Synthetic Biologics, Inc.
Form 8-K
July 09, 2015

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): July 8, 2015

SYNTHETIC BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	001-12584	13-3808303
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

155 Gibbs Street, Ste. 412

Rockville, MD 20850

(Address of principal executive offices and zip code)

617 Detroit Street, Ste. 100

Ann Arbor, MI 48104

(Mailing Address and zip code)

Registrant's telephone number, including area code: (734) 332-7800

(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:

¨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))

Item 1.01 Entry Into a Material Definitive Agreement

On July 8, 2015 (the "Effective Date"), Putney Drug Corp (the "Licensee"), a subsidiary of Synthetic Biologics, Inc. (the "Company"), and The Regents of the University of California ("The Regents") entered into an amendment (the "License Amendment") to their License Agreement, dated as of July 11, 2005 (as amended previously, the "License Agreement"), and an amendment (the "CTA Amendment") to their Clinical Trial Agreement, dated as of April 29, 2010 (the "CTA"). As so amended, the License Agreement grants Licensee licenses under additional patent rights and other intellectual property of The Regents, including related know-how, not currently licensed to the Licensee, which is related to the use of Estriol (and related compounds) for the treatment, prevention or palliation of any autoimmune disease, condition or indication, including, without limitation, multiple sclerosis (the "Field of Use"). In addition, The Regents agreed in the CTA Amendment to provide to the Licensee and, as directed by the Licensee, to its third party consultants, all data and results (redacted for patient-identifying information) from the prior clinical trial study under the CTA (the "Documentation"). The Licensee agreed to fund the costs of the analysis by a third party contractor of the data it receives and to reimburse The Regents for its costs, including overhead, in preparing the databases and materials for access by Licensee. The Licensee has also agreed to use commercially reasonable efforts to seek and obtain a development and commercialization partner for Estriol in the Field of Use, within twelve months of the Effective Date.

The Licensee was also granted certain rights of first negotiation to expand the Field of Use to other indications and uses. If the Licensee does not find a development partner that is a pharmaceutical company with annual net sales of at least $100,000,000 (a "Development Partner") to develop Licensed Products (as defined in the License Agreement) in at least the U.S or Europe within 12 months of the Effective Date, the Licensee will continue to retain rights to the Licensed Products in the Field of Use, and will have 25 months after the Effective Date to initiate a Phase III clinical trial. If the Licensee licenses its rights in the Licensed Products (as defined in the License Agreement) to a Development Partner within 12 months of the Effective Date then the diligence obligations will be adjusted as follows: (a) within 24 months of the delivery to Licensee of all patient name redacted MRI image and electronic data created under the clinical study on Estriol conducted under the CTA the Development Partner shall complete all clinical trials requested by the U.S. Food and Drug Administration (the "FDA") to be completed prior to initiating Phase III clinical trials; and (b) the Development Partner must initiate a Phase III clinical trial on a Licensed Product within 6 months of completing the trials covered in (a) above. The above time frames are subject to reasonable extensions for delays caused by regulatory issues out of the Development Partners' control. In consideration of the rights received, Licensee agreed to additional one-time milestone payments (for Licensee's achievement of certain milestone events) of (i) $2,000,000 upon dosing the first patient in the first Phase III clinical trial;(ii) $3,000,000 upon filing a New Drug Application (an "NDA") with the FDA for a Licensed product; (iii) $1,500,000 upon approval by the FDA of the NDA; (iv) $1,500,000 upon achievement of $50,000,000 in annual Net Sales (as defined in the License Agreement) for a License Product; and (v) $3,000,000 upon achievement of $100,000,000 in annual Net Sales for a Licensed Product. The Licensee also agreed to pay to The Regents 40% of sublicensing income payments received based on sublicensing, which includes all consideration received from a Sublicensee (as defined in the License Agreement) including milestone payments, sales-based payments, upfront license payments, but subject to certain exceptions; provided, however sublicensing fee payments will not be less than 5% of the Net Sales of the Licensed Products or Licensed Methods (as defined in the License Agreement) by the Sublicensee or other specified entities. The Licensee agreed to pay The Regents an earned royalty equal to 7% of the Net Sales (as defined in the License Agreement) for Licensee's sales of Licensed Products and Licensed Methods. If the Licensee incurs Development Costs (as defined in

the License Amendment) in the aggregate of $14,000,000 following the Effective Date, then thereafter the Sublicense Percentage (as defined in the License Amendment) will be reduced by one percentage point for each $4,000,000 of additional Development Costs incurred, provided, that the Sublicense Percentage may never fall below 25%. The parties also entered into a mutual release.

The information contained in this Item 1.01 regarding the License Amendment and the CTA Amendment is qualified in its entirety by the copy of the License Amendment and CTA Amendment attached to this Current Report on Form 8-K as Exhibits 10.2 and 10.4 and are incorporated herein by reference.

Item 8.01. Other Events

The Company has received data from four of 12 expected participants in the first SYN-004 Phase 2a open-label clinical trial evaluating the gastrointestinal (GI) antibiotic-degrading effects and the safety of SYN-004, which is designed to degrade certain intravenous (IV) beta-lactam antibiotics within the GI tract and maintain the natural balance of the gut microbiome for the prevention of *C. difficile* infection, antibiotic-associated diarrhea (AAD) and secondary antibiotic-resistant infections.

The data from this Phase 2a open-label study are consistent with the Company's expectations and the positive pharmacokinetics (PK) and safety results demonstrated in the SYN-004 Phase 1a and Phase 1b studies previously reported in March 2015; SYN-004 degraded IV ceftriaxone in the chyme of the four healthy participants with functioning ileostomies without affecting the ceftriaxone in the bloodstream. However, this clinical trial remains ongoing and analysis of the data from the first four participants may not be consistent with the final data from the trial.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit is being filed as part of this Report.

Exhibit

Number	**Description**
10.1	Fifth Amendment To the License Agreement
10.2	Sixth Amendment To The License Agreement
10.3	Clinical Trial Agreement
10.4	Amendment to Clinical Trial Agreement

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.

SYNTHETIC BIOLOGICS, INC.

Date: July 9, 2015 By: /s/ Jeffrey Riley
Name: Jeffrey Riley
Title: Chief Executive Officer

EXHIBIT INDEX

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