ultimately commercialize, not only will Synlogic compete with any existing therapies and those therapies currently in development, but it will also have to compete with new therapies that may become available in the future.

Competitors to Synlogic's efforts to provide living medicines to patients with a wide range of indications include other synthetic biology companies developing other synthetic biology methods, cellular and microbiome-based companies, DNA and RNA-based companies, as well as companies developing small molecules or other biologics. In the case of indications that Synlogic is targeting with Synlogic's own Synthetic Biotic medicines, competitors include, but are not limited to:

- *UCD*
 - Horizon Pharma plc has a licensed product; and
 - Dimension Therapeutics, Inc., Aeglea Biotherapeutics, Inc., Arcturus Therapeutics Inc., Castle Creek Pharma LLC, PhaseRx, Inc., RaNA Therapeutics and Selecta Biosciences, Inc. are each involved with discovery or pre-clinical stage product candidates.
- *HE*
 - Valeant Pharmaceuticals International, Inc. has a licensed product; and
 - Ocera Therapeutics, Inc., Umechrine Cognition AB and Salix Pharmaceuticals, Ltd, as well as other pre-clinical and discovery stage companies are each developing product candidates.

-
- *PKU*
 - BioMarin, Inc. has a licensed and development stage product; and
 - MipSalus ApS, Codexis, Inc., Dimension Therapeutics, Inc. and Synthetic Biologics, Inc. are each developing product candidates.

The Synlogic Team: Executives, Founders and Scientific Advisors

Synlogic's team of executives has proven track records of successfully translating scientific visions into successful commercial therapeutic products, solving complex issues in developing novel therapeutics and progressing new and novel products through regulatory approval. Synlogic's scientific founders, Timothy Lu, M.D., Ph.D., and James Collins, Ph.D., are experts in the emerging field of synthetic biology. In addition to Synlogic's management team and founders, it has established advisory relationships with researchers and clinicians dedicated to the development of Synthetic Biotic therapeutic products for patients with significant unmet medical needs and whose expertise spans synthetic biology, metabolic engineering, metabolism, immuno-modulation and immune-oncology arenas. Synlogic's scientific advisors include Dr. Lu and Dr. Collins; Christopher Voigt, Ph.D., Cammie Lesser, M.D., Ph.D. and Kristala Prather, Ph.D., experts in synthetic biology and bacterial metabolism; and Charles Mackay, Ph.D., Ulrich von Andrian, M.D., Ph.D. and Sangeeta Bhatia, M.D., Ph.D., experts in immunomodulation and oncology. Synlogic intends to expand its advisory boards as Synlogic grows. All of Synlogic's founders and advisors are equity holders in Synlogic and receive compensation as scientific advisors. Although they are regularly available for scientific consultation, Synlogic's arrangements with these individuals do not entitle Synlogic to any of their existing or future intellectual property derived from their independent research or research with other third parties.

Employees

As of July 1, 2017, Synlogic had 38 full-time employees, 25 of whom have an M.D. or Ph.D. Of Synlogic's full-time employees, 28 were primarily engaged in research and development activities. None of Synlogic's employees are subject to a collective bargaining agreement. Synlogic believes that it has good relations with its employees.

Facilities

Synlogic currently leases facilities at 200 Sidney Street, Suite 320, Cambridge, Massachusetts 02139 containing its research and development, laboratory and office spaces. This facility consists of approximately 14,390 square feet. Synlogic's lease expires in April 2021. However, this lease is likely to be terminated prematurely by agreement as Synlogic negotiates to enter into a new lease to replace the current Sidney Street facilities with increased occupancy in the first quarter of 2018.

Legal Proceedings

Synlogic is not currently a party to any material legal proceedings.

Corporate Information

Synlogic was incorporated in Delaware on March 14, 2014 under the name TMC Therapeutics, Inc. Its principal executive offices are located at 200 Sidney Street, Suite 320, Cambridge, Massachusetts 02139 and its telephone number is (617)-401-9947. Synlogic's website is www.synlogictx.com. References to Synlogic's website are inactive textual references only and the content of Synlogic's website should not be deemed incorporated by reference into this proxy statement/prospectus/information statement.

The following is an excerpt of portions of the prospectus contained in the Form S-4 registration statement (File No. 333-218885) as declared effective by the Securities and Exchange Commission on July 13, 2017. Such information is as of July 13, 2017 (unless an earlier date is indicated).

RISK FACTORS

The combined organization will be faced with a market environment that cannot be predicted and that involves significant risks, many of which will be beyond its control. In addition to the other information contained in this proxy statement/prospectus/information statement, you should carefully consider the material risks described below before deciding how to vote your shares of stock. In addition, you should read and consider the risks associated with the business of Mirna because these risks may also affect the combined organization—these risks can be found in Mirna’s Annual Report on Form 10-K, as updated by subsequent Quarterly Reports on Form 10-Q, all of which are filed with the SEC and incorporated by reference into this proxy statement/prospectus/information statement. You should also read and consider the other information in this proxy statement/prospectus/information statement and the other documents incorporated by reference into this proxy statement/prospectus/information statement. Please see the section entitled “Where You Can Find More Information” in this proxy statement/prospectus/information statement.

Risks Related to the Mirna Common Stock

Mirna’s stock price is volatile and Mirna Stockholders may not be able to resell shares of Mirna Common Stock at or above the price they paid.

The trading price of Mirna Common Stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond the company’s control. These factors include those discussed in this “Risk Factors” section of this proxy statement/prospectus/information statement and others such as:

- announcements relating to the Merger or any other strategic transaction;
- announcements relating to collaborations that Mirna may enter into with respect to the development or commercialization of Mirna’s product candidates;
- announcements relating to the receipt, modification or termination of government contracts or grants;
- product liability claims related to Mirna’s 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 Mirna’s intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting Mirna or its industry;
- sales of Mirna Common Stock by the company, its executive officers and directors or Mirna Stockholders in the future;
- future sales or issuances of equity or debt securities by us;
- lack of an active, liquid and orderly market in the Mirna Common Stock;
- fluctuations in Mirna’s quarterly operating results; and
- the issuance of new or changed securities analysts’ reports or recommendations regarding Mirna.

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 the Mirna 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 the Mirna Stockholders were to bring such a lawsuit against Mirna, the company could incur substantial costs defending the lawsuit and the attention of Mirna’s management would be diverted from the operation of the company’s business.

The Mirna Common Stock may be delisted from the NASDAQ Global Market if Mirna is unable to maintain compliance with NASDAQ’s continued listing standards.

NASDAQ imposes, among other requirements, continued listing standards including minimum bid and public float requirements. The price of the Mirna Common Stock must trade at or above \$1.00 to comply with NASDAQ’s minimum bid requirement for continued listing on the NASDAQ Global Market. If Mirna’s stock trades at bid prices of less than \$1.00 for a period in excess of 30 consecutive business days, NASDAQ could send a deficiency notice to the company for not remaining in compliance with the minimum bid listing standards. During the first quarter of fiscal year 2017, the Mirna Common Stock never traded below \$1.00.

However, if the closing bid price of the Mirna Common Stock fails to meet NASDAQ's minimum closing bid price requirement, or if Mirna otherwise fails to meet any other applicable requirements of NASDAQ and Mirna is unable to regain compliance, NASDAQ may make a determination to delist the Mirna Common Stock.

Any delisting of the Mirna Common Stock could adversely affect the market liquidity of the Mirna Common Stock and the market price of the Mirna Common Stock could decrease. Furthermore, if the Mirna Common Stock were delisted it could adversely affect Mirna's ability to obtain financing for the continuation of the company's operations and/or result in the loss of confidence by investors, customers, suppliers and employees.

Mirna's principal stockholders and management own a significant percentage of Mirna's stock and are able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of the Mirna Common Stock as of July 1, 2017, Mirna's officers and directors, together with holders of 5% or more of the Mirna Common Stock outstanding and their respective affiliates, beneficially own approximately 68% of Mirna Common Stock. Accordingly, these stockholders have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, the Merger, consolidation or sale of all or substantially all of Mirna's 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 of the company, even if such a change of control would benefit the other Mirna Stockholders, which could deprive Mirna Stockholders of an opportunity to receive a premium for their Mirna Common Stock as part of a sale of the company or its assets and might affect the prevailing market price of the Mirna Common Stock. The significant concentration of stock ownership may adversely affect the trading price of the Mirna Common Stock due to investors' perception that conflicts of interest may exist or arise.

Mirna is an "emerging growth company" and it cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the Mirna Common Stock less attractive to investors.

Mirna is 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 Mirna's 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. Mirna cannot predict if investors will find the Mirna Common Stock less attractive because Mirna may rely on these exemptions. If some investors find the Mirna Common Stock less attractive as a result, there may be a less active trading market for the Mirna Common Stock and Mirna's 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, Mirna is choosing to "opt out" of such extended transition period, and as a result, Mirna 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 Mirna's decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

Future sales of Mirna Common Stock or securities convertible or exchangeable for Mirna Common Stock may depress Mirna's stock price.

If the existing Mirna Stockholders or holders of Mirna's options sell, or indicate an intention to sell, substantial amounts of Mirna Common Stock in the public market, the trading price of Mirna Common Stock could decline. The perception in the market that these sales may occur could also cause the trading price of Mirna Common Stock to decline. As of July 1, 2017, there are a total of 20,856,693 shares of Mirna Common Stock outstanding.

In addition, based on the number of shares subject to outstanding awards under Mirna's 2008 Long Term Incentive Plan (the "2008 Stock Plan"), as of July 1, 2017, and including the initial reserves under the Mirna 2015 Plan and Mirna's Employee Stock Purchase Plan (the "ESPP"), approximately 5.1 million shares of Mirna Common Stock that are either subject to outstanding options, outstanding but subject to vesting, or reserved for future issuance under the 2008 Stock Plan, Mirna 2015 Plan or ESPP will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. Mirna also filed a registration statement permitting certain shares of Mirna Common Stock issued in the future pursuant to the 2008 Plan, Mirna 2015 Plan and ESPP to be freely resold by plan participants in the public market, subject to the applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. The Mirna 2015 Plan and ESPP also contain provisions for the annual increase of the number of shares reserved for issuance under such plans, which shares Mirna also intends to register. If the shares Mirna may issue from time to time under the 2008 Stock Plan, Mirna 2015 Plan or ESPP are sold, or if it is perceived that they will be sold, by the award recipient in the public market, the trading price of Mirna Common Stock could decline.

An active, liquid and orderly market for shares of Mirna Common Stock may not be sustained.

Prior to Mirna's IPO in October 2015, there had been no public market for the Mirna Common Stock, and an active public market for Mirna's shares may not be sustained. Further, certain of Mirna's existing institutional investors, including investors affiliated with certain of the company's directors, purchased approximately 2.4 million shares of Mirna Common Stock in the company's IPO and consequently fewer shares may be actively traded in the public market because these stockholders are restricted from selling the shares by restrictions under applicable securities laws, which would reduce the liquidity of the market for the Mirna Common Stock. If an active market for shares of Mirna Common Stock is not maintained it may be difficult for Mirna Stockholders

to sell their shares at the time they wish to sell them or at a price that they consider reasonable or it may result in volatility in Mirna's stock price. An inactive market may also impair Mirna's ability to raise capital by selling shares and may impair Mirna's ability to acquire other businesses or technologies or in-license new product candidates using Mirna's shares as consideration.

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

Mirna expects its operating results to be subject to quarterly fluctuations. Mirna's net loss and other operating results will be affected by numerous factors, including:

- variations in the level of the company's operating expenses;
- receipt, modification or termination of government contracts or grants, and the timing of payments Mirna receives under these arrangements;
- Mirna's execution of any collaborative, licensing or similar arrangements, and the timing of payments Mirna may make under these arrangements; and
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which Mirna may become involved.

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

Provisions of Mirna's charter documents or Delaware law could delay or prevent an acquisition of the company, even if the acquisition would be beneficial to Mirna Stockholders, and could make it more difficult for you to change management.

Provisions in Mirna's amended and restated certificate of incorporation and Mirna's amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that Mirna Stockholders may consider favorable, including transactions in which Mirna Stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by Mirna Stockholders to replace or remove the company's current management by making it more difficult to replace or remove the Mirna 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 the Mirna Board of Directors to elect a director to fill a vacancy created by the expansion of the Mirna Board of Directors or the resignation, death or removal of a director;
- a requirement that special meetings of Mirna Stockholders be called only by the Mirna Board of Directors, the chairman of the Mirna 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 the Mirna Board of Directors to issue preferred stock with such terms as the Mirna Board of Directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of Mirna's capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of Mirna's 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, Mirna's 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 Mirna by Mirna Stockholders. Mirna believes 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 Mirna's 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 Mirna, a court could find the choice of forum provisions contained in Mirna's amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

Provisions in Mirna's charter and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of Mirna Common Stock.

Mirna's employment agreements with its officers may require the company to pay severance benefits to any of those persons who are terminated in connection with a change of control of Mirna, which could harm its business, financial condition or results of operations.

Mirna's current executive officers are parties to employment agreements providing for aggregate cash payments of up to approximately \$1.4 million at July 1, 2017 for severance and other benefits in the event of a termination of employment in connection with a change of control of Mirna. The payment of these severance benefits could harm Mirna's 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 Mirna.

Mirna does not anticipate paying any cash dividends on Mirna Common Stock in the foreseeable future; therefore, capital appreciation, if any, of Mirna Common Stock will be your sole source of gain for the foreseeable future.

Mirna has never declared or paid cash dividends on Mirna Common Stock. Mirna does not anticipate paying any cash dividends on Mirna Common Stock in the foreseeable future. Mirna currently intends to retain all available funds and any future earnings to fund its 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 Mirna Common Stock. As a result, capital appreciation, if any, of Mirna 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 Mirna's business, Mirna's stock price and trading volume could decline.

The trading market for Mirna Common Stock will depend, in part, on the research and reports that securities or industry analysts publish about Mirna or its business. Securities and industry analysts do not currently, and may never, publish research on the company. If no securities or industry analysts commence coverage of the company, the trading price for Mirna Common Stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover Mirna downgrade the Mirna Common Stock or publish inaccurate or unfavorable research about Mirna's business, its stock price would likely decline. In addition, if the company's operating results fail to meet the forecast of analysts, its stock price would likely decline. If one or more of these analysts cease coverage of the company or fail to publish reports on Mirna regularly, demand for Mirna Common Stock could decrease, which might cause Mirna's stock price and trading volume to decline.

Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges or require Mirna to change its 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 Mirna to reclassify, restate or otherwise change or revise its financial statements, including those contained in this periodic report.

Risks Related to Synlogic's Financial Condition and Capital Requirements

Synlogic is a clinical-stage biopharmaceutical company with a history of losses, and it expects to continue to incur losses for the foreseeable future, and it may never achieve or maintain profitability.

Synlogic is a clinical-stage biopharmaceutical company focused on the development of Synthetic Biotics and it has incurred significant operating losses since its inception in 2014. Synlogic's net loss was \$21.0 million and \$8.5 million for the fiscal years ended December 31, 2016 and 2015, respectively, and \$7.4 million for the fiscal quarter ended March 31, 2017. As of March 31, 2017, Synlogic had an accumulated deficit of \$38.6 million. To date, Synlogic has not generated any product revenue. Substantially all of Synlogic's losses have resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations. Synlogic has no products on the market and it has initiated clinical development for only one product candidate, SYN1020, and expects that it will be many years, if ever, before Synlogic has a product candidate ready for commercialization.

Synlogic has not generated, and does not expect to generate, any product revenue for the foreseeable future, and Synlogic expects 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 Synlogic's potential future losses is uncertain. To achieve profitability, Synlogic 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 its business activities. Synlogic may never succeed in these activities and, even if it does, may never generate revenues that are significant or large enough to achieve profitability. Even if Synlogic does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Synlogic's failure to become and remain profitable would decrease the value of the company and could impair its ability to raise capital, maintain its research and development efforts, expand its business or continue its operations. A decline in the value of Synlogic could also cause its stockholders to lose all or part of their investment.

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

Synlogic has used substantial funds to discover and develop its 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 its product candidates, seek regulatory approvals for its product candidates and manufacture and market any products that are approved for commercial sale. Synlogic expects that the capital resources available to it as of March 31, 2017 will be sufficient to meet its anticipated cash requirements for at least the next 12 months. Synlogic's future capital requirements and the period for which it expects its existing resources to support its operations may vary significantly from what Synlogic expects. Synlogic's monthly spending levels vary based on new and ongoing research and development and corporate activities. Because Synlogic cannot be certain of the length of time or activities associated with successful development and commercialization of its product candidates, Synlogic is unable to estimate the actual funds it will require to develop and commercialize them.

Synlogic does not expect to realize any appreciable revenue from product sales or royalties in the foreseeable future, if at all. Synlogic's revenue sources will remain very limited unless and until its product candidates complete clinical development and are approved for commercialization and successfully marketed. To date, Synlogic has primarily financed its operations through sales of its securities and third party collaborations. Synlogic intends 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. Synlogic's ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond its control. Additional funds may not be available to Synlogic on acceptable terms or at all. If Synlogic raises additional funds by issuing equity or convertible debt securities, its stockholders will suffer dilution and the terms of any financing may adversely affect the rights of its stockholders. In addition, as a condition to providing additional funds to Synlogic, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, may involve restrictive covenants limiting Synlogic's 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 Synlogic is unable to obtain funding on a timely basis or on acceptable terms, or at all, it may have to delay, limit or terminate its research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo reductions in its workforce or other corporate restructuring activities. Synlogic also could be required to seek funds through arrangements with collaborators or others that may require it to relinquish rights to some of its product candidates or technologies that Synlogic would otherwise pursue on its own.

Synlogic's short operating history may make it difficult for stockholders to evaluate the success of its business to date and to assess its future viability.

Synlogic is a clinical-stage biopharmaceutical company with a limited operating history. Synlogic commenced active operations in 2014. Its operations to date have been limited to organizing and staffing its company, research and development activities, business planning and raising capital. Synlogic recently initiated a Phase I clinical trial with SYNBI020 in June 2017, but all of Synlogic's other therapeutic programs are still in the preclinical development stage. Synlogic will need to transition from a company with a research focus to a company capable of supporting clinical development and commercial activities. In addition, Synlogic expects to complete pre-clinical studies and to initiate a Phase I clinical trial of SYNBI618 in the first half of 2018. Synlogic has not yet demonstrated its ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on its 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. Synlogic may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may hinder its success in commercializing one or more of its product candidates. Further, drug development is a capital-intensive and highly speculative undertaking that involves a substantial degree of risk. You should consider Synlogic's 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 Synlogic's future prospects, plans or viability may not be as accurate as they may be if Synlogic had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Risks Related to the Development of Synlogic's Product Candidates

Clinical trials are costly, time consuming and inherently risky, and Synlogic 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. Synlogic cannot guarantee that any clinical trials it undertakes 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 Synlogic's product candidates include but are not limited to:

- inability to generate satisfactory pre-clinical or other non-clinical trials, 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 ("IRB") 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;

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- delays in recruiting qualified patients in its clinical trials;
 - failure by clinical sites or CROs or other third parties to adhere to clinical trial requirements;
 - failure by Synlogic, 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 Synlogic's 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 cost of clinical trials of Synlogic's product candidates;
 - negative or inconclusive results from Synlogic's clinical trials that may result in Synlogic deciding, or regulators requiring Synlogic, 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 reaching agreement on acceptable terms with third-party manufacturers or delays or failure in manufacturing sufficient quantities of its product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for its product candidates could result in additional costs to Synlogic or impair its ability to generate revenue. In addition, if Synlogic makes manufacturing or formulation changes to its product candidates, Synlogic may need to conduct additional pre-clinical studies 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 Synlogic's product candidates and may allow competitors to develop and bring products to market before Synlogic does, which could impair its ability to successfully commercialize its product candidates and may harm its business and results of operations.

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

Synlogic's 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.

Synlogic has concentrated its research and development efforts to date on a limited number of product candidates based on its Synthetic Biotic therapeutic platform and identifying its initial targeted disease indications. Synlogic's future success depends on its successful development of viable product candidates. There can be no assurance that Synlogic will not experience problems or delays in developing its 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 therapeutics can 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 Synlogic's product candidates in either the United States or the European Union or how long it will take to commercialize its product candidates, even if approved for marketing. Approvals by the European Commission may not be indicative of what the FDA, and vice versa, may require for approval and different or additional pre-clinical studies or clinical trials may be required to support regulatory approval in each respective jurisdiction. In addition, the FDA has advised Synlogic that the clinical development of SYNBI020 does not require submission to the National Institutes of Health's ("NIH") Recombinant DNA Advisory Committee ("RAC"), a committee that reviews human gene transfer protocols. Nevertheless, if RAC review is deemed necessary by one or more of Synlogic's clinical trial sites that receives NIH funding, its clinical trials could be delayed. Synlogic's product candidates do not involve gene transfers to humans, and Synlogic believes that they do not meet any of the criteria for that type of review. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease Synlogic's ability to generate sufficient product revenue, and Synlogic's business, financial condition, results of operations and prospects may be harmed.

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

A key element of Synlogic's strategy is to use its targeted focus and experienced management and scientific team to create Synthetic Biotic medicines that can be deployed against a broad range of human disease in order to build a pipeline of product candidates. Although Synlogic's research and development efforts to date have resulted in potential product candidates, Synlogic may not be able to continue to identify and develop additional product candidates. Even if Synlogic is successful in continuing to build its pipeline, the potential product candidates that Synlogic identifies 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 Synlogic does not successfully develop and commercialize product candidates based upon its approach, Synlogic will not be able to obtain product revenue in future periods, which likely would result in significant harm to its financial position. There is no assurance that Synlogic will be successful in its preclinical and clinical development, and the process of obtaining regulatory approvals will, in any event, require the expenditure of substantial time and financial resources.

Synlogic's 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 its product candidates could cause Synlogic or regulatory authorities to interrupt, delay or terminate Synlogic's 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 Synlogic's product candidates for their proposed indications.

Additionally, even if one or more of its product candidates receives marketing approval, and Synlogic 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 such products;
- regulatory authorities may require additional warnings on the labels of such products;
- Synlogic may be required to create a risk evaluation and mitigation strategy ("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;
- Synlogic could be sued and held liable for harm caused to patients; and
- Synlogic's reputation may suffer.

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

Synlogic's product development program may not uncover all possible adverse events that patients who take its product candidates may experience. The number of subjects exposed to Synlogic's 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, Synlogic cannot be fully assured that uncommon or severe side effects of its 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 Synlogic amend the labeling of the product or recall the product, or may even withdraw approval for the product. Any of these events could prevent Synlogic from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm its business, results of operations, and prospects.

Synlogic is heavily dependent on the success of its product candidates. Some of its product candidates have produced results in pre-clinical settings to date, but none of its product candidates have completed clinical trials, and Synlogic cannot give any assurance that it will generate data for any of its product candidates sufficient to receive regulatory approval in its planned indications, which will be required before they can be commercialized.

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

In addition, only Synlogic's lead product candidate has advanced into clinical trials, and none of Synlogic's product candidates have advanced into any pivotal clinical trial, for Synlogic's proposed indications and it may be years before any additional clinical trials, including any pivotal clinical trial, are initiated and completed, if at all. Synlogic is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and Synlogic may never receive such regulatory approval for any of its product candidates. Synlogic cannot be certain that any of its product candidates will be successful in clinical trials or receive regulatory approval. Further, its product candidates may not receive regulatory approval even if they are successful in clinical trials. If Synlogic does not receive regulatory approvals for its product candidates, Synlogic may not be able to continue its operations.

If Synlogic fails to obtain or maintain orphan drug exclusivity for some of its products, its competitors may obtain approval to sell the same drugs to treat the same conditions and its revenues will be reduced.

As part of Synlogic's business strategy, it has developed and may in the future develop product candidates that may be eligible for FDA and EU orphan drug designation. In August 2016, FDA granted orphan drug designation to SYN1020 for the treatment of UCD. 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 available in the EU with a ten-year period of market exclusivity.

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

Even though Synlogic has obtained orphan drug designation for its lead product candidate, and intends to seek orphan drug designation for other product candidates, there is no assurance that Synlogic will be the first to obtain marketing approval for any particular rare indication. Further, even though Synlogic has obtained orphan drug designation for its lead product candidate, or even if Synlogic obtains orphan drug designation for other potential product candidates, such designation may not effectively protect Synlogic 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 the same 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 pre-clinical 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. Synlogic has limited experience in designing clinical trials and it may be unable to design and execute clinical trials to support regulatory approval of its product candidates. In addition, pre-clinical study and clinical trial data are often susceptible to varying interpretations and analyses. Product candidates that seemingly perform satisfactorily in pre-clinical 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 Synlogic's clinical development could negatively affect its business and operating results.

If Synlogic experiences delays or difficulties in the enrollment of patients in clinical trials, Synlogic's 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, Synlogic's 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, Synlogic's success may depend, in part, on its ability to identify patients who qualify for its clinical trials, or are likely to benefit from any product candidate that it 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 Synlogic's current product candidates are targeted, may have relatively low prevalence. For example, Synlogic estimates 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 Synlogic, or any third parties that Synlogic engages to assist it, are unable to successfully identify patients with these diseases, or experience delays in doing so, then Synlogic may not realize the full commercial potential of any product candidate it develops.

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

The use or misuse of Synlogic's product candidates in clinical trials and the sale of any products for which Synlogic may obtain marketing approval exposes Synlogic to the risk of potential product liability claims. Product liability claims might be brought against Synlogic by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with its product candidates and approved products, if any. There is a risk that Synlogic's product candidates may induce adverse events. If Synlogic cannot successfully defend against product liability claims, it could incur substantial liability and costs. Patients with the diseases targeted by Synlogic's product candidates may already be in severe and advanced stages of disease and have both known and unknown significant preexisting 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 Synlogic's product candidates. Such events could subject Synlogic to costly litigation, require it to pay substantial amounts of money to injured patients, delay, negatively impact or end its opportunity to receive or maintain regulatory approval to market its products, or require Synlogic to suspend or abandon its commercialization efforts. Even in a circumstance in which an adverse event is unrelated to Synlogic's product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay Synlogic's regulatory approval process or impact and limit the type of regulatory approvals its 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 Synlogic's business, financial condition or results of operations.

Although Synlogic has product liability insurance, which covers any clinical trial it may conduct in the United States, its insurance may be insufficient to reimburse it for any expenses or losses Synlogic may suffer. Synlogic will also likely be required to increase its product liability insurance coverage for the advanced clinical trials that it plans to initiate. If Synlogic obtains marketing approval for any of its product candidates, it will need to expand its insurance coverage to include the sale of commercial products. There is no way to know if Synlogic will be able to continue to obtain product liability coverage and obtain expanded coverage it may require, in sufficient amounts to protect it against losses due to liability, on acceptable terms, or at all. Synlogic may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, its insurance coverage. Where Synlogic has provided indemnities in favor of third parties under its 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 Synlogic alleging that one of its 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 Synlogic, 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, its 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 Synlogic's product liability insurance, which Synlogic would then be required to pay itself;
- an increase in Synlogic's 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 Synlogic's business; and
- damage to Synlogic's reputation and the reputation of its products and its technology.

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

Risks Related to Regulatory Approval of Synlogic's Product Candidates and Other Legal Compliance Matters

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

Synlogic may seek a breakthrough therapy designation from the FDA for some of its 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 while minimizing the number of patients placed in ineffective control regimens. 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 Synlogic believes one of its 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 Synlogic's 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.

Synlogic may seek Fast Track designation for one or more of its product candidates, but it might not receive such designation, and even if Synlogic does, 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. If Synlogic seeks Fast Track designation for one or more of its product candidates, Synlogic may not receive such designation. However, even if Synlogic receives Fast Track designation, Fast Track designation does not ensure that Synlogic will receive marketing approval for the product candidate or that approval will be granted within any particular timeframe. Synlogic 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 Synlogic's clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Even if Synlogic obtains regulatory approval for a product candidate, Synlogic will remain subject to ongoing regulatory requirements.

If any of Synlogic's product candidates are approved for marketing, Synlogic 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 ("cGMP") regulations and corresponding foreign regulatory manufacturing requirements. As such, Synlogic and its contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or marketing authorization application.

Any regulatory approvals that Synlogic receives for its 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. Synlogic 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 its original marketing approval for a product candidate was obtained through an accelerated approval pathway, Synlogic could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for its 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 Synlogic, including requiring withdrawal of the product from the market. If Synlogic fails 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;
- suspend any of Synlogic's ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by Synlogic;
- impose restrictions on Synlogic's operations, including closing its contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would be expected to require Synlogic 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 Synlogic's ability to develop and commercialize its products and the value of Synlogic and its operating results would be adversely affected.

Healthcare legislative reform measures may have a material adverse effect on Synlogic's business, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, 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.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017 that authorizes the implementation of legislation that would repeal portions of the ACA. Although such budget resolution is not a law, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. As of June 2017, the House of Representatives has passed a new plan that would repeal and significantly alter many of the ACA's provisions if it were ever enacted, and the Senate is working on its own bill to accomplish the same goals. At this time, the immediate impact of the Executive Order and any of the legislation being considered by Congress is not clear. In addition, other legislative changes have been proposed or adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on Synlogic's customers and, accordingly, its financial operations.

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 Synlogic's customers may receive for its 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 Synlogic from being able to generate revenue, attain profitability or commercialize its products.

Synlogic 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 Synlogic is unable to comply, or has not fully complied, with such laws, it could face substantial penalties.

If Synlogic obtains FDA approval for any of its product candidates and begins commercializing those products in the United States, its 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, Synlogic's proposed sales, marketing, and education programs. In addition, Synlogic may be subject to patient privacy regulation by both the federal government and the states in which Synlogic conducts its business. The laws that may affect Synlogic's 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 Synlogic's 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 Synlogic's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to Synlogic, Synlogic 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 its operations, any of which could adversely affect Synlogic's ability to operate its business and its results of operations.

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

Synlogic's research and development activities and its third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of its product candidates and other hazardous compounds. Synlogic and its 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 Synlogic's and its manufacturers' facilities pending their use and disposal. Synlogic cannot eliminate the risk of contamination, which could cause an interruption of its 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 Synlogic believes that the safety procedures utilized by it and its third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, Synlogic cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, Synlogic may be held liable for any resulting damages and such liability could exceed its resources and state or federal or other applicable authorities may curtail Synlogic's use of specified materials and/or interrupt its business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. Synlogic cannot predict the impact of such changes and cannot be certain of its future compliance. Given the nature of the research and development work conducted by Synlogic, the company does not currently carry biological or hazardous waste insurance coverage.

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

To develop, manufacture and sell certain products outside the United States, Synlogic must dedicate resources to comply with numerous laws and regulations in each jurisdiction in which Synlogic operates. The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. 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-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. These laws may preclude Synlogic from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit Synlogic's growth potential and increase its 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.

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

Synlogic's internal computer systems and those of its 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. While Synlogic has not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of Synlogic's development programs and its business operations, whether due to a loss of its trade secrets or other proprietary information or other similar disruptions. For example, the loss of pre-clinical or clinical trial data could result in delays in Synlogic's regulatory approval efforts and significantly increase its 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, Synlogic's data or applications, or inappropriate disclosure of confidential or proprietary information, Synlogic could incur liability, its competitive position could be harmed and the further development and commercialization of its product candidates could be delayed.

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

Synlogic's 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 Synlogic's technologies, product candidates and processes. If Synlogic and its collaborators are not able to overcome the ethical, legal and social concerns relating to synthetic biology and genetic engineering, Synlogic's 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 Synlogic's programs or the public acceptance and commercialization of Synthetic Biotic medicines. Further, there is a risk that Synthetic Biotic medicines made using Synlogic's technologies could result in adverse health effects or other adverse events, which could also lead to negative publicity. Synlogic designs and produces 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 Synlogic's business, financial condition or results of operations and Synlogic may have exposure to liability for any resulting harm.

Risks Related to Synlogic's Intellectual Property

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

Presently, Synlogic has rights to certain intellectual property, through licenses from third parties and under patents and patent applications owned by Synlogic. The growth of Synlogic's business will likely depend in part on Synlogic's ability to obtain, maintain or enforce its and its licensors' intellectual property rights and also acquire or in-license additional proprietary rights. For example, Synlogic's programs may involve additional product candidates or delivery systems that may require the use of additional proprietary rights held by third parties. Synlogic's 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. Synlogic may be unable to acquire or in-license any relevant third-party intellectual property rights that Synlogic identifies as necessary or important to its business operations.

In addition, Synlogic's product candidates may require specific formulations to work effectively and efficiently and these rights may be held by other third parties. Synlogic 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 it identifies. 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 Synlogic may consider attractive. These companies could have a competitive advantage over Synlogic due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, Synlogic has previously and may continue to collaborate with academic institutions to accelerate its pre-clinical 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, Synlogic may be unable to negotiate a license within the specified time frame or under terms that are acceptable to it. If Synlogic is unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking Synlogic's ability to pursue its program.

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

Synlogic intends to rely on patent rights and the status of its 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 its markets.

Synlogic relies or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to its technologies and product candidates. Its success depends in large part on its and its 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 its proprietary technology and products.

Synlogic has sought to protect its proprietary position by filing patent applications in the United States and abroad related to its product candidates that are important to its business. This process is expensive and time consuming, and Synlogic 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 Synlogic will fail to identify patentable aspects of its 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 Synlogic owns or in-licenses may fail to result in issued patents with claims that cover its product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to Synlogic's 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 Synlogic's 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, Synlogic's patents and patent applications may not adequately protect its intellectual property, provide exclusivity for its product candidates, or prevent others from designing around Synlogic's claims. Any of these outcomes could impair Synlogic's ability to prevent competition from third parties, which may have an adverse impact on its business.

Synlogic, independently or together with its licensors, has filed several patent applications covering various aspects of its product candidates. Synlogic 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 Synlogic after patent issuance could deprive Synlogic of rights necessary for the successful commercialization of any product candidates that Synlogic may develop. Further, if Synlogic encounters delays in regulatory approvals, the period of time during which Synlogic could market a product candidate under patent protection could be reduced.

Even if Synlogic cannot obtain and maintain effective protection of exclusivity from its regulatory efforts and intellectual property rights, including patent protection, data exclusivity or orphan drug exclusivity, for its product candidates, Synlogic believes that its 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. If a biosimilar version of one of Synlogic's product candidates were approved in the U.S., it could have a negative effect on Synlogic's business.

Synlogic may not have sufficient patent term protections for its product candidates to effectively protect its 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 Synlogic's product candidates are obtained, once the patent life has expired for a product candidate, Synlogic may be open to competition from generic medications. 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 Synlogic's product candidates. Synlogic will likely seek patent term extensions, and Synlogic cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, Synlogic may not be able to maintain exclusivity for its product candidates for an extended period after regulatory approval, if any, which would negatively impact its business, financial condition, results of operations and prospects. If Synlogic does not have sufficient patent terms or regulatory exclusivity to protect its product candidates, its 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 Synlogic's ability to protect its products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of its patent applications and the enforcement or defense of its issued patents.

As is the case with other biotechnology companies, Synlogic's 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 Synlogic's 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 Synlogic's ability to obtain new patents or to enforce Synlogic's existing patents and patents that it might obtain in the future.

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

In addition to the protection afforded by patents, Synlogic relies on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that Synlogic elects not to patent. Synlogic also utilizes processes for which patents are difficult to enforce. In addition, other elements of Synlogic's products, and many elements of its 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. Synlogic seeks to protect its proprietary technology and processes, in part, by entering into confidentiality agreements with its employees, consultants, collaborators, advisors, independent contractors or other third parties. Synlogic also seeks to preserve the integrity and confidentiality of its data and trade secrets, including by maintaining physical and electronic security of its premises and its information technology systems. While Synlogic has confidence in these individuals, organizations and systems, agreements or security measures may be breached, and Synlogic may not have adequate remedies for any breach. In addition, competitors may otherwise gain access to Synlogic's 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, Synlogic may encounter significant problems in protecting and defending its intellectual property both in the United States and abroad. If Synlogic is unable to prevent unauthorized material disclosure of its intellectual property to third parties, or misappropriation of its intellectual property by third parties, it may not be able to establish or maintain a competitive advantage in its market, which could materially adversely affect its business, operating results, and financial condition.

Although Synlogic expects all of its employees and consultants to assign their inventions to Synlogic, and all of its employees, consultants, collaborators, advisors, independent contractors and any third parties who have access to its proprietary know-how, information, or technology to enter into confidentiality agreements, Synlogic cannot provide any assurances that all such agreements have been duly executed or that its trade secrets and other confidential proprietary information will not be disclosed or that

competitors will not otherwise gain access to its trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of Synlogic's trade secrets could impair its competitive position and may have a material adverse effect on its business, financial condition or results of operations. Additionally, if the steps taken to maintain its trade secrets are deemed inadequate, Synlogic may have insufficient recourse against third parties for misappropriating the trade secret.

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

Synlogic's commercial success depends in part on its ability to develop, manufacture, market and sell its product candidates and use its 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 Biotics. Synlogic is aware of U.S. and foreign patents and pending patent applications owned by third parties that cover similar therapeutic uses as the product candidates Synlogic is developing. Synlogic is currently monitoring these patents and patent applications. Synlogic 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, Synlogic 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 its product candidates or technologies, Synlogic may not be free to manufacture or market its product candidates as planned, absent such a license, which may not be available to Synlogic on commercially reasonable terms, or at all.

It is also possible that Synlogic has 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 Synlogic, to identify all third-party patent rights that may be relevant to its 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. Synlogic 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 its technology. In addition, Synlogic 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 Synlogic may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by its activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover Synlogic's technologies, its product candidates or the use of its 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 Synlogic is developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that its product candidates may be subject to claims of infringement of the patent rights of third parties.

Parties making claims against Synlogic may obtain injunctive or other equitable relief, which could effectively block its ability to further develop and commercialize one or more of its 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 Synlogic's business. In the event of a successful claim of infringement against Synlogic, Synlogic may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign its infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Synlogic depends, in part, on its licensors to file, prosecute, maintain, defend and enforce patents and patent applications that are material to its business.

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

If Synlogic fails to comply with obligations in the agreements under which Synlogic licenses intellectual property and other rights from third parties or otherwise experiences disruptions to its business relationships with its licensors, Synlogic could lose license rights that are important to its business.

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

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

Competitors may infringe Synlogic's patents or the patents of its licensors. To cease such infringement or unauthorized use, Synlogic or one of its licensing partners may be required to file patent infringement claims against a third party to enforce one of its patents which can be expensive, time-consuming and unpredictable. In addition, in an infringement proceeding or a declaratory judgment action against Synlogic, a court may decide that one or more of Synlogic's 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 Synlogic's patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of Synlogic's patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put its 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 Synlogic's business.

If Synlogic or one of its licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of Synlogic's product candidates, the defendant could counterclaim that the patent covering Synlogic's 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 Synlogic's patents in such a way that they no longer cover and protect Synlogic's product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of Synlogic's patents, for example, Synlogic cannot be certain that there is no invalidating prior art of which Synlogic, its 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, Synlogic may lose at least part, and perhaps all, of the patent protection on its product candidates. Such a loss of patent protection could have a material adverse impact on Synlogic's business.

Interference or derivation proceedings provoked by third parties or brought by Synlogic or declared by the USPTO may be necessary to determine the priority of inventions or correct inventorship with respect to Synlogic's patents or patent applications or those of its licensors. An unfavorable outcome could result in a loss of Synlogic current patent rights and could require Synlogic to cease using the related technology or to attempt to license rights to it from the prevailing party. Synlogic's business could be harmed if the prevailing party does not offer Synlogic a license on commercially reasonable terms. Synlogic's defense of litigation, derivation or interference proceedings may result in a decision adverse to Synlogic's interests and, even if successful, may result in substantial costs and distract its management and other employees. In addition, Synlogic may be unable to raise the funds necessary to conduct its clinical trials, continue its research programs, license necessary technology from third parties, or enter into development partnerships that would help Synlogic bring its 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 Synlogic's 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 Synlogic's business. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of Synlogic's common stock.

Synlogic may be subject to claims challenging the inventorship of its patents and other intellectual property.

Synlogic may in the future be subject to claims that former employees, consultants, collaborators, advisors, independent contractors or other third parties have an interest in its patents or other intellectual property as an inventor or co-inventor or other claims challenging the inventorship of its patents or ownership of its intellectual property (including patents and intellectual property that Synlogic in-licenses). Therefore, Synlogic's rights to these patents may not be exclusive and third parties, including competitors, may have access to intellectual property that is important to Synlogic's business. In addition, co-owners from whom Synlogic does 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 Synlogic would not have rights under its 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, Synlogic may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing its product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship of Synlogic's patents. If Synlogic fails in defending any such claims, in addition to paying monetary damages, Synlogic 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 Synlogic's business. Even if Synlogic is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Synlogic has received confidential and proprietary information from third parties. In addition, Synlogic employs individuals who were previously employed at universities, academic research institutions and at other biotechnology or pharmaceutical companies, including Synlogic's competitors or potential competitors. Although Synlogic has written agreements with and makes every effort to ensure that its 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 Synlogic, Synlogic may in the future be subject to claims that its 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 Synlogic fails in defending any such claims, in addition to paying monetary damages, Synlogic may lose valuable intellectual property rights or personnel, which could adversely impact its business. Even if Synlogic is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Synlogic may not be able to protect its intellectual property rights throughout the world.

Synlogic has 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, Synlogic may not be able to prevent third parties (including competitors) from practicing its inventions in all countries outside the United States, or from selling or importing products made using Synlogic's inventions in and into the United States or other jurisdictions. Competitors may use Synlogic's technologies in jurisdictions where Synlogic has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where Synlogic has patent protection, but where enforcement rights are not as strong as those in the United States. These products may compete with Synlogic's products and Synlogic's 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 Synlogic to stop the infringement or misappropriation of its patents or other intellectual property rights, or the marketing of competing products in violation of Synlogic proprietary rights. Proceedings to enforce Synlogic's patents and other intellectual property rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert Synlogic's efforts and attention from other aspects of its business. Furthermore, such proceedings could put Synlogic's patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put its patent applications at risk of not issuing and could provoke third parties to assert claims of infringement or misappropriation against Synlogic. Synlogic may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, its efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that Synlogic develops or licenses.

If Synlogic's trademarks and trade names are not adequately protected, it may not be able to build name recognition in its markets of interest and its business may be adversely affected.

Synlogic has filed for trademark registration of certain marks relating to its current branding. If Synlogic's trademarks and trade names are not adequately protected, it may not be able to build name recognition in its markets of interest and its business may be adversely affected. Synlogic's unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Synlogic may not be able to protect its rights to these trademarks and trade names, which it needs to build name recognition among potential partners or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to Synlogic's, thereby impeding its 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 Synlogic's unregistered trademarks or trade names. Over the long term, if Synlogic is unable to successfully register its trademarks and trade names and establish name recognition based on its trademarks and trade names, then Synlogic may not be able to compete effectively and its business may be adversely affected. Synlogic's efforts to enforce or protect its 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 its financial condition or results of operations.

Risks Related to Synlogic's Reliance on Third Parties

Synlogic relies, and expects to continue to rely, on third parties to conduct some aspects of its compound 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.

Synlogic does not independently conduct all aspects of its drug discovery activities, compound formulation research or preclinical studies of product candidates. Synlogic currently relies, and expects to continue to rely, on third parties to conduct some aspects of its research and development and preclinical studies. Any of these third parties may terminate their engagements with Synlogic at any time. If Synlogic needs to enter into alternative arrangements, it would delay Synlogic's product development activities. Synlogic's reliance on these third parties for research and development activities reduces its control over these activities but

does not relieve Synlogic of its responsibilities. For example, for product candidates that Synlogic develops and commercializes on its own, Synlogic will remain responsible for ensuring that each of its studies that support its clinical trial applications and its 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 Synlogic's studies in accordance with regulatory requirements or its stated study plans and protocols, Synlogic will not be able to complete, or may be delayed in completing, the necessary preclinical studies to enable Synlogic or its strategic alliance partners to select viable product candidates for clinical trial application submissions and will not be able to, or may be delayed in its efforts to, successfully develop and commercialize such product candidates.

Synlogic relies on third-party supply and manufacturing partners for drug supplies for its research and development, preclinical activities, and clinical activities, and may do the same for any commercial supplies of its product candidates.

Synlogic relies on third-party supply and manufacturing partners to supply the materials and components for, and manufacture, a portion of its research and development and preclinical study drug supplies and may do the same for any clinical trial drug supplies. Synlogic has not yet manufactured or formulated any product candidate on a commercial scale and may not be able to do so for any of its product candidates. Synlogic will work to develop and optimize its manufacturing process, and Synlogic cannot be sure that the process will result in therapies that are safe, potent or effective.

Synlogic does not own manufacturing facilities or supply sources for such components and materials, but may develop these capabilities in the future. There can be no assurance that Synlogic's 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 Synlogic may engage could require significant effort and expertise because there may be a limited number of qualified replacements.

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 cGMP regulations. In the event that any of Synlogic's suppliers or manufacturers fails to comply with such requirements or to perform its obligations to Synlogic in relation to quality, timing or otherwise, or if Synlogic's supply of components or other materials becomes limited or interrupted for other reasons, Synlogic may be forced to manufacture the materials itself, for which Synlogic currently does not have the capabilities or resources, or enter into an agreement with another third party, which Synlogic may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture Synlogic's product candidates may be unique or proprietary to the original manufacturer and Synlogic may have difficulty, or there may be contractual restrictions prohibiting Synlogic from, transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase Synlogic's reliance on such manufacturer or require Synlogic to obtain a license from such manufacturer in order to have another third party manufacture its product candidates. If Synlogic is required to change manufacturers for any reason, it 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 Synlogic's ability to develop product candidates in a timely manner or within budget.

Synlogic may rely on third party manufacturers if it receives regulatory approval for any product candidate. To the extent that Synlogic has existing, or enters into future, manufacturing arrangements with third parties, it 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 Synlogic is unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, Synlogic may not be able to develop and commercialize its product candidates successfully. Synlogic's or a third party's failure to execute on Synlogic's manufacturing requirements could adversely affect Synlogic's business in a number of ways, including:

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

Synlogic enters into various contracts in the normal course of its business in which Synlogic indemnifies the other party to the contract. In the event Synlogic has to perform under these indemnification provisions, it could have a material adverse effect on its business, financial condition and results of operations.

In the normal course of business, Synlogic periodically enters into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to Synlogic's academic and other research agreements, Synlogic typically indemnifies 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 Synlogic has secured licenses, and from claims arising from Synlogic's or its sublicensees' exercise of rights under the agreement. With respect to Synlogic's collaboration agreements, Synlogic indemnifies its 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, Synlogic indemnifies consultants from claims arising from the good faith performance of their services.

Should Synlogic's obligation under an indemnification provision exceed applicable insurance coverage or should Synlogic be denied insurance coverage, Synlogic's business, financial condition and results of operations could be adversely affected. Similarly, if Synlogic is relying on a collaborator to indemnify Synlogic 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 Synlogic, its business, financial condition and results of operations could be adversely affected.

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

Synlogic is currently party to an agreement with AbbVie. Biotechnology companies sometimes become dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of product candidates. If Synlogic elects to enter into collaborative arrangements or strategic alliances, these arrangements may place the development of its product candidates outside its control, may require it to relinquish important rights or may otherwise be on terms unfavorable to it.

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

- Synlogic may not be able to control the amount and timing of resources that its collaborators may devote to the relevant product candidates;
- Synlogic's collaborators may experience financial difficulties;
- Synlogic 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 its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including Synlogic's competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing Synlogic's drug candidates.

Synlogic may attempt to form collaborations in the future with respect to its product candidates, but it may not be able to do so, which may cause it to alter its development and commercialization plans.

Synlogic may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to its programs or platform that it believes will complement or augment its existing business. Synlogic may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. Synlogic may not be successful in its efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable to it, or at all. This may be because Synlogic's product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, its 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 its 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 Synlogic's product candidates could delay the development or commercialization of Synlogic's product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, Synlogic would need to undertake development and/or commercialization activities at its own expense. If Synlogic elects to fund and undertake development and/or commercialization activities on its own, it may need to obtain additional expertise and additional capital, which may not be available to it on acceptable terms or at all. If Synlogic is unable to do so, it may not be able to develop its product candidates or bring them to market and its business may be materially and adversely affected.

If Synlogic commits certain material breaches under its agreement with the Gates Foundation, and fails to cure them, the Gates Foundation may exercise a right to obtain a license to certain of Synlogic's intellectual property or require Synlogic to redeem shares of Synlogic Capital Stock held by the Gates Foundation and its affiliates.

In September 2014, Synlogic entered into a letter agreement with the Bill & Melinda Gates Foundation (the "Gates Foundation"). In connection with the agreement, the Gates Foundation purchased \$1.0 million of Series A-1 preferred stock, \$1.4 million of Series A-2 preferred stock and \$2.6 million of Class A-3 preferred units, and Synlogic committed to use a portion of the investment by the Gates Foundation to generally develop its Synthetic Biotic platform for potential use in neglected diseases prioritized by the Gates Foundation. In the event the Gates Foundation terminates the agreement for certain specified uncured material breaches by Synlogic, Synlogic will be obligated, among other remedies, to redeem the securities purchased by the Gates Foundation or to facilitate the purchase of such securities by a third party (in certain circumstances, Synlogic may instead satisfy such obligation by registering the resale of the securities into the public markets or through the ability of the Gates Foundation to resell the securities without volume limitations in reliance on Rule 144 under the Securities Act), and/or the Gates Foundation may exercise its right to obtain a non-exclusive license to certain of Synlogic's intellectual property for use in certain prioritized diseases in developing countries. Additionally, in the six months following such sale or redemption, if Synlogic engages in certain specified corporate transactions that

would value the sold or redeemed shares at more than 200% of the valuation used for the sale or redemption, Synlogic will be required to compensate the Gates Foundation for the difference between what the Gates Foundation would have received and what it actually received under the sale or redemption. If Synlogic instead elects to register the resale of the securities into the public markets or the Gates Foundation resells the securities in reliance on Rule 144, Synlogic will be required to compensate the Gates Foundation for the difference between what the Gates Foundation initially invested and what it actually received under such resale if there is any shortfall. If Synlogic is required to redeem such shares or to compensate the Gates Foundation following a specified corporate transaction or a resale, Synlogic's financial condition could be materially and adversely affected. If the Gates Foundation exercises its right to obtain a non-exclusive license and develops and commercializes product candidates and products that Synlogic is also developing and commercializing, such exercise could have an adverse impact on Synlogic's market position.

Risks Related to Commercialization of Synlogic's Product Candidates

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

Synlogic currently has no sales, marketing or distribution capabilities or experience. If any of Synlogic's product candidates is approved for marketing and commercialization, Synlogic 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 Synlogic decides to market its products directly, Synlogic 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 Synlogic relies on third parties with such capabilities to market its products or decides to co-promote products with collaborators, Synlogic will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that Synlogic 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 Synlogic receives 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 Synlogic is not successful in commercializing any product approved for marketing and commercialization in the future, either on its own or through third parties, Synlogic's business, financial condition, results of operations and prospects may be adversely affected.

If the market opportunities for its product candidates are smaller than Synlogic believes they are, Synlogic may not meet its revenue expectations and, assuming approval of a product candidate, its business may suffer. Because the patient populations in the market for its product candidates may be small, Synlogic 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 Synlogic is targeting, its eligible patient population and pricing estimates may differ significantly from the actual market addressable by its product candidates. Synlogic's 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 its product candidates, are based on its 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 its product candidates may be limited or may not be amenable to treatment with its product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect Synlogic's business, financial condition, results of operations and prospects.

Synlogic faces substantial competition and its competitors may discover, develop or commercialize products faster or more successfully than Synlogic.

The development and commercialization of new products is highly competitive. Synlogic faces competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to its product candidates that it may seek to develop or commercialize in the future. For example, Horizon Pharma plc, Dimension Therapeutics, Inc., Aeglea Biotherapeutics, Inc., Arcturus Therapeutics Inc., Castle Creek Pharma LLC, PhaseRx, Inc., Rana Therapeutics and Selecta Biosciences, Inc. have developed or are developing product candidates for the treatment of UCD; Valeant Pharmaceuticals International, Inc., Ocera Therapeutics, Inc., Umechrine Cognition AB, Salix Pharmaceuticals, Ltd, as well as other preclinical and discovery stage companies have developed or are each developing product candidates for the treatment of HE; and BioMarin, Inc., MipSalus ApS, Codexis, Inc., Dimension Therapeutics, Inc. and Synthetic Biologics, Inc. have developed or are developing product candidates for the treatment of PKU. Synlogic's competitors may succeed in developing, acquiring or licensing technologies and products that are more effective or less costly than the product candidates that Synlogic is currently developing or that it may develop, which could render Synlogic's product candidates obsolete and noncompetitive.

In addition to the competition Synlogic faces from alternative therapies for the diseases it intends to target with its product candidates, Synlogic is 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 Synlogic's 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 Synlogic's competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than Synlogic, it could result in its competitors establishing a strong market position before Synlogic is able to enter the market.

Many of Synlogic's competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than it does. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in Synlogic's competitors. Large pharmaceutical companies in particular have extensive expertise in pre-clinical 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 Synlogic's competitors. Failure of Synlogic's product candidates to effectively compete against established treatment options or in the future with new products currently in development would harm Synlogic's business, financial condition, results of operations and prospects.

The commercial success of any of Synlogic's 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 Synlogic's products will depend in part on the health care providers, patients, and third-party payors accepting Synlogic's product candidates as medically useful, cost-effective, and safe. Any product that Synlogic brings to the market may not gain market acceptance by physicians, patients and third-party payors. The degree of market acceptance of any of Synlogic's 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 these therapies;
- the perceived ratio of risk and benefit of these therapies by physicians, patients, and payors, 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 its products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other health care providers, Synlogic will not be able to generate sufficient revenue to become or remain profitable.

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

Although a substantial amount of Synlogic's effort will focus on the clinical testing, potential approval, and commercialization of its existing product candidates, the success of Synlogic's business is also expected to depend in part upon its 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. Synlogic may focus its efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Synlogic's 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:

- Synlogic's research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- Synlogic may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- Synlogic's product candidates may not succeed in pre-clinical or clinical testing;
- Synlogic's 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 Synlogic's product candidates obsolete or less attractive;
- product candidates Synlogic develops 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, Synlogic may be forced to abandon its development efforts for one or more product candidates, or Synlogic may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on its business, financial condition or results of operations and could potentially cause Synlogic to cease operations.

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

The pricing, coverage, and reimbursement of Synlogic's approved products, if any, must be sufficient to support its 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 Synlogic's approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of its 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, Synlogic may have to subsidize or provide products for free or Synlogic may not be able to successfully commercialize its 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 Synlogic's and what reimbursement codes its 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 Synlogic believes 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 Synlogic is able to charge for its products, if any. Accordingly, in markets outside the United States, the potential revenue from the sale of Synlogic's 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 its products. Synlogic expects 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 Synlogic's products, if any, may be more difficult to achieve even if they receive regulatory approval.

Risks Related to Synlogic's Business Operations and Employees

Synlogic's failure to attract and retain senior management and key scientific personnel may prevent it from successfully developing its product candidates or any future product candidate, conducting its clinical trials and commercializing any products.

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

Although Synlogic has not historically experienced significant difficulties attracting and retaining qualified employees, it 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 Synlogic's industry. Synlogic will need to hire additional personnel as it expands its clinical development and commercial activities. Synlogic may not be able to attract and retain quality personnel on acceptable terms, or at all.

Synlogic's 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.

Synlogic is exposed to the risk that its 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 Synlogic is performing activities in relation to its 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 Synlogic's reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions Synlogic takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting itself 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 Synlogic, and Synlogic is not successful in defending itself or asserting its rights, those actions could have a significant impact on Synlogic's 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 its operations, any of which could adversely affect Synlogic's ability to operate its business and its results of operations.

Risks Related to the Combined Organization

Mirna's stock price is expected to be volatile, and the market price of Mirna Common Stock may drop following the Merger.

The market price of Mirna Common Stock following the Merger could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of Mirna Common Stock to fluctuate following the Merger include:

- the ability of the combined organization to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- the failure of any of the combined organization's product candidates, if approved for marketing and commercialization, to achieve commercial success;
- issues in manufacturing the combined organization's approved products, if any, or product candidates;
- the results of current, and any future, preclinical or clinical trials of the combined organization's product candidates;
- the entry into, or termination of, key agreements, including key licensing or collaboration agreements;
- the initiation of material developments in, or conclusion of, litigation to enforce or defend any of the combined organization's intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments;
- adverse publicity relating to the combined organization's markets, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies competing with potential products of the combined organization;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover the Mirna Common Stock;
- general and industry-specific economic conditions potentially affecting the combined organization's research and development expenditures;
- changes in the structure of health care payment systems;
- period-to-period fluctuations in the combined organization's financial results;
- failure to meet or exceed financial and development projections the combined organization may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislators, regulators, and the investment community;
- adverse regulatory decisions;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and the combined organization's ability to obtain patent protection for its technologies;
- sales of the Mirna Common Stock by the combined organization or its stockholders in the future;
- trading volume of the Mirna Common Stock; and
- period-to-period fluctuations in the combined organization's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies or the biotechnology sector. These broad market fluctuations may also adversely affect the trading price of the combined organization's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management's attention and resources, which could significantly harm the combined organization's profitability and reputation.

The combined organization will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm the combined organization's operating results.

The combined organization will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. The combined organization will also incur costs associated with complying with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, as well as rules implemented by the SEC or NASDAQ or any other stock exchange or inter-dealer quotations system on which the Mirna Common Stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. Synlogic expects that these rules and regulations will substantially increase Synlogic's legal and financial compliance costs and to make some activities more time-consuming and costly. Synlogic is unable currently to estimate these costs with any degree of certainty. Synlogic also expects that these new rules and regulations may make it difficult and expensive for the combined organization to obtain director and officer liability insurance, and if the combined organization is able to obtain such insurance, it may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for the combined organization to attract and retain qualified individuals to serve on its board of directors or as its executive officers.

Anti-takeover provisions in the combined organization's charter documents and under Delaware law could make an acquisition of the combined organization more difficult and may prevent attempts by the combined organization's stockholders to replace or remove the combined organization's management.

Provisions in the combined organization's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of the combined organization's stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because the combined organization will be incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding combined organization's voting stock from merging or combining with the combined organization. Although Mirna and Synlogic believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with the combined organization's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the combined organization's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Mirna and Synlogic do not anticipate the combined organization will pay any cash dividends in the foreseeable future.

The current expectation is the combined organization will retain its future earnings to fund the development and growth of the combined organization's business. As a result, capital appreciation, if any, of the Mirna Common Stock will be your sole source of gain, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause the Mirna Common Stock price to decline.

If existing Mirna Stockholders and Synlogic Stockholders sell, or indicate an intention to sell, substantial amounts of Mirna Common Stock in the public market after the post-Merger lock-up and other legal restrictions on resale discussed in this proxy statement/prospectus/information statement lapse, the trading price of Mirna Common Stock could decline. Based on shares outstanding as of July 1, 2017, upon completion of the Merger, the combined organization is expected to have outstanding a total of approximately 24.8 million shares of Mirna Common Stock (after giving effect to the proposed Mirna Reverse Stock Split). Of these shares, only approximately 7.5 million shares of Mirna Common Stock will be freely tradable, without restriction, in the public market.

The lock-up agreements entered into between Mirna and certain of the combined organization's securityholders provide that the shares subject to the lock-up restrictions will be released from such restrictions 180 days from the Closing of the Merger. Based on shares outstanding as of July 1, 2017, upon the expiration of the lock-up restrictions, approximately 17.3 million shares of Mirna Common Stock (after giving effect to the proposed Mirna Reverse Stock Split) will become eligible for sale in the public market, approximately 13.9 million of which will be held by directors, executive officers of the combined organization, and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, and various vesting agreements. In addition, approximately 0.1 million shares of Mirna Common Stock subject to outstanding options of Mirna as of July 1, 2017 (assuming the full exercise of all such options prior to the Closing of the Merger), and approximately 0.7 million shares of Mirna Common Stock subject to outstanding options of Synlogic as of July 1, 2017 (in each case, after giving effect to the proposed Mirna Reverse Stock Split) will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the Mirna Common Stock could decline.

If the ownership of the Mirna Common Stock is highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined organization's stock price to decline.

Executive officers and directors of the combined organization, and affiliates of executive officers and directors of the combined organization, are expected to beneficially own or control approximately 31% of the outstanding shares of the Mirna Common Stock following the completion of the Merger (after giving effect to the exercise of all outstanding vested and unvested options and warrants). Accordingly, these executive officers, directors, and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation, or sale of all or substantially all of the combined organization's assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the combined organization, even if such a change of control would benefit the other stockholders of the combined organization. The significant concentration of stock ownership may adversely affect the trading price of Mirna Common Stock due to investors' perception that conflicts of interest may exist or arise.

An active trading market for the Mirna Common Stock may not develop and the combined organization's stockholders may not be able to resell their shares of Mirna Common Stock for a profit, if at all.

Prior to the Merger, there had been no public market for Synlogic Capital Stock. An active trading market for Mirna Common Stock may never develop or be sustained. If an active market for Mirna Common Stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

If the combined organization fails to maintain proper and effective internal controls, the combined organization's ability to produce accurate and timely financial statements could be impaired, which could harm its operating results, its ability to operate its business and investors' views of the combined organization.

The combined organization will be required to comply with Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors. Ensuring that the combined organization has adequate internal financial and accounting controls and procedures in place so that it can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. The combined organization's failure to maintain the effectiveness of its internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on its business. The combined organization could lose investor confidence in the accuracy and completeness of its financial reports, which could have an adverse effect on the price of its common stock. In addition, if the combined organization's efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against the combined organization and its business may be harmed.

If securities or industry analysts do not publish, or cease publishing, research or reports about the combined organization, its business or its market, or if they change their recommendations regarding the Mirna Common Stock adversely, the Mirna Common Stock price and trading volume could decline.

If a trading market for the combined organization's Mirna Common Stock develops, the trading market for its Mirna Common Stock will be influenced by whether industry or securities analysts publish research and reports about the combined organization, its business, its market or its competitors and, if any analysts do publish such reports, what they publish in those reports. The combined organization may not obtain analyst coverage in the future. Any analysts that do cover the combined organization may make adverse recommendations regarding the Mirna Common Stock, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about the combined organization's competitors. If any analyst who may cover the combined organization in the future were to cease coverage of the combined organization or fail to regularly publish reports on the combined organization, or if analysts fail to cover the combined organization or publish reports about the combined organization at all, the combined organization could lose, or never gain, visibility in the financial markets, which in turn could cause the stock price or trading volume of the Mirna Common Stock to decline.

The combined organization will have broad discretion in the use of proceeds from Synlogic's recent Series C preferred stock financing and may invest or spend the proceeds of Synlogic's Series C preferred stock financing in ways with which you do not agree and in ways that may not increase the value of your investment.

The combined organization will have broad discretion over the use of proceeds from Synlogic's Series C financing. You may not agree with the combined organization's decisions, and its use of the proceeds may not yield any return on your investment. The combined organization's failure to apply the net proceeds of Synlogic's Series C financing effectively could compromise its ability to pursue its growth strategy and the combined organization might not be able to yield a significant return, if any, on its investment of these net proceeds. You will not have the opportunity to influence the combined organization's decisions on how to use the net proceeds from Synlogic's Series C financing.

Mirna's pre-Merger net operating loss carryforwards and certain other tax attributes may be limited. The pre-Merger net operating loss carryforwards and certain other tax attributes of Synlogic and of the combined organization may also be limited as a result of ownership changes, including as a result of the Closing of the Merger.

In general, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of a corporation’s common stock, applying certain look-through and aggregation rules, increases by more than 50 percentage points over such stockholders’ lowest percentage ownership during the testing period, generally three years. As described in the section entitled “*Risks Related to Mirna—Mirna’s ability to utilize its net operating loss carryforwards and certain other tax attributes may be limited*” in this proxy statement/prospectus/information statement, Mirna believes that it has experienced at least one ownership change in the past. Mirna may also experience additional ownership changes as a result of subsequent shifts in its stock ownership, including as a result of the Closing of the Merger. It is possible that Synlogic’s net operating loss carryforwards and certain other tax attributes may also be subject to limitation as a result of ownership changes in the past and/or the Closing of the Merger. Consequently, even if the combined organization achieves profitability, it may not be able to utilize a material portion of Mirna’s, Synlogic’s or the combined organization’s net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

SYNOLOGIC, LLC
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2016 and 2015

Consolidated Financial Statements:

<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	4
<u>Consolidated Statements of Contingently Redeemable Preferred Units and Equity</u>	5
<u>Consolidated Statements of Cash Flows</u>	7
<u>Notes to Consolidated Financial Statements</u>	8

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Synlogic, Inc.:

We have audited the accompanying consolidated balance sheets of Synlogic, LLC and its subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, contingently redeemable preferred units and equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Synlogic, LLC and its subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

(signed) KPMG LLP

Cambridge, Massachusetts
June 19, 2017

SYNLOGIC, LLC AND SUBSIDIARIES

Consolidated Balance Sheets
(in thousands, except unit amounts)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash	\$ 14,586	\$ 6,179
Prepaid expenses and other current assets	1,477	136
Total current assets	16,063	6,315
Property and equipment, net	3,504	664
Restricted cash	50	50
Other assets	422	338
Total assets	\$ 20,039	\$ 7,367
Liabilities, Redeemable Preferred Units and Equity		
Current liabilities:		
Accounts payable	\$ 988	\$ 641
Accrued expenses	2,296	1,273
Deferred revenue	444	444
Deferred rent	255	—
Capital lease obligations	203	66
Total current liabilities	4,186	2,424
Long-term liabilities:		
Deferred revenue, net of current portion	1,112	1,556
Deferred rent, net of current portion	1,061	—
Capital lease obligations, net of current portion	177	27
Total long-term liabilities	2,350	1,583
Commitments and contingencies (note 16)		
Contingently Redeemable Class A Preferred Units		
Issued and outstanding 1,413,039 and 758,874 units as of December 31, 2016 and 2015, respectively	5,000	2,383
Equity		
Class B Preferred Units		
Issued and outstanding 1,861,626 units as of December 31, 2016	13,611	—
Class A Preferred Units		
Issued and outstanding 7,089,713 and 3,464,716 units as of December 31, 2016 and 2015, respectively	25,548	11,048
Common units		
Issued and outstanding 3,339,869 and 3,402,369 units as of December 31, 2016 and 2015, respectively	592	223
Accumulated deficit	(31,248)	(10,294)
Total equity	8,503	977
Total liabilities and equity	\$ 20,039	\$ 7,367

See accompanying notes to consolidated financial statements.

SYNOLOGIC, LLC AND SUBSIDIARIES

**Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except unit and per unit amounts)**

	Years Ended December 31,	
	2016	2015
Revenue	\$ 444	\$ —
Operating expenses:		
Research and development	15,010	4,024
General and administrative	6,398	4,500
Total operating expenses	<u>21,408</u>	<u>8,524</u>
Loss from operations	(20,964)	(8,524)
Interest income (expense), net	10	(8)
Net loss	<u>\$ (20,954)</u>	<u>\$ (8,532)</u>
Net loss per unit attributable to common unit holders—basic and diluted	<u>\$ (7.36)</u>	<u>\$ (3.13)</u>
Weighted-average common units used in computing net loss per unit attributable to common unit holders—basic and diluted	2,848,081	2,723,630
Comprehensive loss	<u>\$ (20,954)</u>	<u>\$ (8,532)</u>

See accompanying notes to consolidated financial statements.

SYNOLOGIC, LLC AND SUBSIDIARIES

Consolidated Statements of Contingently Redeemable Preferred Units and Equity
(in thousands, except unit amounts)

	Contingently redeemable Class A preferred units		Contingently redeemable Class A preferred stock		Class B preferred units		Class A preferred units		Series A convertible preferred stock	
	Units	Amount	Shares	Amount	Units	Amount	Units	Amount	Shares	Amount
Balance at December 31, 2014	—	\$ —	363,636	\$ 1,000	—	\$ —	—	\$ —	1,287,042	\$ 3,439
Sale of Series A-2 Convertible Preferred Stock, net of issuance costs of \$13	—	—	395,238	1,383	—	—	—	—	1,976,190	6,904
Grant of restricted shares	—	—	—	—	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	—	—	—	—
Exchange of common and Series A Preferred Stock of Synlogic Inc. for common and Class A Preferred Units of Synlogic, LLC	758,874	2,383	(758,874)	(2,383)	—	—	3,263,232	10,343	(3,263,232)	(10,343)
Sale of Class A-2 Preferred Units, net of issuance costs of \$0	—	—	—	—	—	—	201,484	705	—	—
Equity-based compensation expense	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance at December 31, 2015	758,874	2,383	—	—	—	—	3,464,716	11,048	—	—
Sale of Class A-3 Preferred Units, net of issuance costs of \$0	654,165	2,617	—	—	—	—	3,624,997	14,500	—	—
Sale of Class B Preferred Units, net of issuance costs of \$317	—	—	—	—	1,861,626	13,611	—	—	—	—
Repurchase of founders' units	—	—	—	—	—	—	—	—	—	—
Equity-based compensation expense	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
Balance at December 31, 2016	<u>1,413,039</u>	<u>\$ 5,000</u>	<u>—</u>	<u>\$ —</u>	<u>1,861,626</u>	<u>\$ 13,611</u>	<u>7,089,713</u>	<u>\$ 25,548</u>	<u>—</u>	<u>\$ —</u>

See accompanying notes to consolidated financial statements.

SYNOLOGIC, LLC AND SUBSIDIARIES

Consolidated Statements of Contingently Redeemable Preferred Units and Equity (continued)
(in thousands, except unit amounts)

	<u>Common units</u>		<u>Common shares</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total equity</u>
	<u>Units</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance at December 31, 2014	—	\$ —	2,700,000	\$ —	\$ 32	\$ (1,762)	\$ 1,709
Sale of Series A-2 Convertible Preferred Stock, net of issuance costs of \$13	—	—	—	—	—	—	6,904
Grant of restricted shares	—	—	655,494	—	—	—	—
Exercise of stock options	—	—	46,875	—	1	—	1
Exchange of common and Series A Preferred Stock of Synlogic Inc. for common and Class A Preferred Units of Synlogic, LLC	3,402,369	33	(3,402,369)	—	(33)	—	—
Sale of Class A-2 Preferred Units, net of issuance costs of \$0	—	—	—	—	—	—	705
Equity-based compensation expense	—	190	—	—	—	—	190
Net loss	—	—	—	—	—	(8,532)	(8,532)
Balance at December 31, 2015	<u>3,402,369</u>	<u>223</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>(10,294)</u>	<u>977</u>
Sale of Class A-3 Preferred Units, net of issuance costs of \$0	—	—	—	—	—	—	14,500
Sale of Class B Preferred Units, net of issuance costs of \$317	—	—	—	—	—	—	13,611
Repurchase of founders' units	(62,500)	—	—	—	—	—	—
Equity-based compensation expense	—	369	—	—	—	—	369
Net loss	—	—	—	—	—	(20,954)	(20,954)
Balance at December 31, 2016	<u>3,339,869</u>	<u>\$ 592</u>	<u>—</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (31,248)</u>	<u>\$ 8,503</u>

See accompanying notes to consolidated financial statements.

SYNLOGIC, LLC AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (20,954)	\$ (8,532)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	692	117
Loss on disposal of assets	4	—
Equity-based compensation expense	369	190
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,341)	(334)
Accounts payable and accrued expenses	1,329	1,515
Deferred revenue	(444)	2,000
Deferred rent	21	—
Other assets	(84)	—
Net cash used in operating activities	(20,408)	(5,044)
Cash flows from investing activities:		
Increase in restricted cash	—	(50)
Proceeds from sale of property and equipment	8	—
Purchases of property and equipment	(1,841)	(451)
Net cash used in investing activities	(1,833)	(501)
Cash flows from financing activities:		
Payments on capital lease obligations	(80)	(68)
Proceeds from exercise of stock options and grant of restricted stock	—	1
Proceeds from sale of convertible preferred stock, net of issuance costs	—	8,287
Proceeds from sale of preferred units, net of issuance costs	30,728	705
Net cash provided by financing activities	30,648	8,925
Net increase in cash	8,407	3,380
Cash at beginning of period	6,179	2,799
Cash at end of period	\$ 14,586	\$ 6,179
Supplemental disclosure of non-cash investing and financing activities:		
Purchase under capital lease	\$ 367	\$ 161
Cash paid for interest	\$ 8	\$ 5
Landlord funded allowance for tenant improvements	\$ 1,296	\$ —
Property and equipment purchases included in accounts payable and accrued expenses	\$ 57	\$ 16

See accompanying notes to consolidated financial statements.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(1) Nature of Business

Organization

Synlogic, LLC, together with its wholly owned and consolidated subsidiaries (“Synlogic” or the “Company”) is an early stage biopharmaceutical company focused on discovering and developing Synthetic Biotic™ medicines: a novel class of living medicines to treat a broad range of human diseases ranging from genetic and acquired metabolic disorders to inflammation and cancer. Synlogic applies the principles and tools of synthetic biology to engineer beneficial, probiotic bacteria to perform or deliver critical therapeutic functions, compensating for missing or damaged pathways in patients with these serious diseases. As living medicines, Synthetic Biotic medicines are designed to sense a local disease context within a patient’s body and respond by metabolizing toxic substances or delivering combinations of therapeutic factors. Since incorporation, the Company has devoted substantially all of its efforts to the research and development of its product candidates.

The Company was founded and began operations on March 14, 2014, as TMC Therapeutic, 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 shareholders of Synlogic, Inc. executed the Synlogic, LLC Contribution Agreement (the “Contribution Agreement”), which contributed their equity interests in Synlogic, Inc. 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, the Company entered into license, option, and merger agreements with AbbVie S.à.r.l. (“AbbVie”) for the development of treatments for inflammatory bowel diseases (“IBD”) (Note 12). In May 2017, the Company completed a series of transactions pursuant to which Synlogic, LLC, merged with and into Synlogic, Inc. which continued to exist as the surviving corporation (Note 19).

Risks and Uncertainties

At December 31, 2016, the Company had cash of approximately \$14.6 million and an accumulated deficit of approximately \$31.2 million. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital, and has primarily financed its operations through the issuance of preferred stock. 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. The Company secured multiple rounds of new funding including proceeds from:

- the sale of Class A Preferred Units and Contingently Redeemable Class A Preferred Units in February 2016, generating approximately \$17.1 million in net proceeds,
- the sale of Class B Preferred Units in February 2016, generating approximately \$13.6 million in net proceeds,
- the sale of Class B Preferred Units in March 2017, generating approximately \$26.6 million in net proceeds,
- the sale of Series C Convertible Preferred Stock in May 2017, generating approximately \$40.4 million in net proceeds,

As a result of the proceeds generated from the recent financings, management believes that the Company has sufficient cash to fund its operations through at least twelve months from the issuance of these financial statements, or the second quarter of 2018.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

As an early stage company, the Company is subject to a number of risks common to other life science companies, including, but not limited to, raising additional capital, development by its competitors of new technological innovations, risk of failure in preclinical studies, safety and efficacy of its product candidates in clinical trials, 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

(a) Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP" or "GAAP").

(b) Principles of Consolidation

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

The July 2, 2015 exchange of common and preferred shares of Synlogic, Inc. for common and preferred units in Synlogic, LLC pursuant to the 2015 Reorganization was accounted for based on existing carrying amounts and there was no change to the reporting entity because there was no change in ownership by the investors.

(c) Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, the Company's management evaluates its estimates, including those related to revenue recognition, income taxes including the valuation allowance for deferred tax assets, research and development, accrued expenses, contingencies and equity-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgements about the carrying values of assets and liabilities. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

SYNLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

(d) Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk include amounts held as cash and restricted cash. The Company uses a high quality, accredited financial institution to maintain its cash and restricted cash and, accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has no financial instruments with off-balance sheet risk of loss.

(e) Restricted Cash

The Company held cash of \$50,000 at December 31, 2016 and 2015 in a separate restricted bank account as collateral for the Company's credit card program. The Company has classified these deposits as long-term restricted cash on its balance sheet.

(f) Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, are used to measure fair value:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Significant unobservable inputs including the Company's own assumptions in determining fair value.

There were no financial instruments recorded at fair value as of December 31, 2016 and 2015. The carrying amounts of cash, restricted cash, accounts payable, and accrued expenses approximate their fair values due to their short-term maturities.

(g) Property and Equipment

Property and equipment, including leasehold improvements, are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Repairs and maintenance costs are expensed as incurred, whereas major improvements are capitalized as additions to property and equipment.

Depreciation begins at the time the asset is placed in service. Depreciation is provided over the following estimated useful lives:

<u>Asset classification</u>	<u>Useful life</u>
Computer and office equipment	3 years
Furniture and fixtures	5 years
Laboratory equipment	5 years
Leasehold improvements	Lesser of useful life or remaining lease term

Notes to Consolidated Financial Statements (continued)

(h) Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If this comparison indicates that there is impairment, the amount of impairment is calculated as the difference between the carrying value and fair value of the asset. To date, no such impairments have been recognized.

(i) Rent Expense

The Company's lease for its 200 Sidney Street facility in Cambridge, Massachusetts provides for a rent-free period as well as fixed increases in minimum annual rental payments. The total amount of rental payments due over the lease term is being charged to rent expense on a straight-line basis over the term of the lease. Tenant improvement allowances and other incentives are recorded as deferred rent and amortized as a reduction of periodic rent expense, over the term of the lease. Deferred rent consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the Company's facility.

(j) Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. The Company defers and capitalizes nonrefundable advance payments made by the Company for research and development activities until the related goods are received or the related services are performed.

Research and development expenses are comprised of costs incurred in performing research and development activities, including salary and benefits, equity-based compensation expense, laboratory supplies and other direct expenses, facilities expenses, overhead expenses, contractual services and other outside expenses.

(k) Revenue recognition

The Company generates revenue through a collaboration and license arrangement with a strategic partner for the development and commercialization of product candidates.

The Company recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 605, *Revenue Recognition* ("ASC 605"). Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

The Company evaluates collaboration agreements with respect to FASB ASC Topic 808, *Collaborative Arrangements*, considering the nature and contractual terms of the arrangement and the nature of its business operations to determine the classification of the transactions. When the Company is an active participant in the activity and exposed to significant risks and rewards dependent on the commercial success of the collaboration, it will record its transactions on a gross basis in the consolidated financial statements and describe the rights and obligations under the collaborative arrangement in the notes to the consolidated financial statements.

Multiple-Element Arrangements

The Company evaluates multiple-element arrangements based on the guidance in FASB ASC Topic 605-25, *Revenue Recognition—Multiple -Element Arrangements* (“ASC 605-25”). Pursuant to this guidance, the Company identifies the deliverables included in the arrangement and determines whether the individual deliverables have value to the customer on a stand-alone basis and represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a stand-alone basis and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. In assessing whether an item has stand-alone value, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner; the retention of any key rights by the Company; and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s) and whether there are other vendors that can provide the undelivered element(s).

In situations where the Company has identified multiple units of accounting, the arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The Company determines the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, the Company determines the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence (“VSOE”) of selling price, if available; third-party evidence (“TPE”) of selling price if VSOE is not available; or best estimate of selling price (“BESP”) if neither VSOE nor TPE is available.

Then, the applicable revenue recognition criteria in ASC 605-25 are applied to each of the separate units of accounting to determine the appropriate period and pattern of recognition. The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting. The Company will recognize as revenue, upon delivery, arrangement consideration attributed to deliverables that have stand-alone value from the other deliverables to be provided in an arrangement. For deliverables that do not have stand-alone value from the other deliverables to be provided in an arrangement, revenue is recognized over the Company’s estimated performance period as the arrangement would be accounted for as a single unit of accounting.

If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement for the single unit of accounting on a straight-line basis over the period the Company is expected to complete its

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

performance obligations. Alternatively, if the pattern of performance in which the service is provided to the customer can be determined and objectively measurable performance measures exist, then the Company recognizes revenue under the arrangement using the proportional performance method. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line method or proportional performance method, as applicable.

Milestones

Contingent consideration from research and development activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. At the inception of an arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. The Company recognizes revenue associated with substantive milestones in accordance with FASB ASC Topic 605-28, *Revenue Recognition—Milestone Method* upon successful accomplishment of each milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met.

(l) Equity-Based Compensation

The Company measures equity-based compensation to employees and directors based on the grant date fair value of the awards and recognizes the associated expense in the financial statements over the requisite service period of the award, which is generally the vesting period.

Equity-based compensation costs for nonemployee awards are recognized as services are provided, which is generally the vesting period, on a straight-line basis. The measurement date for nonemployee awards is generally the date the performance of services required from the nonemployee is complete. The Company believes that the fair value of the equity is more reliably measurable than the fair value of the services rendered. The fair value of the award granted to a nonemployee is remeasured at each reporting date until performance is completed with any increase or decrease in fair value recorded as equity-based compensation expense.

In determining the exercise price for options granted, the Company's Board of Directors considered the fair value of the common stock as of the grant date. The Board of Directors determined the estimated per share fair value of our common stock at various dates considering contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, or the Practice Aid. The fair value of the common stock was determined by the Board of Directors at each award grant date based on assumptions, each of which are subjective and generally

SYNLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

require judgement and estimation by management, including results obtained from independent third-party valuations, the Company's financial position and historical financial performance, the status of technological developments within the Company's products, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, the current business climate in the marketplace, the illiquid nature of the common stock, arm's length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred share, and the prospects of a liquidity event.

The fair value of each option was estimated on the date of grant or remeasurement using the Black-Scholes option-pricing model. Expected volatility for the Company's common stock was determined based on an average of the historical volatility of a peer-group of similar public companies. The expected term of options granted for employees was calculated using the simplified method, which represented the average of the contractual term of the option and the weighted-average vesting period of the option. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The risk-free rate is based upon the U.S. Treasury yield curve commensurate with the expected term at the time of grant or remeasurement. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from the Company's estimates. Subsequent changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change, and will also impact the amount of share-based compensation expense in future periods. The Company uses historical data to estimate forfeiture rates.

In determining the threshold price for an incentive units, the Company's Board of Directors determines the price at which an incentive unit would have a liquidation value of zero at the date of grant in setting the threshold price for incentive units. The Board of Directors considers the fair value of its assets and performs an analysis to determine the per unit amount that a holder would receive upon a distribution event. In determining the fair value of its assets, the Company relies on independent third-party valuations, which take into account a variety of factors, including the Company's financial position and historical financial performance, the status of technological developments within the Company's products, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, the current business climate in the marketplace, the illiquid nature of the common stock and incentive units, arm's-length sales of the Company's equity, the effect of the rights and preferences of the preferred unit holders, and the prospects of a liquidity event, among others.

The fair value of each incentive unit award is estimated on the date of grant or remeasurement using the Black-Scholes with barrier option-pricing model. Assumptions utilized in the model for valuing the incentive units including expected volatility, dividend yield and risk-free interest rate are arrived at in the same manner as those utilized for the stock option model described above. Additionally, forfeitures are treated in the manner described above. Incentive units do not have an expiration date, thus, the expected term of incentive units granted is determined based on the probability-weighted estimated term to a distribution event.

The Company records the expense for equity grants subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

The Company classifies equity-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

(m) *Income Taxes*

Effective July 2, 2015, the Company was organized as a limited liability company and subject to the provisions of Subchapter K of the Internal Revenue Code. As such, the Company is not viewed as a taxpaying entity in any jurisdiction and does not require a provision for income taxes. Each partner is responsible for the tax liability, if any, related to its proportionate share of the partnership's taxable income.

Each of the wholly owned corporate subsidiaries is a taxpaying entity and does require a provision for income taxes. The wholly owned subsidiaries are considered a brother—sister controlled group and a tax provision has been prepared for each of the subsidiaries individually.

Any reference to a provision for income taxes, deferred income taxes and offsetting valuation allowance represents the aggregate activity of the Company's wholly owned corporations.

The wholly owned corporate subsidiaries, as well as the Company prior to the 2015 Reorganization, account for income taxes under the asset and liability method. Using this method, the Company records deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the net deferred tax assets to the amount that will more likely than not be realized.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

(n) *Net Loss Per Unit*

Basic net loss per unit is computed using the weighted-average number of common units outstanding during the period. Diluted net loss per unit is computed using the sum of the weighted-average number of common units outstanding during the period and if dilutive, the weighted-average number of potential common units, including unvested restricted common unit awards.

The Company applies the two-class method to calculate its basic and diluted net loss per unit attributable to common unit holders, as all of its contingently redeemable preferred units and preferred units (together the "Preferred Units") are participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common unit holders. However, for the periods presented, the two-class method does not impact the net loss per common unit as the Company was in a net loss position for each of the periods presented and holders of the Preferred Units do not participate in losses.

The Company's Preferred Units contractually entitle the holders of such units to participate in dividends but do not contractually require the holders of such units to participate in losses of the Company. Accordingly, for periods in which the Company reports a net loss attributable to common unit holders, diluted net loss per unit attributable to common unit holders is the same as basic net loss per unit attributable to common unit holders, since dilutive common units are not assumed to have been issued if their effect is anti-dilutive.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

(o) Comprehensive Loss

Comprehensive loss is the change in equity of a company during a period from transactions and other events and circumstances, excluding transactions resulting from investments by owners and distributions to owners. The Company's net loss equals comprehensive loss for all periods presented.

(p) Segment Information

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates in one operating segment: the discovery and development of Synthetic Biotic medicines. The Company's chief executive officer, as chief operating decision maker, manages and allocates resources to the operations of the Company on a total company basis. All of the Company's equipment, leasehold improvements and other fixed assets are physically located within the United States, and all agreements with its partners are denominated in U.S. dollars, except where noted.

(q) Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09— *Revenue from Contracts with Customers (Topic 606)* , which supersedes all existing revenue recognition requirements, including most industry-specific guidance. This standard is based on the principle that an entity should recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive. This standard also requires additional disclosure about the nature, amount, timing and uncertainty of assets recognized from costs incurred to fulfill a contract. It will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted any time after the original effective date, which for the Company is January 1, 2017. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The Company is currently assessing the impact that this standard will have on its financial statements and the expected method of transition.

In August 2014, the FASB issued ASU 2014-15— *Presentation of Financial Statements—Going Concern* (“ASU 2014-15”), on disclosure of uncertainties about an entity's ability to continue as a going concern. This guidance addresses management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. The guidance is effective for fiscal years ending after December 15, 2016 and for annual periods and interim periods thereafter, with early adoption permitted. The Company adopted ASU 2014-15 as of December 31, 2016 and it did not have a material effect on its consolidated financial statements.

In February 2015, the FASB issued ASU 2015-02, *Consolidation (Topic 810)* (“ASU 2015-02”) to address financial reporting considerations for the evaluation as to the requirement to consolidate certain legal entities. This standard is effective for fiscal years and for interim periods within those fiscal years beginning after December 15, 2015. The Company has evaluated the impact of ASU 2015-02 and has concluded that it has no effect on the consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17— *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*, that provides guidance on the presentation of deferred income taxes which requires deferred tax assets and liabilities, along with related valuation allowances, to be classified as noncurrent on the balance sheet. As a result, each tax jurisdiction will now only have one

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

net noncurrent deferred tax asset or liability. The new guidance does not change the existing requirement that prohibits offsetting deferred tax liabilities from one jurisdiction against deferred tax assets of another jurisdiction. The new guidance is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods, with early application permitted. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company does not expect the adoption of this standard to have a material impact on its financial statements.

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. The Company is currently assessing the impact that adoption of this guidance will have on its financial statements and footnote disclosures.

In March 2016, the FASB issued ASU 2016-09— *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* . The amendment is to simplify several aspects of the accounting for stock-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in ASU No. 2016-09 are effective for interim and annual reporting periods beginning after December 15, 2016. The Company does not expect the adoption of this standard to have a material impact on its financial statements.

In November 2016, the FASB issued ASU 2016-18— *Statement of Cash Flows (Topic 230): Restricted Cash* , which requires companies to include cash and cash equivalents that have restrictions on withdrawal or use in total cash and cash equivalents on the statement of cash flows. This ASU is effective for public business entities for annual and interim periods in fiscal years beginning after December 15, 2017. The Company is currently assessing the impact of ASU 2016-18 on its financial statements and related disclosures.

(3) Property and Equipment, net

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

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
Laboratory equipment	\$1,534	\$ 592
Computer and office equipment	252	65
Furniture and fixtures	220	7
Leasehold improvements	2,308	—
Fixed assets in progress	—	122
	<u>4,314</u>	<u>786</u>
Less accumulated depreciation	(810)	(122)
	<u>\$3,504</u>	<u>\$ 664</u>

In both 2016 and 2015, the Company entered into a lease for certain laboratory equipment which had a bargain purchase option at the end of the lease term. As such, as of December 31, 2016 and 2015, the Company had approximately \$0.5 million and \$0.2 million, respectively, of assets under a capital lease with accumulated depreciation of approximately \$0.1 million and \$32,000, respectively.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

Depreciation expense for the years ended December 31, 2016 and 2015 was \$0.7 million and \$0.1 million, respectively.

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consists of the following (in thousands):

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
Prepaid insurance	\$ 71	\$ 17
Prepaid research and development	1,163	12
Other prepaid	212	107
Other current assets	31	—
	<u>\$1,477</u>	<u>\$136</u>

(5) Accrued Expenses

Accrued expenses consists of the following (in thousands):

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
Payroll related	\$1,341	\$ 819
Professional fees	522	378
Research and development	273	—
Other	160	76
	<u>\$2,296</u>	<u>\$1,273</u>

(6) Convertible Preferred Stock

(a) Convertible Preferred Stock

Synlogic's Certificate of Incorporation authorized the issuance of up to 7,150,945 shares of Series A Convertible Preferred Stock ("Series A Preferred Stock"). In July 2014 and in September 2014, Synlogic issued and sold 1,143,884 and 363,636 shares, respectively, of Series A-1 Convertible Preferred Stock and Contingently Redeemable Series A-1 Preferred Stock, (together "Preferred Stock"), respectively at \$2.75 per share to investors for total net proceeds of approximately \$4.0 million. Total Issuance costs related to these transactions of approximately \$0.1 million were recorded as a reduction of proceeds within Series A Preferred Stock.

In May 2015, Synlogic sold and issued 1,976,190 shares of Series A-2 Convertible Preferred Stock and 395,238 shares of Contingently Redeemable Series A-2 Preferred Stock at \$3.50 per share to investors for total net proceeds of \$8.3 million. Issuance costs related to these transactions of \$13,000 were recorded as a reduction of proceeds within Series A Preferred Stock.

Pursuant to the July 2, 2015 Contribution Agreement, each share of Synlogic's Series A Preferred Stock and Contingently Redeemable Series A Preferred Stock was exchanged for a like type and number of the Company's Class A Preferred Units and Contingently Redeemable Class A Preferred Units, respectively, (Note 7) and there is no outstanding Preferred Stock at December 31, 2016.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

(b) Rights and Preferences

Preferred Stock had the following rights and preferences:

(i) Voting

The holders of the Preferred Stock were entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote, except with respect to matters on which Delaware General Corporation Law required that a vote would be by a separate class. Each holder of Preferred Stock was entitled to the number of votes equal to the number of common shares into which each preferred share was convertible at the time of such vote.

(ii) Dividends

In the event that a dividend was declared for the holders of common stock, the holders of the Preferred Stock would be entitled to the amount of dividends on an as-converted basis. Through December 31, 2016 and 2015, no dividends were declared or paid.

(iii) Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Preferred Stock then outstanding would have been entitled to be paid, on a pari passu basis, out of the assets of the Company available for distribution to its stockholders before any payment would have been made to the holders of common stock by reason of their ownership thereof, with respect to each series of Preferred Stock, an amount per share equal to the greater of (i) the applicable original issue price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares been converted into common stock immediately prior to such liquidation, dissolution or winding up of the Company.

If upon any such liquidation, dissolution or winding up of the Company, the assets of the Company available for distribution to its stockholders were insufficient to pay the holders of shares of preferred stock the full amount to which they should have been entitled, the holders of shares of preferred stock would share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

(iv) Par Value

Par value was assigned as \$0.0001.

(v) Conversion

Each share of preferred stock, at the option of the holder, was convertible into that number of fully paid shares of common stock as determined by dividing the sum of the original issue price (\$2.75 for the Series A-1 or \$3.50 for the Series A-2), plus any declared but unpaid dividends, by the conversion price in effect at the time of conversion. The initial conversion price for each preferred share was the original issue price, subject to adjustment in accordance with antidilution provisions. Conversion was automatic upon the vote of 70% of the holders of Series A Preferred Stock or immediately upon the closing of a firm commitment underwritten public offering in which the public offering price equals or exceeds \$13.75 per share (adjusted to reflect subsequent stock dividends, stock splits, or recapitalization) and the aggregate proceeds raised were not less than \$35.0 million.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

(vi) *Redemption*

The Preferred Stock was not redeemable pursuant to the Series A Convertible Preferred Stock Purchase Agreement except upon a deemed liquidation event. Deemed liquidation events included the merger, acquisition or sale of all or substantially all of the Company's assets. All holders of equally and more subordinated equity instruments of the Company would have been entitled to receive the same form of consideration upon the occurrence of a deemed liquidation event, consequently, the Preferred Stock was classified as permanent equity.

In September 2014, the Company entered into a letter agreement with the Bill & Melinda Gates Foundation ("the Gates Foundation") with respect to the Gates Foundation purchase of 1,413,039 shares of the Company's Series A Preferred Stock. The Gates Foundation investment was made in three tranches of 363,636 shares in September 2014, 395,238 shares in May 2015 and 654,165 shares in February 2016. Under the letter agreement, the Company was required to spend the approximately \$5.0 million invested by the Gates Foundation for research on a particular disease, further develop the Company's proprietary technology platform and provide assistance with access to use of such technology in developing countries. If the Company fails to spend the amount appropriately, or defaults under certain other commitments in the agreement and the Company does not cure such default within 90 days of notice, if requested by the Gates Foundation, the Company would be obligated to redeem the shares of Series A Preferred Stock or shares of common stock into which they had converted then held by the Gates Foundation or find a third party to purchase such shares at a price equal to the greater of the initial purchase price and the then current fair value of such shares. In either case, if the Company, over the 6 months following such redemption, sells substantially all of its equity or assets or completes an initial public offering at a value greater than 200% of the price paid upon redemption, then the Company must reimburse the Gates Foundation for the difference.

(c) *Participation Rights in Future Equity Issuances*

All holders of Preferred Stock had a pro rata right and obligation, based on their percentage equity ownership in the Company, to participate in subsequent issuances of equity securities of the Company approved by 70% vote of holders of Preferred Stock. Should any such holder have chosen not to purchase its full pro rata share, they would have been deemed a defaulting purchaser and all Preferred Stock held by a defaulting purchaser would have been automatically converted into common stock of the Company.

(7) **Preferred Units**

Preferred Units

The following represent the Preferred Unit transactions of the Company:

- Pursuant to the Contribution Agreement, on July 2, 2015, each share of Synlogic's Series A Preferred Stock and Series A Contingently Redeemable Preferred Stock was exchanged for a like type and number of the Company's Class A Preferred Units and Contingently Redeemable Class A Preferred Units, respectively.
- In November 2015, Synlogic issued and sold an additional 201,484 units of Class A-2 Preferred Units at \$3.50 per unit to an investor for net proceeds of approximately \$0.7 million. There were no issuance costs related to this transaction.
- In February 2016, Synlogic issued and sold 3,624,997 units of Class A-3 Preferred Units and 654,165 units of Contingently Redeemable Class A-3 Preferred Stock at \$4.00 per unit to investors for net proceeds of approximately \$17.1 million. There were no issuance costs related to these transactions.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

- In February 2016, Synlogic also issued and sold 1,861,626 units of Class B Preferred Units at \$7.4818 per unit to investors for net proceeds of approximately \$13.6 million. Issuance costs related to this transaction of approximately \$0.3 million were recorded as a reduction of proceeds within Class B Preferred Units (together with the Class A Preferred Units, Contingently Redeemable Class A Preferred Units, Class A-2 Preferred Units, Class A-2 Contingently Redeemable Preferred Units, Class A-3 Preferred Units and Contingently Redeemable Class A-3 Preferred Units, the “Preferred Units”).

(a) *Rights and Preferences*

The Preferred Units have substantially similar rights and preferences as were conferred upon the Preferred Stock as follows:

(i) Voting

The holders of the Preferred Units are entitled to vote, together with the holders of the Company’s common units as a single class, on all matters submitted to unit holders for a vote. In addition, holders of at least a majority of the outstanding Preferred Units and common units voting as a single class are entitled to take any action required or permitted to be taken at any meeting of the members, unless a different vote is required by the Delaware Limited Liability Company Act or the Company’s operating agreement.

(ii) Distributions

Distributions are governed by the Company’s operating agreement (Note 11). No distributions were made through December 31, 2016.

(iii) Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the assets of the Company are to be distributed, after the payout or provision for payment of all creditors of the Company, in accordance with the same order of priority as distributions (Note 11).

(iv) Par Value

The Preferred Units do not have a par value.

(v) Redemption

The Preferred Units are not redeemable pursuant to the Series A Convertible Preferred Stock Purchase Agreement, the Synlogic LLC Contribution Agreement and the Class B Preferred Unit Purchase Agreement except upon a deemed liquidation event. Deemed liquidation events include the merger, acquisition or sale of all or substantially all of the Company’s assets. All holders of equally and more subordinated equity instruments of the Company would be entitled to receive the same form of consideration upon the occurrence of a deemed liquidation event, consequently, the Preferred Units are classified as permanent equity.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

In September 2014, the Company entered into a letter agreement with the Bill & Melinda Gates Foundation (“the Gates Foundation”) with respect to the Gates Foundation purchase of 1,413,039 shares of the Company’s Series A Preferred Stock. The Gates Foundation investment was made in three tranches of 363,636 shares in September 2014, 395,238 shares in May 2015 and 654,165 units in February 2016. The first two tranches, totaling 758,874 shares were exchanged for Class A Preferred Units pursuant to the 2015 Reorganization in July 2015. Under the letter agreement, the Company is required to spend the approximately \$5.0 million invested by the Gates Foundation for research on a particular disease, further develop the Company’s proprietary technology platform and provide assistance with access to use of such technology in developing countries. If the Company fails to spend the amount appropriately, or defaults under certain other commitments in the agreement and the Company does not cure such default within 90 days of notice, if requested by the Gates Foundation, the Company would be obligated to redeem the shares of Series A Preferred Stock or shares of common stock into which they have converted then held by the Gates Foundation or find a third party to purchase such shares at a price equal to the greater of the initial purchase price and the then current fair value of such shares. In either case, if the Company, over the 6 months following such redemption, sells substantially all of its equity or assets or completes an initial public offering at a value greater than 200% of the price paid upon redemption, then the Company must reimburse the Gates Foundation for the difference. As a result, 1,413,039 and 758,874 units of Class A Preferred Units with a cost of approximately \$5.0 million and \$2.4 million, respectively, were classified as Contingently Redeemable Preferred Units in mezzanine equity, as of December 31, 2016 and 2015, respectively.

(vi) Participation Rights

Holders of Class A Preferred Units have the right and obligation to participate in additional closings of Class A Preferred Units upon the achievement of certain milestones by the Company. If any holder of Class A Preferred Units does not purchase the number of Class A Preferred Units required to be purchased by it at any such additional closing, then each Class A Preferred Unit held by such member shall automatically be converted into common units at the applicable adjustment ratio in effect with respect to such units immediately prior to such closing. To date, all holders of Class A Preferred Units have participated in additional closings at the required levels.

Holders of Class B Preferred Units have the right and obligation to participate in additional closings of Class B Preferred Units upon the achievement of certain milestones by the Company. If any holder of Class B Preferred Units does not purchase the number of Class B Preferred Units required to be purchased by it at any such additional closing, then each Class B Preferred Unit held by such member shall automatically be converted into common units at the applicable adjustment ratio in effect with respect to such units immediately prior to such closing.

(vii) Initial Public Offering

In connection with preparation for an initial public offering, upon request of holder of at least 70% of the Preferred Units, all unit holders will take appropriate steps to implement a reorganization of the Company that may include, for example, contribution of their units to a newly formed corporation.

(8) Common Stock

Synlogic, Inc.’s Certificate of Incorporation authorized the issuance of up to 11,039,567 shares of common stock with a par value of \$0.0001. In April 2014, the Company sold a total of 2,700,000 shares of common stock, for consideration totaling approximately \$3,000, to four founders and an investor, who were responsible for incubating and forming the Company. The Company holds

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

repurchase options relating to 2,200,000 of these shares at a price equal to the initial purchase price by the founder. The repurchase option is exercisable should the founder cease providing services to the Company prior to the end of a four-year period beginning in April 2014. The Company's repurchase option expires over a four-year period. The common stock of Synlogic was exchanged pursuant to the Contribution Agreement on July 2, 2015. (Note 9).

(9) Common Units

Pursuant to the Contribution Agreement, on July 2, 2015, each share of Synlogic's common stock was exchanged for the same number of common units, substantially conferred with the same rights and responsibilities. The repurchase options, as described in Note 8, continue to remain in effect for the applicable units. Common units do not have a par value and participate in distributions as described in Note 11. As of December 31, 2016, the Company has exercised its repurchase option on 62,500 common units.

(10) Equity-based Compensation and Equity Incentive Plans

(a) Equity Compensation

Equity compensation during the years ended December 31, 2016 and 2015 is derived from a number of equity instruments. In the first half of 2015, stock options were issued to both employees and nonemployees and a restricted stock award was issued to an employee under the Synlogic, Inc. 2014 Stock Incentive Plan ("2014 Stock Incentive Plan"). In July 2015, in connection with the 2015 Reorganization, all outstanding stock options were canceled. In the second half of 2015 and the year ended December 31, 2016, the Company issued incentive units under the Synlogic, LLC 2015 Equity Incentive Plan ("2015 Equity Incentive Plan").

The Company has recorded total equity-based compensation expense of approximately \$0.4 million and \$0.2 million for the years ended December 31, 2016 and 2015, respectively, which is based on the number of awards ultimately expected to vest.

The following table summarizes equity-based compensation expense within the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2016 and 2015 (in thousands):

	<u>Years ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
Research and development	\$ 154	\$ 16
General and administrative	215	174
	<u>\$ 369</u>	<u>\$ 190</u>

The following table summarizes equity-based compensation expense by type of award for the years ended December 31, 2016 and 2015 (in thousands):

	<u>Years ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
Stock options	\$ —	\$ 50
Restricted stock awards	—	17
Incentive units	235	56
Restricted common unit awards	134	67
	<u>\$ 369</u>	<u>\$ 190</u>

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

(b) Awards Issued under the Synlogic, Inc. 2014 Stock Incentive Plan

(i) Stock Options

The Board of Directors adopted the 2014 Stock Incentive Plan, which provided for the grant of qualified incentive stock options and nonqualified stock options or other awards to the Company's employees, officers, directors, advisors, and outside consultants to purchase up to an aggregate of 1,188,622 shares of the Company's common stock. In April 2015, the Board of Directors authorized an increase in the aggregate shares of the Company's common stock available under the 2014 Stock Incentive Plan to 1,688,622. Awards issued under the 2014 Stock Incentive Plan generally vested 25% after one year and ratably monthly thereafter over a three-year period and expired ten years from the date of grant. In 2015, 176,822 stock options were issued to employees. In July 2015, the 2014 Stock Incentive Plan was terminated, resulting in the cancellation of all issued and outstanding stock options.

In 2014, 582,000 options were issued to nonemployees. The Company used the remaining contractual life to estimate the expected term for options granted to nonemployees. For the year ended December 31, 2015, approximately \$26,000 in equity-based compensation expense was recognized associated with nonemployee stock options. No expense was recognized in 2016 as these options were canceled in July 2015 in conjunction with the 2015 Reorganization.

The weighted-average assumptions used in the Black-Scholes option-pricing model for awards issued under the 2014 Stock Incentive Plan since inception were:

	Year ended December 31, 2015	
	Employees	Nonemployees
Expected term (in years)	6.1	8.8 - 9.7
Risk-free interest rate	1.6%	1.9%
Expected volatility	78.9%	78.9%
Dividend yield	0%	0%

The following table represents a summary of stock option activity under the 2014 Stock Incentive Plan:

	Stock options outstanding			
	Number of options	Weighted- average exercise price	Weighted- average remaining contractual term	Intrinsic value
Outstanding at December 31, 2014	667,360	\$ 0.26	8.2	\$ 156,000
Granted	176,822	0.49	—	—
Exercised	(46,875)	0.01	—	—
Forfeited	(5,000)	0.49	—	—
Options cancelled upon 2015 Reorganization	(792,307)	0.32	—	—
Outstanding at December 31, 2015	—			\$ —

(ii) Restricted Stock Award

The restricted stock award vested 25% after one year and ratably monthly thereafter over the next 36 months, provided the employee remained continuously employed with the Company through each vesting date. The fair value of the restricted stock award was based on methods and assumptions as

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

discussed above. Compensation expense was recognized over the applicable service period. In July 2015, the 2014 Stock Incentive Plan was terminated and no restricted stock awards vested under the 2014 Stock Incentive Plan. Pursuant to the Contribution Agreement, the restricted stock award was exchanged for the same number of common units, substantially conferred with the same rights and responsibilities. The repurchase options continue to remain in effect for the applicable units. Common units do not have a par value and participate in distributions as described in Note 11.

The following table represents a summary of restricted stock activity for awards:

	Restricted stock awards	
	Number of shares	Grant date fair value (\$ per share)
Outstanding at December 31, 2014	—	\$ —
Granted	655,494	0.82
Forfeited	—	—
Awards exchanged upon 2015 Reorganization	(655,494)	0.82
Outstanding at December 31, 2015	—	\$ —

(c) Awards Issued Under the Synlogic, LLC 2015 Equity Incentive Plan

(i) Incentive Units

In October 2015, the Company's Board of Directors adopted the 2015 Equity Incentive Plan, which provides for the grant of equity incentive units to employees, officers, directors or consultants. The awards generally vest 25% after one year and ratably monthly thereafter over the next 36 months. Certain awards provide for accelerated vesting upon a change in control, as defined in the 2015 Equity Incentive Plan. Incentive units do not expire. Holders of incentive units have no voting rights in connection with such incentive units. Each incentive unit is intended to be a profits interest within the meaning of IRS regulations. Each incentive unit has a threshold price, which is the price above which an incentive unit will participate in distributions. In this way, an incentive unit is designed to participate in the future profits and appreciation. Holders of incentive units will be entitled to receive profits when and if distributions are in excess of the threshold price of the award set by the Board of Directors on the date of grant (Note 11).

The Company granted awards under the 2015 Equity Incentive Plan to individuals whose options were terminated under the 2014 Stock Incentive Plan pursuant to the 2015 Reorganization. These newly issued incentive units had similar vesting schedules and strike prices to the canceled awards. The Company treated this as a modification to the original option grant because the cancellation and reissuance was deemed to be concurrent. The calculation of the incremental compensation expense is based on the excess of the fair value of the award measured immediately before and after the modification. Due to the inclusion of the threshold price setting a barrier for participation in distributions, the fair value of an incentive unit is less than the fair value of a stock option valued using similar assumptions. As a result, the Company did not recognize any incremental compensation expense associated with the modification.

During the year ended December 31, 2016, the Company granted 1,317,502 incentive units to employees or directors and 35,000 incentive units to nonemployees. One of the nonemployee grants contains provisions for accelerated vesting upon the achievement of certain performance-based milestones.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

The weighted-average assumptions used in the Black-Scholes with barrier option-pricing model for awards issued under the 2015 Equity Incentive Plan are:

	<u>Year ended December 31, 2016</u>		<u>Year ended December 31, 2015</u>	
	<u>Employee</u>	<u>Nonemployee</u>	<u>Employee</u>	<u>Nonemployee</u>
Expected term (in years)	2.5	0.6 - 3.3	2.9	2.9
Risk-free interest rate	1.1%	0.9%	1.0%	1.1%
Expected volatility	77.0%	71.6%	69.8%	70.0%
Dividend yield	0%	0%	0%	0%

The following table represents a summary of incentive unit activity under the 2015 Equity Incentive Plan during 2016 and 2015:

	<u>Incentive units</u>			
	<u>Number of units</u>	<u>Weighted-average strike price</u>	<u>Weighted-average threshold price</u>	<u>Weighted-average grant date fair value</u>
Nonvested units at December 31, 2014	—	\$ —	\$ —	\$ —
Incentive units replacing cancelled options	792,307	0.32	2.53	0.45
Granted	492,038	1.23	2.53	0.43
Vested	(237,120)	0.30	2.53	0.46
Forfeited	(149,110)	\$ 0.63	\$ 2.53	\$ 0.41
Nonvested units at December 31, 2015	898,115	\$ 0.56	\$ 2.53	\$ 0.49
Granted	1,352,502	3.53	3.53	0.60
Vested	(289,676)	0.93	2.61	0.65
Forfeited	(204,061)	0.56	2.53	0.43
Nonvested units at December 31, 2016	<u>1,756,880</u>	\$ 0.56	\$ 2.53	\$ 0.49
Vested or expected to vest at December 31, 2016	2,065,813	\$ 2.28	\$ 3.09	\$ 0.56

As of December 31, 2016, there was approximately \$0.8 million of total unrecognized compensation expense related to unvested incentive units granted to employees under the 2015 Equity Incentive Plan that is expected to be recognized over a weighted-average period of 3.6 years.

In addition, there was approximately \$0.3 million in unrecognized compensation expense related to unvested incentive units granted to non-employees that is expected to be recognized over a weighted-average period of 2.2 years. The amount of equity based compensation expense related to nonemployees that will ultimately be recorded will depend on the remeasurement of the outstanding awards through their vesting date.

(ii) *Restricted Common Units*

In July 2015, pursuant to the Contribution Agreement, the restricted stock award was exchanged for the same number of common units, substantially conferred with the same rights and responsibilities. The purchase options continue to remain in effect and the vesting schedule remains such that 25% vests after one year from the original grant date and vesting continues ratably monthly thereafter over the next 36 months. Compensation expense is recognized over the applicable service period.

The Company treated the cancellation of the restricted stock award issued under the 2014 Stock Incentive Plan and reissuance of restricted common units as a modification to the original award because the cancellation and reissuance were deemed to be concurrent. The calculation of the

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

incremental compensation expense is based on the excess of the fair value of the award measured immediately before and after the modification. The Company did not recognize any incremental compensation expense associated with the modification as the fair value of the restricted stock award was the same as the fair value of the restricted common unit.

No restricted common unit awards were issued in 2016. During 2016, 259,465 restricted common unit awards vested and approximately \$0.1 million in equity based compensation was recognized. Unrecognized compensation expense related to unvested restricted common unit awards as of December 31, 2016 was approximately \$0.3 million and is expected to be recognized over a period of approximately 2.4 years.

The following table presents a summary of restricted common unit activity during 2016 and 2015:

	<u>Restricted common units</u>	
	<u>Number of units</u>	<u>Grant date fair value (\$ per unit)</u>
Restricted common units at December 31, 2014	—	\$ —
Awards exchanged upon 2015 Reorganization	655,494	0.82
Granted	—	—
Forfeited	—	—
Restricted common units at December 31, 2015	655,494	0.82
Granted	—	—
Forfeited	—	—
Restricted common units at December 31, 2016	<u>655,494</u>	\$ 0.82
Vested or expected to vest at December 31, 2016	655,494	\$ 0.82

(11) Distributions

The Board of Directors has the authority to determine the amount, if any, of proceeds available for distribution to unit holders. In the event that a distribution of proceeds is declared by the Board of Directors, such proceeds are to be distributed in accordance with the following order of priority:

- First, to holders of Class B Preferred Units, pro rata in proportion to their unpaid contributed capital, until such holder has received an amount equal to its capital contribution;
- Second, to holders of Class A Preferred Units and Contingently Redeemable Class A Preferred Units, pro rata in proportion to their unpaid contributed capital, until such holder has received an amount equal to its capital contribution;
- Third, to all holders of Preferred Units, common units and incentive units, pro rata in proportion to the remaining amount to be distributed, until an aggregate amount has been distributed in respect of each Preferred Unit, common unit and incentive unit equal to the greatest aggregate amount per unit distributed in respect of any Preferred Unit under the first and second priority described above; provided, that no holder of an incentive unit shall participate in any distributions until a total amount equal to the threshold price with respect to such incentive unit has been distributed in respect of any common unit outstanding on the date of issuance of such incentive unit subsequent to the issuance of such incentive unit;
- Fourth, to each holder of certain incentive units for which the Board of Directors has established a strike price, pro rata in proportion to the remaining amount to be distributed, an amount equal to the difference between the strike price for such incentive unit, and the threshold price for such incentive unit; and

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

- Thereafter, to all holders of Preferred Units, common units and incentive units, pro rata in proportion to their percentage interest. No distributions were made through December 31, 2016.

(12) AbbVie Collaboration Agreement

In July 2015 the Company entered into an Agreement and Plan of Merger (the "Agreement") with AbbVie under which the Company granted an exclusive option to AbbVie to purchase IBDCo and agreed to collaborate in researching and developing an Investigatory New Drug ("IND") candidate for the treatment of IBD.

In exchange for the exclusive option to acquire IBDCo, initial research and development services, ongoing patent defense, and participation on the A joint steering committee ("JSC"), AbbVie agreed to pay IBDCo an upfront, nonrefundable cash payment of \$2.0 million, which IBDCo received in December 2015. AbbVie also agreed to pay IBDCo up to \$16.5 million related to certain development milestones, all of which were considered substantive, as well as an option excise fee upon the execution of their option to buy IBDCo. The agreement also provides for royalty payments and payments upon the achievement of certain clinical, regulatory and commercial milestones.

The Agreement sets forth the Company's and AbbVie's respective obligations for development and delivery of an IND candidate package using reasonable commercial efforts. The JSC will make a determination as to the continuation of the collaboration at the achievement of the milestones.

At the inception of the Agreement, the Company identified the following deliverables: (i) an exclusive option to purchase IBDCo, (ii) research and development services and ongoing patent defense, and (iii) participation on the JSC. The Company also identified contingent deliverables related to four research and development milestones, delivery of an IND candidate package milestone, and transfer of ownership of IBDCo upon exercise of the option to buy IBDCo. The contingent deliverables have been excluded from the initial allocation and will be treated as a separate unit of accounting when and if delivered.

The Company concluded that none of the three deliverables identified at the inception of the Agreement has stand-alone value from the other undelivered elements. Accordingly, these deliverables represent a single unit of accounting.

As of December 31, 2016, the only consideration that is fixed and determinable is the nonrefundable upfront payment of \$2.0 million. The consideration relates to the three identified deliverables that comprise the single unit of accounting, which will be recognized evenly over the period of performance. The period of performance will be through the option period, which is closely tied to the completion of the research and development collaboration with AbbVie, and has been estimated to be 54 months. The Company will periodically review and, if necessary, revise the estimated period of performance.

During the year ended December 31, 2016, the Company recognized approximately \$0.4 million in revenue associated with the Agreement as substantive activities commenced in 2016. As of December 31, 2016, there was approximately \$1.6 million of deferred revenue related to the Agreement, which is classified as current or noncurrent in the consolidated balance sheets based on the Company's estimate of revenue that will be recognized within the next twelve months. All costs

SYNLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

associated with the collaboration agreement will be recorded in research and development expense in the consolidated statements of operations and comprehensive loss in the period incurred.

(13) Income Taxes

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. Deferred tax assets consist of the following (in thousands):

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	\$ 11,236	\$ 3,516
Tax credit carryforwards	957	365
Accrued expenses	170	268
Property and equipment	34	—
Deferred rent	516	—
Other	321	230
Gross deferred tax assets	<u>13,234</u>	<u>4,379</u>
Deferred tax liability:		
Property and equipment	—	(17)
Deferred revenue	(174)	—
Valuation allowance	<u>(13,060)</u>	<u>(4,362)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of the Company's deferred tax assets, which are comprised principally of net operating loss carryforwards, and determined that it is more likely than not that the Company will not recognize the benefits of the deferred tax assets. As a result, a full valuation allowance of approximately \$13.1 million and \$4.4 million was established at December 31, 2016 and 2015, respectively.

A reconciliation of income tax expense computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows (dollars in thousands):

	Years ended December 31,			
	2016		2015	
	Amount	Tax Rate	Amount	Tax Rate
Income tax benefit using U.S. federal statutory rate	\$(7,125)	34%	\$(2,902)	34%
State income taxes, net of federal benefit	(1,078)	5%	(438)	5%
Other permanent differences	100	— %	30	— %
Foreign rate differential	—	— %	—	— %
Tax credits	(591)	3%	(291)	3%
Other items	(4)	— %	3	— %
Net change in valuation allowance	<u>8,698</u>	<u>(42)%</u>	<u>3,598</u>	<u>(42)%</u>
Income tax expense (benefit)	<u>\$ —</u>	<u>—%</u>	<u>\$ —</u>	<u>—%</u>

SYNLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

A roll-forward of the valuation allowance for the years ended December 31, 2016 and 2015 is as follows (in thousands):

	Years ended December 31,	
	2016	2015
Balance at beginning of year	\$ (4,362)	\$ (764)
Increase in valuation allowance	(8,698)	(3,598)
Balance at end of year	\$(13,060)	\$(4,362)

As of December 31, 2016 and 2015, the Company had federal and state net operating loss carryforwards that may be available to reduce future taxable income of approximately \$28.7 million and \$8.9 million and approximately \$28.2 million and \$8.8 million, respectively, which begin to expire in 2034. In addition, at December 31, 2016, the Company had federal and state research and development tax credit carryforwards available to reduce future tax liabilities of approximately \$0.7 million and \$0.4 million, respectively. These credits begin to expire in 2034 and 2029, respectively.

Pursuant to Section 382 of the Internal Revenue Code of 1986 (“IRC”), certain substantial changes in the Company’s ownership may result in a limitation on the amount of net operating loss (“NOL”) carryforwards and research and development credit (“R&D credit”) carryforwards that may be used in future years. Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the IRC due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since its formation, due to a significant complexity and related costs associated with such a study. There could be additional ownership changes in the future that may result in additional limitations on the utilization of NOL carryforwards and credits.

The Company adopted the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which required the Company to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. The Company has not recognized any liability for unrecognized tax benefits as of December 31, 2016.

The Company files tax returns, on an entity-level basis, as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. Tax years from 2014 to the present are open to examination under the statute. The Company’s policy is to record interest and penalties related to income taxes as part of the tax provision. There are no interest or penalties accrued at December 31, 2016 and 2015.

SYNLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

(14) Net Loss per Unit

The following table sets forth the computation of basic and diluted net loss per unit attributable to common unit holders (in thousands, except for unit and per unit amounts):

	<u>Years ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
Numerator:		
Net loss attributable to common unitholders	\$ (20,954)	\$ (8,532)
Denominator:		
Weighted-average common units outstanding—basic and diluted	2,848,081	2,723,630
Net loss per unit attributable to common unitholders—basic and diluted	\$ (7.36)	\$ (3.13)

The Company's potentially dilutive units, which include unvested restricted common unit awards, are considered to be common unit equivalents and are only included in the calculation of diluted net loss per unit when their effect is dilutive.

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

	<u>As of December 31,</u>	
	<u>2016</u>	<u>2015</u>
Unvested restricted common unit awards	396,029	655,494

(15) Leases

The Company recorded rent expense of approximately \$1.0 million and \$0.4 million for the years ended December 31, 2016 and 2015, respectively.

Operating Leases

On November 14, 2014, the Company entered into an operating sublease for office space with a termination option at the Company's discretion or when the parties mutually agree. The operating lease provided for annual rent of approximately \$0.3 million, payable on a monthly basis. The Company was responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises. Additionally, the Company maintained a security deposit of approximately \$72,000 with the lessor and recorded the deposit in other assets in its consolidated balance sheet. The Company mutually agreed with the lessor to terminate the sublease effective March 4, 2016.

On July 23, 2015, the Company entered into an operating lease for office and laboratory space in Cambridge, Massachusetts. The operating lease term commenced in February 2016 and expires in April 2021 with a one year renewal option to extend the lease. Rent expense commenced on February 1, 2016 and is recognized on a straight-line basis over the duration of the term. The operating lease provided for annual rent of approximately \$0.9 million, payable on a monthly basis, which will increase at a rate of 3% annually, and includes three months of rent abatement during the first year. The Company is responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises. Pursuant to the lease, the Company provided a security deposit of approximately \$0.2 million to the lessor and recorded the deposit in other assets in its consolidated balance sheet. The

SYNLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

operating lease also provides for a tenant improvement allowance, at the cost of the lessor, not to exceed approximately \$1.3 million, all of which was incurred in 2016. The Company was deemed to be the accounting owner of the tenant improvements primarily because it was responsible for project cost overruns. Therefore, the amounts were recorded as a leasehold improvement and deferred rent and are being recorded as a reduction to rent expense ratably over the lease term of 63 months.

Capital Leases

In January 2015, the Company entered into a twenty-four month, non-cancellable lease agreement for approximately \$0.2 million for certain lab equipment. Due to the existence of a bargain purchase option, the lease has been accounted for as a capital lease. At December 31, 2016, the interest rate on the outstanding capital lease obligation was approximately 7.6%.

In October 2016, the Company entered into a twenty-four month, non-cancellable lease agreement for approximately \$0.4 million for certain lab equipment. Due to the existence of a bargain purchase option, the lease has been accounted for as a capital lease. At December 31, 2016, the interest rate on the outstanding capital lease obligation was approximately 9.6%.

Future minimum lease payments under the Company's operating and capital leases as of December 31, 2016, are as follows (in thousands):

	<u>Operating leases</u>	<u>Capital leases</u>
Fiscal year:		
2017	\$ 946	\$ 230
2018	975	186
2019	1,004	—
2020	1,034	—
2021	353	—
Thereafter	—	—
Total future minimum lease payments	<u>\$ 4,312</u>	<u>\$ 416</u>
Less amounts representing interest		<u>36</u>
Capital lease obligations at December 31, 2016		380
Less current portion of capital lease obligations		<u>203</u>
Capital lease obligations, net of current portion		<u>\$ 177</u>

(16) Commitments and Contingencies

On November 9, 2015, the Company exercised an option to enter into a license agreement with the Massachusetts Institute of Technology in exchange for \$50,000 and reimbursement of prior patent costs of approximately \$0.1 million. These amounts were recorded as research and development expense in the year ended December 31, 2016. The agreement will require future maintenance fees totaling approximately \$0.1 million through the year ending December 31, 2020 and \$50,000 per year thereafter during the period the license is effective, and may also require future payments of up to approximately \$1.9 million upon achievement of certain regulatory milestones.

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

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

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.

(17) Employee Benefits

In 2014, the Company adopted a defined contribution 401(k) plan for eligible employees. Employees are eligible to participate in the plan beginning on their date of hire. Under the terms of the plan, employees may make voluntary contributions as a percentage of compensation. The Company has not made any matching contributions since the adoption of the 401(k) plan.

(18) Related-Party Transactions

The Company contracted services from one of its principal investors for the Company's former president and chief executive officer and former chief medical officer who were both employed by the principal investor, as well as employed to support separate portfolio companies of the investor. The Company paid a separate portfolio company approximately \$0.1 million relating to reimbursement for a portion of the salary of the former chief medical officer for the year ended December 31, 2016 and \$0.1 million relating to reimbursement for a portion of the salary of the former chief executive officer and chief medical officer during the year ended December 31, 2015.

The Company contracted the services of The Orphan Group, which specializes in supporting biotechnology companies in developing therapeutics toward diseases of high unmet medical needs in rare disorders. The Orphan Group is owned by the Company's former chief operating officer. The Company paid the Orphan Group approximately \$13,000 and approximately \$15,000 for contracted services in the year ended December 31, 2016 and 2015, respectively.

In September 2016, the Company issued a loan to its chief executive officer of approximately \$0.2 million which was repaid, including interest which accrued at a rate of 0.6%, in June 2017.

(19) Subsequent Events

The Company has evaluated subsequent events through June 19, 2017, which is the date the financial statements were available to be issued.

In March 2017, the Company sold and issued 3,564,203 units of Class B-2 Preferred Units at \$7.4818 per unit to investors for total consideration of approximately \$26.6 million, net of offering costs of approximately \$18,000. The Class B-2 Preferred Units were issued with substantially the same terms as the existing Class B-1 Preferred Units.

In April 2017, the Company exercised an option associated with the October 2014 agreement with Boston University and the Massachusetts Institute of Technology to acquire a license for certain intellectual property in exchange for \$50,000. The execution of this option triggered an equity award for the issuance of 325,377 common units and the Company was required to pay approximately \$0.3 million for prior patent costs incurred in connection with the option agreement.

In May 2017, the Company completed a series of transactions ("2017 Reorganization") pursuant to which Synlogic, LLC merged with and into Synlogic, Inc. which continued to exist as the surviving corporation. Pursuant to the 2017 Reorganization, the common units and Preferred Units of Synlogic, LLC, together consisting of Class A Preferred Units, Contingently Redeemable Class A Preferred Units and Class B Preferred Units, were exchanged for common stock and Preferred Stock of Synlogic, Inc. The Synlogic Preferred Stock has substantially similar rights and preferences as the Preferred Units, except that the Preferred Stock is convertible into common stock at the option of the holder, on a one-for-one basis, subject to an antidilution adjustment. Conversion of the Preferred Stock is automatically triggered upon a firm-commitment underwritten public offering or upon a supermajority preferred interest vote.

SYNOLOGIC, LLC AND SUBSIDIARIES

Notes to Consolidated Financial Statements (continued)

In May 2017, the Company adopted the Synlogic, Inc. 2017 Stock Incentive Plan (“2017 Stock Incentive Plan”). Under the 2017 Stock Incentive Plan, Synlogic may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. Pursuant to the 2017 Reorganization, Synlogic issued restricted common stock awards under the 2017 Stock Incentive Plan to replace the cancelled incentive units pursuant to the termination of the 2015 Equity Incentive Plan.

In May 2017, the Company sold and issued 5,210,922 shares of Series C Convertible Preferred Stock to investors for total consideration of approximately \$40.4 million, net of issuance costs of approximately \$1.6 million.

In May 2017, Synlogic entered into a definitive merger agreement with Mirna Therapeutics, Inc. (NASDAQ: MIRN) under which Synlogic will merge with a wholly owned subsidiary of Mirna in an all-stock transaction. The proposed merger remains subject to certain conditions, including the approval of Mirna stockholders. If approved, upon closing of the transaction, Mirna will be renamed Synlogic, Inc.

In May 2017, the Company achieved a development milestone under the AbbVie agreement for which it will receive \$2.0 million.

SYNLOGIC, INC. AND SUBSIDIARIES

Table of Contents

	Page(s)
Unaudited Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016	1-2
Unaudited Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2017 and 2016	3
Unaudited Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2017 and 2016	4
Notes to Unaudited Consolidated Financial Statements	5

SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Balance Sheets

(In thousands, except share/unit amounts)

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets:		
Cash	\$66,826	\$ 14,586
Accounts receivable	2,000	—
Prepaid expenses and other current assets	2,443	1,477
Total current assets	71,269	16,063
Property and equipment, net of accumulated depreciation of \$1,264 and \$810 as of June 30, 2017 and December 31, 2016, respectively	3,555	3,504
Restricted cash	50	50
Other assets	233	422
Total assets	<u>\$75,107</u>	<u>\$ 20,039</u>
Liabilities, Contingently Redeemable Preferred Shares/Units and Equity		
Current liabilities:		
Accounts payable	\$ 1,865	\$ 988
Accrued expenses	4,074	2,296
Deferred revenue	444	444
Deferred rent	269	255
Capital lease obligations	185	203
Total current liabilities	<u>6,837</u>	<u>4,186</u>
Long-term liabilities:		
Deferred revenue, net of current portion	890	1,112
Deferred rent, net of current portion	920	1,061
Capital lease obligations, net of current portion	82	177
Total long-term liabilities	<u>1,892</u>	<u>2,350</u>
Commitments and contingencies		
Contingently Redeemable Class A Preferred Shares		
Issued and outstanding 1,413,039 and 0 shares as of June 30, 2017 and December 31, 2016, respectively	5,000	—
Contingently Redeemable Class A Preferred Units		
Issued and outstanding 0 and 1,413,039 units as of June 30, 2017 and December 31, 2016, respectively	—	5,000

See accompanying notes to the unaudited consolidated financial statements.

SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Balance Sheets (continued)

(In thousands, except share/unit amounts)

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Equity		
Series C Convertible Preferred Shares, \$0.0001 par value		
Issued and outstanding 5,210,922 and 0 shares as of June 30, 2017 and December 31, 2016, respectively	40,434	—
Series B Convertible Preferred Shares, \$0.0001 par value		
Issued and outstanding 5,425,829 and 0 shares as of June 30, 2017 and December 31, 2016, respectively	40,260	—
Class B Preferred Units		
Issued and outstanding 0 and 1,861,626 units as of June 30, 2017 and December 31, 2016, respectively	—	13,611
Series A Convertible Preferred Shares, \$0.0001 par value		
Issued and outstanding 7,089,713 and 0 shares as of June 30, 2017 and December 31, 2016, respectively	25,548	—
Class A Preferred Units		
Issued and outstanding 0 and 7,089,713 units as of June 30, 2017 and December 31, 2016, respectively	—	25,548
Common shares, \$0.0001 par value		
Issued and outstanding 4,909,280 and 0 shares as of June 30, 2017 and December 31, 2016, respectively	—	—
Common units		
Issued and outstanding 0 and 3,339,869 units as of June 30, 2017 and December 31, 2016	—	592
Additional paid-in capital	3,163	—
Accumulated deficit	(48,027)	(31,248)
Total equity	<u>61,378</u>	<u>8,503</u>
Total liabilities and equity	<u>\$ 75,107</u>	<u>\$ 20,039</u>

See accompanying notes to the unaudited consolidated financial statements.

SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share/unit and per share/unit amounts)

	For the three months ended		For the six months ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Revenue	\$ 2,111	\$ 111	\$ 2,222	\$ 222
Operating expenses:				
Research and development	8,532	3,426	\$ 13,650	\$ 5,750
General and administrative	3,036	1,656	\$ 5,403	\$ 3,269
Total operating expenses	11,568	5,082	19,053	9,019
Loss from operations	(9,457)	(4,971)	(16,831)	(8,797)
Interest income (expense), net	69	(1)	\$ 75	(2)
Net loss	\$ (9,388)	\$ (4,972)	\$ (16,756)	\$ (8,799)
Comprehensive loss	\$ (9,388)	\$ (4,972)	\$ (16,756)	\$ (8,799)
Net loss per share attributable to common shareholders - basic and diluted	\$ (2.60)	\$ —	\$ (5.09)	\$ —
Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted	3,610,356	—	3,293,033	—
Net loss per unit attributable to common unit holders - basic and diluted	\$ —	\$ (1.75)	\$ —	\$ (3.15)
Weighted-average common units used in computing net loss per unit attributable to common unit holders - basic and diluted	—	2,834,897	—	2,791,370

See accompanying notes to the unaudited consolidated financial statements.

SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Statements of Cash Flows

(In thousands)

	<u>Six Months Ended</u> <u>June 30, 2017</u>	<u>Six Months Ended</u> <u>June 30, 2016</u>
Cash flows from operating activities:		
Net loss	\$ (16,756)	\$ (8,799)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	454	298
Loss on disposal of assets	—	3
Equity-based compensation expense	797	153
Common shares issued for license acquisition	1,751	—
Changes in operating assets and liabilities:		
Accounts receivable	(2,000)	—
Prepaid expenses and other current assets	119	(548)
Accounts payable and accrued expenses	1,255	(185)
Deferred revenue	(222)	(222)
Deferred rent	(127)	134
Other assets	189	107
Net cash used in operating activities	<u>(14,540)</u>	<u>(9,059)</u>
Cash flows from investing activities:		
Proceeds from sale of property and equipment	—	4
Purchases of property and equipment	(419)	(1,495)
Net cash used in investing activities	<u>(419)</u>	<u>(1,491)</u>
Cash flows from financing activities:		
Payments on capital lease obligations	(113)	(32)
Deferred transaction costs	(34)	—
Proceeds from sale of preferred shares, net of issuance costs	40,697	—
Proceeds from sale of preferred units, net of issuance costs	26,649	30,938
Net cash provided by financing activities	<u>67,199</u>	<u>30,906</u>
Net increase in cash	52,240	20,356
Cash at beginning of period	14,586	6,179
Cash at end of period	<u>\$ 66,826</u>	<u>\$ 26,535</u>
Supplemental disclosure of non-cash activity:		
Cash paid for interest	\$ 15	\$ 3
Landlord funded allowance for tenant improvements	\$ —	\$ 1,295
Adjustment to property and equipment purchases included in accounts payable and accrued expenses	\$ 86	\$ 34
Adjustment to transaction costs for amounts included in accounts payable and accrued expenses	\$ 1,051	\$ —
Issuance costs from sale of preferred shares in accounts payable and accrued expenses	\$ 263	\$ 100

See accompanying notes to the unaudited consolidated financial statements.

SYNOLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

(1) Nature of Business

Organization

Synlogic, Inc., together with its wholly owned and consolidated subsidiaries (“Synlogic” or the “Company”) is an early clinical-stage pharmaceutical company focused on discovering and developing Synthetic Biotic™ medicines: a novel class of living medicines to treat a broad range of human diseases ranging from genetic and acquired metabolic disorders to inflammation and cancer. Synlogic applies the principles and tools of synthetic biology to engineer beneficial, probiotic bacteria to perform or deliver critical therapeutic functions, compensating for missing or damaged pathways in patients with these serious diseases. As living medicines, Synthetic Biotic medicines are designed to sense a local disease context within a patient’s body and respond by metabolizing toxic substances or delivering combinations of therapeutic factors.

The Company was founded and began operations on March 14, 2014, as TMC Therapeutic, 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 shareholders of Synlogic, Inc. executed the Synlogic, LLC Contribution Agreement (the “Contribution Agreement”), which contributed their equity interests in Synlogic, Inc. 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 (“2015 Reorganization”). In conjunction with the 2015 Reorganization, the Company entered into a merger agreement with AbbVie S.à.r.l. (“AbbVie”), and other agreements, for the development of treatments for inflammatory bowel disease (“IBD”) (Note 9). In May 2017, the Company completed a series of transactions pursuant to which Synlogic, LLC, merged with and into Synlogic, Inc. which continued to exist as the surviving corporation (Note 6). Also in May 2017, Synlogic entered into a definitive merger agreement with Mirna Therapeutics, Inc. (NASDAQ: MIRN) (“Mirna”) under which Synlogic agreed to merge with a wholly owned subsidiary of Mirna in an all-stock transaction. The merger closed on August 28, 2017 and Mirna was renamed Synlogic, Inc. (Notes 3 and 14).

The Company operates in one operating segment: the discovery and development of Synthetic Biotic medicines. The Company’s chief executive officer, as chief operating decision maker, manages and allocates resources to the operations of the Company on a total company basis. Since incorporation, the Company has devoted substantially all of its efforts to the research and development of its product candidates.

Risks and Uncertainties

At June 30, 2017, the Company had cash of approximately \$66.8 million and an accumulated deficit of approximately \$48.0 million. Since its inception through June 30, 2017, the Company has primarily financed its operations through the issuance of preferred stock and the AbbVie collaboration. 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. The Company secured multiple rounds of new funding from the sale of Class B Preferred Units in March 2017, generating approximately \$26.6 million in net proceeds, and the sale of Series C Convertible Preferred Stock in May 2017, generating approximately \$40.4 million in net proceeds. Subsequent to June 30, 2017, through the date of the issuance of these financial statements, the Company generated approximately \$42.6 million in proceeds from its merger with Mirna. As a result of the merger with Mirna, the proceeds from the Series C financing in May 2017 and the Series B financing in February 2017, management believes that the Company has sufficient cash to fund its operations through at least twelve months from the issuance of these financial statements, or the third quarter of 2018.

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 studies, safety and efficacy of its product candidates in clinical trials, 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

SYNOLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

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**

(a) ***Basis of Presentation***

The accompanying consolidated financial statements and the related disclosures as of June 30, 2017 and for the three and six months ended June 30, 2017 and 2016 are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP" or "GAAP") and the rules and regulations of the Securities Exchange Commission ("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 2016 and 2015 audited consolidated financial statements and notes thereto contained elsewhere in this Form 8-K/A. The December 31, 2016 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, 2017 and 2016. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or any other interim period or future year or period.

(b) ***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.

(c) ***Use of Estimates***

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, the Company's management evaluates its estimates, including those related to revenue recognition, income taxes including the valuation allowance for deferred tax assets, research and development, accrued expenses, contingencies and equity-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgements about the carrying values of assets and liabilities. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

(d) ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk include amounts held as cash and restricted cash. The Company uses a high quality, accredited financial institution to maintain its cash and restricted cash, and accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses in such

SYNOLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has no financial instruments with off-balance sheet risk of loss.

(e) *Recently Issued Accounting Pronouncements*

The recently issued accounting pronouncements described in the Company's consolidated financial statements as of and for the year ended December 31, 2016, and the notes thereto have had no material changes during the three and six months ended June 30, 2017, except as described below.

In May 2014, the FASB issued ASU 2014-09—Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. This standard is based on the principle that an entity should recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive. This standard also requires additional disclosure about the nature, amount, timing and uncertainty of assets recognized from costs incurred to fulfill a contract. It will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual periods. Early adoption is permitted any time after the original effective date, which for the Company is January 1, 2017. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The Company is continuing to assess the impact that this standard will have on its financial statements and the expected method of transition. The Company's revenue during the six months ended June 30, 2017 is from its collaboration arrangement. During the second half of 2017, the Company plans to complete its review to determine the impact that this standard could have on its consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU 2016-09—Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). The amendments in ASU 2016-09 are to simplify several aspects of the accounting for stock-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. In addition, companies will now have to elect whether to account for forfeitures on share-based payments by (1) recognizing forfeitures of awards as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The Company adopted ASU 2016-09 on April 1, 2017 on a modified retrospective basis, and elected to recognize forfeitures as they occur. The Company recorded an insignificant cumulative effect adjustment as a result of the adoption of this amendment. The adoption did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805) Clarifying the Definition of a Business, which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The Company adopted ASU 2017-01 on April 1, 2017 and is currently evaluating the impact of adopting this guidance as it relates to the merger with Mirna.

(3) **Merger with Mirna Therapeutics**

On May 15, 2017, Synlogic entered into a definitive merger agreement with Mirna Therapeutics, Inc. (NASDAQ: MIRN) under which Synlogic will merge with a wholly owned subsidiary of Mirna and will continue as a wholly owned subsidiary of Mirna and the surviving corporation of the Merger. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code").

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, (a) each outstanding share of Synlogic common stock and Synlogic preferred stock will be converted into the right to receive a number of shares of Mirna's common stock equal to the exchange ratio (as described in the Merger Agreement); and (b) each outstanding Synlogic stock option that has not previously been exercised prior to the effective time of the Merger will be assumed by Mirna.

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

Pursuant to the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, the former Synlogic securityholders are expected to own approximately 83% of the outstanding shares of Mirna's common stock on a fully-diluted basis and securityholders of Mirna as of immediately prior to the Merger are expected to own approximately 17% of the outstanding shares of Mirna's common stock on a fully-diluted basis. The exchange ratio will be adjusted to the extent that Mirna's net cash at closing is greater than or less than \$40 million, as of immediately prior to the effective time of the Merger, as described further in the Merger Agreement.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Mirna and Synlogic, and Mirna's satisfaction of a minimum net cash threshold of \$33.5 million immediately prior to the effective time of the Merger. In accordance with the terms of the Merger Agreement, (i) certain executive officers, directors and stockholders of Synlogic (solely in their respective capacities as Synlogic stockholders) holding approximately 77% of the shares of outstanding Synlogic capital stock (after giving effect to Synlogic's Series C financing) have entered into support agreements with Mirna to vote all of their shares of Synlogic capital stock in favor of adoption of the Merger Agreement and approval of the transactions contemplated by the Merger Agreement (the "Synlogic Support Agreements") and (ii) certain executive officers, directors and stockholders of Mirna (solely in their respective capacities as Mirna stockholders) holding approximately 33% of the outstanding shares of Mirna's common stock have entered into support agreements with Synlogic to vote all of their shares of Mirna common stock in favor of adoption of the Merger Agreement and approval of the transactions contemplated by the Merger Agreement (together with the Synlogic Support Agreements, the "Support Agreements"). The Support Agreements include covenants with respect to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any competing acquisition proposals and place certain restrictions on the transfer of the shares of Mirna and Synlogic held by the respective signatories thereto.

Concurrently with the execution of the Merger Agreement, certain officers, directors and stockholders of Mirna holding approximately 33% of the outstanding shares of Mirna common stock and certain officers, directors and stockholders of Synlogic holding approximately 81% of the outstanding shares of Synlogic capital stock (giving effect to Synlogic's Series C financing) have entered into lock-up agreements pursuant to which, among other things, they have accepted certain restrictions on the transfer of shares of our common stock during the 180-day period following the closing of the Merger.

The Merger Agreement contains certain termination rights for both Mirna and Synlogic, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of \$2.0 million, or in some circumstances reimburse the other party's expenses up to a maximum of \$1.0 million.

At the effective time of the Merger, the board of directors of the merged company is expected to consist of seven members, five of whom will be designated by Synlogic and two of whom will be designated by Mirna.

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

(4) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consists of the following (in thousands):

	June 30, 2017	December 31, 2016
Prepaid insurance	\$ 54	\$ 71
Prepaid research and development	1,121	1,163
Other prepaid	118	212
Other current assets	1,150	31
	<u>\$ 2,443</u>	<u>\$ 1,477</u>

Other current assets include approximately \$1.1 million of deferred transaction costs related to the merger with Mirna.

(5) Accrued Expenses

Accrued expenses consists of the following (in thousands):

	June 30, 2017	December 31, 2016
Payroll related	\$ 975	\$ 1,341
Professional fees	1,827	522
Research and development	1,129	273
Other	143	160
	<u>\$ 4,074</u>	<u>\$ 2,296</u>

(6) 2017 Reorganization

In May 2017, the Company completed a series of transactions (“2017 Reorganization”) pursuant to which Synlogic, LLC, merged with and into Synlogic, Inc., which continued to exist as the surviving corporation. Pursuant to the 2017 Reorganization, the common units and Preferred Units of Synlogic, LLC, together consisting of Class A Preferred Units, Contingently Redeemable Class A Preferred Units and Class B Preferred Units, were exchanged for common stock and Preferred Stock of Synlogic, Inc, respectively. Additionally, Synlogic issued equity awards under the 2017 Stock Incentive Plan to replace the canceled incentive units pursuant to the termination of the 2015 Equity Incentive Plan (Note 8).

(7) Preferred Stock

Pursuant to the 2017 Reorganization, Preferred Stock was granted to all holders of Preferred Units at the time of the reorganization. The Synlogic Preferred Stock has substantially similar rights and preferences as the Preferred Units, except that the Preferred Stock is convertible into common stock at the option of the holder, on a one-for-one basis, subject to an antidilution adjustment. Conversion of the Preferred Stock is automatically triggered upon a firm-commitment underwritten public offering or upon a supermajority preferred interest vote.

In May 2017, the Company sold and issued 5,210,922 units of Series C Preferred Stock at \$8.06 per share to investors for total consideration of approximately \$40.4 million, net of offering costs of approximately \$1.6 million. The Series C Preferred Stock were issued with the same terms as the existing Preferred Stock.

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

(a) *Rights and Preferences*

Preferred Stock have the following rights and preferences:

(i) *Voting*

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote, except with respect to matters on which Delaware General Corporation Law required that a vote would be by a separate class. Each holder of Preferred Stock is entitled to the number of votes equal to the number of common shares into which each preferred share is convertible at the time of such vote.

(ii) *Dividends*

In the event that a dividend is declared for the holders of common stock, the holders of the Preferred Stock will be entitled to the amount of dividends on an as-converted basis. Through June 30, 2017 and 2016, no dividends were declared or paid.

(iii) *Liquidation Preference*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Preferred Stock then outstanding will be entitled to be paid, on a pari passu basis, out of the assets of the Company available for distribution to its stockholders before any payment is made to the holders of common stock by reason of their ownership thereof, with respect to each series of Preferred Stock, an amount per share equal to the greater of (i) the applicable original issue price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares been converted into common stock immediately prior to such liquidation, dissolution or winding up of the Company.

If upon any such liquidation, dissolution or winding up of the Company, the assets of the Company available for distribution to its stockholders are insufficient to pay the holders of shares of preferred stock the full amount to which they should have been entitled, the holders of shares of preferred stock will share ratably in any distribution of the assets available for distribution in proportion to the respective amounts that would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

(iv) *Par Value*

Par value was assigned as \$0.0001.

(v) *Conversion*

Each share of preferred stock, at the option of the holder, is convertible into that number of fully paid shares of common stock as determined by dividing the sum of the original issue price, plus any declared but unpaid dividends, by the conversion price in effect at the time of conversion. The initial conversion price for each preferred share is the original issue price, subject to adjustment in accordance with antidilution provisions. Each share of preferred stock is automatically converted upon the closing of a firm commitment underwritten public offering in which the public offering price exceeds \$12.09 (adjusted to reflect subsequent stock dividends, stock splits or recapitalization) and the aggregate proceeds raised are not less than \$50,000,000, or upon the vote or written consent of a supermajority preferred interest (or a majority preferred interest in the event of a public offering that does not result in the offering price or aggregate proceeds amount set forth in this sentence).

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

(vi) *Redemption*

The Preferred Stock is not redeemable except upon a deemed liquidation event. Deemed liquidation events include a merger or acquisition in which the majority of the stock of the pre-merger corporation is not owned by the majority of the stockholders of the post-merger entity or the sale of all or substantially all of the Company’s assets. All holders of equally and more subordinated equity instruments of the Company will be entitled to receive the same form of consideration upon the occurrence of a deemed liquidation event, consequently, the Preferred Stock is classified as permanent equity.

In September 2014, the Company entered into a letter agreement with the Bill & Melinda Gates Foundation (“the Gates Foundation”) with respect to the Gates Foundation purchase of 1,413,039 shares of the Company’s Series A Preferred Stock. The Gates Foundation investment was made in three tranches of 363,636 shares in September 2014, 395,238 shares in May 2015 and 654,165 shares in February 2016. Under the letter agreement, the Company was required to spend the approximately \$5.0 million invested by the Gates Foundation for research on a particular disease, further develop the Company’s proprietary technology platform and provide assistance with access to use of such technology in developing countries. If the Company fails to spend the amount appropriately, or defaults under certain other commitments in the agreement and the Company does not cure such default within 90 days of notice, if requested by the Gates Foundation, the Company would be obligated to redeem the shares of Series A Preferred Stock or shares of common stock into which they had converted then held by the Gates Foundation or find a third party to purchase such shares at a price equal to the greater of the initial purchase price and the then current fair value of such shares. In either case, if the Company, over the 6 months following such redemption, sells substantially all of its equity or assets or completes an initial public offering at a value greater than 200% of the price paid upon redemption, then the Company must reimburse the Gates Foundation for the difference.

(b) *Participation Rights in Future Equity Issuances*

For series of Preferred Stock that were issued in multiple tranches, all holders of Preferred Stock had a pro rata right and obligation, based on their percentage equity ownership within the series, to participate in subsequent issuances within the same series of equity securities of the Company approved by 70% vote of holders of Preferred Stock. Should any such holder have chosen not to purchase its full pro rata share, they would have been deemed a defaulting purchaser and all Preferred Stock held by a defaulting purchaser would have been automatically converted into common stock of the Company.

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

(a) *Equity Compensation*

Equity compensation during the three and six months ended June 30, 2017 and June 30, 2016 is derived from restricted stock awards and stock options issued under the Synlogic, Inc. 2017 Equity Incentive Plan (“2017 Plan”) and from incentive units issued under the Synlogic, LLC 2015 Equity Incentive Plan (“2015 Plan”) and a restricted common unit grant. The Company has recorded total equity-based compensation expense of approximately \$0.7 million and \$0.8 million for the three and six months ended June 30, 2017, respectively, and approximately \$0.1 million and \$0.2 million for the three and six months ended June 30, 2016, respectively, which is based on the number of awards ultimately expected to vest.

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, 2017 and 2016 (in thousands):

	Three months ended		Six months ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Research and development	\$ 444	\$ 27	\$ 503	\$ 54
General and administrative	223	53	\$ 294	\$ 99
	<u>\$ 667</u>	<u>\$ 80</u>	<u>\$ 797</u>	<u>\$ 153</u>

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

The following table summarizes equity-based compensation expense by type of award for the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Stock options	\$ 484	\$ —	\$ 484	\$ —
Restricted stock awards	125	—	125	—
Incentive units	\$ 36	\$ 47	132	86
Restricted common units	22	33	56	67
	<u>\$ 667</u>	<u>\$ 80</u>	<u>\$ 797</u>	<u>\$ 153</u>

(b) *Awards Issued Under the Synlogic, LLC 2015 Equity Incentive Plan*

(i) *Incentive Units*

In October 2015, the Company's Board of Directors adopted the 2015 Plan, which provided for the grant of equity incentive units to employees, officers, directors or consultants. The awards generally vested 25% after one year and ratably monthly thereafter over the next 36 months. Certain awards provided for accelerated vesting upon a change in control, as defined in the 2015 Plan. Incentive units did not expire. Holders of incentive units had no voting rights in connection with such incentive units. Each incentive unit was intended to be a profits interest within the meaning of IRS regulations. Each incentive unit had a threshold price, which was the price above which an incentive unit would participate in distributions. In this way, an incentive unit was designed to participate in the future profits and appreciation. Holders of incentive units would have been entitled to receive profits when and if distributions were in excess of the threshold price of the award set by the Board of Directors on the date of grant.

The Company measured and recorded the value of incentive units granted to non-employees over the period of time that services were provided and, as such, unvested portions were subject to remeasurement at subsequent reporting periods.

No incentive units were issued during the three and six months ended June 30, 2017 and 133,136 incentive units were issued during both the three and six months ended June 30, 2016. In May 2017, all incentive units were cancelled pursuant to the 2017 Reorganization and reissued as restricted common stock. As a result, there was no unrecognized compensation expense related to incentive units as of June 30, 2017.

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

The following table represents a summary of incentive unit activity under the 2015 Plan:

	Incentive units			
	Number of units	Weighted-average strike price	Weighted-average threshold price	Weighted-average grant date fair value
Nonvested units at December 31, 2016	1,756,880	\$ 2.89	\$ 3.28	\$ 0.56
Granted	—	—	—	—
Vested	(133,259)	2.22	3.06	0.48
Forfeited	(470,255)	2.32	3.08	0.58
Nonvested units cancelled upon 2017 Reorganization	(1,153,366)	3.20	3.40	0.58
Nonvested units at June 30, 2017	—	\$ —	\$ —	\$ —
Vested or expected to vest at June 30, 2017	—	\$ —	\$ —	\$ —

(ii) *Restricted Common Units*

No restricted common unit awards were issued during the three and six months ended June 30, 2017 and 2016. During the three and six months ended June 30, 2017, 27,312 and 68,280 units, respectively, vested and approximately \$22,000 and \$0.1 million, respectively, in equity compensation was recognized. During both the three and six months ended June 30, 2016, 177,529 units vested and approximately \$34,000 and approximately \$0.1 million, respectively, in equity based compensation was recognized. In May 2017, the restricted common unit award was cancelled pursuant to the 2017 Reorganization and reissued as restricted common stock. As a result, there was no unrecognized compensation expense related to unvested restricted common units as of June 30, 2017.

(c) *Awards Issued Under the Synlogic, Inc 2017 Stock Incentive Plan*

In May 2017, the Company adopted the Synlogic, Inc. 2017 Stock Incentive Plan (“2017 Plan”). Under the 2017 Stock Incentive Plan, Synlogic may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. Pursuant to the 2017 Reorganization, Synlogic issued restricted common stock awards under the 2017 Stock Incentive Plan to replace the canceled incentive units pursuant to the termination of the 2015 Equity Incentive Plan. In certain instances, the Company also issued stock options related to the cancelled incentive units.

(i) *Stock Options*

During the three and six months ended June 30, 2017, 1,174,514 stock options were granted to employees and consultants.

SYNOLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

The weighted average assumptions used in the Black-Scholes option-pricing model for awards issued under the 2017 Stock Incentive Plan during both the three and six months ended June 30, 2017 were:

	Six months ended June 30, 2017	
	Employee	Nonemployee
Expected term	6.1 years	0.2 - 1.6 years
Weighted-average, risk-free interest rate	2.0%	0.9%
Expected volatility	70.0%	61.0%
Dividend yield	—	—

The following table summarizes stock option activity under the 2017 Plan.

	Stock options outstanding			
	Number of options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate Intrinsic value (in thousands)
Outstanding at December 31, 2016	—	\$ —	—	\$ —
Options granted upon 2017 Reorganization	533,832	7.48	5.7	1,614
Granted	640,682	7.48	6.3	1,703
Exercised	—	—	—	—
Forfeited	(1,432)	7.48	6.3	(4)
Outstanding at June 30, 2017	<u>1,173,082</u>			<u>\$ 3,313</u>
Vested or expected to vest at June 30, 2017	<u>1,174,514</u>	7.48	6.0	<u>\$ 3,154</u>
Exercisable at June 30, 2017	<u>77,928</u>	7.48	4.7	<u>\$ 183</u>

During the three and six months ended June 30, 2017, approximately \$0.5 million in equity compensation was recognized related to stock options related to employees.

The weighted average grant date fair value per share of options granted to employees during the three and six months ended June 30, 2017 was approximately \$4.75. The grant date fair value of the options awarded to employees during the three and six months ended June 30, 2017 was approximately \$5.4 million. No options were exercised during the three and six months ended June 30, 2017.

As of June 30, 2017, there was approximately \$5.0 million of unrecognized share-based compensation related to employees, for unvested stock option grants which is expected to be recognized over a weighted average period of 5.8 years. The total share-based compensation cost will be adjusted for future forfeitures as they occur. In addition, there was approximately \$6,000 of unrecognized share-based compensation, related to unvested stock option grants to non-employees which is expected to be recognized over a weighted average period of 0.8 years. The amount of equity based compensation expense related to non-employees that will ultimately be recorded will depend on the remeasurement of the outstanding awards through their vesting date.

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

(ii) *Restricted Common Stock*

During the three and six months ended June 30, 2017, 1,916,000 shares of common stock were granted under restricted stock agreements in exchange for the restricted common units that were cancelled as part of the 2017 Reorganization. The newly issued shares retained the same vesting schedule as the cancelled units. The Company treated these as modifications to the original grants of incentive units because the cancellation and reissuance was deemed to be concurrent. The calculation of the incremental compensation expense is based on the excess of the fair value of the award measured immediately before and after the modification. As a result of the modification, the Company recognized approximately \$26,000 in equity-based compensation during the three and six months ended June 30, 2017. No restricted stock was granted during the three and six months ended June 30, 2016.

The following table shows restricted stock activity:

	<u>Restricted stock awards</u>	
	<u>Number of shares</u>	<u>Grant date fair value (per share)</u>
Unvested at December 31, 2016	—	\$ —
Replacement awards granted upon 2017 Reorganization	1,916,000	7.48
Granted	—	—
Vested	(934,899)	7.48
Forfeited	(3,376)	7.48
Unvested at June 30, 2017	<u>977,725</u>	<u>\$ 7.48</u>

During the three and six months ended June 30, 2017, 932,151 shares of restricted stock vested, of which 906,058 shares were vested at the time of grant and 26,093 shares represent continued vesting of the grants. During the three and six months ended June 30, 2017, approximately \$0.1 million in equity compensation was recognized associated with restricted stock awards. During both the three and six months ended June 30, 2016, no restricted stock vested and no equity based compensation was recognized associated with restricted stock awards.

As of June 30, 2017, there was approximately \$0.8 million of unrecognized share-based compensation, net of estimated forfeitures, related to restricted stock awards granted to employees, which is expected to be recognized over a weighted average period of 2.7 years. The total unrecognized share-based compensation cost will be adjusted for future changes in estimated forfeitures. In addition, there was approximately \$0.3 million of unrecognized share-based compensation, related to unvested restricted stock awards granted to non-employees which is expected to be recognized over a weighted average period of 1.0 years.

(9) **Significant Agreements**

(a) *AbbVie Collaboration Agreement*

In July 2015, the Company entered into an Agreement and Plan of Merger (“the Agreement”) with AbbVie under which the Company granted an exclusive option to AbbVie to purchase IBDCo and agreed to collaborate in researching and developing an Investigatory New Drug (“IND”) candidate for the treatment of IBD.

In exchange for the exclusive option to acquire IBDCo, initial research and development services, ongoing patent defense, and participation on the joint steering committee (“JSC”), AbbVie agreed to pay IBDCo an upfront, nonrefundable cash payment of \$2.0 million, which IBDCo received in December 2015. AbbVie also agreed to pay IBDCo up to \$16.5 million in development milestone payments, all of which were considered substantive, as well as an option exercise fee upon the execution of their option to buy IBDCo. As of June 30, 2017, the Company has achieved the first development milestone under the Agreement for consideration of \$2.0 million. Contingent consideration from research and development activities

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. Accordingly, the Company recognized \$2.0 million in revenue associated with the first development milestone. The agreement also provides for royalty payments and payments upon the achievement of certain clinical, regulatory and commercial milestones.

The Agreement sets forth the Company's and AbbVie's respective obligations for development and delivery of an IND candidate package using reasonable commercial efforts. The JSC will make a determination as to the continuation of the collaboration at the achievement of the milestones.

At the inception of the Agreement, the Company identified the following deliverables: (i) an exclusive option to purchase IBDCo, (ii) research and development services and ongoing patent defense, and (iii) participation on the JSC. The Company also identified contingent deliverables related to four research and development milestones, delivery of an IND candidate package milestone, and transfer of ownership of IBDCo upon exercise of the option to buy IBDCo. The contingent deliverables have been excluded from the initial allocation and will be treated as a separate unit of accounting when and if delivered.

The Company concluded that none of the three deliverables identified at the inception of the Agreement has stand-alone value from the other undelivered elements. Accordingly, these deliverables represent a single unit of accounting.

As of June 30, 2017, the only consideration that is fixed and determinable is the nonrefundable upfront payment of \$2.0 million. The consideration relates to the three identified deliverables that comprise the single unit of accounting, which will be recognized over the period of performance. The period of performance will be through the option period, which is closely tied to the completion of the research and development collaboration with AbbVie, and has been estimated to be 54 months. The Company will periodically review and, if necessary, revise the estimated period of performance.

During the three and six months ended June 30, 2017, the Company recognized approximately \$2.1 million and approximately \$2.2 million, respectively, in revenue associated with the Agreement. During the three and six months ended June 30, 2016, the Company recognized approximately \$0.1 million and approximately \$0.2 million, respectively, in revenue associated with the Agreement. As of June 30, 2017, there was approximately \$1.3 million of deferred revenue related to the Agreement, which is classified as current or noncurrent in the consolidated balance sheets based on the Company's estimate of revenue that will be recognized within the next twelve months. All costs associated with the collaboration agreement will be recorded in research and development expense in the consolidated statements of operations and comprehensive loss in the period incurred.

(b) License Agreement with the Massachusetts Institute of Technology and Boston University

In April 2017, the Company exercised an option associated with the October 2014 agreement with Boston University and the Massachusetts Institute of Technology to acquire a license for certain intellectual property in exchange for \$50,000, and equity issued in the amount of 325,377 common units, which were converted to 325,377 common shares upon the Company's 2017 Reorganization. The Company recognized license fees of approximately \$1.8 million upon issuance of the common units associated with the equity issued. Additionally, the Company was required to pay approximately \$0.3 million for prior patent costs incurred in connection with the option agreement. The Company recorded these amounts, including the fair value of the common stock issued to the licensors as research and development expense, as the licenses do not have future alternative use, in accordance with ASC Topic 730, *Research and Development*.

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

(10) Income Taxes

The Company is subject to taxation in the U.S. For the three and six months ended June 30, 2017 and 2016, the Company did not record an income tax provision or benefit.

The Company's reserves related to taxes and its accounting for uncertain tax positions are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more-likely-than-not to be realized following resolution of any potential contingencies present related to the tax benefit.

(11) Net Loss per Share/Unit

Basic net loss per share/unit is computed using the weighted-average number of common shares/units outstanding during the period. Diluted net loss per share/unit is computed using the sum of the weighted-average number of common shares/units outstanding during the period and if dilutive, the weighted-average number of potential common shares/units, including unvested restricted common shares/units and outstanding stock options and convertible preferred stock.

The Company computed basic and diluted net loss per share/unit using the two-class method, which gives effect to the impact of outstanding participating securities. As the three and six months ended June 30, 2017 and 2016 resulted in net losses attributable to common shareholders/unit holders, 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/unit because the preferred shareholders/unit holders do not participate in losses of the Company. Accordingly, for periods in which the Company reports a net loss attributable to common shareholders/ unit holders, diluted net loss per share/unit attributable to common shareholders/ unit holders is the same as basic net loss per share/unit attributable to common shareholders/unit holders, since dilutive common shares/units are not assumed to have been issued if their effect is anti-dilutive.

As the 2017 Reorganization resulted in a one for one conversion of Preferred Units for Preferred Shares and common units for common stock, the conversion was not substantive for the purposes of this calculation and the weighted average was calculated as if outstanding equity was outstanding from the beginning of the period presented. The following table sets forth the computation of basic and diluted net loss per share attributable to common shareholders/unit holders (in thousands, except for share/unit and per share/unit amounts):

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Numerator:				
Net loss attributable to common shareholders	\$ (9,388)	\$ —	\$ (16,756)	\$ —
Denominator:				
Weighted-average common shares outstanding - basic and diluted	3,610,356	—	3,293,033	—
Net loss per share attributable to common shareholders - basic and diluted	\$ (2.60)	\$ —	\$ (5.09)	\$ —
Numerator:				
Net loss attributable to common unit holders	\$ —	\$ (4,972)	\$ —	\$ (8,799)
Denominator:				
Weighted-average common units outstanding - basic and diluted	—	2,834,897	—	2,791,370
Net loss per unit attributable to common unit holders - basic and diluted	\$ —	\$ (1.75)	\$ —	\$ (3.15)

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

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

	<u>As of June 30,</u>	<u>As of June 30,</u>
	<u>2017</u>	<u>2016</u>
Unvested restricted common unit awards	—	655,494
Unvested restricted common stock awards	980,473	—
Outstanding options to purchase common stock	1,173,082	—
Contingently redeemable preferred shares	1,413,039	—
Convertible preferred shares	17,726,464	—

(12) 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.

SYNOLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

(13) Related-Party Transactions

During the three months ended June 30, 2017, the Company received repayment of the loan to its chief executive officer of approximately \$0.2 million. The loan was repaid in June 2017, including interest which accrued at a rate of 0.6%.

The Company contracted services from one of its principal investors for the Company's former chief medical officer who was employed by the principal investor, as well as employed to support separate portfolio companies of the investor. The Company made no payments during the three and six months ended June 30, 2017 and paid approximately \$0.1 million related to reimbursement for a portion of the salary of the former chief medical officer for both the three and six months ended June 30, 2016.

The Company contracted the services of The Orphan Group whom specializes in supporting biotechnology companies in developing therapeutics toward diseases of high unmet medical needs in rare disorders. The Orphan Group is owned by the Company's former chief operating officer. The Company made no payments to the Orphan Group during the three and six months ended June 30, 2017 and paid approximately \$4,000 and \$13,000 for contracted services during the three and six months ended June 30, 2016, respectively.

(14) Subsequent Events

(a) Merger Consummation

On August 28, 2017, Synlogic, Inc., formerly known as Mirna Therapeutics, Inc. completed its business combination with Synlogic, Inc. in accordance with the terms of 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 Synlogic (the "Merger Agreement"), pursuant to which Merger Sub merged with and into Synlogic, with Synlogic surviving as a wholly owned subsidiary of Mirna (the "Merger"). On August 25, 2017, in connection with, and prior to the completion of, the Merger, Mirna effected a 1:7 reverse stock split of its common stock (the "Reverse Stock Split"), and on August 28, 2017, immediately after completion of the Merger, Mirna changed its name to "Synlogic, Inc." (NASDAQ: SYBX).

Under the terms of the Merger Agreement, Mirna issued shares of its common stock to Synlogic's stockholders, at an exchange ratio of 0.5532 shares of Mirna's common stock, after taking into account the Reverse Stock Split, for each share of Synlogic common stock and preferred stock outstanding immediately prior to the Merger. The exchange ratio was determined through arms'-length negotiations between Mirna and Synlogic. Mirna assumed all of the stock options outstanding under the Synlogic 2017 Stock Incentive Plan (the "Synlogic Plan"), with such stock options henceforth representing the right to purchase a number of shares of Mirna's common stock equal to 0.5532 multiplied by the number of shares of Synlogic common stock previously represented by such options. Mirna also assumed the Synlogic Plan.

Immediately after the Merger, there were 16,282,496 shares of Mirna's common stock outstanding. Immediately after the Merger, the former stockholders and optionholders of Synlogic owned, or held rights to acquire, approximately 82.4% of the fully-diluted common stock of Mirna, which for these purposes is defined as the outstanding common stock of Mirna, plus "in the money" options, assuming that all "in the money" options of Mirna outstanding immediately prior to the Merger are exercised on a cashless basis immediately prior to the closing of the Merger (the "Fully-Diluted Common Stock of Mirna"), with Mirna's stockholders and optionholders immediately prior to the Merger owning approximately 17.6% of the Fully-Diluted Common Stock of Mirna. Approximately 70% of Mirna's common stock outstanding immediately after the Merger is held by stockholders party to lock-up agreements, pursuant to which such stockholders have agreed, except in limited circumstances, not to sell or transfer, or engage in swap or similar transactions with respect to, shares of the Mirna's common stock, including, as applicable, shares received in the Merger and issuable upon exercise of certain warrants and options, for a period of 180 days following the completion of the Merger.

SYNLOGIC, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements (continued)

(b) Leases

In July 2017, the Company entered into an agreement to lease approximately 41,346 square feet of laboratory and office space in Cambridge, Massachusetts. Annual rent is approximately \$3.1 million. The ten-year lease is estimated to commence in January 2018 and contains provisions for a free-rent period, annual rent increases and an allowance for tenant improvements. Additionally, the Company has committed to a tenant improvement investment. In conjunction with the lease, the Company is required to establish a letter of credit of approximately \$1.0 million.

In July 2017, the Company entered into an agreement to terminate its existing lease of laboratory and office space in Cambridge, Massachusetts at a date that is 30 days after the commencement of its new lease. No penalties are associated with the termination of the lease.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

On August 28, 2017, Mirna Therapeutics, Inc., a Delaware corporation now known as Synlogic, Inc. (the “Company”) completed its merger with privately-held Synlogic, Inc. (“Private Synlogic”) in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated May 15, 2017, whereby one of the Company’s wholly owned subsidiaries merged with and into Private Synlogic, with Private Synlogic surviving as the Company’s wholly owned subsidiary (the “Merger”). In connection with the Merger, the Company changed its name from Mirna Therapeutics, Inc. to Synlogic, Inc. All references to the “Company” refer to Synlogic, Inc. as of and following the closing of the Merger on August 28, 2017 (the “Closing Date”) and all references to “Mirna” refer to Mirna Therapeutics, Inc. prior to the closing of the Merger on the Closing Date.

Upon the closing of the Merger, each outstanding share of Private Synlogic’s common stock converted into the right to receive approximately 0.5532 shares of common stock of Mirna. Immediately after the Merger, there were 16,282,496 shares of the Company’s common stock outstanding. Immediately after the Merger, the former stockholders and optionholders of Private Synlogic owned, or held rights to acquire, approximately 82.4% of the fully-diluted common stock of the Company, which for these purposes is defined as the outstanding common stock of the Company, plus “in the money” options, assuming that all “in the money” options of the Company outstanding immediately prior to the Merger were exercised on a cashless basis immediately prior to the closing of the Merger (the “Fully-Diluted Common Stock of the Company”), with Mirna’s stockholders and optionholders immediately prior to the Merger owning approximately 17.6% of the Fully-Diluted Common Stock of the Company.

The following unaudited pro forma condensed combined financial statements give effect to the Merger and were prepared in accordance with the regulations of the Securities and Exchange Commission (“SEC”). The unaudited pro forma condensed combined financial statements were prepared using the acquisition method of accounting under U.S. GAAP. For accounting purposes, Private Synlogic is considered to be acquiring Mirna in the Merger. Private Synlogic was determined to be the accounting acquirer based upon the terms of the Merger Agreement and other factors including: (i) Private Synlogic stockholders owned approximately 82.4% of the combined organization immediately following the Closing of the Merger, (ii) Private Synlogic directors held a majority of board seats in the combined organization and (iii) Private Synlogic management held all key positions in the management of the combined organization. For the purpose of these unaudited pro forma condensed combined financial statements, management of Mirna and Private Synlogic have determined a preliminary purchase price, calculated as described in Note 2 to these unaudited pro forma condensed combined financial statements. The net tangible assets acquired and liabilities assumed in connection with the transaction are recorded at their estimated acquisition date fair values. A final determination of these estimated fair values will be based on the actual net tangible assets of Mirna that exist as of the date of completion of the transaction.

The unaudited pro forma condensed combined balance sheet as of June 30, 2017 assumes that the Merger took place on June 30, 2017 and combines the historical balance sheets of Mirna and Private Synlogic as of June 30, 2017. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2017 and for the year ended December 31, 2016 assume that the Merger took place as of January 1, 2016, and combines the historical results of Mirna and Private Synlogic for the six months ended June 30, 2017 and for the year ended December 31, 2016, respectively. The historical financial statements of Mirna and Private Synlogic, have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results.

The unaudited pro forma condensed combined financial statements are based on the assumptions and adjustments that are described in the accompanying notes. The unaudited pro forma condensed combined financial statements and pro forma adjustments have been prepared based on preliminary estimates of the fair value of assets acquired and liabilities assumed. Differences between these preliminary estimates and the final fair value of assets and liabilities acquired may occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial statements and the combined organization’s future results of operations and financial position. The actual amounts recorded as of the completion of the Merger may differ materially from the information presented in these unaudited pro forma combined financial statements as a result of estimates related to working capital that were made in determining Mirna’s assets and liabilities at the closing of the Merger.

The unaudited pro forma condensed combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the acquisition. The unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Mirna and Private Synlogic been a combined organization during the specified period. The unaudited pro forma condensed combined financial statements, including the notes thereto, should be read in conjunction with the Mirna and Private Synlogic historical audited financial statements for the year ended December 31, 2016 and the unaudited condensed financial statements for the six months ended June 30, 2017 included elsewhere in this Form 8-K or previously filed with the SEC.

Unaudited Pro Forma Condensed Combined Balance Sheet
as of June 30, 2017
(in thousands)

	<u>Mirna</u>	<u>Private Synlogic</u>	<u>Pro Forma Merger Adjustments</u>		<u>Combined Organization</u>
Assets					
Current assets:					
Cash and cash equivalents	\$ 15,219	\$ 66,826	\$ —		\$ 82,045
Short-term marketable securities	32,502	—	—		32,502
Accounts receivable	—	2,000	—		2,000
Prepaid expenses and other current assets	387	2,443	(1,085)	A	1,745
Total current assets	<u>48,108</u>	<u>71,269</u>	<u>(1,085)</u>		<u>118,292</u>
Property and equipment, net	13	3,555	—		3,568
Restricted cash	—	50	—		50
Other assets	—	233	—		233
Total assets	<u>\$ 48,121</u>	<u>\$ 75,107</u>	<u>\$ (1,085)</u>		<u>\$ 122,143</u>
Liabilities, Contingently Redeemable Preferred Shares and Equity					
Current liabilities:					
Accounts payable	\$ 47	\$ 1,865	\$ —		\$ 1,912
Accrued expenses	1,375	4,074	4,118	B	10,690
	—	—	1,123	C	
Deferred revenue	—	444	—		444
Deferred rent	—	269	—		269
Capital lease obligations	—	185	—		185
Total current liabilities	<u>1,422</u>	<u>6,837</u>	<u>5,241</u>		<u>13,500</u>
Long-term liabilities:					
Deferred revenue, net of current portion	—	890	—		890
Deferred rent, net of current portion	—	920	—		920
Capital lease obligations, net of current portion	—	82	—		82
Total liabilities	<u>1,422</u>	<u>8,729</u>	<u>5,241</u>		<u>15,392</u>
Commitments and contingencies					
Contingently Redeemable Series A Preferred Stock	—	5,000	(5,000)	D	—
Stockholders' equity (deficit)					
Series A Preferred Stock	—	25,548	(25,548)	D	—
Series B Preferred Stock	—	40,260	(40,260)	D	—
Series C Preferred Stock	—	40,434	(40,434)	D	—
Common Stock	21	—	19	D	40
Additional paid in capital	163,847	3,163	111,223	D	154,755
	—	—	(117,152)	E	—
	—	—	(7,057)	E	—
	—	—	2,939	F	—
	—	—	(1,123)	C	—
	—	—	(1,085)	A	—
Accumulated deficit	(117,152)	(48,027)	117,152	E	(48,027)
	—	—	7,057	E	—
	—	—	(4,118)	B	—
	—	—	(2,939)	F	—
Accumulated other comprehensive loss	(17)	—	—		(17)
Total stockholders' equity	<u>46,699</u>	<u>61,378</u>	<u>(1,326)</u>		<u>106,751</u>
Total liabilities, contingently redeemable preferred shares and stockholders' equity	<u>\$ 48,121</u>	<u>\$ 75,107</u>	<u>\$ (1,085)</u>		<u>\$ 122,143</u>

Unaudited Pro Forma Condensed Combined Statements of Operations
(in thousands, except per share amounts)

	For the Year Ended December 31, 2016			
	<u>Mirna</u>	<u>Private Synlogic</u>	<u>Pro Forma Merger Adjustments</u>	<u>Combined Organization</u>
Revenue	\$ —	\$ 444	\$ —	\$ 444
Operating expenses:				
Research and development	13,930	15,010	(1,466) G	27,474
General and administrative	8,118	6,398	(50) A	15,932
			1,466 G	
Restructuring expense	4,442	—	—	4,442
Loss on disposal of assets	128	—	—	128
Total operating expenses	<u>26,618</u>	<u>21,408</u>	<u>(50)</u>	<u>47,976</u>
Loss from operations	(26,618)	(20,964)	50	(47,532)
Interest income (expense), net	350	10	—	360
Net loss	<u>\$ (26,268)</u>	<u>\$ (20,954)</u>	<u>\$ 50</u>	<u>\$ (47,172)</u>
Other comprehensive loss:				
Unrealized gain/(loss) on available for sale securities, net of tax	(4)	—	—	(4)
Total other comprehensive loss	<u>\$ (26,272)</u>	<u>\$ (20,954)</u>	<u>\$ 50</u>	<u>\$ (47,176)</u>
Net loss per share, basic and diluted	<u>\$ (8.83)</u>	<u>\$ (7.36)</u>	<u>\$ 0.01</u>	<u>\$ (3.58)</u>
Weighted-average common shares	2,976,280	2,848,081	7,342,953 H	13,167,314

Unaudited Pro Forma Condensed Combined Statements of Operations
(in thousands, except per share amounts)

	For the Six Months Ended June 30, 2017			
	<u>Mirna</u>	<u>Private Synlogic</u>	<u>Pro Forma Merger Adjustments</u>	<u>Combined Organization</u>
Revenue	\$ —	\$ 2,222	\$ —	\$ 2,222
Operating expenses:				
Research and development	5,321	13,650	—	18,971
General and administrative	6,496	5,403	(3,181) A	8,718
Restructuring expense	2,723	—	—	2,723
Total operating expenses	<u>14,540</u>	<u>19,053</u>	<u>(3,181)</u>	<u>30,412</u>
Loss from operations	(14,540)	(16,831)	3,181	(28,190)
Interest income (expense), net	182	75	—	257
Net loss	<u>\$ (14,358)</u>	<u>\$ (16,756)</u>	<u>\$ 3,181</u>	<u>\$ (27,933)</u>
Other comprehensive loss:				
Unrealized gain/(loss) on available for sale securities, net of tax	(13)	—	—	(13)
Total other comprehensive loss	<u>\$ (14,371)</u>	<u>\$ (16,756)</u>	<u>\$ 3,181</u>	<u>\$ (27,946)</u>
Net loss per share, basic and diluted	<u>\$ (4.82)</u>	<u>\$ (5.09)</u>	<u>\$ 0.35</u>	<u>\$ (1.82)</u>
Weighted-average common shares	2,979,090	3,293,033	9,115,696 H	15,387,818

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of Transactions and Basis of Presentation

Description of Transactions

On May 15, 2017, Mirna entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) with Synlogic, with Synlogic becoming a wholly owned subsidiary of Mirna and the surviving corporation following completion of the merger (the “Merger”) in accordance with the Merger Agreement.

Immediately after the Merger, Synlogic owned approximately 82.4% of the fully-diluted common stock of the combined organization, with Mirna security holders owning approximately 17.6% of the fully-diluted common stock of the combined organization.

Basis of Presentation

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the Securities and Exchange Commission (“SEC”). The unaudited pro forma condensed combined balance sheet as of June 30, 2017 is presented as if the Merger had been completed on June 30, 2017. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2017 and for the year ended December 31, 2016 assume that the Merger took place on January 1, 2016, and combines the historical results of Mirna and Synlogic for the six months ended June 30, 2017, and for the year ended December 31, 2016, respectively. For accounting purposes, Synlogic is considered to be acquiring Mirna in the Merger. Synlogic was determined to be the accounting acquirer based upon the terms of the Merger Agreement and other factors including: (i) Synlogic Stockholders owned approximately 82.4% of the combined organization immediately following the Closing of the Merger, (ii) Synlogic directors held a majority of the board seats in the combined organization and (iii) Synlogic management held all key positions in the management of the combined organization. Accordingly, the assets and liabilities of Synlogic will be recorded as of the Merger closing date at their respective carrying value and the acquired net assets of Mirna will be recorded as of the Merger closing date at their fair value. For the purpose of these unaudited pro forma financial statements, management of Synlogic and Mirna have determined a preliminary estimated purchase price for the asset acquisition, and such amount has been calculated as described in Note 2 to these unaudited pro forma condensed combined financial statements. The net assets acquired in connection with the transaction are based on preliminary estimated fair values. A final determination of the fair values will be based on the actual net acquired assets of Mirna as of the Merger closing date.

During May 2017, in contemplation of the merger transaction, Synlogic undertook a legal reorganization into a corporation. In connection with that transaction, all preferred stock and common units were converted 1:1 into preferred and common stock. As such, application of the anticipated Exchange Ratio and the impacts on the related pro forma adjustments to earnings per share contemplate the conversion of Synlogic’s preferred and common units into preferred and common stock immediately prior to the conversion to Mirna Common Stock.

2. Preliminary Purchase Price

The estimated purchase price of approximately \$42.6 million was determined using the estimated fair value of Mirna’s net assets on the date of acquisition. Mirna’s net assets are predominantly comprised of cash, cash equivalents and short-term investments offset by current liabilities.

The preliminary estimated acquired net assets of Mirna based on their estimated fair values are as follows (in thousands):

	Purchase Consideration
Cash and cash equivalents	\$ 19,653
Marketable securities	22,850
Interest receivable	108
Prepaid assets	80
Accounts payable and accrued expenses	(101)
Total Purchase consideration	<u>\$ 42,590</u>

The purchase price allocation will remain preliminary until Synlogic has completed the determination of the fair values of assets acquired and liabilities assumed as of the Merger closing date. The final amounts allocated to assets acquired and liabilities assumed could differ significantly from the amounts presented in the unaudited pro forma condensed combined financial statements as a result of estimates related to working capital that were included in the determination of Mirna's assets and liabilities at the closing of the Merger.

3. Pro Forma Adjustments

The unaudited pro forma condensed combined financial statements include pro forma adjustments to give effect to the acquisition of Mirna's net assets by Synlogic. The pro forma adjustments reflecting the completion of the Merger are based upon the assumptions set forth below.

- A. To reflect elimination of transaction costs, such as severance and benefits, advisor fees, and transactional fees, of both Mirna and Synlogic.
- B. To record Mirna's estimated transaction costs, such as severance and benefits, advisory fees and transactional fees that were not incurred as of June 30, 2017.
- C. To record Synlogic's estimated transaction costs, such as advisory fees and transactional fees that were not incurred as of June 30, 2017.
- D. To reflect the conversion of all convertible preferred stock to Mirna Common Stock.
- E. To reflect the elimination of Mirna's historical accumulated deficit, including the impact of the pro forma adjustments to Mirna's current liabilities.
- F. To record stock compensation expense for the acceleration of certain executive and employee stock options outstanding at June 30, 2017, which fully vest upon completion of the Merger in accordance with the terms of the employment contracts for which there is no future service requirement.
- G. To reflect the alignment of the accounting for certain expenses related to intellectual property.
- H. To reflect the conversion of Synlogic Common Stock to Mirna Common Stock.