

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): **May 9, 2019**

SYNLOGIC, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37566
(Commission
File Number)

26-1824804
(IRS Employer
Identification No.)

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

02142
(Zip Code)

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

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instruction A.2. below):

- 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SYBX	The Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Condition

On May 9, 2019, Synlogic, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the supplemental materials that will be used during the Company's conference call to discuss the financial results for the quarter ended March 31, 2019 is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 and Exhibit 99.2) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

[99.1](#) [Press Release dated May 9, 2019](#)

[99.2](#) [Supplemental materials dated May 9, 2019](#)

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.

Date: May 9, 2019

By: /s/ Todd Shegog
Name: Todd Shegog
Title: Chief Financial Officer

Synlogic Reports First Quarter 2019 Financial Results and Provides Business Update

– Company will host a conference call and webcast at 5:00 pm ET today –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 9, 2019--Synlogic, Inc. (Nasdaq: SYBX), a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, today reported its financial results for the first quarter ended March 31, 2019.

“We made significant progress on our 2019 goals in the first quarter of the year providing a strong foundation for the continued development of our Synthetic Biotic™ platform and clinical pipeline,” said Aoife Brennan, M.B., Ch.B. Synlogic’s president and chief executive officer. “We strengthened our scientific leadership with the appointment of two experienced drug developers, Dr. Scott Plevy, as Chief Scientific Officer, and Dr. Patricia Hurter, who joined our board of directors and brings additional relevant experience in manufacturing. In addition, we have manufactured clinical trial material in-house for our IO program and made significant advances in developing processes to reliably and reproducibly manufacture solid formulations of our orally administered Synthetic Biotic medicines. The new formulation has a more patient-friendly stability profile and provides a path to longer out-patient studies and eventual commercialization.”

Recent Highlights**Corporate**

- **Appointment of Scott Plevy, M.D., as Synlogic’s Chief Scientific Officer.** Dr. Plevy has responsibility for Synlogic’s research organization. He most recently served as Vice President, Gastroenterology Disease Area Leader and IL-23 Pathway Leader at Janssen Research & Development, LLC, after a successful career in academia. He has served as the lead investigator on multiple early-phase clinical trials, published on a breadth of topics from disease-specific targets to basic immunology and molecular biology, and performed translational research to advance the understanding of novel immunologic interventions in inflammatory bowel disease, other inflammatory conditions, and microbiome-related diseases.
 - **Appointment of Patricia N. Hurter, Ph.D., to Synlogic’s board of directors.** Dr. Hurter served as Senior Vice President at Vertex from 2011 to 2019, during which time her responsibilities grew to include all CMC and preclinical development activities of Vertex’s R&D portfolio, as well as the internal GMP manufacturing facility that provides drug substance and product for clinical development and commercial supply. Dr. Hurter also served as Interim Head of Global Regulatory Affairs at Vertex and played a leadership role in the development and commercialization of four transformative therapies for Vertex. Prior to joining Vertex, Dr. Hurter was Director, Formulation Design and Characterization for Merck.
-

Pipeline

- **Presentation of data at the Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT) demonstrating the development of a robust and reproducible process to generate a solid oral formulation of Synlogic's Synthetic Biotic medicine for future studies and potential commercial use.** The ASGCT presentation focused on preparation and characteristics of a solid oral preparation of SYNBI618, Synlogic's Synthetic Biotic medicine for the treatment of phenylketonuria (PKU). The data demonstrate that Synlogic has developed a robust and reproducible process to generate a solid formulation of SYNBI618 with minimal impact on cell viability and phenylalanine consuming activity compared to a liquid formulation that is currently being evaluated in an ongoing Phase 1 /2a clinical study in patients with PKU. Synlogic expects to have data from the Phase 1 /2a study in patients in the third quarter of 2019.
- **Publication in Science Translational Medicine of first in human clinical data and supporting preclinical data from investigational Synthetic Biotic candidate, SYNBI020.** The data support the continued development of SYNBI020 which is currently being evaluated in a Phase 1b/2a clinical trial in patients with cirrhosis and elevated blood ammonia with data expected in the third quarter of 2019.
- **In-house manufacturing of clinical trial material for Synlogic's first immuno-oncology program, SYNBI891, a dual innate immune activator.** Synlogic expects to file an investigational new drug (IND) application for SYNBI891 in the second half of 2019.
- **Advancement of investigational Synthetic Biotic medicines to lead optimization stage in AbbVie collaboration.** Synlogic and AbbVie are developing an oral treatment for inflammatory bowel disease (IBD).

First Quarter 2019 Financial Results

For the three months ended March 31, 2019, Synlogic reported a consolidated net loss of \$12.9 million, or \$0.51 per share, compared to a consolidated net loss of \$11.2 million, or \$0.55 per share, for the corresponding period in 2018. The increase in net loss was primarily due to increases in compensation-related expenses due to increased headcount, as well as increases in research and development expenses to support Synlogic's advancing clinical programs.

Research and development expenses were \$10.4 million for the three months ended March 31, 2019 compared to \$8.4 million for the corresponding period in 2018. The increase was primarily due to an increase in compensation-related expenses associated with increased headcount and increased expenses associated with manufacturing and pre-clinical and clinical studies of Synlogic's Synthetic Biotic programs.

General and administrative expenses for the three months ended March 31, 2019 were \$3.7 million compared to \$3.6 million for the corresponding period in 2018.

Revenue was \$0.3 million for the three months ended March 31, 2019 compared to \$0.4 million for the same period in 2018. Revenue for both periods is associated with services performed under Synlogic's collaboration with AbbVie to develop a Synthetic Biotic medicine for the treatment of IBD.

As of March 31, 2019, Synlogic had cash, cash equivalents, and short-term investments of \$109.8 million.

Conference Call & Webcast Information

Synlogic will host a conference call and live webcast today at 5:00 pm ET today, Thursday, May 9, 2019. To access the live webcast, please visit the “Event Calendar” page within the Investors and Media section of the Synlogic website. Alternatively, investors may listen to the call by dialing +1 (844) 815-2882 from locations in the United States or +1 (213) 660-0926 from outside the United States. The conference ID number is 2154739. For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors and Media section of the Synlogic website.

About Synlogic

Synlogic is pioneering the development of a novel class of living medicines, Synthetic Biotic medicines, based on its proprietary drug development platform. Synlogic leverages the tools and principles of synthetic biology to genetically engineer probiotic microbes to perform or deliver critical functions missing or damaged due to disease. The company’s two lead programs, SYNBI020 and SYNBI1618, target hyperammonemia as a result of liver damage or genetic disease, and PKU, respectively. When delivered orally, Synthetic Biotic medicines can act from the gut to compensate for the dysfunctional metabolic pathway and have a systemic effect, with the potential to significantly improve symptoms of disease for affected patients. In addition, the company is leveraging the broad potential of its platform to create Synthetic Biotic medicines for the treatment of more common diseases, including liver disease, inflammatory and immune disorders, and cancer. Synlogic is collaborating with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease (IBD). For more information, please visit www.synlogictx.com.

Forward-Looking Statements

This press release contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this press release, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” and similar expressions and their variants, as they relate to Synlogic may identify forward-looking statements. Examples of forward-looking statements, include, but are not limited to, statements regarding the potential of Synlogic’s platform to develop therapeutics to address a wide range of diseases including: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; the potential of Synlogic’s technology to treat hyperammonemia and phenylketonuria; and the expected timing of Synlogic’s anticipated clinical trial initiations. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including: the uncertainties inherent in the preclinical development process; the ability of Synlogic to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading “Risk Factors” in Synlogic’s filings with the SEC. The forward-looking statements contained in this press release reflect Synlogic’s current views with respect to future events. Synlogic anticipates that subsequent events and developments will cause its views to change. However, while Synlogic may elect to update these forward-looking statements in the future, Synlogic specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Synlogic’s view as of any date subsequent to the date hereof.

Synlogic, Inc.
Condensed Consolidated Statements of Operations
(unaudited)

(in thousands except share and per share data)

	For the three months ended	
	March 31, 2019	March 31, 2018
Revenue	\$ 338	\$ 354
Operating expenses		
Research and development	10,384	8,361
General and administrative	3,651	3,629
Total operating expenses	14,035	11,990
Loss from operations	(13,697)	(11,636)
Other income(expense), net	751	471
Net loss	\$ (12,946)	\$ (11,165)
Net loss per share attributable to common shareholders - basic and diluted	\$ (0.51)	\$ (0.55)
Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted	25,293,791	20,145,881

Synlogic, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands)

Assets

Cash, cash equivalents and short-term investments
Fixed assets
Other assets
Total assets

	March 31, 2019		December 31, 2018
\$	109,835	\$	122,729
	14,348		14,841
	19,836		2,770
\$	144,019	\$	140,340

Liabilities and Stockholders' Equity

Current liabilities
Long-term liabilities
Total liabilities
Total stockholders' equity
Total liabilities and stockholders' equity

\$	9,721	\$	8,341
	22,089		7,901
	31,810		16,242
	112,209		124,098
\$	144,019	\$	140,340

CONTACT:

MEDIA:

Synlogic

Courtney Heath
Phone: 617-872-2462
Email: courtney@scientpr.com

INVESTORS:

Synlogic

Elizabeth Wolffe, Ph.D.
Phone: 617-207-5509
Email: liz@synlogictx.com

Synlogic

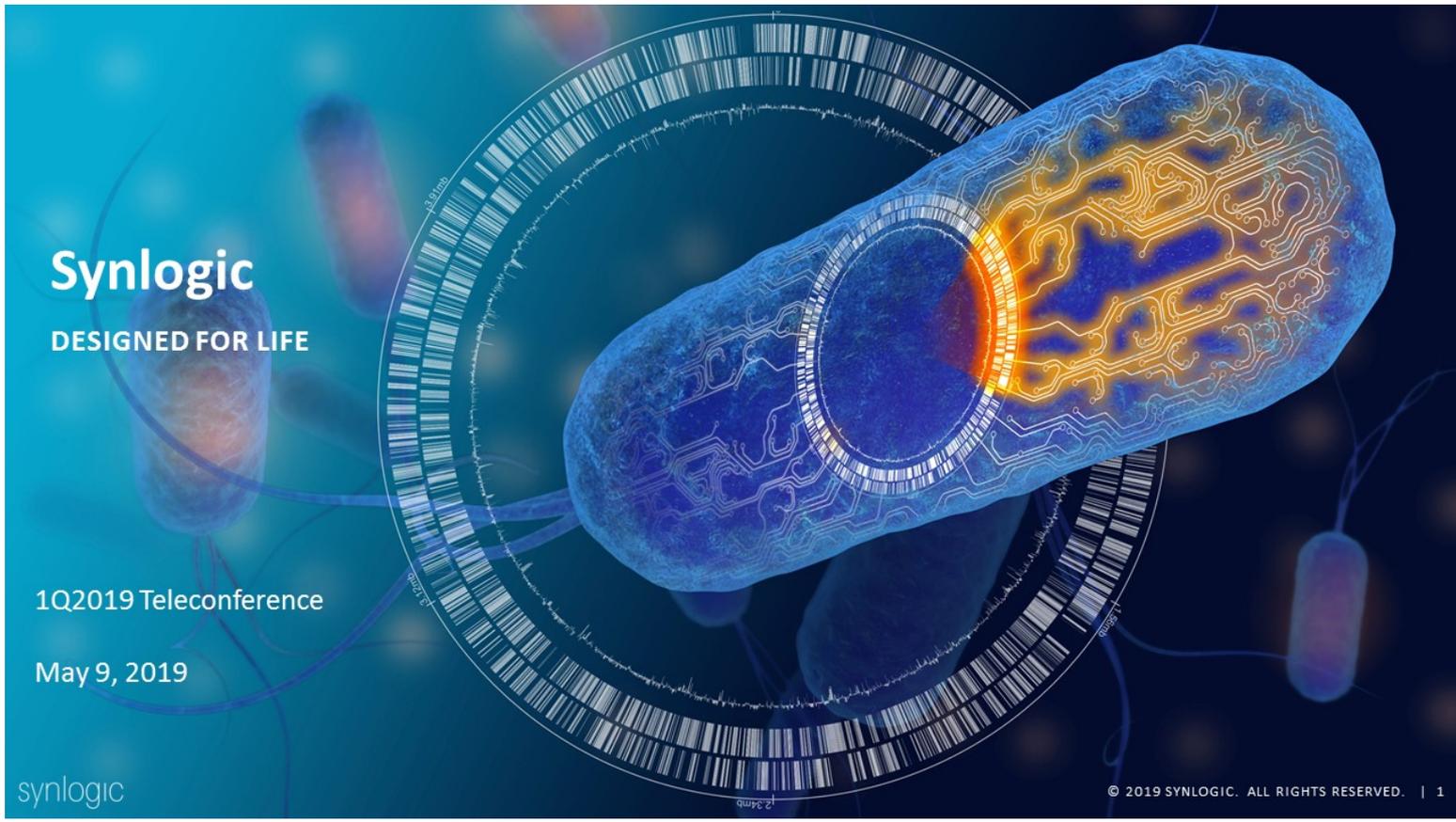
DESIGNED FOR LIFE

1Q2019 Teleconference

May 9, 2019

synlogic

© 2019 SYNLOGIC. ALL RIGHTS RESERVED. | 1



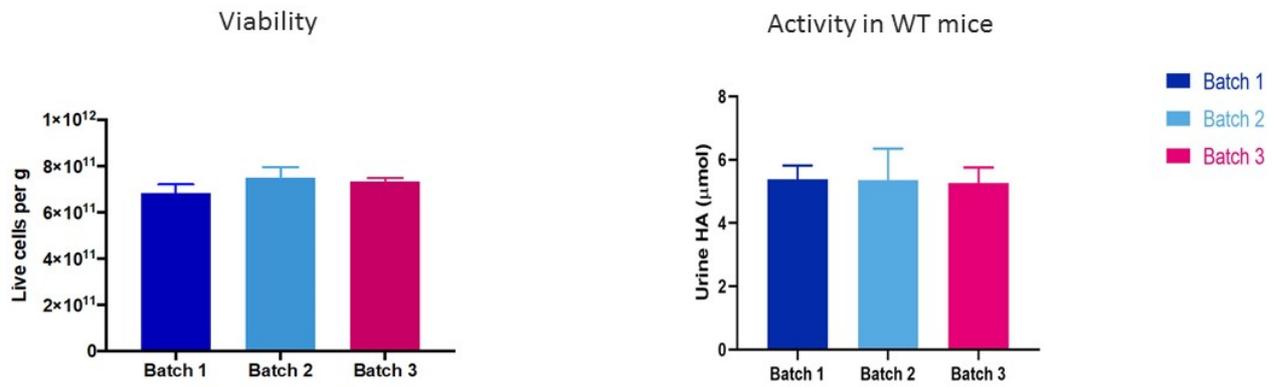
Forward Looking Statements

This presentation contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this presentation regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this presentation, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” and similar expressions and their variants may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, the approach we are taking to discover and develop novel therapeutics using synthetic biology; statements regarding the potential of our platform to develop therapeutics to address a wide range of diseases, including: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; the future clinical development of Synthetic Biotic medicines; the potential of our technology to treat hyperammonemia and phenylketonuria; the expected timing of our anticipated clinical trial initiations; the benefit of orphan drug and fast track status; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials; the results of our collaborations; and the difficulty in predicting the time and cost of development of our product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the uncertainties inherent in the preclinical development process; our ability to protect our intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading “Risk Factors” in our filings with the SEC. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in our most recent Quarterly Report on Form 10-Q filed with the SEC on May 9, 2019. The forward-looking statements contained in this presentation reflect our current views with respect to future events. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our view as of any date subsequent to the date hereof.

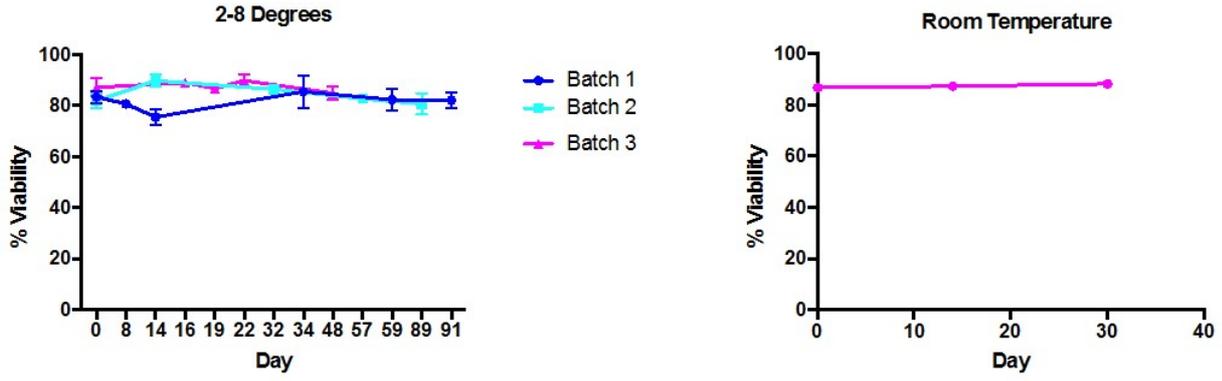
Demonstrated Progress in Development of Lyophilized SYN1618

- Improved fermentation process enables production of a solid formulation of SYN1618 with minimal impact on cell viability or activity
- Lyophilized SYN1618 is similarly active to frozen liquid in terms of consumption of Phe or production of TCA/HA *in vitro* and *in vivo*
- New solid process material is expected to have improved quality attributes including less free protein and reduced viscosity
- Process is robust and reproducible at 30 L production scale
- Lyophilized SYN1618 is stable for >90 days at 2-8 °C and >30 days at room temperature
- Suite build-out complete and ready to manufacture cGMP lyophilized SYN1618

Batch to Batch Consistency of SYN1618 Solid Formulation



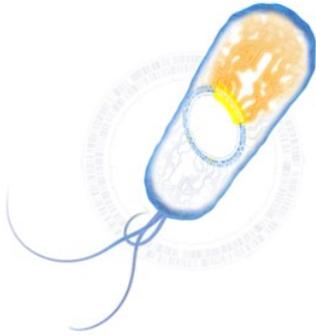
Stability of SYN1618 Solid Formulation



2019 Progress and Milestones

SYNB1618 in PKU

- Complete ongoing study in patients
- Data expected 3Q2019 (safety, tolerability and biomarkers)

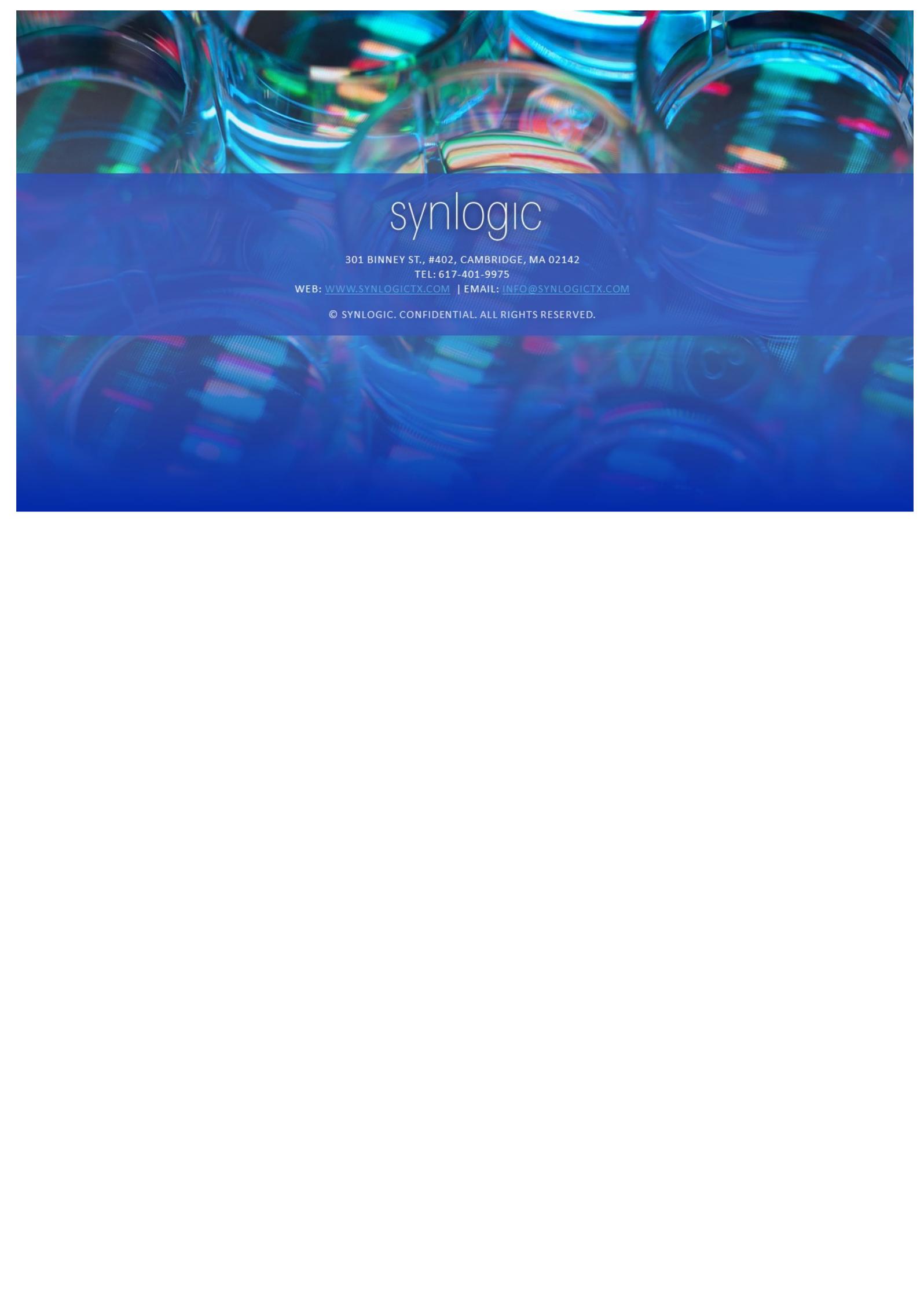


SYNB1020 in Hyperammonemia

- ✓ Preclin. and HV clin. data published in *Sci. Transl. Med.*
- Complete ongoing study in patients with cirrhosis
- Data expected 3Q2019 (safety, tolerability and ammonia-lowering)
- With ammonia-lowering data define development plan

SYNB1891 in Immuno-Oncology

- IND submission 2H2019
- ✓ Advance **AbbVie collaboration**
- Advance **preclinical pipeline**



synlogic

301 BINNEY ST., #402, CAMBRIDGE, MA 02142
TEL: 617-401-9975

WEB: WWW.SYNLOGICTX.COM | EMAIL: INFO@SYNLOGICTX.COM

© SYNLOGIC. CONFIDENTIAL. ALL RIGHTS RESERVED.