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): August 7, 2019

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.)

9605 Medical Center Drive, Suite 270
Rockville, MD 20850
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (301) 417-4364

N/A
(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))

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, par value $0.001 per share	SYN	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by checkmark 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 August 7, 2019, Synthetic Biologics, Inc. (the "Company") entered into a clinical trial agreement ("CTA") with Washington University School of Medicine in St. Louis ("Washington University") to conduct a Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic hematopoietic cell transplant (HCT) recipients (the "Study"). Under the terms of the CTA, the Company will serve as the sponsor of the Study and supply SYN-004 (ribaxamase), the Company's first-in-class oral enzyme designed to protect the gut microbiome from disruption caused by commonly used intravenous (IV) beta-lactam antibiotics, as well as compensate Washington University for all research services to be provided in connection with the Study which is estimated to cost approximately $3,200,000. Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University will serve as the principal investigator of the trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

The Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial is designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic HCT recipients. Study participants will be enrolled into three sequential cohorts administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 and four will receive placebo. Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic. The Study will also evaluate potential protective effects of SYN-004 on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 in allogeneic HCT recipients. Enrollment is expected to begin during the first quarter of 2020, contingent upon approval of the clinical study protocol by the Washington University School of Medicine's Institutional Review Board (IRB) and the U.S. Food & Drug Administration (FDA).

The CTA continues in effect until completion of all obligations under the CTA. Either party may terminate the CTA prior to completion of its obligations (i) if authorization of the study is withdrawn by the FDA; (ii) if the emergence of any adverse reaction or side effect with the Study Drug administered in the Study is of such magnitude or incidence in the opinion of either party to support termination; or (iii) upon a breach of the terms of the CTA if the breaching party fails to cure the breach within 30 days after receipt of notice. The Company has the right to terminate the CTA (i) effective immediately if Washington University fails to perform the study in accordance with the terms of the protocol, the CTA or applicable laws or regulations or if Washington University or the principal investigator become debarred or (ii) upon 14 days written notice and Washington University has the right to terminate the CTA upon 14 days notice if the principal investigator becomes unable to perform or complete the Study and the parties have not, prior to the expiration of such fourteen (14) day period, agreed to an alternative principal investigator.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1*	Clinical Trial Agreement between Washington University School of Medicine in St. Louis and Synthetic Biologics, Inc. dated August 7, 2019

*Confidential portions of this exhibit have been omitted from the exhibit.

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.

Dated: August 8, 2019

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Title: Chief Executive Officer
and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
10.1*	Clinical Trial Agreement between Washington University School of Medicine in St. Louis and Synthetic Biologics, Inc. dated August 7, 2019

*Confidential portions of this exhibit have been omitted from the exhibit.

PORTIONS HEREIN IDENTIFIED BY [*****] HAVE BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE EXCLUDED INFORMATION IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

CLINICAL TRIAL AGREEMENT
FOR SYNTHETIC BIOLOGICS, INC.

THIS CLINICAL TRIAL AGREEMENT (the "Agreement"), effective this 7th day of August, 2019 (the "Effective Date"), is made by and between Synthetic Biologics, Inc., a Nevada corporation, having a place of business at 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850 ("Sponsor") and Washington University, having a place of business at 660 S. Euclid Avenue, St. Louis, MO 63110 ("Institution"). Sponsor and Institution are sometimes individually referred to herein singly as a "Party" and collectively as the "Parties."

WHEREAS, Sponsor desires that Institution perform the Study, as defined herein below, under the direction of Erik Dubberke, M.D. ("Principal Investigator"), an employee of Institution;

WHEREAS, Institution has expertise in conducting human clinical trials of pharmaceutical products in accordance with applicable laws, rules and regulations;

WHEREAS, Institution has access to facilities that are suitable for the performance of human clinical trials of pharmaceutical products in accordance with applicable laws; and

WHEREAS, Institution has agreed to perform the Study, on the terms and conditions set forth herein.

NOW, THEREFORE, the Parties, intending to be legally bound, have entered into this Agreement and do specifically agree as follows:

1.0 STUDY PROTOCOL

The scope and nature of the clinical trial to be performed by Institution (the "Study") will be in strict accordance with the protocol entitled, "Phase 1b/2a Evaluation of the Safety and Tolerability of SYN-004 in Adult Allogenic Hematopoietic Cell Transplantation Recipients ," which has been provided to Institution, and any subsequent amendments thereto (the "Protocol"). The Protocol fully details the clinical research activities and responsibilities to be undertaken by Institution. The Protocol will be considered final after it is signed by the Principal Investigator and approved by the pertinent Institutional Review Board(s) ("IRB") and/or Ethics Committee(s) ("EC") (hereinafter, the "IRB/EC"). Thereafter, the Protocol may be amended only by prior written consent of Sponsor and subsequent approval of the IRB/EC. In the event of a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement shall prevail for all legal, administrative, and business matters and the terms of the Protocol shall prevail for all patient care, scientific, and medical matters.

2.0 CONDUCT OF STUDY

The Study will be conducted in accordance with applicable laws, rules, and regulations governing the conduct of clinical trials and pertaining to investigational drugs, generally accepted good clinical practice and the conditions specified in the Statement of Investigator, U.S. Food and Drug Administration ("FDA") Form 1572, as described in 21 Code of Federal Regulations ("CFR") 312.53, which Institution and Principal Investigator shall have signed and Institution shall have returned to Sponsor prior to the commencement of the Study. Institution acknowledges and agrees that it is responsible for (A) the actions, performance, and conduct of the Principal Investigator, and (B) Principal Investigator's compliance with all of Principal Investigator's obligations set forth in this Agreement. Any failure by the Principal Investigator to perform or satisfy an obligation herein shall be considered a breach of this Agreement by Institution. Institution agrees to use its reasonable efforts to ensure that the Principal Investigator complies fully with the terms of the Protocol. In the performance of the Study the Institution specifically represents that it shall, and shall require the Principal Investigator and all employees engaged in the performance of the Study to:

a. Exercise independent medical judgment as to the compatibility of each patient with Protocol requirements;

b. Obtain from each patient in the Study and before the Study subject begins participating in the Study a signed informed consent form in a form which has been approved by the IRB/EC and reviewed and approved by Sponsor in accordance with the Protocol and with 21 CFR Part 50 and/or the International Conference on Harmonisation Guidelines for Good Clinical Practice as adopted by the FDA ("ICH GCPs"), as applicable Institution will allow Sponsor and/or their respective designees to inspect signed informed consent forms or make photocopies thereof during monitoring visits or audits conducted in accordance with the terms of this Agreement ;

c. Properly perform and direct the Study in accordance with applicable laws, the Protocol and ICH GCPs and FDA GCPs;

d. Ensure that all advertising, recruitment, and training materials developed by Institution, Principal Investigator, or any of Institution's employees, affiliates or agents in connection with the Study will comply with the Protocol, as well as all applicable laws, regulations, codes and rules, and receive prior review and approval by Sponsor and the IRB/EC, as applicable;

e. Review all patient case report forms (hereinafter "CRFs") to assure their accuracy and completeness, and assist Sponsor's representatives and clinical monitors upon request in promptly resolving any discrepancies or errors on CRFs and in performing random audits on original patient records, laboratory reports or other raw data sources and underlying data recorded on the CRFs (such audits to be performed in accordance with the terms of this Agreement);

f. Submit all Protocol-required data and information to the Sponsor, IRB/EC and all regulatory authorities, as applicable and undertake all Protocol-required activities, so that the time schedules set forth in the Protocol and this Agreement are strictly met;

g. Record all adverse events on the Adverse Events page(s) of the CRF in accordance with the Protocol. In the event of serious adverse events ("SAEs"), as defined in the Protocol and applicable regulations, Institution shall promptly and fully comply with all the notification procedures, time frames and requirements stated in the Protocol. If the Protocol does not identify the party(s) that is to be notified of SAEs, then the Institution shall promptly notify Sponsor, by both telephone and telefax, of all SAEs within 24 hours of becoming aware of the occurrence. In the event of SAEs that are immediately life-threatening or that result in death, the Institution shall immediately notify the party(s) specified in the Protocol by both telephone and telefax, and if the Protocol does not identify the parties who are to be notified of SAEs, the Institution shall immediately notify the Sponsor by both telephone and telefax. Investigator will promptly notify Sponsor and/or their respective designee, of any other safety information, that is not a serious adverse event, and information regarding drug experience associated with the Study or the Study Drug as specified in the Protocol;

h. Maintain records of patient identification, clinical observations, laboratory tests, and drug receipt and disposition as specified in the Protocol. Institution shall maintain all such records for the Study until the later of: (i) such period required by federal, state, national and local laws and regulations; (ii) two (2) years following the date a New Drug Application is approved for the Study Drug that is the subject of the Study; or (iii) two (2) years after the Investigational New Drug Application for such Study Drug is terminated or withdrawn. During the time periods stated in (i) – (iii) above, Institution shall not destroy any such records until it has obtained Sponsor's prior written permission to do so. After such time period has elapsed, Institution shall be free to dispose of the records as it sees fit so long as it has provided Sponsor with sixty (60) days' notice of disposal or destruction of records and an opportunity within such sixty (60) day period to take possession of such records;

i. Cooperate with Sponsor and its agents (including, without limitation, its designated clinical research organization) in all of their efforts to monitor the Study, including but not limited to allowing direct access to records that are maintained as Electronic Medical Records or in Institution's clinical files. Any such access will be upon reasonable advanced notice and at mutually agreeable times during Institution's normal business hours; it being agreed that ten (10) business days is reasonable advance notice. The Institution reserves the right to restrict access to patient areas and may require Sponsor to meet certain standards required by applicable laws or Institution policy for access to records or patient care areas. The Sponsor will, and will cause its agents and representatives to, use and disclose any patient information in accordance with the patient's informed consent form and applicable laws and regulations. No access to Institution's financial records will be provided;

j. Promptly notify Sponsor of any FDA regulatory inspections of which it becomes aware relating to the Study. If legally permissible and practicable, Sponsor shall be permitted to be present at any such inspections and shall have the opportunity to provide, review, and comment on any responses that may be required;

k. Ensure that all clinical data is accurate, complete, and legible, and promptly and fully disclosed to and produced for the inspection and use of Sponsor or its agents in accordance with Section 2.0(i) above; and

l. Supply to Sponsor or its agents written notice documenting continuing IRB/EC review. Institution and Principal Investigator will provide Sponsor or its designee with a copy of IRB's approval of Institution's, Principal Investigator's and study personnel's conduct of the Study at Institution and/or at Institution's affiliated hospitals, including approval of the Protocol, the informed consent form to be executed by all Study subjects enrolled by Institution and Principal Investigator in the Study and the HIPAA authorization, including any amendments to the foregoing, together with all relevant correspondence with the IRB regarding such approval and/or the Study.

3.0 STAFF AND FACILITIES

a. The Study shall be carried out at the Institution and/or its affiliated hospitals and under the review of an appropriate IRB/EC and under the supervision of the Principal Investigator;

b. Institution represents that it has or has access to adequate staff and facilities to complete the Study in a timely manner in accordance with the terms of the Protocol and this Agreement, and that Institution, Principal Investigator, and all of Institution's employees, facilities, affiliates or agents that will be used in connection with the Study have all necessary licenses, permits and certifications under all applicable laws, regulations, codes, and rules;

c. Institution represents that it is not party to, and Institution represents that, during the Term of this Agreement, it will not enter into any agreement to provide services which would prevent its ability to complete the Study in a timely manner and no additional interventional research may be conducted on Study subjects during any exclusion period specified in the Protocol unless it is approved in advance by Sponsor in writing. Sponsor will be notified in writing of additional interventional research to be conducted on Study Subjects after the Exclusion Period until the end of the Study;

d. Except where Sponsor has otherwise expressly agreed in writing, Institution shall arrange and pay for all necessary laboratory and other facilities, equipment, supplies and physicians and clinical support staff required to discharge its obligations under the Study;

e. All matters, terms and payments of compensation, benefits and other conditions of engagement of any nature for the Institution's staff and any other support used in the Study shall be solely a matter between Institution and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of Institution;

f. Institution represents that: (i) the Principal Investigator is not currently involved in any litigation, and it is unaware of any pending litigation proceedings relating to Principal Investigator's role in the conduct of a clinical trial for any third party; and (ii) it has not received any warnings from the FDA (or any equivalent oversight body in a country other than the United States) relating to services the Principal Investigator has provided to third parties during the conduct of a clinical trial;

g. Institution represents that the Principal Investigator has executed the signature page of the Protocol and this Agreement, and that Institution shall require that the Principal Investigator shall comply with all applicable terms of this Agreement, including, without limitation, federal and state laws and regulations governing record keeping, Study conduct, receipt and disposition of Study Drug, disclosure requirements, and the obtaining of an informed consent from patients participating in the Study;

h. Institution represents that it will properly supervise its employees and agents, and other persons performing the Study under its direction and shall require that such persons comply with the terms of this Agreement; and

4.0 REIMBURSEMENT

In consideration for performance of the Study, Sponsor will compensate Institution in accordance with the Budget and Payment Schedule attached asExhibit A, which the Parties agree is intended to represent fair market value in full consideration of the research services to be performed by Institution hereunder in accordance with the Protocol. The Parties further agree that the terms of this Agreement are not determined in a manner that takes into account the volume or value of any referrals or business, if any, otherwise generated between the Parties. Institution will make reasonable efforts to complete the Study within the maximum budget set forth on said Exhibit A (the "Budget") and will not commit to any expenses in excess of such maximum amount without Sponsor's prior written consent. If, prior to completion of the Study, this Agreement is terminated in accordance with Article 11 hereof for any reason other than by Sponsor for cause, Sponsor shall pay such amount for the research services and non-cancelable expenses documented and/or actually rendered/incurred by Institution/Principal Investigator hereunder in accordance with the Protocol prior to termination as determined in the manner set forth in Exhibit A. If Sponsor terminates this Agreement for cause, Sponsor shall have no obligation to pay Institution for those items set forth in the Budget that are incurred after the date such termination becomes effective or for such services that were not performed in accordance with the Protocol, and Institution shall, upon written request, promptly refund to Sponsor all advance payments made by Sponsor under the Budget as set forth below and not yet spent by Institution (without limitation of any other rights Sponsor may have in law or equity). Only research service expenditures that are agreed to be compensated under Exhibit A will be compensated upon termination, and Sponsor shall not be responsible for any lost profits or lost opportunities. Final payment will be made after the Institution completes all study activities as they pertain to the primary outcomes and Sponsor has received all patient data and any corresponding queries in an acceptable form, and if requested, all other Confidential Information as defined in Article 5 hereof.

A taxpayer identification number for Institution shall be provided to Sponsor before a payment will be issued. Should the Study or this Agreement terminate prematurely, any payments made by Sponsor exceeding the documented actual amount earned or non-cancellable expenses incurred in accordance with the Budget will be promptly returned upon written request.

Institution shall be solely responsible for ensuring that its practices, and those of the Principal Investigator, with respect to billing, coding or otherwise seeking reimbursement directly or indirectly from any third party, including patients, insurance companies, governmental entities, or others in connection with any Institution or Principal Investigator activities or services performed in accordance with the Study are fully compliant with all applicable laws and third party billing requirements, and Sponsor shall not be liable for any payment or non-payment by any third party. Institution acknowledges and agrees that Sponsor has not provided and will not provide advice with respect to such billing, coding, or reimbursement.

5.0 CONFIDENTIAL INFORMATION

All non-public information (including, but not limited to, electronically stored or transmitted information), materials (including, but not limited to, the Study Drug), and documents provided to either Party to the other Party or its agents under this Agreement and during the course of the Study, including preclinical data, case report forms (before they are completed), Protocol, investigator's brochure, and verbal and written information, will be kept strictly confidential in accordance with the terms of this Section 5.0 and shall be confined to the receiving Party personnel involved in conducting the Study who have a need to know such information in order to conduct the Study, have been advised of the confidential nature of such information and are required to comply with the confidentiality and nondisclosure obligations contained herein.

In addition, all reports and/or information, including but not limited to, CRFs or Study progress reports will constitute confidential information of Sponsor and will not be provided by the Institution to any parties not involved in the conduct of the Study, other than to Sponsor and its agents or as permitted by Article 7 (Publication) of this Agreement.

All confidential information as described in this Article 5 shall hereinafter be referred to as "Confidential Information". Such Confidential Information shall be and remain the confidential and proprietary property of the disclosing Party; provided that Study Data (as defined in Article 6) that constitutes Confidential Information shall be deemed the Confidential Information of Sponsor. Sponsor shall have no restrictions on use or disclosure of Study Data. Notwithstanding the foregoing, Principal Investigator and Institution may use and disclose Study Data for the purposes of future research and for its own research, educational and patient care purposes or programs so long as such use is not in concert with industry partners or in collaboration or partnership with a competitor of Sponsor and so long as it is not used to create a product that competes with a product of Sponsor and neither will use or permit others to use Study Data for the commercial benefit of any third party.

During the Study and for a period of seven (7) years after the termination, abandonment or completion of the Study at all facilities, the receiving Party shall maintain in strict confidence all of the disclosing Party's Confidential Information and not disclose or disseminate to any third party (other than in the case of Institution, its affiliated hospitals) or use for any purpose other than the performance of the Study, or as required for regulatory or legal purposes, any of the same. The foregoing obligation of nondisclosure shall not apply to information that:

a. Is or becomes publicly available, through no fault of the receiving Party, to any of the receiving Party's employees, affiliates or agents;

b. Is disclosed to the receiving Party by a third party who, to receiving Party's knowledge, is entitled to disclose such information not subject to any obligation of confidence to the disclosing Party;

c. Is already known to the receiving Party prior to disclosure hereunder, as shown by receiving Party's prior written records;

d. Is necessary to be included in any patient's written informed consent form (to the extent necessary for purposes of such approval and/or inclusion; and provided that the disclosing Party shall be entitled to review and revise as appropriate such informed consent form or any modification thereof prior to use by Institution, subject to subsequent approval by the IRB/EC and with the understanding that the ultimate contents of the informed consent is within the purview of the IRB/EC, as per applicable law);

e. Is required by applicable law to be disclosed to federal, state or local authorities; provided that, in the event that the receiving Party receives a non-routine request to disclose any Confidential Information under this subsection, to the extent permitted by law, the receiving Party shall: (i) promptly notify the disclosing Party of the existence, terms, and circumstances surrounding such a request; (ii) consult with the disclosing Party on the advisability of taking steps to lawfully resist or narrow that request; (iii) if disclosure of Confidential Information is required, furnish only such portion which is legally required to be disclosed, and, if requested by the disclosing Party prior to such disclosure, mark any such disclosure as FOIA-exempt, to the extent applicable; and (iv) cooperate with the disclosing Party in its efforts to obtain an order or other reliable assurance that confidential treatment will be accorded to that portion of information that is required to be disclosed;

f. Can be documented to have been independently developed at the receiving Party by someone not involved in the Study and not privy to the Confidential Information; or

g. Is published by the receiving Party in accordance with Article 7 (Publication) herein.

Notwithstanding anything to the contrary herein, all individually identifiable patient health information (including information relating to patients and/or Study patients whose identities may be ascertained by the exercise of reasonable effort through investigation or through use of other public or private databases) ("PHI") shall be treated as confidential by the Parties in accordance with all applicable federal, national, state and local laws, rules and regulations governing the confidentiality and privacy of PHI, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 and any regulations and official guidance promulgated thereunder (collectively, "HIPAA"); and the Parties agree to take such additional steps and/or to negotiate such amendments to this Agreement as may be required to ensure that the Parties are and remain in compliance with HIPAA.

6.0 REPORTS AND STUDY DATA

Institution shall prepare, maintain and retain all: Protocol-required documentation, records, case report forms, laboratory worksheets, data queries, protocols, raw data, specimens, test articles, control materials, slides, reports or other work product generated in the performance of the Study whether in written, electronic, video or other tangible form including, without limitation, the completed CRFs, Study Drug inventory records, laboratory records, worksheets, reports, radiologic examinations, observations, signed informed consent forms (collectively the “Study Data”) in a timely, accurate, complete, and legible manner in the form described in the Protocol and Applicable Laws. Sponsor shall be the sole owner of the Study Data; provided that Principal Investigator and Institution each may use such Study Data for its own research, educational and patient care purposes or programs so long as such use is not in concert with industry partners or in collaboration or partnership with a competitor of Sponsor and so long as it is not used to create a product that competes with a product of Sponsor and neither will use or permit others to use Study Data for the commercial benefit of any third party. Notwithstanding the foregoing, all original patient medical records are and shall remain the property of Institution and are specifically excluded from the definition of Study Data; however, if requested, Sponsor shall have a right to review such patient medical records in accordance with the terms of this Agreement. During the Study and in accordance with the terms of Section 2.0(i) of this Agreement, Sponsor or Sponsor’s representatives shall be provided and have the right to review, verify, and copy all Study Data including, without limitation, radiographs, ECG tracings, original reports of laboratory tests and examination findings, and all other notes, charts, reports, or memoranda relating to patients enrolled in the Study. Promptly (but no later than sixty (60) days after completion or termination of the Study, Institution shall cause Principal Investigator to complete and submit to Sponsor or its designated agent all outstanding case report forms and data queries resulting from the Study and shall transfer to Sponsor all Study Data. Raw data in paper or magnetic form will be retained by Principal Investigator in compliance with regulatory requirements. The Institution shall complete data entry on a CRF or to respond to any queries within the timelines provided for in the Protocol.

7.0 PUBLICATION

Notwithstanding any other provisions of this Agreement, upon completion of the Study and submission of the data to the appropriate regulatory agencies which shall occur within thirty (30) business days after completion of the Study and database lock or earlier termination of the Study, Principal Investigator shall have the right to publish its own results of the Study; *provided*, *however*, that Sponsor shall have the right to review any proposed publication, including oral presentations and abstracts, that utilize data or results generated from the Study. Institution shall cause Principal Investigator to submit a complete copy of the proposed publication to Sponsor at least sixty (60) days prior to presentation or submission to any third party (the "Review Period"). Sponsor shall review the publication and give its comments to the Institution within the Review Period. Institution shall cause Principal Investigator to comply with Sponsor's requests to delete references to Sponsor's Confidential Information (except Study results) and shall consider Sponsor's other comments (with the understanding that ultimate editorial control belongs to the Principal Investigator). Upon any revision of publication in response to Sponsor's comments, the Principal Investigator shall submit the final version of the publication to Sponsor for its information prior to presenting or submitting the publication to the publisher. In any event, Institution shall require Principal Investigator and any co-authors employed by Institution to withhold publication an additional sixty (60) days to permit Sponsor to obtain patent protection if Sponsor so requests. Institution shall require compliance of any subinvestigators, employee, other individual or subcontractor involved in the Study with the provisions of this paragraph. Institution and Principal Investigator shall give the Sponsor appropriate credit and/or recognition for co-authorship in accordance with academic standards for contributions made by Sponsor, subject to the Sponsor's prior consent. Sponsor shall adhere to ICMJE's requirement on clinical trial registration and represents and warrants that the Study is registered accordingly prior to the recruitment of the first Study subject.

8.0 DRUG STORAGE AND RETURN OF STUDY MATERIALS

SYN-004(ribaxamase) (quantities provided for use in the Study, the "Study Drug") and any comparator drugs provided in connection with the Study shall be used by the Institution solely for the purpose of completing the Study according to the Protocol. The Institution shall keep all Study Drug and any comparator drugs in a locked, secured area at all times and maintain complete, up-to-date records showing receipt, dispensing and returns of the Study Drug and any comparator drugs as required by the Protocol, and applicable federal, state and local laws, regulations, and rules. Institution agrees that it: (i) will use the Study Drug or any comparator drugs provided by Sponsor pursuant to this Agreement only in the Study and for no other purposes; and (ii) will not knowingly and purposefully charge or collect payment of any type from patients, insurance companies, governmental entities, or others for the Study Drug or any comparator drugs provided to Institution by Sponsor hereunder. If such payment is erroneously collected, Institution shall promptly refund the patient, insurance company, governmental entity, or other payer. Upon completion of the Study, all unused Study Drug, compounds, drugs, devices, equipment and related materials and all copies of Sponsor Confidential Information that were furnished to the Institution shall be, at the expense of Sponsor, returned to the Sponsor or destroyed with a written notice of destruction returned to the Sponsor. Notwithstanding the foregoing, Institution may retain one copy of Sponsor Confidential Information in a secure location for purposes of identifying Institution's obligations under this Agreement.

9.0 INDEPENDENT CONTRACTOR

The relationship of Sponsor and Institution and Sponsor and Principal Investigator under this Agreement is that of independent contractors, and this Agreement shall not, and is not intended to, make the Parties partners, joint venturers or agents of one another. Neither Party, including the Principal Investigator, shall have the power to bind or obligate the other Party.

10.0 NON-DEBARMENT/NON-EXCLUSION

Institution represents that neither Institution, nor Principal Investigator, nor to its knowledge any of Institution's employees, affiliates or agents performing the Study have ever been: (i) debarred, under Section 306(a) or (b) of the Generic Drug Enforcement Act of 1992; (ii) excluded from participation in federal health care programs; or (iii) debarred from federal contracting. Institution represents that it and Principal Investigator have never been and, to the best of its knowledge after due inquiry, none of its employees, affiliates or agents has ever been (a) threatened to be debarred or excluded or (b) indicted for a crime or otherwise engaged in conduct for which a person can be so debarred or excluded. Institution will promptly notify Sponsor in the event of any such debarment, exclusion, conviction, threat or indictment, and at Sponsor's option, this Agreement shall terminate effective as of the date of such debarment, exclusion, conviction, threat or indictment. The terms of the preceding sentence shall survive the termination or expiration of this Agreement.

11.0 TERM AND TERMINATION

This Agreement shall be effective as of the Effective Date and shall continue until completion of all obligations herein, including receipt by Sponsor or its designated agent of all Study Data, Confidential Information (except the one (1) archival copy permitted to be retained) and any corresponding queries in a form reasonably acceptable to Sponsor, or until termination as set forth below.

This Agreement may be terminated prior to completion as established above on written notice if any of the following conditions occur:

a. By either Party, effective immediately, if the authorization and approval to conduct the Study is withdrawn by the FDA or other governmental or regulatory authority, or by Sponsor if Sponsor is unable to obtain authorization and approval to conduct the Study;

b. By either Party, effective immediately, if the emergence of any adverse reaction or side effect with the Study Drug administered in the Study is of such magnitude or incidence in the opinion of either the Institution or Sponsor to support termination, subject to Institution's obligations under Section 2(g) of this Agreement;

c. By Sponsor, effective immediately, if the Institution fails to perform the Study in accordance with the terms of the Protocol, this Agreement, or applicable laws or regulations including FDA or ICH GCP guidelines, or the Institution or Principal Investigator become debarred or excluded or become subject to a threat of debarment or exclusion;

d. By either Party if the other Party otherwise breaches this Agreement and such breaching Party fails to cure the breach within thirty (30) days after receipt of written notice from the non-breaching Party specifying in detail the nature of the breach;

e. By Sponsor, upon fourteen (14) days written notice; or

f. By Institution upon fourteen (14) days written notice if Principal Investigator becomes unable to perform or complete the Study and the Parties have not, prior to the expiration of such fourteen (14) day period, agreed to an alternative Principal Investigator. Institution shall use reasonable efforts to find a replacement Principal Investigator with similar qualifications as the Principal Investigator being replaced.

After termination for any reason, both Parties shall continue activities under this Agreement solely as deemed necessary by mutual agreement of the Parties based on reasonable medical judgment to protect the health of patients participating in the Study.

12.0 PATENT RIGHTS AND INVENTIONS

For purposes of this Article 12, "Invention" means any discovery or invention, whether or not patentable, conceived, made, or developed as a result of conducting the Study, or made using the Study Drug or Sponsor Confidential Information, together with all intellectual property rights relating thereto. Inventions shall include, but not be limited to, processes, compositions, methods, software, tangible research products, formulas and techniques, patents, and copyrights, and any improvements related thereto. It is recognized and understood that the inventions and technologies, existing prior to execution of this Agreement, of Sponsor or Institution are their separate property, respectively, and are not affected by this Agreement (including, but not limited to the Confidential Information) and neither Sponsor nor Institution shall have any claims to or rights in such existing inventions and technologies of the other, even where Study Data generated under the Study is used to support patent applications regarding such existing inventions.

Institution and Principal Investigator shall promptly disclose in writing to Sponsor all Inventions, including, without limitation, those Inventions made by: (a) employees, subcontractors, agents, affiliates, and related personnel (including, but not limited to postgraduate students and other students) of Institution and/or (b) the Principal Investigator and subinvestigators.

Ownership of any Inventions shall be in accordance with inventorship which shall be determined in accordance with U.S. patent law.

Institution agrees to ensure that each of its employees, subcontractors and agents rendering services hereunder, including, without limitation, the Principal Investigator, are familiar with and shall have an obligation to abide by the terms of this Article 12. Institution shall ensure that each of its employees and any subcontractors or agents performing any part of the Study, shall assign all Inventions and intellectual property rights therein created, discovered, or generated by such personnel as a result of performing the Study to Institution so that Institution can comply with its obligations under this Article 12, and Institution shall promptly obtain such assignments.

The parties shall jointly own all by-products and derivatives of Protocol-required biological samples including, without limitation, tissue samples and blood samples, provided by or taken from any patient in connection with such patient's participation in the Study ("Biological Samples"). The parties shall jointly own all Study Data resulting from the use and testing of any and all Biological Samples. Principal Investigator and Institution each may use such Study Data for its own research, educational and patient care purposes or programs so long as such use is not in concert with industry partners or in collaboration or partnership with a competitor of Sponsor and so long as it is not used to create a product that competes with a product of Sponsor and neither will use or permit others to use Study Data for the commercial benefit of any third party.

The foregoing obligations shall continue beyond the termination of this Agreement with respect to Inventions and shall be binding upon Institution and Institution's employees and agents.

Institution shall grant and hereby grants to Sponsor an option to negotiate for an exclusive worldwide, sublicensable (through multiple tiers as negotiated by the parties) license to practice Institution's rights to any Invention owned by Institution. The license agreement will contain terms and conditions, including without limitation, terms consistent with industry standard for similar licenses. Sponsor hereby grants to Institution a non-exclusive, royalty-free license to practice Sponsor's rights to any Invention owned by Sponsor for internal, non-commercial purposes for the purpose of performing the Study.

13.0 INDEMNIFICATION; LIMITATION OF LIABILITY

Sponsor shall indemnify, defend, and hold harmless Institution, its affiliated hospitals, its IRB, Principal Investigator and their respective affiliates, agents, officers, directors and employees ("Institution Indemnitees") from and against any and all loss, damage, cost, claim or liability (collectively, "Claims") resulting from (i) the use by or on behalf of a Sponsor Indemnitee of the results of the Study, (ii) a Sponsor Indemnitee's negligence or willful misconduct, or (iii) a subject's participation in the Study. Sponsor's obligation to indemnify and hold harmless Institution Indemnitees under this Section shall be reduced only if and only to the extent the losses are ultimately adjudged to have been caused by the negligence or intentional misconduct of an Institution Indemnitee, an Institution Indemnitee's failure to follow any Applicable Laws, an Institution Indemnitee's failure to comply with this Agreement, the Protocol or other written instructions or recommendations provided by or on behalf of Sponsor or Sponsor designee to the Institution Indemnitees provided that such instructions are not in conflict with the Protocol unless the conflicting instructions are related to the safety, welfare, or well-being of the patient, treatment of the Study subject prior to or outside of the Study, failure to obtain informed consent from the Study subject using the then current informed consent form in the form approved by Sponsor (provided that the injury is related to the failure of not getting informed consent), or unauthorized warranties or representations made by an Institution Indemnitee concerning the Study Drug or a comparator drug (provided that the injury is related to the unauthorized warranties or representations made by an Institution Indemnitee concerning the Study Drug or a comparator drug) (each, an "Excluding Condition").

Institution shall indemnify and hold harmless Sponsor and its affiliates, agents, officers, directors and employees ("Sponsor Indemnitees") from and against any and all loss, damage, cost, claim or liability found to result from an Excluding Condition.

The Party seeking indemnification shall promptly notify the indemnifying Party in writing of all claims for which indemnification is sought and allow the indemnifying Party to handle such claims (including settlement negotiations); *provided*, *however*, that the indemnifying Party shall not have the right to agree to any settlement pursuant to which liability or culpability on the part of the indemnified Party or its Indemnitees is acknowledged. The indemnified Party shall cooperate fully with the indemnifying Party in its handling of all claims. A failure to promptly notify of any claim will serve to reduce the indemnity rights of the party seeking indemnification only if and only to the extent such failure materially prejudiced the indemnifying party's actual defense of the claim.

Sponsor agrees to reimburse Institution for the reasonable and necessary medical expenses for medical treatment of an adverse reaction that is the direct result of administering the Study Drug pursuant to and in compliance with the Protocol, unless due to the negligence or intentional misconduct of an Institution Indemnitee, the use of the Study Drug by any Institution Indemnitee in any manner not in compliance with the Protocol, or breach of this Agreement, the Protocol or any applicable law, rule or regulation by an Institution Indemnitee. Provided that, if any patients are Medicare or Medicaid beneficiaries, the Parties shall comply with the reporting and other applicable requirements under Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) relating to agreeing to pay for patient's study injuries, if applicable.

WITHOUT LIMITING THE INDEMNIFICATION OBLIGATIONS,CONFIDENTIALITY OBLIGATIONS OR INTELLECTUAL PROPERTY OBLIGATIONS HEREUNDER, NOTWITHSTANDING THE FOREGOING, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INDIRECT, CONSEQUENTIAL, LOSS OF PROFITS, OR OTHER DAMAGES SUFFERED BY THE OTHER PARTY, ANY LICENSEE, OR ANY OTHERS RESULTING FROM THE USE OF THE RESEARCH, STUDY DATA OR ANY INVENTION OR PRODUCT ARISING FROM THE STUDY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR (A) WORK STOPPAGE, LOST DATA, LOST PROFITS OR ANY OTHER RELIANCE OR EXPECTANCY, DIRECT OR INDIRECT, OR (B) SPECIAL OR CONSEQUENTIAL DAMAGES, OF ANY KIND.

INSTITUTION AND PRINCIPAL INVESTIGATOR EACH UNDERSTAND AND AGREE THAT THE STUDY DRUG IS EXPERIMENTAL IN NATURE AND THAT NO WARRANTY, EITHER EXPRESS OR IMPLIED, IS MADE BY SPONSOR NOR ANY OTHER PARTY REGARDING THE STUDY DRUG EXCEPT THAT THE STUDY DRUG HAS BEEN MANUFACTURED IN ACCORDANCE WITH APPLICABLE LAW.

Institution shall maintain in full force and effect during the term of this Agreement a policy or program of insurance or self-insurance at levels sufficient to support the indemnification and contractual obligations set forth in this Agreement. Upon request, Institution will provide evidence of its insurance or self-insurance and will provide Sponsor thirty (30) days prior written notice of any cancellation of its coverage. Sponsor shall maintain in full force and effect during the term of this Agreement adequate liability insurance coverage to maintain its ability to cover its indemnification and contractual responsibilities hereunder, provided that such insurance shall not be less than $2,000,000 per occurrence and $5,000,000 aggregate. Sponsor shall provide evidence of such insurance upon request. At least thirty (30) days prior to any loss or reduction in such insurance coverage, Sponsor shall notify Institution. The specified minimum insurance coverages and limits outlined above do not constitute a limitation on Sponsor's liability or obligation to indemnify or defend Institution and any other Indemnitees under this Agreement.

14.0 COMPLETE AGREEMENT

This Agreement constitutes the sole, full and complete Agreement by and between the Institution and Sponsor and supersedes all other written and oral agreements and representations between the Institution and Sponsor with respect to the Study. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties. Any requests for changes or amendments or other notices or communications concerning this Agreement should be in writing and shall be deemed to have been given when mailed by U.S. Mail postage prepaid or bonded courier and forwarded to the following:

To Synthetic Biologics, Inc.:
Steven Shallcross, CEO, CFO
Synthetic Biologics, Inc.
9605 Medical center Drive, Suite 270
Rockville, Maryland 20850

With a copy to:
Leslie Marlow, Esq
Gracin & Marlow, LLP
The Chrysler Building, 26th Floor
405 Lexington Avenue
New York, New York 10174

To Institution:	Washington University Joint Research Office for Contracts One Brookings Drive, CB 1054 St. Louis, MO 63130 Attn: Dubberke/P19-07190
With a copy to:	Washington University 660 S. Euclid Ave., CB 8009 St. Louis, MO 63110 Attn: Dubberke/P19-07190

15.0 BINDING EFFECT

This Agreement shall be binding upon the Parties, their legal representatives, successors and assigns. The obligations of the Parties contained in Articles 2h, 2j, 3f, 4 (Reimbursement), 5 (Confidential Information), 6 (Reports and Work Product), 7 (Publication), 8 (Drug Storage and Return of Study Materials), 9 (Independent Contractor), 10 (Non-Debarment/Non-Exclusion), 12 (Patent Rights and Inventions), 13 (Indemnification; Limitation of Liability), 14 (Complete Agreement), 15 (Binding Effect), 16 (Release of Information), 17 (Financial Disclosure) and 18 (Applicable Law) shall survive the termination or expiration of this Agreement.

16.0 RELEASE OF INFORMATION

To the extent allowable by law, Sponsor may use, refer to, and disseminate reprints of scientific, medical and other published articles relating to the Study which disclose the name of Institution and/or Principal Investigator or any subinvestigators, consistent with applicable copyright laws. Neither Party shall otherwise use the name of the other Party or the Principal Investigator or any subinvestigators in connection with any advertising or promotion of any product or service without the prior written permission of such Party or the Principal Investigator as appropriate. Each Party agrees that it will not disclose the terms of this Agreement to any third party without the permission of the other Party. Institution may acknowledge in general terms the existence of this Agreement and Institution's receipt of financial support from Sponsor without Sponsor's prior approval. Moreover, this provision shall not be construed so as to prohibit the Institution or the Principal Investigator from identifying Sponsor in any publication in accordance with this Agreement. Notwithstanding anything to the contrary contained herein, Sponsor may make public the amount of funding provided hereunder for the conduct of the Study and may identify Institution as a site at which the Study was conducted and may identify those individuals responsible for conducting the Study, including the Principal Investigator as part of this disclosure. Institution represents that it has or shall obtain the Principal Investigator's consent to this disclosure

17.0 FINANCIAL DISCLOSURE

So that Sponsor may fulfill its certification and other financial disclosure obligations under 21 CFR Part 54 to the United States Food and Drug Administration and such other laws and regulations as may from time to time be or become applicable with respect thereto, Institution shall cause Principal Investigator and each sub-investigator to provide financial disclosures to Sponsor or its designated agent prior to commencing the Study, and more frequently as Sponsor may request from time to time. During the time the Study is being conducted and for one (1) year thereafter, Institution shall cause Principal Investigator and each subinvestigator to update such forms promptly and provide same to Sponsor or its agent: (i) whenever any change occurs in the information disclosed by a previous form such that such form is no longer truthful and accurate, or (ii) as may be requested by Sponsor or its agent when the financial information required to be disclosed by an applicable regulatory authority changes. By completing a disclosure, the Principal Investigator and the subinvestigators shall certify that the disclosure supplied is truthful and accurate. In addition, prior to the commencement of the Study, the Principal Investigator shall have completed, signed, and delivered to Sponsor a Statement of Investigator, Form FDA-1572, as described in 21 C.F.R. § 312.53.

In addition, Institution agrees that Institution and/or Principal Investigator and any subinvestigators, as applicable: (a) will be required to disclose the existence and nature of this Agreement, as may be required by any Institution formulary and/or clinical guidance committee(s) (or such committee in which Principal Investigator or any subinvestigator participates as a member, an advisor and/or in a similar capacity); and (b) Principal Investigator and any subinvestigators will be required to comply with any applicable institutional conflict of interest, disclosure, or approval policies. If applicable and permitted by Institution policies, Institution agrees to provide to Sponsor copies of any such applicable Institution policies or guidelines.

18.0 APPLICABLE LAW

The parties agree to remain silent on the issue of governing law.

19.0 WAIVER AND SEVERABILITY

Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect. If any part of this Agreement is held unenforceable, the rest of the Agreement will nevertheless remain in full force and effect.

20.0 ASSIGNMENT

Institution shall not subcontract, assign or transfer any of its rights or obligations under this Agreement without the written consent of Sponsor. In the event that Sponsor does so consent, then any agreement entered into by Institution with the permitted third party subcontractor, assignee, or transferee shall, at a minimum, provide for ownership and allocation of intellectual property rights and for obligations of confidentiality of information, record-keeping, access, and rights to data that are consistent with the intent and terms of this Agreement. Institution shall remain liable for the performance of any of its obligations hereunder that it delegates to a subcontractor, assignee, or transferee. Sponsor shall not subcontract, assign or transfer any of its rights or obligations under this Agreement without providing prior notification of such to Institution.

21.0 POWER AND AUTHORITY

Institution represents to Sponsor that Institution has the full right, power and authority and legal capacity to enter into this Agreement, and the execution, delivery and performance of this Agreement by Institution does not constitute a breach of any order, judgment, agreement or instrument to which Institution is a party. Sponsor represents to Institution that Sponsor has the full right, power and authority and legal capacity to enter into this Agreement, and the execution, delivery and performance of this Agreement by Sponsor does not constitute a breach of any order, judgment, agreement or instrument to which Sponsor is a party.

22.0 COUNTERPARTS

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

23.0 ACCREDITATION BY THE ASSOCIATION FOR ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS ("AAAHRP") REQUIRED LANGUAGE

During and for a period of at least two (2) years after the completion of the Study, Sponsor shall promptly report to the Principal Investigator any information that could directly and materially affect the health or safety of past or current Study subjects or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the Principal Investigator and Institution shall be free to communicate these findings to each Study subject and the IRB.

ACCEPTED AND AGREED TO:

SYNTHETIC BIOLOGICS, INC.:

/s/Steven A. Shallcross (Signature)	August 7, 2019 Date
Name: Steven A. Shallcross	Title: Chief Executive Officer

[INSTITUTION]:

/s/Melanie Roewe, JD (Signature)	July 30,2019 Date
Name: Melanie Roewe, JD	Title: Associate Vice Chancellor for Joint Research Office of Contracts

PORTIONS HEREIN IDENTIFIED BY [*****] HAVE BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE EXCLUDED INFORMATION IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Read and acknowledged:

PRINCIPAL INVESTIGATOR:

/s/ Erik Dubberke	July 29, 2019
(Signature)	Date

Name: Erik Dubberke

PORTIONS HEREIN IDENTIFIED BY [*****] HAVE BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE EXCLUDED INFORMATION IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit A

Activity	**Costs**	**Includes**
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
[*****]	[*****]	

Proposed payment schedule:	
Milestone 1: execution of contract	$483,487
Milestone 2: IRB approval	$593,078
Milestone 3: approval to start enrollment for cohorts 3 and 4	$1,073,342
Milestone 4: approval to start enrollment for cohorts 5 and 6	$805,006
Milestone 5: completion of all study activities as they pertain to the primary outcomes and receipt by Synthetic Biologics of all patient data and any corresponding queries in an acceptable form, and if requested, all other Confidential Information as defined in Article 5 of the attached Clinical Trial Agreement of which this is Exhibit A.	$268,335
Total	**$3,223,248**

Notes:

[*****]

[*****]

[*****]

[*****]

[*****]