

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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): December 7, 2018

SYNOLOGIC, 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 BinneySt., Suite 402
Cambridge, MA
(Address of principal executive offices)

02142
(Zip Code)

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

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.

Item 1.01 Entry into a Material Definitive Agreement.

On December 7, 2018, Synlogic Operating Company, Inc., a wholly-owned subsidiary of Synlogic, Inc. (the “Company”), entered into a Statement of Work (the “SOW”) with Azzur Group (d/b/a Azzur of New England LLC) (“Azzur”) pursuant to a Master Contract Services Agreement (the “Master Services Agreement”), dated September 8, 2018, between the Company and Azzur. In accordance with the Master Services Agreement, upon execution of the SOW, the SOW automatically became a part of the Master Services Agreement.

Pursuant to the SOW, Azzur has agreed to provide the Company with access to, and the use of, an approximately 700 square foot cleanroom space to be constructed in Waltham, Massachusetts (the “Azzur Suite”), for a period of 44 months, from May 1, 2019 to December 31, 2022 (the “Term”). Azzur has also agreed to provide the Company with storage space and personnel support at the Azzur Suite, including project management, sampling, material receipt/release, training and general consulting services, as well as certain other services, including access to process gasses and shipping of materials to and from the Azzur Suite.

The Company has agreed to pay Azzur a fixed price on a monthly basis for access to, and use of, the cleanroom and storage space at the Azzur Suite, and has also agreed to pay Azzur for the personnel support and the other services on a variable cost basis, with the amounts invoiced varying depending on the extent of the Company’s use of such personnel support and other services. Pursuant to the SOW, the total estimated project cost during the Term for access to, and use of, the cleanroom and storage space, and the personnel support and other services, is \$4,785,000.

The Company has an option to extend the Term beyond December 31, 2022 for a minimum period of three additional months. In addition, during the six months following the expiration of the Term, the Company has a right of first refusal to rent the Azzur Suite on substantially the same terms offered by Azzur to a third party during such six-month period.

The Company may terminate the SOW on four months’ prior written notice at any time during the Term. In addition, either party may terminate the Master Services Agreement (including the SOW) due to a breach by the other party and failure to cure. If the Azzur Suite is not ready for use by the Company as of May 1, 2019, the Company may (i) elect to terminate the SOW, (ii) wait for the Azzur Suite to become available, without incurring any costs (other than a deposit) relating to the Azzur Suite until it becomes available, or (iii) accept an alternate cleanroom space from Azzur on different terms.

The foregoing summary of the SOW does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the SOW and the Master Services Agreement of which the SOW is a part. The Company intends to file copies of the SOW and the Master Services Agreement with its Annual Report on Form 10-K for its fiscal year ending December 31, 2018, portions of which will be subject to a FOIA Confidential Treatment Request which will be submitted to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The omitted material will be included in the request for confidential treatment.

Item 8.01. Other Events.

On December 12, 2018, the Company issued a press release announcing the entry into the SOW. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 8.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of 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 United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
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99.1	Press Release, December 12, 2018.
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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: December 12, 2018

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

Synlogic Expands Capabilities in Manufacturing with the Appointment of Head of Technical Operations and Establishment of In-house Production of Clinical Trial Material for its Synthetic Biotic™ Medicines

– Good Manufacturing Process (GMP) infrastructure enables advancement of clinical programs through early and mid-phase studies –

– Capabilities support production of both liquid and solid oral formulations –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--December 12, 2018--Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage drug discovery and development company applying synthetic biology to beneficial microbes to develop novel living medicines, today announced the appointment of Antoine Awad as Head of Technical Operations, and the expansion of its manufacturing capabilities to produce clinical trial material for mid-stage studies of its oral and immuno-oncology programs, through entry into an agreement to lease GMP clean-room space from the Azzur Group, LLC.

“We are delighted to welcome Tony to Synlogic at this critical stage in the Company’s development as we expand our manufacturing capabilities enabling the production of high-quality, clinical trial material in-house,” said Aoife Brennan, M.B., Ch. B., Synlogic’s president and chief executive officer. “His expertise in biologics process sciences and his operational experience in scaling processes from research to commercial production will be invaluable as we enter this new phase of manufacturing development. This new clean-room facility provides an affordable and flexible option that maximizes control over our process and timelines enabling us to move efficiently through clinical development to bring our Synthetic Biotic medicines to patients.”

“Synlogic has an exciting drug-development platform and is applying the rigor of pharmaceutical standards to bacterial therapeutics through analytics and science-based processes,” said Mr. Awad. “ I look forward to bringing my experience in biologics process development, manufacturing and formulation to continue to expedite clinical development of our Synthetic Biotic medicines.”

Mr. Awad, who has been serving as a consultant with Synlogic since October 2018, will join the company full-time in mid-December and will be responsible for upstream and downstream process development and manufacturing of Synlogic’s Synthetic Biotic medicines. Prior to joining Synlogic he served as senior vice president of operations and CMC and head of manufacturing for Abpro Therapeutics, a private company focused on the development of novel bi-specific antibodies for oncology. Earlier, Mr. Awad held positions of increasing responsibility over a ten-year period at Merrimack Pharmaceuticals. As Head of Manufacturing and Process Sciences, he transitioned to Ipsen Bioscience to integrate and lead the commercial site for production of ONYVIDE®, which Ipsen S.A. acquired from Merrimack.

Synlogic has entered into a forty-four-month agreement with the Azzur Group, a MA-based engineering and consulting group specializing in GMP manufacturing solutions. Under the agreement, Synlogic will lease clean-room space in Azzur's Waltham facility that Synlogic staff will use for manufacturing and formulation of GMP material for Synlogic's early clinical studies of its first immuno-oncology program, intratumorally administered SYN1891, and mid-stage studies of solid formulations of its orally administered Synthetic Biotic medicines. In addition to the use of Azzur's facility, as part of the agreement, Azzur will provide personnel and other resources as needed to support activities, including project management, sampling, material receipt/release, inventory control, training and general consulting for the duration of Synlogic's use of the facility.

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 beneficial microbes to perform or deliver critical functions missing or damaged due to disease. Synthetic Biotic medicines are designed to act locally and have a systemic effect to address disease in patients. Synlogic's two lead programs, SYN1020 and SYN1618, are orally administered and target hyperammonemia as a result of liver damage or genetic disease, and phenylketonuria, respectively. Synlogic is also developing SYN1891 as an intratumorally administered Synthetic Biotic medicine for the treatment of cancer. In addition, the company is leveraging the broad potential of its platform to create additional Synthetic Biotic medicines for the treatment of liver disease, as well as inflammatory and immune disorders including Synlogic's collaboration 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: cancer, inborn errors of metabolism, liver disease, and inflammatory and immune disorders; 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 cancer, hyperammonemia, and phenylketonuria. 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.

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