UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q
(Amendment No. 1)

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-12584

SYNTHETIC BIOLOGICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Nevada	**13-3808303**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
9605 Medical Center Drive, Suite 270 **Rockville, MD**	**20850**
(Address of Principal Executive Offices)	*(Zip Code)*

(301) 417-4364
(*Registrant's Telephone Number, Including Area Code*)

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	SYN	NYSE American

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer, "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of November 6, 2020, the registrant had 19,993,390 shares of common stock, $0.001 par value per share, outstanding.

EXPLANATORY NOTE

Synthetic Biologics, Inc. is filing this Quarterly Report on Form 10-Q/A (Amendment No.1) (the "Quarterly Report on Form 10-Q/A") to amend in its entirety the following sections in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 filed with the Securities and Exchange Commission on November 10, 2020 (the "Original Report"): Item 2 of Part I, "Management's Discussion and Analysis of Financial Condition and Results of Operations," solely to provide updated information regarding the termination of its exclusive license agreement related to its SYN-010 program, "Item 6 of Part II, "Exhibits," the signature page, the Exhibit Index and new certifications filed as Exhibits 31.2 and 32.2.

We have made no attempt in this Quarterly Report on Form 10-Q/A to modify or update the disclosures presented in the Original Report other than as noted in the previous paragraph. Except as noted above, this Quarterly Report on Form 10-Q/A does not reflect events occurring after the filing of the Original Report. Accordingly, this Quarterly Report on Form 10-Q/A should be read in conjunction with the Original Report, and the Company's other filings with the SEC subsequent to the filing of the Original Report, including any amendments thereto.

SYNTHETIC BIOLOGICS, INC.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q/A contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In particular, statements contained in this Quarterly Report on Form 10-Q/A, including but not limited to, statements regarding the timing of our clinical trials, the development and commercialization of our pipeline products, the sufficiency of our cash, our ability to finance our operations and business initiatives and obtain funding for such activities and the timing of any such financing, our future results of operations and financial position, business strategy and plan prospects, or costs and objectives of management for future research, development or operations, are forward-looking statements. These forward-looking statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as "may," "will," "should," "expects," "plans," "anticipates," "intends," "targets," "projects," "contemplates," "believes," "seeks," "goals," "estimates," "predicts," "potential" and "continue" or similar words. Readers are cautioned that these forward-looking statements are based on our current beliefs, expectations and assumptions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q/A, and those identified under Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019 (the "2019 Form 10-K") filed with the SEC on February 20, 2020. Therefore, actual results may differ materially and adversely from those expressed, projected or implied in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q/A, "Synthetic Biologics," the "Company," "we," "us" and "our" refer to Synthetic Biologics, Inc.

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q/A are the property of their respective owners.

SYNTHETIC BIOLOGICS, INC.

FORM 10-Q/A

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PART I–FINANCIAL INFORMATION

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q/A, and our audited consolidated financial statements and notes thereto for the year ended December 31, 2019 included in our 2019 Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Our actual results and the timing of events could differ materially from those expressed or implied by the forward-looking statements due to important factors and risks including, but not limited to, those set forth below under "Risk Factors" and elsewhere herein, and those identified under Part I, Item 1A of our 2019 Form 10-K. All share and per share numbers set forth in this Management's Discussion and Analysis of Financial Conditions and Results of Operations reflect the one-for-thirty five reverse stock split effected August 10, 2018.

Overview

We are a diversified clinical-stage company developing therapeutics designed to treat gastrointestinal (GI) diseases in areas of high unmet need. Our lead clinical development candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the GI tract to prevent microbiome damage, *Clostridioides difficile* infection (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR), and acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases.

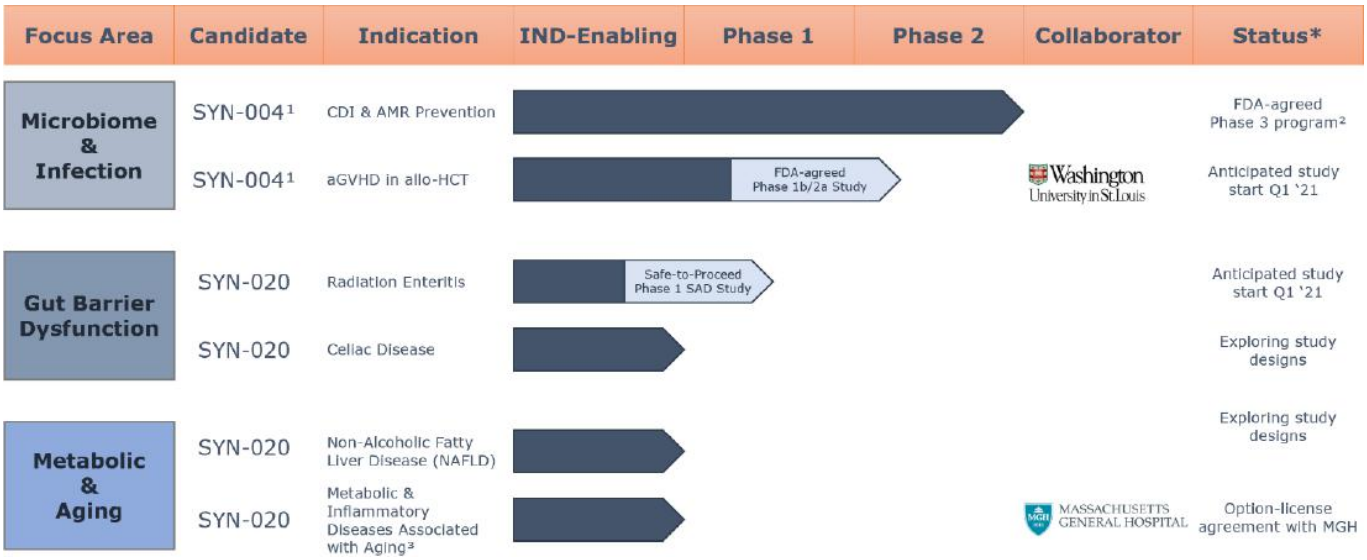
We were also developing SYN-010 to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). On September 30, 2020, Cedars Sinai Medical Center's (CSMC) (the Company's SYN-010 clinical development partner) informed the Company that it agreed to discontinue the ongoing Phase 2b investigator-sponsored clinical study of SYN-010 in IBS-C patients. Based on the results of a planned interim futility analysis, it was concluded that although SYN-010 was well tolerated, it was unlikely to meet its primary endpoint by the time enrollment is completed. On November 9, 2020, we and CSMC mutually agreed to terminate the exclusive license agreement (the "Exclusive License Agreement") that we and our subsidiary, Synthetic Biomics, Inc. entered into with CSMC date December 5, 2013 and all amendments thereto and the clinical trial agreement relating to SYN-010.

As a result of the decision to discontinue the ongoing Phase 2b investigator-sponsored clinical study of SYN-010, we plan to explore and evaluate a range of strategic options, which may include: in-licensing opportunities; evaluation of potential acquisitions; or other potential strategic transactions. In the meantime, we remain focused on working with our clinical development partners to advance the planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic hematopoietic cell transplant (HCT) patients, and advancing the clinical development program for SYN-020 intestinal alkaline phosphatase (IAP) in multiple potential indications. Both of these programs are unrelated to SYN-010, and therefore, we remain encouraged by the outlook and potential for these programs in addressing large, underserved markets.

We are in close contact with our clinical sites and are assessing the impact of COVID-19 on our studies and current timelines and costs. To maximize patient participation and safeguard the trials integrity and patient safety, initiation of the Company's Phase 1b/2a clinical study of SYN-004 to be conducted by Washington University in Allogeneic HCT Recipients is deferred until Q1 2021, pandemic conditions permitting. If the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our clinical development timeline, which would adversely affect our business, financial condition, results of operations and growth prospects.

In response to the spread of COVID-19 as well as public health directives and orders, we have implemented a number of measures designed to ensure employee safety and business continuity. We have limited access to our offices and are allowing our administrative employees to continue their work outside of our offices in order to support the community efforts to reduce the transmission of COVID-19 and protect employees, complying with guidance from federal, state and local government and health authorities. The effects of the governmental orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Our Product Pipeline:



aGVHD acute graft-vs-host disease; allo-HCT allogeneic hematopoietic cell transplant patients; AMR antimicrobial resistance; CDI*Clostridioides difficile* infection. SAD single ascending dose

[1]Additional products with preclinical proof-of-concept include SYN-006 (carbapenemase) to prevent aGVHD and infection by vancomycin resistant enterococci and SYN-007 (ribaxamase) DR to prevent antibiotic associated diarrhea with oral β-lactam antibiotics.
[2]Dependent on funding/partnership.
[3]Announced option-license agreement with Massachusetts General Hospital to develop SYN-020 in several potential indications related to inflammation and gut barrier dysfunction.
*Based on management's current beliefs and expectations.

Summary of Current Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Developments & Milestones
Prevention of microbiome damage, CDI, overgrowth of pathogenic organisms, AMR, and aGVHD in allogeneic HCT recipients (Degrade IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	· Announced outcomes from End of Phase 2 meeting, including FDA-proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval on the basis of a single Phase 3 clinical trial (Q4 2018) · Anticipate initiation of the Phase 3 clinical program proposed by the FDA for the prevention of CDI only after securing additional potential funding via a strategic partnership · Clarified market/potential partner needs and identified potential additional indications in specialty patient populations such as allogeneic hematopoietic cell transplant patients · Announced clinical trial agreement (CTA) with Washington University School of Medicine to conduct a Phase 1b/2a clinical trial to evaluate safety, tolerability and pharmacokinetics in up to 36 evaluable adult allogeneic HCT recipients (Q3 2019) · Received official meeting minutes from FDA Type-C meeting held on December 2, 2019 to discuss development in allogeneic HCT recipients who are administered IV beta-lactam antibiotics in response to fever (Q1 2020) · Received written notification from the FDA informing the Company that the FDA determined the Phase 1b/2a clinical program in adult allogeneic hematopoietic cell transplant (HCT) recipients may proceed per the submitted clinical program protocol (Q3 2020) · Proposed Phase 1b/2a clinical trial to be conducted by Washington University in adult allogeneic HCT is anticipated to commence during Q1 2021, subject to COVID-19 global pandemic
Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	· Confirmed key elements of Pivotal Phase 2b/3 clinical trial design pursuant to consultations with FDA (Q1 2017) · Entered into agreement with CSMC for an investigator-sponsored Phase 2b clinical study of SYN-010 to evaluate SYN-010 dose response and inform Phase 3 clinical development (Q3 2018) · Patient recruitment and enrollment in the Phase 2b investigator-sponsored clinical study recommenced following a temporary halt in Q1 and Q2 due to the COVID-19 global pandemic (Q3 2020) · Announced results from a planned interim futility analysis which concluded that although SYN-010 was well-tolerated, it was unlikely to meet its primary objective by the time enrollment is completed. As a result, CSMC has agreed to discontinue the trial and will conduct a comprehensive review of the final data set and publish its findings (Q3 2020). Terminated Exclusive License Agreement (Q4 2020)

Preserve gut barrier, treat local GI inflammation, and restore gut microbiome	SYN-020 (oral IAP enzyme)	· Generated high expressing manufacturing cell lines for intestinal alkaline phosphatase (IAP) (1H 2017) · Identified basic drug supply manufacturing process and potential tablet and capsule formulations (2H 2017) · Identified potential clinical indications with unmet medical need including enterocolitis associated with radiation therapy for cancer (Q1 2019) · Completed pre-IND (Investigational New Drug) meeting with the FDA to clarify requirements for IND-enabling toxicology studies and manufacturing requirements (Q2 2019) · Entered into an agreement with Massachusetts General Hospital ("MGH") granting the Company an option for an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age-related diseases (Q2 2020) · Submitted IND application with U.S. FDA supporting an initial indication for the treatment of radiation enteropathy secondary to pelvic cancer therapy (Q2 2020) · Received study-may-proceed letter from U.S. FDA to conduct a Phase 1 single ascending dose study in healthy volunteers, designed to evaluate SYN-020 for safety, tolerability, and pharmacokinetic parameters (Q3 2020)
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV carbapenem antibiotics)	SYN-006 (oral enzyme)	· Identified P2A as a potent carbapenemase that is stable in the GI tract · Manufactured a formulated research lot for oral delivery (2017) · Demonstrated microbiome protection in a pig model of ertapenem administration (Q1 2018) · Reported supporting data demonstrating SYN-006 attenuated emergence of antibiotic resistance genes in a pig model, including those encoding beta-lactamases and genes conferring resistance to a broad range of antibiotics such as aminoglycosides and macrolides (Q1 2019)

Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade oral beta-lactam antibiotics)	SYN-007 (oral enzyme)	· Preclinical work ongoing to expand the utility of SYN-004 (ribaxamase) for use with oral beta-lactam antibiotics · Reported supportive data from a second canine animal model demonstrating that when co-administered with oral amoxicillin and oral Augmentin, oral SYN-007 did not interfere with systemic absorption of antibiotics but did diminish microbiome damage associated with these antibiotics (Q2 2018) · Reported supportive data demonstrating SYN-007 mitigated antibiotic-mediated gut microbiome alterations and maintained gut microbiome integrity when co-administered with oral amoxicillin in a dose-response canine study (Q2 2019) · Reported supportive data demonstrating SYN-007 protected the gut microbiome of dogs from amoxicillin and the beta-lactam/beta-lactamase inhibitor combination amoxicillin/clavulanate and also reduced the emergence of antibiotic resistance in a canine study (Q1 2020)
Prevention and treatment of pertussis	SYN-005 (monoclonal antibody therapies)	· Reported supportive preclinical data demonstrating that an extended half-life version of hu1B7, a component of SYN-005, provided protection from pertussis for five weeks in a neonatal non-human primate study (Q4 2017)

Our Gastrointestinal (GI) and Microbiome-Focused Pipeline

Our SYN-004 (ribaxamase) and SYN-020 clinical programs are focused on the gastrointestinal tract (GI) and the gut microbiome, which is home to billions of microbial species and composed of a natural balance of both “good” beneficial species and potentially “bad” pathogenic species. When the natural balance or normal function of these microbial species is disrupted, a person’s health can be compromised. All of our programs are supported by our growing intellectual property portfolio. We are maintaining and building our patent portfolio through: filing new patent applications; prosecuting existing applications; and licensing and acquiring new patents and patent applications.

Recent Developments

Clinical and Pre-Clinical Update

SYN-004 (ribaxamase) — Prevention of antibiotic-mediated microbiome damage, C. difficile infections (CDI), overgrowth of pathogenic organisms, the emergence of antimicrobial resistance (AMR) and acute graft-versus-host disease (aGVHD) in allogeneic HCT recipients

Phase 1b/2a Clinical Study in Allogeneic HCT Recipients

In August 2019, we entered into a Clinical Trial Agreement (CTA) with the Washington University School of Medicine (Washington University) to conduct a Phase 1b/2a clinical trial of SYN-004 (ribaxamase). Under the terms of this agreement, we will serve as the sponsor of the study and supply SYN-004 (ribaxamase). Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University and a member of the SYN-004 (ribaxamase) steering committee will serve as the principal investigator of the clinical trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

On January 7, 2020, we announced the receipt of official meeting minutes from the FDA following a Type-C meeting held on December 2, 2019 at our request to discuss the development of SYN-004 (ribaxamase) for treatment of allogeneic HCT recipients who are administered IV beta-lactam antibiotics in response to fever. Based on the final meeting minutes, the Phase 1b/2a clinical trial will comprise a single center, randomized, double-blinded, placebo-controlled clinical trial of oral SYN-004 (ribaxamase) in up to 36 evaluable adult allogeneic HCT recipients. The goal of this study is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of 150 mg oral SYN-004 (ribaxamase) administered to allogeneic HCT recipients four times per day who receive an IV beta-lactam antibiotic to treat fever. 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 (ribaxamase) and four will receive placebo. On July 30, 2020 we received written notification from the FDA informing us that they determined the Phase 1b/2a clinical program in adult allogeneic HCT recipients may proceed per the submitted clinical program protocol.

Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee (DSMC), which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic. The clinical trial will also evaluate potential protective effects of SYN-004 (ribaxamase) on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 (ribaxamase) in allogeneic HCT recipients.

Due to the unique challenges posed by the global COVID-19 pandemic, Washington University continues to evaluate non-essential activities, which may have a direct impact on planned and ongoing clinical trials. Initiation of the Phase 1b/2a clinical trial remains largely at their discretion and is contingent upon Washington University's ability to conduct this clinical program free from the impact of COVID-19, and approval from their IRB and the FDA. At this time, we have determined that postponing the initiation of the planned Phase 1b/2a clinical trial in allogeneic HCT recipients until at least the first quarter of 2021 remains the appropriate course of action in the current operating environment. We remain in close contact with Washington University and are actively monitoring the crisis caused by the spread of COVID-19 and its impact to the clinical development plans for our SYN-004 (ribaxamase) program.

SYN-010 — Treatment of Irritable Bowel Syndrome with Constipation (IBS-C)

On September 5, 2018, we entered into an agreement with CSMC for an investigator-sponsored Phase 2b clinical study of SYN-010 to be co-funded by us and CSMC. The Phase 2b study was being conducted out of the Medically Associated Science and Technology (MAST) Program at CSMC and was a 12-week, placebo-controlled, double-blind, randomized clinical trial to evaluate two dose strengths of oral SYN-010 21 mg and 42 mg in as many as 150 patients diagnosed with IBS-C using a breath methane screening level as a criterion for patient enrollment.

The primary objective for the study was to determine the efficacy of SYN-010, measured as an improvement from baseline in the weekly average number of complete spontaneous bowel movements (CSBMs) during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses relative to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 were intended measure changes from baseline in abdominal pain, bloating, stool frequency as well as the use of rescue medication relative to placebo. Exploratory outcomes included Adequate Relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires. Importantly, this study was intended to generate a comprehensive and meaningful data set to provide additional insights and address specific queries into potential SYN-010 clinical efficacy, including dose response, length of treatment and microbiome effects, intended to be evaluated in the FDA-agreed Phase 2b/3 adaptive design clinical program.

Enrollment in this study commenced in January 2019 and was temporarily halted during the first and second quarter of 2020 due to the unique challenges posed by the global COVID-19 pandemic which required CSMC to temporarily limit all non-essential activities, directly impacting their ability to actively recruit and screen new patients. During this time, active study participants who did not complete the study prior to the decision to halt all non-essential activities were given the opportunity to complete the study as CSMC took steps to ensure data from this group was collected in accordance with the clinical trial protocol.

During the third quarter of 2020, a planned interim futility analysis of the Phase 2b investigator-sponsored clinical study was completed. Based on the review of the interim analysis, it was concluded that although SYN-010 was well-tolerated, it failed to meet the prespecified efficacy criteria and was unlikely to meet the primary objective of the study by the time enrollment is completed. On September 30, 2020 CSMC formally agreed to discontinue the study and on November 9, 2020, we and CSMC mutually agreed to terminate the Exclusive License Agreement. CSMC has been unblinded and intends to conduct a comprehensive review of the data set and publish its findings.

SYN-020 — Oral Intestinal Alkaline Phosphatase

SYN-020 is a quality-controlled, recombinant version of bovine Intestinal Alkaline Phosphatase (IAP) produced under cGMP conditions and formulated for oral delivery. The published literature indicates that IAP functions to diminish GI inflammation, tighten the gut barrier to diminish "leaky gut," promote a healthy microbiome, and diminish GI and systemic inflammation. Based on these known mechanisms as well as our own supporting animal model data, we are initially developing SYN-020 to mitigate the intestinal damage caused by radiation therapy that is routinely used to treat pelvic cancers, including the treatment and prevention of radiation enteropathy secondary to cancer therapy. Despite its broad therapeutic potential, a key hurdle to commercialization has been the high cost of IAP manufacture which is commercially available for as much as $10,000 per gram. We believe we have developed technologies to traverse this hurdle and now have the ability to produce more than 3 grams per liter of SYN-020 for roughly a few hundred dollars per gram at commercial scale.

On June 30, 2020, we submitted an Investigational New Drug (IND) application to the FDA in support of an initial indication for the treatment of radiation enteropathy secondary to pelvic cancer therapy. On July 30, 2020 we announced that we received a study-may-proceed letter from the FDA to conduct a Phase 1 single ascending dose study in healthy volunteers designed to evaluate SYN-020 for safety, tolerability and pharmacokinetic parameters. The Phase 1 clinical program is anticipated to commence during the first quarter of 2021 and is intended to support the clinical development of SYN-020 for multiple indications.

During the second quarter of 2020, we also announced that we entered into an agreement with Massachusetts General Hospital ("MGH") granting us an option for an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age-related diseases. Research published by a team of investigators led by Richard Hodin, MD, Chief of the Massachusetts General Hospital Division of General and Gastrointestinal Surgery and Professor of Surgery, Harvard Medical School, evaluated long-term oral supplementation of IAP, including SYN-020, in mice. Dr. Hodin's research demonstrated that IAP administration, starting at 10 months of age, slowed the microbiome changes, gut-barrier dysfunction, and gastrointestinal and systemic inflammation that normally accompany aging. Additionally, the IAP administration resulted in improved metabolic profiles in the aged mice, diminished frailty, and extended lifespan. Under the terms of the agreement, we are granted exclusive rights to negotiate a worldwide license with MGH to commercially develop SYN-020 to treat and prevent metabolic and inflammatory diseases associated with aging. If executed, we plan to use this license in the advancement of an expanded clinical development program for SYN-020. In addition, we continue to explore and evaluate potential future indications that have been associated with decreased IAP expression and intestinal barrier dysfunction. Such potential indications include inflammatory bowel disease (IBD) and celiac disease, as well as metabolic syndrome and associated non-alcoholic fatty liver-disease (NAFLD).

Intellectual Property

All of our programs are supported by growing patent estates that we either own or exclusively license. Each potential product has issued patents that provide protection. In total, we have over 90 U.S. and foreign patents and over 70 U.S. and foreign patents pending. The SYN-004 (ribaxamase) program is supported by IP that is assigned to Synthetic Biologics, namely U.S. patents and foreign patents (in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others) and U.S. and foreign patents pending in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others). For instance, U.S. Patent Nos. 8,894,994 and 9,587,234, which include claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004 (ribaxamase), have patent terms to at least 2031. Further, U.S. Patent 9,301,995 and 9,301,996, both of which will expire in 2031, cover various uses of beta-lactamases, including SYN-004 (ribaxamase), in protecting the microbiome, and U.S. Patent Nos. 9,290,754, 9,376,673, 9,404,103, 9,464,280, and 9,695,409 which will expire in at least 2035, covers further beta-lactamase compositions of matter related to SYN-004 (ribaxamase).

Our goal is to (i) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (ii) preserve our trade secrets, and (iii) operate without infringing on the proprietary rights of other parties worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

Critical Accounting Policies

The condensed consolidated financial statements are prepared in conformity with U.S. GAAP, which requires the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses in the periods presented. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods. The critical accounting estimates that affect the condensed consolidated financial statements and the judgments and assumptions used are consistent with those described under Part II, Item 7 of our 2019 Form 10-K.

Results of Operations

Three Months Ended September 30, 2020 and 2019

General and Administrative Expenses

General and administrative expenses increased by 9% to $1.2 million for the three months ended September 30, 2020, from $1.1 million for the three months ended September 30, 2019. This increase is primarily due to increased insurance costs and stock registration fees, offset by a decrease in legal costs. The charge related to stock-based compensation expense was $67,000 for the three months ended September 30, 2020, compared to $68,000 the three months ended September 30, 2019.

Research and Development Expenses

Research and development expenses decreased by 78% to $0.9 million for the three months ended September 30, 2020, from $4.1 million for the three months ended September 30, 2019. This decrease is primarily the result of the response to the global COVID-19 pandemic by our clinical development partners which led to the postponement of the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients as well as the discontinuation of the Phase 2b investigator sponsored clinical trial of SYN-010. The charge related to stock-based compensation expense was $15,000 for the three months ended September 30, 2020, compared to $23,000 for the three months ended September 30, 2019.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended September 30, 2020 and 2019. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development expenses related to employee costs, facilities, stock-based compensation and research and development support services that are not directly allocated to specific drug candidates.

Therapeutic Areas ***(in thousands)***	**September 30, 2020**	**September 30, 2019**
SYN-004 (ribaxamase	$ 76	$ 73
SYN-010	45	174
SYN-005	1	7
Total direct costs	122	254
Total indirect costs	792	3,890
Total	$ 914	$ 4,144

Other Income/Expense

Other income was $134 for the three months ended September 30, 2020, compared to other income of $92,000 for the three months ended September 30, 2019. Other income for the three months ended September 30, 2020 and 2019 is primarily comprised of interest income.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was $2.7 million, or $0.14 per basic and dilutive common share for the three months ended September 30, 2020, compared to a net loss of $5.3 million, or $0.31 per basic common share and dilutive common share for the three months ended September 30, 2019. Net loss attributable to common stockholders for the three months ended September 30, 2020 excludes net loss attributable to non-controlling interest of $8,000 and includes the accretion of Series B preferred discount of $519,000 on converted shares and Series A Preferred Stock accrued dividends of $64,000. Net loss attributable to common stockholders for the three months ended September 30, 2019 excludes net loss attributable to non-controlling interest of $30,000 and includes the accretion of Series B preferred discount of $70,000 on converted shares and $63,000 of Series A accrued dividends.

Nine Months Ended September 30, 2020 and 2019

General and Administrative Expenses

General and administrative expenses increased by 18% to $3.9 million for the nine months ended September 30, 2020, from $3.3 million for the nine months ended September 30, 2019. This increase is primarily due to increased legal costs related to business development, patent execution, employee contract matters, vacation expense, insurance costs and registration fees. The charge related to stock-based compensation expense was $199,000 for the nine months ended September 30, 2020, compared to $193,000 for the nine months ended September 30, 2019.

Research and Development Expenses

Research and development expenses decreased by 55% to $4.1 million for the nine months ended September 30, 2020, from $9.2 million for the nine months ended September 30, 2019. This decrease is primarily the result of the response to the global COVID-19 pandemic by our clinical development partners which led to the postponement of the Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients and a temporary the discontinuation of the Phase 2b investigator sponsored clinical trial of SYN-010. Research and development expenses also include a charge relating to stock-based compensation expense of $52,000 for the nine months ended September 30, 2020, compared to $53,000 for the nine months ended September 30, 2019.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the nine months ended September 30, 2020 and 2019. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development expenses related to employee costs, facilities, stock-based compensation and research and development support services that are not directly allocated to specific drug candidates.

Therapeutic Areas *(in thousands)*	**September 30, 2020**	**September 30, 2019**
SYN-010	$ 293	$ 426
SYN-004 (ribaxamase)	181	185
Other therapeutic areas	30	23
Total direct costs	504	634
Total indirect costs	3,648	8,522
Total	$ 4,152	$ 9,156

Other Income

Other income was $44,000 for the nine months ended September 30, 2020, compared to other income of $217,000 for the nine months ended September 30, 2019. Other income for the nine months ended September 30, 2020 and 2019 is primarily comprised of interest income.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was $9.4 million, or $0.52 per basic and dilutive common share for the nine months ended September 30, 2020, compared to a net loss of $12.9 million, or $0.79 per basic common share and dilutive common share for the nine months ended September 30, 2019. Net loss attributable to common stockholders for the nine months ended September 30, 2020 excludes net loss attributable to non-controlling interest of $50,000 and includes the accretion of Series B preferred discount of $1.3 million on converted shares and Series A Preferred Stock accrued dividends of $189,000. Net loss attributable to common stockholders for the nine months ended September 30, 2019 excludes net loss attributable to non-controlling interest of $73,000 and includes the accretion of Series B preferred discount of $585,000 on converted shares and $185,000 of Series A accrued dividends.

Liquidity and Capital Resources

With the exception of the three months ended June 30, 2010 and the three months ended December 31, 2017, we have experienced significant losses since inception, incurred negative cash flows from operations, and have a significant accumulated deficit. We have incurred an accumulated deficit of $245 million as of September 30, 2020 and expect to continue to incur losses in the foreseeable future. Our ability to continue as a going concern is dependent upon our ability to raise additional debt and equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us. These factors raise substantial doubt about our ability to continue as a going concern.

We do not have sufficient capital to fund our operations beyond the next twelve months. In order to address our capital needs, including our planned clinical trials, we are actively pursuing additional equity or debt financing in the form of either a private placement or a public offering. We have been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. Such additional financing opportunities might not be available to us when and if needed, on acceptable terms or at all. If we are unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, our operating results and prospects will be adversely affected.

Our cash and cash equivalents totaled $6.0 million as of September 30, 2020, a decrease of $9.0 million from December 31, 2019. During the three months ended September 30, 2020, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $2.1 million for the three months ended September 30, 2020. With the cash available in early November 2020, we believe these resources will be sufficient to fund our operations through at least the end of the first quarter of 2021.

As a result of the global COVID-19 pandemic, management has been able to further extend our cash runway since our clinical development partners CSMC and Washington University) reduced their operating capacity when necessary during 2020 to include only essential activities, which excluded all planned and ongoing clinical trials of SYN-004 and SYN-010. However, this reduction in operating activity has adversely impacted our planned clinical trial timelines. We anticipate reduced research and development costs through the end of the year, since we anticipate that our proposed Phase 1b/2a clinical trial to be conducted by Washington University will be postponed until 2021, subject to further COVID-19 developments.

On September 30, 2020, CSMC agreed to discontinue the ongoing Phase 2b investigator-sponsored clinical study of SYN-010 following the results of a planned interim futility analysis. Although it was concluded that SYN-010 was well tolerated, it was also concluded that SYN-010 is unlikely to meet its primary endpoint by the time enrollment is completed. As a result, the Company anticipates additional reductions in clinical development expense during the remainder of 2020 due to the discontinuation of this clinical study.

We anticipate our current cash will allow us to cover overhead costs, manufacturing costs for clinical supply, commercial scale up costs and limited research efforts, including completing our funding requirements for the initiation of the Phase 1b/2a SYN-004 (ribaxamase) clinical trial and the planned Phase 1 single ascending dose (SAD) study of SYN-020. Due to the unique challenges posed by the global COVID-19 pandemic, we have determined that postponing the commencement of the planned Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients until the first quarter of 2021 remains the appropriate response to the novel coronavirus pandemic. We do not anticipate any additional expense related to the Phase 1b/2a SYN-004 (ribaxamase) clinical trial until the trial is cleared for commencement by Washington University. Commencement of a future Phase 3 clinical trial of SYN-004 remains subject to our successful pursuit of opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete our plan. We will be required to obtain additional funding in order to continue the development of our current product candidates beyond our planned Phase 1b/2a clinical study of SYN-004 in allogeneic HCT recipients, the planned Phase 1 SAD study of SYN-020 in healthy volunteers within the anticipated time periods, if at all, and to continue to fund operations at the current cash expenditure levels. Currently, we do not have commitments from any third parties to provide us with capital. If we fail to obtain additional funding for our clinical trials, whether through the sale of securities or a partner or collaborator, and otherwise when needed, we will not be able to fully execute our business plan as planned and we will be forced to cease certain development activities until funding is received and our business will suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the COVID-19 pandemic, including uncertainty regarding our clinical timelines, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Historically, we have financed our operations primarily through public and private sales of our securities, and we expect to continue to seek to obtain our required capital in a similar manner. During the year ended December 31, 2019 and the nine months ended September 30, 2020, we did not engage in any financing activity as our financings conducted during the year ended December 31, 2018 were sufficient to satisfy our cash needs during 2019 and the nine months ended September 30, 2020. During the year ended December 31, 2018, our only sources of funding were from our underwritten public offering (the "Offering") described below pursuant to which we received net proceeds of approximately $16.7 million and sales of 3.5 million shares of our Common Stock in our at-the-market offering program through the FBR Sales Agreement pursuant to which we received net proceeds of approximately $12.2 million. The FBR Sales Agreement enables us to offer and sell shares of our Common Stock from time to time through FBR Capital Markets & Co. as our sales agent, provided that we meet certain conditions. Sales of Common Stock under the FBR Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act. FBR Capital Markets & Co. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of our Common Stock sold on our behalf.

On October 15, 2018, we closed the Offering pursuant to which we received gross proceeds of approximately $18.6 million before deducting underwriting discounts, commissions and other offering expenses payable by us and sold an aggregate of (i) 2,520,000 Class A Units (the "Class A Units"), with each Class A Unit consisting of one share of Common Stock, and one five-year warrant to purchase one share of Common Stock at an exercise price of $1.38 per share (the "October 2018 Warrants"), with each Class A Unit offered to the public at a public offering price of $1.15, and (ii) 15,723 Class B Units (the "Class B Units), with each Class B Unit offered to the public at a public offering price of $1,000 per Class B Unit and consisting of one share of our Series B Convertible Preferred Stock (the "Series B Preferred Stock"), with a stated value of $1,000 and convertible into shares of Common Stock at the stated value divided by a conversion price of $1.15 per share, with all shares of Series B Preferred Stock convertible into an aggregate of 13,672,173 shares of Common Stock, and issued with an aggregate of 13,672,173 October 2018 Warrants. A.G.P./Alliance Global Partners (the "Underwriters") acted as sole book-running manager for the Offering. In addition, pursuant to the Underwriting Agreement that we entered into with the Underwriters on October 10, 2018, we granted the Underwriters a 45 day option (the "Over-allotment Option") to purchase up to an additional 2,428,825 shares of Common Stock and/or additional October 2018 Warrants to purchase an additional 2,428,825 shares of Common Stock. The Underwriters partially exercised the Over-allotment Option by electing to purchase from us additional October 2018 Warrants to purchase 1,807,826 shares of Common Stock. The Units were offered by us pursuant to a registration statement on Form S-1 (File No. 333-227400), as amended, filed with the SEC, which was declared effective by the SEC on October 10, 2018. As of December 31, 2019, 8,085 shares of Series B Preferred Stock have been converted to Common Stock and 7,638 shares of Series B Preferred Stock remain outstanding.

We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development efforts, preparation for our planned clinical trials, performance of clinical trials and our research and discovery efforts. Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our long-term expected plans as it is anticipated that we will not have enough cash to continue our operations beyond the next twelve months. We will be required to obtain additional funding in order to continue the development of certain product candidates within the anticipated time periods, if at all, and to continue to fund operations at the current cash expenditure levels.

Our ability to continue as a going concern is dependent upon our ability to raise additional capital. Our cash and cash equivalents will not be sufficient to enable us to meet our long-term expected plans, including initiation or completion of a future potential Phase 3 clinical program of SYN-004 (ribaxamase) for prevention of CDI and/or the prevention of aGVHD in allogeneic HCT recipients, or later-stage clinical trials of SYN-020. Therefore, we do not intend to commence future Phase 3 clinical programs of SYN-004 (ribaxamase) for prevention of CDI and/or the prevention of aGVHD in allogeneic HCT recipients, or later-stage clinical trials of SYN-020 until we are confident that we have funding necessary to complete such trials. We are actively pursuing additional equity or debt financing, in the form of either a private placement or a public offering and have been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. However, we do not currently have commitments from any third parties to provide us with capital. Potential sources of financing that we are pursuing include strategic relationships, public or private sales of our equity (including through the FBR Sales Agreement) or debt and other sources. Such additional financing opportunities might not be available to the Company when and if needed, on acceptable terms or at all. We cannot assure that we will meet the requirements for use of the FBR Sales Agreement especially in light of the fact that we are currently limited by rules of the SEC as to the number of shares of Common Stock that we can sell pursuant to the FBR Sales Agreement due to the market value of our Common Stock held by non-affiliates. Even if we meet the requirements for use of the FBR Sales Agreement, there can be no assurance that we will be able to continue to raise funds through the sale of shares of Common Stock through the FBR Sales Agreement. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. If we are unable to obtain additional capital (which is not assured at this time), our long-term business plan may not be accomplished and we may be forced to cease certain development activities. More specifically, the completion of future Phase 3 and/or registrational clinical studies will require significant financing or a significant partnership. If we raise funds by selling additional shares of Common Stock or other securities convertible into Common Stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain funding for future clinical trials when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of future clinical trials until such time as we obtain adequate financing and our operating results and prospects will be adversely affected.

Following the completion of our planned Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients and planned Phase 1 SAD study of SYN-020, we will need to obtain additional funds for future clinical trials. We anticipate that our future clinical trials will be much larger in size and require larger cash expenditures than the current planned Phase 1b/2a clinical trial of SYN-004 (ribaxamase) to be conducted by Washington University and Phase 1 SAD study of SYN-020 IAP. We do not have any committed sources of financing for future clinical trials at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all.

On January 30, 2020, the World Health Organization (WHO) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the COVID-19 outbreak) and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. As the COVID-19 coronavirus continues to spread around the globe, we have experienced disruptions that impact our business and clinical trials, including halting the enrollment of new patients in our ongoing Phase 2b investigator-sponsored clinical trial of SYN-010 clinical study and postponement of clinical site initiation of the Phase 1b/2a clinical trial of SYN-004. The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations. We are actively monitoring the global situation and its potential impact on our financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, we are not able to estimate the future effects of the COVID-19 outbreak on our results of operations, financial condition, or liquidity.

Off-Balance Sheet Arrangements

During the three and nine months ended September 30, 2020, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Contractual Obligations

Leases

At the inception of a contract we determine if the arrangement is, or contains, a lease. Right-of-use ("ROU") assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term.

We have made certain accounting policy elections whereby we (i) do not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases. ROU assets are included in other noncurrent assets and lease liabilities are included in other current and non-current liabilities in our condensed consolidated balance sheets. As of September 30, 2020, we did not have any material finance leases.

PART II–OTHER INFORMATION

ITEM 6. EXHIBITS

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q/A are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q/A (Amendment No. 1) to be signed on its behalf by the undersigned thereunto duly authorized.

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Executive Officer, Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: November 12, 2020

EXHIBIT INDEX

Exhibit Number	Exhibit Title
10.1	Termination of Exclusive License Agreement, effective November 9, 2020, by and among Cedars- Sinai Medical Center, Synthetic Biologics, Inc. and Synthetic Biomics, Inc.**
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)**
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
31.2	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)*
32.2	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS	XBRL Instance Document**
101.SCH	XBRL Taxonomy Extension Schema**
101.CAL	XBRL Taxonomy Extension Calculation Linkbase**
101.DEF	XBRL Taxonomy Extension Definition Linkbase**
101.LAB	XBRL Taxonomy Extension Label Linkbase**
101.PRE	XBRL Taxonomy Extension Presentation Linkbase**

*Filed herewith.
** Previously filed with the Company's Quarterly Report on Form 10-Q (File No. 001-12584) filed with the SEC on November 10, 2020.

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven A. Shallcross, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q/A (Amendment No. 1) of Synthetic Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 12, 2020

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Chief Executive Officer, Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Synthetic Biologics, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Quarterly Report on Form 10-Q/A (Amendment No. 1) of the Registrant for the quarter ended September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 12, 2020

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Chief Executive Officer, Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)