UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 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 Number)*
9605 Medical Center Drive, Ste. 270 Rockville, MD	20850
(Address of Principal Executive Offices)	*(Zip Code)*

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

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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ¨ No x

Indicate by check mark whether the issuer: (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 x 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 (section 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 x 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. (Check one):

Large Accelerated Filer ¨	Accelerated Filer ¨
Non-accelerated Filer x	Smaller Reporting Company x
	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ¨

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

Yes ¨ No x

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2020, the last business day of the registrant's recently completed second quarter, was approximately $8.46 million based on $0.51, the closing price of the registrant's common stock as reported by the NYSE American on that date.

As of March 3, 2021, the registrant had 129,654,575 shares of common stock outstanding.

Documents incorporated by reference: None

SYNTHETIC BIOLOGICS, INC.

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PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") 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"), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases you can identify forward-looking statements by

terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements.

You should refer to Item 1A. "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake any obligation to update any forward-looking statements.

Unless the context requires otherwise, references to "we," "us," "our," and "Synthetic Biologics," refer to Synthetic Biologics, Inc. and its subsidiaries.

Summary Risk Factors

The following is a summary of the key risks relating to the Company. A more detailed description of each of the risks can be found below under Item 1A. Risk Factors.

Business Risks

- We will need to raise additional capital and may be unable to raise the necessary capital to operate our business or obtain funding on acceptable terms or at all, which may reduce or eliminate our development programs or commercialization efforts.

- The continued impact of the COVID-19 (coronavirus) pandemic on our planned operations and clinical studies.

- We have a history of incurring substantial losses and negative operating cash flow and expect to continue to incur significant operating and capital expenditures.

- We have no significant sources of revenue and may never generate significant revenue.

- Our research and development efforts may not succeed in developing a commercially successful product or technology.

- We are largely dependent on the success of our lead product candidates, SYN-004 and SYN-020, which require significant additional clinical testing before we can seek regulatory approval and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

- We may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products.

- We face strong competition and may not be able to compete effectively and our competitors may develop and/or gain FDA approval of our product candidates for a different indication.

- Our ability to develop, manufacture and market our product candidates may be delayed or impaired for reasons that are beyond our control due to our reliance on third party suppliers for raw materials and services.

- We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

- We rely extensively on our information technology systems and are vulnerable to damage and interruption and any failure to maintain the security of information relating to our customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

Regulatory Risks

- We may not be able to obtain the necessary regulatory approvals in the U.S. and/or other countries.

- Clinical trials are expensive, time consuming, and difficult to design and implement, and may return results that may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.

- We may have difficulties in enrolling patients in our clinical trials, or experience delays in enrollment, which could result in increased costs and/or delay our ability to generate revenue.

- Patients who are administered our product candidates may experience unexpected side effects or other safety risks that could cause a halt in their clinical development, preclude approval of our product candidates or limit their commercial potential.

- Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

- We currently have no marketing, sales or distribution organization and have no experience in marketing products as a company. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

Intellectual Property Risks

- If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

- We rely on patent applications and various regulatory exclusivities to protect some of our product candidates and our ability to compete may be limited or eliminated if we are not able to protect our products, additionally, litigation or other proceedings relating to protecting our intellectual property is costly and time consuming.

Risks Related To our Securities

- Our failure to regain compliance with the NYSE American stockholders' equity listing requirements or failure to continue to meet the other listing requirements could result in a de-listing of our common stock.

- We expect to seek to raise additional capital in the future, which may be dilutive to stockholders or impose operational restrictions.

- The market price of our common stock has been and may continue to be volatile and adversely affected by various factors.

COVID-19 Update

We are continuing to assess the potential impact of the COVID-19 pandemic. We are in close contact with our clinical development partners in order to assess the impact of COVID-19 on our studies and current timelines and costs. While we currently do not anticipate any interruptions in our operations due to COVID-19, it is possible that if the COVID-19 pandemic persists for an extended period of time, we could experience significant disruptions to our clinical development timelines due to the COVID-19 pandemic, 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 full extent to which the COVID-19 outbreak will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted. 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.

Item 1. *Business*

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 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.

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) designed to prevent

aGVHD and infection by vancomycin resistant enterococci and SYN-007 (ribaxamase) DR designed 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 Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Current Status
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 Food and Drug Administration (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) • Identified potential additional indications in specialty patient populations such as allogeneic hematopoietic cell transplant (HCT) 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 hematopoietic cell transplant (HCT) recipients may proceed per the submitted clinical program protocol (Q3 2020) • Received approval from the Institutional Review Board (IRB) at Washington University to commence the Phase 1b/2a clinical trial in allogeneic HCT recipients (Q4 2020) • Washington University has begun screening patients for enrollment of the first of three antibiotic cohorts for the Phase 1b/2a clinical trial of SYN-004 in adult HCT recipients (Q1 2021).

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) • A Phase 1 single-ascending-dose (SAD) study is expected to commence during the second quarter of 2021. A topline data readout is anticipated during the third quarter of 2021, pandemic conditions permitting.
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 in a pig model, including encoded 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.

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

SYN-004 (ribaxamase) is a proprietary oral capsule prophylactic therapy designed to degrade certain IV beta-lactam antibiotics excreted into the GI tract and thereby maintain the natural balance of the gut microbiome. Preventing beta-lactam damage to the gut microbiome has a range of potential therapeutic outcomes, including prevention of CDI, suppression of the overgrowth of pathogenic species (particularly antimicrobial-resistant organisms) and potentially reducing the incidence of acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) patients. SYN-004 (ribaxamase) is a beta-lactamase enzyme intended to be co-administered with certain IV beta-lactam antibiotics as two-75 mg capsules which, when released in the proximal small intestine, has been shown to degrade beta-lactam antibiotics in the GI tract without altering systemic antibiotic levels. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics.

Clostridioides difficile Infection

Clostridioides difficile (formerly known as *Clostridium difficile* and often called *C. difficile* or CDI) is the leading type of hospital acquired infection and is frequently associated with IV beta-lactam antibiotic treatment. The Centers for Disease Control and Prevention (CDC) identified *C. difficile* as an "urgent public health threat," particularly given its resistance to many drugs used to treat other infections. CDI is a major unintended risk associated with the prophylactic or therapeutic use of IV antibiotics, which may adversely alter the natural balance of microflora that normally protect the GI tract, leading to *C. difficile* overgrowth and infection. Other risk factors for CDI include hospitalization, prolonged length of stay (estimated at 7 days), underlying illness, and immune-compromising conditions including the administration of chemotherapy and advanced age. According to a paper published in BMC Infectious Diseases (Desai K et al. BMC Infect Dis. 2016; 16: 303) the economic cost of CDI was approximately $5.4 billion in 2016 ($4.7 billion in healthcare settings; $725 million in the community) in the U.S., mostly due to hospitalizations.

Limitations of Current Treatments and Market Opportunity

CDI is a widespread and often drug resistant infectious disease. Approximately 20% of patients who have been diagnosed with CDI experience a recurrence of CDI within one to three months. Furthermore, controlling the spread of CDI has proven challenging, as the *C. difficile* spores are easily transferred to patients via normal contact with healthcare personnel and with inanimate objects. There is currently no vaccine or approved product for the prevention of primary (incident) CDI. The current standard of care for primary CDI, as outlined by the Infectious Disease Society of America (IDSA), is to treat with powerful antibiotics such as fidaxomicin or vancomycin. Prolonged use of fidaxomicin and vancomycin has been shown to further exacerbate damage to the gut microbiome, leading to increased risk of CDI recurrence as well as the emergence of pathogenic and antimicrobial-resistant (AMR) organisms, such as vancomycin-resistant enterococci (VRE). AMR is a serious global threat and one which world leaders have begun to take action against. According to the European Society of Clinical Microbiology and Infections Disease (ECCMID), failure to address AMR could lead to a potential antibiotic Armageddon, resulting in 10 million deaths worldwide by 2050 and may cost as much as $100 trillion in worldwide economic output.

According to a paper published in BMC Infectious Diseases (Desai K (2016) Epidemiological and economic burden of *Clostridium difficile* in the United States: estimates from a modeling approach. BMC Infect Dis 16: 303), it is estimated that approximately 606,000 patients are infected with *C. difficile* annually in the U.S., and it has been reported that approximately 44,500 deaths are attributable to CDI-associated complications each year. According to IMS Health Incorporated*, in 2016, the potential addressable market for SYN-004 (ribaxamase) included approximately 227 million doses of intravenous Penicillin and Cephalosporin antibiotics which were administered in the United States and which may contribute to the onset of CDI. Additional data derived from IMS Health Incorporated states that in 2016, the worldwide market for SYN-004 (ribaxamase)-addressable intravenous beta-lactam antibiotics was approximately 7.5 billion doses, which may represent a multi-billion-dollar market opportunity for us. If approved, SYN-004 (ribaxamase) would be the first therapeutic intervention indicated to prevent the onset of antibiotic-

mediated primary CDI.

Phase 1a and 1b Clinical Trial Pharmacokinetic Data

In March 2015, we reported supportive pharmacokinetic data from a Phase 1a clinical trial, which suggested that SYN-004 (ribaxamase) should have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection. In February 2015, we reported supportive topline results from a subsequent Phase 1b clinical trial of escalating doses of oral SYN-004 (ribaxamase), with no safety or tolerability issues reported at dose levels and dosing regimens that were equivalent to or exceeded those expected to be studied in subsequent clinical trials. The Phase 1a (40 participants) and 1b (24 participants) clinical trials of SYN-004 (ribaxamase) were initiated in December 2014.

Two Phase 2a Clinical Trials: Topline Results

In December 2015, we reported supportive topline results from our first Phase 2a clinical trial of SYN-004 (ribaxamase). The study demonstrated that SYN-004 (ribaxamase) successfully degraded IV ceftriaxone in the chyme of ten participants with ileostomies without affecting the levels of ceftriaxone in the bloodstream. In May 2016, we reported supportive topline results from a second Phase 2a clinical trial of SYN-004 (ribaxamase) in 14 healthy participants with functioning ileostomies administered IV ceftriaxone with and without oral SYN-004 (ribaxamase). This second study demonstrated that the 150 mg dose of SYN-004 (ribaxamase), both alone and in the presence of the proton pump inhibitor (PPI), esomeprazole, degraded ceftriaxone excreted into the chyme resulting in ceftriaxone levels that were low or not-detectable. Ceftriaxone plasma concentrations in participants of the second study were not altered by SYN-004 (ribaxamase) in the presence or absence of an oral PPI, suggesting limited drug-drug interactions. The 150 mg dose strength of SYN-004 (ribaxamase) was well tolerated by all participants in this clinical trial.

Phase 2b Proof of Concept Clinical Trial Design & Results

In September 2015, we initiated a multicenter, randomized, placebo-controlled Phase 2b proof-of-concept clinical study in 412 patients (206 per group).

On January 5, 2017, we announced positive topline data from our Phase 2b proof-of-concept clinical trial intended to evaluate the ability of SYN-004 (ribaxamase) to prevent CDI, CDAD (*C. difficile*-associated diarrhea) and AAD (antibiotic-associated diarrhea) in patients hospitalized for a lower respiratory tract infection and receiving IV ceftriaxone. Results from this study demonstrated that SYN-004 (ribaxamase) achieved its primary endpoint of significantly reducing CDI. Preliminary analysis of the data indicated seven confirmed cases of CDI in the placebo group compared to two cases in the SYN-004 (ribaxamase) treatment group. Patients receiving SYN-004 (ribaxamase) achieved a 71.4% relative risk reduction (p-value=0.045) in CDI rates compared to patients receiving placebo. SYN-004 (ribaxamase) treated patients also demonstrated a significant reduction in new colonization by vancomycin-resistant enterococci (VRE) compared to placebo (p-value=0.002). Results from this trial also demonstrated that patients administered ribaxamase in conjunction with IV-ceftriaxone demonstrated comparable cure rates (approximately 94%) for the treatment of primary infection compared to the placebo group. Results from this trial also demonstrated that the percentage of subjects reporting at least one treatment emergent adverse event (TEAE) was similar between SYN-004 (ribaxamase) and placebo treatment groups (40.8% vs 44.2%). Adverse events reported during this trial were comparable between treatment and placebo arms. Serious adverse events (SAEs) in the treatment arm, including fatal AEs which exceeded those in the placebo arm, were not considered drug-related by investigators at the clinical sites, or by an independent third-party, each of whom determined SAEs were attributable to disparities in the underlying health and comorbidities between the groups.

* This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: IMS Health Analytics for the full year 2016. IMS expressly reserves all rights, including rights of copying, distribution, and republication.

On October 6, 2016 we were awarded a government contract in the amount of $521,014 by the CDC's Broad Agency Announcement (BAA) 2016-N-17812 to examine changes in the gut resistome of patients in our Phase 2b clinical study. Data generated under this contract are consistent with SYN-004's (ribaxamase) mode of action of preserving the normal gut flora by degrading ceftriaxone in the upper GI tract of study participants treated with SYN-004 (ribaxamase). The data further demonstrated that SYN-004 (ribaxamase) significantly reduced the loss of microbial diversity, reduced overgrowth of opportunistically pathogenic species, and reduced the emergence of antimicrobial resistance (AMR) genes (such as VRE) caused by ceftriaxone treatment in SYN-004 (ribaxamase) treated patients compared to placebo.

Future Planning and Potential Regulatory Strategy for Prevention of Primary CDI

On November 21, 2018, we announced results from our End-of-Phase 2 meeting with the FDA during which key elements of a Phase 3 clinical program were confirmed. Pursuant to the meeting, the FDA proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval of SYN-004 (ribaxamase) on the basis of a single Phase 3 clinical trial. The proposed SYN-004 (ribaxamase) Phase 3 clinical program will entail a single, global, event-driven clinical trial with a fixed maximum number of approximately 4,000 patients for total enrollment and will evaluate the potential efficacy and safety of ribaxamase in a broad patient population by enrolling patients with a variety of underlying infections treated with a range of IV beta-lactam antibiotics.

The primary efficacy endpoint of this Phase 3 clinical trial will be the reduction in the incidence of CDI at one month after the last drug dose in the SYN-004 (ribaxamase) treatment group versus placebo. We expect the clinical development costs to complete this trial to be in excess of $80 million and anticipate initiating the Phase 3 clinical program only after securing additional potential financing via a strategic partnership.

Acute Graft-Versus-Host-Disease in Allogeneic Hematopoietic Cell Transplant (allogeneic HCT) Recipients & SYN-004 (ribaxamase)

In parallel with our clinical and regulatory efforts, we completed a Health Economics Outcomes Research (HEOR) study, which was conducted to generate key insights on how we can expect Health Care Practitioners, or HCPs, to evaluate patient access for SYN-004 (ribaxamase) while also providing a framework for potential reimbursement strategies. After evaluating findings from the study, we believe that there is significant potential value in exploring the development of SYN-004 (ribaxamase) in a narrower patient population where the incidence of the disease endpoint is high and the clinical development may be less costly.

We believe allogeneic hematopoietic cell transplant (HCT) recipients, who have a very high risk of CDI, VRE colonization and potentially fatal bacteremia, and acute-graft-vs-host disease (aGVHD) represent such a patient population. Published literature has demonstrated a strong association between these adverse outcomes and microbiome damage caused by IV beta-lactam antibiotics in these patients. Approximately 80-90% of HCT recipients receive IV beta-lactam antibiotics to treat febrile neutropenia. Penicillins and cephalosporins are first-line therapies in the USA and EU, whereas carbapenems are first-line in China. Antibiotic-mediated damage to the gut microbiome is strongly associated with GVHD, bloodstream infections, VRE bacteremia, transplant relapse, and increased mortality in HCT recipients, raising concern over the spectrum of antibiotics used during HCT.

CDI occurs in up to 31% of HCT patients and is associated with GVHD and increased mortality. aGVHD occurs in 30-60% of allogeneic HCT recipients and is recognized as a primary contributor to morbidity and mortality in this patient population. In 2018, there were approximately 9,000 reported allogeneic HCT procedures in the USA, an estimated 19,800 procedures in Europe, 9,600 in China, and 3,500 in Japan. First-line treatments for aGVHD fail in more than 50% of patients and 2-year survival in patients with steroid refractory aGVHD is only 20%. At least one U.S. study found allogeneic HCT recipients who developed aGVHD had 3-times higher in-hospital mortality and almost 2-fold higher median hospital costs than patients who did not develop aGVHD. It has been reported that in-patient costs for allogeneic HCT in the USA range from $180,000-$300,000 depending on the disease severity. In 2014, all-cause costs for allogeneic HCT in the USA were greater than $600,000 per patient (up to 12 months post-transplant). VRE infection is a persistent problem in HCT patients and VRE colonization after HCT has been associated with decreased patient survival.

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. 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.

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. On December 22, 2020, we announced we received approval from the Institutional Review Board (IRB) at Washington University to commence the Phase 1b/2a clinical trial of SYN-004. During the first quarter of 2021, Washington University began screening patients for enrollment of the first of three antibiotic cohorts in the Phase 1b/2a clinical trial of SYN-004 in allogeneic HCT recipients. If enrollment proceeds as planned, we may be positioned to announce as many as three interim data readouts during the next 12-18 months with the first one anticipated from the first antibiotic cohort towards the end of 2021, pandemic conditions permitting.

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. Continuation of the Phase 1b/2a clinical trial including, but not limited to, the enrollment of new patients remains largely at the discretion of Washington University and is contingent upon their ability to conduct this clinical program free from the impact of COVID-19. 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-020 — Oral Intestinal Alkaline Phosphatase (IAP)

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. 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. Based on the known mechanisms as well as our own supporting animal model data, we intended to initially develop 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. And, while we believe SYN-020 may play a pivotal role in addressing acute and long-term complications associated with radiation exposure to the GI tract, we have begun planning to develop SYN-020 in indications that may offer a more accelerated or streamlined pathway to registration while also addressing significant unmet medical needs. Such indications include, celiac disease, non-alcoholic fatty liver disease ("NAFLD"), and indications supported by our collaboration with Massachusetts General Hospital ("MGH"). Across the six major markets, the total prevalent cases of celiac disease are expected to increase from 5.8 million cases in 2013 to an expected 8.1 million cases in 2023, representing an annual growth rate of approximately 4%. During the same period, prevalent cases in the U.S. are expected to increase from 2.8 million in 2013 to an expected 4.3 million in 2023, representing a significant market opportunity.

On June 30, 2020, we submitted an 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 ("SAD") study in healthy volunteers designed to evaluate SYN-020 for safety, tolerability and pharmacokinetic parameters. Enrollment is expected to commence during the second quarter of 2021 and a topline data readout is anticipated during the third quarter of 2021. Planning for a second Phase 1 study evaluating multiple-ascending doses ("MAD") of SYN-020 is also underway and anticipated to commence during the third quarter of 2021. A topline data readout of the Phase 1 MAD clinical study is anticipated during the first quarter of 2022, pandemic conditions permitting. Following the completion of Phase 1 safety studies, we may consider conducting a placebo-controlled Phase 1b/2a challenge study in as many as 40 celiac patients who present with predominantly GI symptoms followed by a Phase 2b proof-of-concept clinical trial in a similar patient population. We may also seek to initiate clinical trials of SYN-020 evaluating its potential therapeutic benefit in NAFLD patients.

During the second quarter of 2020, we announced that we entered into an agreement with Massachusetts General Hospital 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.

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

On December 5, 2013, through our majority owned subsidiary, SYN Biomics, we entered into a worldwide exclusive license agreement (the "CSMC License Agreement") for the right to develop, manufacture, use, and sell products, including SYN-010, for the human and veterinary therapeutic and prophylactic treatments for acute and chronic diseases. SYN-010 is a modified-release formulation of lovastatin lactone that was intended to reduce methane production by certain microorganisms (*Methanobrevibacter smithii*) in the gut while minimizing disruption to the microbiome.

Investigator-Sponsored Phase 2b clinical study

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 in order to further evaluate the efficacy and safety of SYN-010.

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 criteria 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 measured changes from baseline in abdominal pain, bloating and stool frequency as well as the use of rescue medication relative to placebo. Exploratory outcomes include adequate relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires.

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 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 was 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.

Research Programs

Our research programs are primarily directed to the development of GI acting products that have generated preclinical proof-of-concept with two pipeline products (SYN-006 and SYN-007) that expand the potential utility of our beta-lactamase strategy. Our SYN-005 monoclonal antibody program is being developed to both treat and prevent pertussis.

SYN-007 — Prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR)

We are currently developing two pipeline products to expand the potential utility of our beta-lactamase strategy. SYN-007 is a specially formulated version of SYN-004 (ribaxamase) designed to degrade orally administered beta-lactam antibiotics to protect the gut microbiome from antibiotic-mediated dysbiosis. SYN-007 is formulated for release in the distal small intestine to allow systemic absorption of the oral antibiotic while still providing protection upstream of the colon and to the gut microbiome. SYN-007 is designed for patients who have been administered SYN-004 (ribaxamase) in combination with intravenous beta-lactam antibiotics and who are then transferred to an oral beta-lactam antibiotic, thereby extending gut microbiome protection from antibiotic-mediated dysbiosis. An additional indication of potential interest is the prevention of antibiotic-associated diarrhea in patients being treated with amoxicillin clavulanate. Data from a canine study completed during the second half of 2017 demonstrated that, when co-administered with oral amoxicillin, oral SYN-007 did not interfere with amoxicillin absorption and did demonstrate protection of the gut microbiome. The data from this canine study were presented during microbiome conferences in 2017 and 2018. Additional data was reported in 2019 from a dose-response canine study which demonstrated SYN-007 mitigated antibiotic-mediated gut microbiome alteration and

maintained gut microbiome integrity when co-administered with oral amoxicillin. During the first quarter of 2020, we reported additional supporting preclinical 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. Additional preclinical work in the canine model will seek to optimize the dose of SYN-007.

SYN-006 — Prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR)

SYN-006 has the potential to further expand the utility of our SYN-004 (ribaxamase) program to a broader spectrum of IV beta-lactam antibiotics in the GI tract to include carbapenem antibiotics. Carbapenems are broad-spectrum beta-lactam antibiotics that have been shown to significantly damage the gut microbiome, incur a high risk for *C. difficile* infection, and enable GI overgrowth with multidrug resistant organisms. Carbapenems are frequently a last line of defense antibiotic, therefore the emergence and spread of carbapenem resistance presents an urgent threat. SYN-006 is a carbapenemase designed to degrade intravenous (IV) carbapenem antibiotics within the GI tract to maintain the natural balance of the gut microbiome for the prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR). It is anticipated that, by protecting the gut microbiome from exposure to carbapenem antibiotics, SYN-006 may potentially diminish the spread of such resistance. At the ID Week 2017 conference, we presented a poster demonstrating SYN-006's broad activity against four carbapenem antibiotics as well as efficacy in a canine model. The poster also showed data from a porcine model indicating that the carbapenem ertapenem and potently damaged gut microbiomes and mediated expansion of antibiotic resistance genes in the GI tract. We have successfully formulated SYN-006 for oral delivery and evaluated it in a porcine efficacy model in conjunction with IV ertapenem. The data, presented at a clinical conference during the first quarter of 2018, demonstrated that SYN-006 did not interfere with serum levels of ertapenem and did diminish antibiotic-mediated dysbiosis. In addition to its potential ability to prevent IV carbapenem-mediated CDI and AMR, additional clinical indications for SYN-006 could include prevention of carbapenem-resistant Enterobacteriaceae (CRE) in cancer chemotherapy patients. Carbapenems are a first-line treatment for febrile neutropenia (FN) in hematologic cancer patients in China. Infection by CRE is a recognized and increasing health threat in China where the estimated CRE infection rate is between 10% and 20% in non-HCT chemotherapy patients and is associated with high mortality. In 2019, we reported additional supportive preclinical data demonstrating SYN-006 attenuated emergence of antibiotic resistance in a pig model, including encoded beta-lactamases and genes conferring resistance to a broad range of antibiotics such as aminoglycosides and macrolides.

SYN-005 — Pertussis (Whooping Cough)

The SYN-005 program is developing monoclonal antibodies both as a prophylaxis and a treatment for pertussis. *Bordetella pertussis (B. pertussis)* is a gram-negative bacterium that infects the upper respiratory tract, causing uncontrollable and violent coughing. Antibiotic treatment does not have a major effect on the course of pertussis. While such treatment can eliminate the *B. pertussis* bacteria from the respiratory tract, it does not neutralize the pertussis toxin. Infants with pertussis often require hospitalization in pediatric intensive care units, frequently requiring mechanical ventilation. The incidence of pertussis is increasing due to the declining effectiveness of the acellular vaccine introduced in the 1990s, exposure of unvaccinated and under-vaccinated individuals including infants who are not yet fully vaccinated and exposure of individuals whose immunity has diminished over time.

According to the Centers for Disease Control and Prevention (CDC), there are an estimated 24.1 million worldwide cases of whooping cough and about 160,700 deaths per year primarily among unvaccinated children younger than 5 years of age.

In April 2014, and again in September 2014, we received positive preclinical research findings of SYN-005 for the treatment of pertussis in three non-human primate studies (n = 19). In the latter two pertussis studies in particular, SYN-005 rapidly stopped the rise in white blood cell count that is characteristic of the disease and accelerated its

return to baseline.

In September 2014, we received U.S. Orphan Drug Designation from the FDA for SYN-005 for the treatment of pertussis.

In October 2015, the Bill & Melinda Gates Foundation awarded a grant to The University of Texas at Austin (UT Austin) to generate preclinical proof-of-concept data in the neonatal non-human primate model to test the hypothesis that antibody administration at birth may have a role in the prevention of pertussis.

In December 2015, the non-human primate prophylaxis study was initiated by UT Austin to determine if administration of hu1B7, one component of SYN-005, at two days of age could protect animals from a subsequent pertussis infection.

On April 19, 2017, we announced supportive preclinical data demonstrating hu1B7 provided five weeks of protection from pertussis in neonatal non-human primates. Control animals (n=6), infected with *Bordetella pertussis (B. pertussis)* at five weeks of age demonstrated marked elevations in white blood cell counts and most exhibited behavioral signs of pertussis, including coughing and diminished activity. In contrast, the experimental animals (n=7), who were treated with hu1B7 at two days of age and then infected five weeks later, had significantly lower peak white blood cell counts (p=0.004) that remained within the normal range or were only slightly elevated. Importantly, all seven of the animals that received prophylactic hu1B7 appeared healthy and none exhibited any behavioral signs of pertussis. Building on this early success, we performed preclinical testing of a modified version of hu1B7 that has the potential to extend the plasma half-life. The modified hu1B7 achieved higher plasma levels at five weeks than the parental hu1B7 antibody and was efficacious in preventing clinical pertussis. The extended half-life antibody has the potential to substantially reduce the required dose and cost for prophylaxis for application in the Developing World. This study expands the potential clinical utility beyond treatment to also include prophylaxis.

Intellectual Property

All of our programs are supported by growing patent estates that we either own or exclusively license. 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).

The SYN-020 (oral intestinal alkaline phosphatase (IAP)) program is supported by IP that is assigned to Synthetic Biologics, namely U.S. and foreign patent applications (in many major markets, e.g. Europe, Canada, and Australia). These patent applications, which cover various formulations, medical uses and manufacture of SYN-020, are expected to expire in 2038-2040, if granted, and without taking potential patent term extensions or patent term adjustment into account.

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.

Our Collaborations

Cedars-Sinai Medical Center License Agreement

On December 5, 2013, through our majority owned subsidiary, SYN Biomics, we entered into a worldwide exclusive license agreement (the "CSMC License Agreement") for the right to develop, manufacture, use, and sell products for the human and veterinary therapeutic and prophylactic treatments for acute and chronic diseases. The portfolio of intellectual property licensed to SYN Biomics under the CSMC License Agreement included nine issued U.S. patents, 30 issued patents in various European countries, three issued Australian patents, one Canadian patent and one issued Japanese patent as well as several pending U.S. and international patent applications for most fields of use and modalities subject to certain agreed-upon exceptions.

Under the terms of the CSMC License Agreement we issued 9,569 unregistered shares of our common stock to CSMC, as payment of an initial license fee and patent reimbursement fees of $150,000 and $220,000, respectively. The parties also entered into a Stock Purchase Agreement with respect to such stock issuance and other issuances of unregistered shares of our common stock that may be issued to CSMC in lieu of cash, including license fees, milestone payments, expense reimbursements and option fees under the CSMC License Agreement. Commencing on the second anniversary of the CSMC License Agreement, SYN Biomics began paying an annual maintenance fee, which payment was creditable against annual royalty payments owed under the CSMC License Agreement. In addition to royalty payments which are a percentage (in the low single digits and are subject to reduction under certain circumstances) of Net Sales (as defined in the CSMC License Agreement) of Licensed Products (as defined in the CSMC License Agreement) and Licensed Technology products (as defined in the CSMC License Agreement), SYN Biomics was obligated to pay CSMC a percentage of any non-royalty sublicense revenues (ranging from 20% if prior to initiation of Phase 3 clinical trial to 15% if after initiation of a Phase 3 clinical trial). During the year ended December 31, 2016, SYN Biomics paid CSMC an aggregate of $350,000 in milestone payments and was obligated to pay CSMC additional consideration up to $3,500,000 upon the achievement of the following milestones (i) initiation of Phase 3 dosing for each additional indication of a Licensed Product or Licensed Technology Product; (ii) successful Phase 3 trial completion for each Licensed Product and each Licensed Technology Product; (iii) the FDA's acceptance of a New Drug Application for each Licensed Product and each Licensed Technology Product; (iv) regulatory approval for each Licensed Product and each Licensed Technology Product; and (vi) the first commercial sale of each Licensed Product and each Licensed Technology Product. There were no milestone payments made during the years ended December 31, 2020 and 2019.

Prior to the execution of the CSMC License Agreement, SYN Biomics issued shares of common stock of SYN Biomics to each of CSMC and Dr. Mark Pimentel (the primary inventor of the intellectual property), representing 11.5% and 8.5%, respectively, of the outstanding shares of SYN Biomics (the "SYN Biomics Shares"). The Stock Purchase Agreements for the SYN Biomics Shares provide for certain anti-dilution protection until such time as an aggregate of $3.0 million in proceeds from equity financings are received by SYN Biomics as well as a right, under certain circumstances in the event that the SYN Biomics Shares are not then freely tradeable, and subject to NYSE American, LLC approval, as of the 18 and 36 month anniversary date of the effective date of the Stock Purchase Agreements, for each of CSMC and Dr. Pimentel to exchange up to 50% of their SYN Biomics Shares for unregistered shares of our common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of us at the time of each exchange. The Stock Purchase Agreements also provide for tag-along rights in the event of the sale by us of our shares of SYN Biomics.

On August 29, 2015, Dr. Pimentel notified us of his intent to exchange all of the shares of common stock in SYN Biomics owned by him for 38,572 shares of our common stock in accordance with the terms of the Pimentel Stock Purchase Agreement, as amended and the exchange was effectuated on August 31, 2015. We filed a "resale" registration statement to register 5,715 shares issued to Dr. Pimentel, which was declared effective by the SEC on October 15, 2015.

On September 5, 2018, we entered into an agreement with CSMC for CSMC to conduct an investigator-sponsored Phase 2 clinical study of SYN-010 to be co-funded by us and CSMC (the "Study").

In consideration of the support provided by CSMC for the Study, we entered into a Stock Purchase Agreement with CSMC pursuant to which we: (i) issued to CSMC fifty thousand (50,000) shares of our common stock; and (ii) transferred to CSMC an additional two million four hundred twenty thousand (2,420,000) shares of common stock of its SYN Biomics, Inc. owned by us, such that after such issuance CSMC owns an aggregate of seven million four hundred eighty thousand (7,480,000) shares of common stock of SYN Biomics, representing seventeen percent (17%) of the issued and outstanding shares of SYN Biomics' common stock.

The Stock Purchase Agreement also provides CSMC with a right, commencing on the six month anniversary of issuance of the stock under certain circumstances in the event that the shares of stock of SYN Biomics are not then freely tradeable, and subject to NYSE American, LLC approval, to exchange its SYN Biomics shares for unregistered shares of our common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of our company at the time of each exchange all subject to approval of the NYSE American, LLC. The Stock Purchase Agreement also provides for tag-along rights in the event of the sale by us of our shares of SYN Biomics.

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.

Washington University School of Medicine in St. Louis Clinical Trial Agreement

In August 7, 2019, we 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, we will serve as the sponsor of the Study and supply SYN-004 (ribaxamase), 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 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 SYN-004 (ribaxamase) 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. We have 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.

Massachusetts General Hospital Exclusive Option License Agreement

On May 27, 2020, 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 intestinal alkaline phosphatase ("IAP") to maintain gastrointestinal (GI) and microbiome health, diminish systemic inflammation, and treat age-related diseases. If executed, we plan to use this license in the advancement of an expanded clinical development program for SYN-020, our proprietary recombinant version of bovine IAP currently in pre-clinical development. Under the terms of the agreement, Synthetic Biologics is 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.

The University of Texas at Austin License Agreement and Sponsored Research Agreement

On December 19, 2012, we entered into a Patent License Agreement (the "Texas License Agreement") with UT Austin for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to pertussis antibodies developed in the lab of Dr. Jennifer A. Maynard, Associate Professor of Chemical Engineering. In accordance with the terms of the Texas License Agreement we made the following payments to the UT Austin: a payment of past patent expenses, an annual payment of $50,000 per year commencing on the effective date through December 31, 2014 and a $25,000 payment on December 31, 2015. The Texas License Agreement also provides that UT Austin is entitled to milestone payments of $50,000 upon commencement of Phase 1 Clinical Trials, $100,000 upon commencement of Phase 3 Clinical Trials, $250,000 upon NDA submission in the United States, $100,000 upon European Medicines Agency approval and $100,000 upon regulatory approval in an Asian country. In addition, the University is entitled to a running royalty upon Net Product Sales and Net Service Sales (as defined in the Texas License Agreement and currently projected to be 2037 (not accounting for possible extensions)). The License Agreement terminates upon the expiration of the patent rights (as defined in the Texas License Agreement); provided, however that the Texas License Agreement is subject to early termination by us in our discretion and by the University for a breach of the Texas License Agreement by us.

In connection with the Texas License Agreement, we also entered into a Sponsored Research Agreement (the "Sponsored Research Agreement") with the University pursuant to which the University will perform certain research work related to pertussis under the direction of Dr. Jennifer Maynard. All inventions conceived during such research shall be subject to the Texas License Agreement and we will obtain certain rights to patents and technology developed during the course of such research. We paid the University a fixed fee for the first year of $303,287 and the second and third years of $316,438 and $328,758, respectively. The Sponsored Research Agreement was amended on October 22, 2015, to extend its termination date to January 15, 2017, on September 2, 2016 to extend the agreement until January 15, 2018; on August 22, 2017 to extend the agreement until January 17, 2019; on August 24, 2018 to extend the agreement until January 21, 2021; and again on August 18, 2020 which extended the agreement until January 17, 2023; provided, however, the Sponsored Research Agreement is subject to early termination upon the written agreement of the parties, a default in the material obligations under the Sponsored Research Agreement which remain uncured for 60 days after receipt of notice, automatically upon our bankruptcy or insolvency and by us in our sole discretion at any time after the one year anniversary of the date of execution thereof upon no less than 90 days' notice. Upon a termination or due to a breach by the University, we will only be responsible for all reasonable expenses that do not exceed the fixed annual amount and that are incurred by the University prior to the termination date for services performed prior to the termination date.

We have an issued U.S. patent and patents pending in the U.S. and internationally (*e.g.* Europe, China, Japan, Australia, and China) on compositions and uses of SYN-005 that are co-owned by UT Austin and ourselves or licensed to us, and we have an issued U.S. patent and patent applications on other pertussis mAbs licensed from UT Austin.

Infectious Disease Collaboration with Intrexon Corporation

On August 6, 2012, we entered into an Exclusive Channel Collaboration ("ECC") with Intrexon (the "Infectious Disease ECC") that governs a "channel collaboration" arrangement in which we intend to use Intrexon's technology relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of human recombinant monoclonal antibody therapies for the treatment of pertussis (the "Field"). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of our products within the Field ("Synthetic Products"), and otherwise is non-exclusive. We may not sublicense the rights described without Intrexon's written consent. Under the Infectious Disease ECC, and subject to certain exceptions, we are responsible for, among other things, the performance of the Program including the development, commercialization and manufacturing of products.

Subject to certain expense allocations and other offsets provided in the Infectious Disease ECC, we will pay Intrexon royalties on annual net sales of the Synthetic Products, calculated on a Synthetic Product-by-Synthetic Product basis. We have likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement.

We may voluntarily terminate the Infectious Disease ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Infectious Disease ECC if we elect not to pursue the development of a Program identified by Intrexon that is a "Superior Therapy" as defined in the Infectious Disease ECC upon 60 days' notice unless we remedy the circumstances giving rise to the termination during such notice period. Each party has the right to terminate the agreement upon 60 days' notice if the other party commits a material breach of the Infectious Disease ECC, subject to certain cure periods.

Upon termination of the Infectious Disease ECC, we may continue to develop and commercialize any Synthetic Product that at the time of termination satisfies one of the following:

- is being commercialized by us;
- has received regulatory approval;
- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority;
- is a subject of at least a Phase 2 or Phase 3 clinical trial if such termination is by Intrexon due to a material breach by us of the Infectious Disease ECC or by us upon 60 days' notice after the first 18 months.

Our obligation to pay the royalties described above with respect to these "retained" products will survive termination of the Infectious Disease ECC.

In the event of a termination of the Infectious Disease ECC, product candidates that are generating revenue or being considered for approval by the applicable regulatory body or have been approved by the applicable governing body ("Infectious Disease Retained Products") at the time of the Infectious Disease ECC's termination are retained by us, subject to Intrexon's right to receive royalty payments. Except as necessary for us to continue to obtain regulatory approval for or commercialize any Infectious Disease Retained Product, in the event of termination of the Infectious Disease ECC, all rights and licenses granted by Intrexon revert back to Intrexon and we must cease development and commercialization of all products candidates in the Field that are not Retained Products. Upon termination of the Infectious Disease ECC, Intrexon retains any technology access fees or other payments to which we have paid to Intrexon through the date of termination.

On October 16, 2012, we issued 101,492 shares of our common stock as consideration in connection with the Infectious Disease ECC and the related Stock Issuance Agreement with Intrexon that we entered into on August 6, 2012 (the "Second Stock Issuance Agreement").

We also agreed upon the filing of an IND application with the FDA for a Synthetic Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency (both as applicable, the "IND Milestone Event"), to pay Intrexon either (i) $2.0 million in cash, or (ii) that number of shares of Common Stock (the "IND Milestone Shares") having a fair market value equaling $2.0 million where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the IND Milestone Event.

Upon the first to occur of either first commercial sale of a Synthetic Product in a country or the granting of the regulatory approval of that Synthetic Product (both as applicable, the "Approval Milestone Event"), we agreed to pay to Intrexon either (i) $3.0 million in cash, or (ii) that number of shares of Common Stock (the "Approval Milestone Shares") having a fair market value equaling $3.0 million where such fair market value is determined using published market data of the share price for Common Stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the Approval Milestone Event. We will pay Intrexon royalties on annual net sales of products, calculated on a product-by-product basis, equal to a percent of net sales of Synthetic Products (ranging from mid-single digits on the first $100 million of net sales to mid-teen digits on net sales in excess of $100 million). We have likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement.

In connection with the transactions contemplated by the Second Stock Issuance Agreement, and pursuant to the First Amendment to Registration Rights Agreement executed and delivered by the parties at the closing, we filed a "resale" registration statement registering the resale of certain of the shares issued under the Second Stock Issuance Agreement.

Manufacturing

Our product candidates are biologics that can be readily synthesized by processes that we have developed; however, the manufacturing for our clinical programs, including SYN-004 and SYN-020 may require long lead times. We do not own or operate manufacturing facilities for the production of our product candidates for preclinical and clinical activities. We rely on third-party contract manufacturers, and in most cases only one third-party, to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of products we successfully develop through FDA approval. Although we believe we have sufficient quantities of SYN-004 and SYN-020 to complete our planned Phase 1b/2a clinical trial of SYN-004 and our planned Phase 1 clinical trials of SYN-020, we do not currently have a definitive agreement with any third-party vendors for the manufacture of additional quantities of SYN-004 and SYN-020 for potential future clinical trials.

Research and Development

During the years ended December 31, 2020 and 2019, we incurred approximately $5.1 million and $11.1 million, respectively, in research and development expenses.

Government Regulation

In the U.S., the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including primarily the FDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of prescription drugs, such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant cGMP regulations for the preparation, packing, labeling,

and storage of all drugs.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record-keeping requirements, and compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations.

The FDA regulates prescription drug labeling and promotion activities. The FDA actively enforces regulations prohibiting the marketing of products for unapproved uses. The FDA permits the promotion of drugs for unapproved uses in certain circumstances, subject to stringent requirements. We and our product candidates are subject to a variety of state laws and regulations which may hinder our ability to market our products. Whether or not FDA approval has been obtained, approval by foreign regulatory authorities must be obtained prior to commencing clinical trials, and sales and marketing efforts in those countries. These approval procedures vary in complexity from country to country, and the processes may be longer or shorter than that required for FDA approval. We may incur significant costs to comply with these laws and regulations now or in the future.

The FDA, comparable foreign regulators and state and local pharmacy regulators impose substantial requirements upon clinical development, manufacture and marketing of pharmaceutical products. These and other entities regulate research and development and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products. The drug approval process required by the FDA under the Food, Drug, and Cosmetic Act generally involves:

- preclinical laboratory and animal tests;
- submission of an IND, prior to commencing human clinical trials;
- adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;
- submission to the FDA of an NDA or BLA; and
- FDA review and approval of an NDA or BLA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long-term preclinical studies are conducted concurrently with clinical studies.

We will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, in which case, the IND sponsor and FDA must resolve the matters before clinical trials

can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials.

Clinical trials must be supervised by qualified investigators in accordance with good clinical practice (GCP) regulations, which include informed consent requirements. Each study must be approved and monitored by the appropriate Institutional Review Boards (IRBs) which are periodically informed of the study's progress, adverse events and changes in research. Annual updates are submitted to the FDA and more frequently if certain serious adverse events occur.

Human clinical trials of drug candidates typically have three sequential phases that may overlap:

Phase 1: The drug is initially tested in healthy human subjects or patients for safety, dosage tolerance, absorption, metabolism, distribution, and excretion.

Phase 2: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, determine efficacy for specific diseases and establish dosage tolerance and optimal dosage.

Phase 3: When Phase 2 evaluations demonstrate that a dosage range is effective with an acceptable safety profile, Phase 3 trials to further evaluate dosage, clinical efficacy and safety, are undertaken in an expanded patient population, often at geographically dispersed sites.

We cannot be certain that we will successfully complete Phase 1, Phase 2, or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, an IRB or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk. Under the Pediatric Research Equity Act, we also must prepare, within 60 days of an End of Phase 2 meeting, a pediatric study plan or request for waiver or deferral of pediatric studies in the indication under development. Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with cGMP requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. Results of the foregoing are submitted to the FDA as part of a NDA (or BLA in case of biologic products) for marketing and commercial shipment approval. The FDA reviews each NDA or BLA submitted and may request additional information. A 60-day period after the sponsor's submission of an NDA or BLA is used by the FDA to determine whether the application is sufficiently complete to permit substantive review, in which case the application is accepted for filing.

Once the FDA accepts the NDA or BLA for filing, it begins its in-depth review. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted or identify new concerns. The process may be significantly extended by requests for new information or clarification of information already submitted. As part of this review, the FDA may refer the application to an advisory committee, typically a panel of clinicians. Manufacturing establishments often are inspected prior to NDA or BLA approval to assure compliance with GMPs and with manufacturing commitments made in the application.

Submission of an NDA or BLA with clinical data requires payment of a substantial fee. In return, the FDA assigns a goal for review and decision on the application, in which the FDA may approve or deny the NDA or BLA, or issue a complete response letter outlining information needed to support approval, including a potential need for additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA or BLA does not satisfy approval criteria. If the FDA approves the NDA or BLA, the product becomes available for marketing. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as Phase 4 studies, as a condition of approval, and Risk Evaluation and Mitigation Strategies (REMS) requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses.

Even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Increased attention to the containment of health care costs worldwide could result in new government regulations materially adverse to our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the name of the sponsor, identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of Prescription Drug User Fee Act ("PDUFA"), fees, enhanced access to FDA staff and potential waiver of pediatric research requirements.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA,

including the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. The federal Anti-Kickback Statute prohibits any person, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted anti-kickback statues and false claims laws analogous to the False Claims Act. Also, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) created several federal crimes, including healthcare fraud, and false statements relating to the delivery of or payments for healthcare benefits, items or services. HIPAA and its implementing regulations also established uniform federal standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information.

Because of the breadth of these and other laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Competitive Environment

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing. Companies that currently sell or are developing proprietary products for the prevention and treatment of *C. difficile* infection include: Actelion Pharmaceutical Ltd., Artugen Therapeutics, Inc., AzurRx, Inc., Da Volterra, Deinove, Pfizer Inc., Merck & Co. Inc., Merus B.V., Pfizer Inc., Rebiotix, Inc., Seres Therapeutics, Inc., Summit Therapeutics plc. and Vedanata Biosciences Inc. Companies that sell or are developing products for the treatment or prevention of acute graft-versus-host-disease (aGVHD) include: Amgen, Inc., Astellas Pharma, Janssen Biotech, Inc., Mallinckrodt plc, Novartis International AG, Pfizer, Inc. Roche AG and Takeda Pharmaceutical Company Ltd.

Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us.

Corporate History

Our predecessor, Sheffield Pharmaceuticals, Inc., was incorporated in 1986, and in 2006 engaged in a reverse merger with Pipex Therapeutics, Inc., a publicly-traded Delaware corporation formed in 2001. After the merger, we changed our name to Pipex Pharmaceuticals, Inc., and in October 2008 we changed our name to Adeona Pharmaceuticals, Inc. On October 15, 2009, we engaged in a merger with a wholly owned subsidiary for the purpose of reincorporating in the State of Nevada. On February 15, 2012, we changed our name to Synthetic Biologics, Inc. On August 10, 2018, we effected a one for thirty-five reverse stock split of our authorized, issued and outstanding common stock.

Human Capital-Employees

We believe that our success depends upon our ability to attract, develop and retain key personnel. As of March 3, 2021, we employed 10 individuals, all of whom are full-time employees, of which 5 were part of our research and clinical development team and 5 were part of our financial reporting and accounting team. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be in good standing. Although we continually seek to add additional talent to our work force, management believes that it has sufficient human capital to operate its business successfully.

Competitive Pay and Benefits

Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. Specifically:

- we provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location;

- we engage nationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking against our peers within the industry;

- we align our executives' long-term equity compensation with our shareholders' interests by linking realizable pay with stock performance; and

- all employees are eligible for health insurance, paid and unpaid leaves, a retirement plan and life and disability/accident coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including flexible time-off, telemedicine, and unpaid parental leave.

Health and Safety

The health and safety of our employees is our highest priority, and this is consistent with our operating philosophy. Accordingly, with the global spread of the ongoing novel coronavirus pandemic, we have implemented plans designed to address and mitigate the impact of the COVID-19 pandemic on the safety of our employees and our business, which include:

- adding work from home flexibility;

- adjusting attendance policies to encourage those who are sick to stay home;

- increasing cleaning protocols across all locations; and

- initiating regular communication regarding impacts of the COVID-19 pandemic, including health and safety protocols and procedures.

Properties

Our principal executive offices are located at 9605 Medical Center Drive, Suite 270, Rockville, Maryland 20850.

Available Information

Additional information about Synthetic Biologics is contained at our website, *www.syntheticbiologics.com*. Information contained on our website is not incorporated by reference into, and does not form any part of, this Annual Report on Form 10-K. We have included our website address as a factual reference and do not intend it to be an active link to our website. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the Audit Committee, Compensation Committee and Nominations Committee of the Board of Directors. Our phone number is (301) 417-4364 and our facsimile number is (301) 417-4367.

Item 1A. *Risk Factors*

Investing in our securities involves a high degree of risk. In addition to the risks related to our business set forth in this Annual Report and the other information included in this Annual Report, you should carefully consider the risks described below before purchasing our securities. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.

RISKS RELATING TO OUR BUSINESS

We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts.

During the year ended December 31, 2020, our operating activities used net cash of approximately $12.2 million and as of December 31, 2020 our cash and cash equivalents were $6.2 million. With the exception of the three months ended December 31, 2017 and June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2020, our accumulated deficit totaled approximately $248.1 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Based on our current plans, our cash and cash equivalents will be sufficient to complete our planned Phase 1a/2a clinical trial of SYN-004, our planned Phase 1 single-ascending and multiple-ascending dose clinical trials of SYN-020, and a potential Phase 2a clinical trial of SYN-020 but, may not be sufficient for post-Phase 2a future clinical programs for SYN-020 or additional trials of SYN-004, which are expected to require significant cash expenditures. In addition, based on the significant anticipated cost of a Phase 3 clinical program in a broad indication for SYN-004, we expect it will not be feasible for us to initiate and complete this trial at this time without a partner given the capital constraints tied to our current market cap and share price. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and also have a dilutive effect on our stockholders. A failure otherwise to secure additional funds when needed in the future whether through an equity or debt financing or a sufficient amount of capital without a strategic partnership could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

The COVID-19 global health crisis has impacted our planned operations, including our clinical studies

In January 2020, the World Health Organization declared a global pandemic for the novel strain of coronavirus, COVID-19. Since then, the COVID-19 coronavirus has spread to multiple countries, including throughout the United States. We have experienced disruptions that have impacted our business and clinical trials and expect to experience additional disruptions as the pandemic continues, including:

- unwillingness of potential study participants to enroll in new clinical trials and/or visit healthcare facilities;
- postponement of enrollment in our SYN-004 Phase 1b/2a clinical study;
- postponement of the initiation of our SYN-020 single ascending and multiple ascending dose studies;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical site visits by study participants and clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;

- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and

- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19.

Our business and the business of the suppliers of our clinical product candidates has been and is expected to continue to be materially and adversely affected by the pandemic. Such events could result in the continued delay or complete or partial closure of clinical trial sites or one or more manufacturing facilities which could impact our supply of our clinical product candidates. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships.

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.

In addition. the COVID-19 outbreak could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office, or due to quarantines. The COVID-19 illness could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

The global outbreak of the virus continues to rapidly evolve. The extent to which the virus may continue to impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. We do not yet know the full extent of potential delays or impacts on our business, operations, or the global economy as a whole. While the spread of COVID-19 may eventually be contained or mitigated, there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business.

We recently have experienced delays in clinical testing of our product candidates due to COVID-19 and may in the future experience other delays. These delays may result in the need for trials to be redesigned and will impact whether they will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the COVID-19 pandemic, delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Manufacturing considerations for clinical development candidates may include an expected several month lead time following a decision to commence any clinical trial(s) and capacity considerations of our third-party contract manufacturers to provide clinical supply of our product candidates could cause delays in clinical trials. Furthermore, due to the COVID-19 pandemic, many manufacturers have been prioritizing the manufacture of COVD-19 related products, increasing the manufacturing lead times for non-COVID-19 related products. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs

approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidates versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and timeliness and approval process and delay our ability to generate revenue.

We expect to continue to incur significant operating and capital expenditures.

Other than with respect to the three months ended December 31, 2017 and June 30, 2010, we have a history of losses and we have incurred, and will continue to incur, substantial losses and negative operating cash flow. Even if we succeed in developing and commercializing one or more of our product candidates, we may still incur substantial losses for the foreseeable future and may not sustain profitability. We expect that later stage clinical trials, including a Phase 3 clinical program of SYN-004 (ribaxamase) for the prevention of CDI will enroll a greater number of patients than our prior clinical trials and will be more costly than our prior clinical trials. In addition, we anticipate a need for additional employees as we undertake later stage clinical trials. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will substantially increase in the foreseeable future as we do the following:

- continue to undertake preclinical development and mid and late-stage clinical trials for our product candidates, including SYN-004 (ribaxamase), and SYN-020;
- seek regulatory approvals for our product candidates;
- develop our product candidates for commercialization;
- implement additional internal systems and infrastructure;
- license or acquire additional technologies;
- lease additional or alternative office facilities;
- manufacture product for clinical trials; and
- hire additional personnel, including members of our management team.

We may experience negative cash flow for the foreseeable future as we fund our development and clinical programs with capital expenditures. As a result, we will need to raise additional capital or generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability, which we do not anticipate will occur in the near future, could negatively impact the value of our common stock and underlying securities.

The actual amount of funds we will need to operate is subject to many risk factors, some of which are beyond our control.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;

- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements and amount of funding received from partners and collaborators;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs associated with manufacturing-related services to produce materials for use in our clinical trials;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs incurred to screen and enroll patients; and
- The costs and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing 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.

We currently have no products approved for commercial sale, have no significant source of revenue and may never generate significant revenue.

Our ability to generate revenue depends heavily on:

- our ability to raise additional capital on a timely basis to continue to fund our clinical trials;
- demonstration in current and future clinical trials that our lead product candidates, SYN-004 (ribaxamase) for the prevention *C. difficile* infection and aGVHD and SYN-020, are safe and effective;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- successful manufacture and commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates are in various stages of development and will require extensive additional clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, even if we successfully develop, achieve regulatory approval and commercialize our products, we may be unable to generate revenue for many years, if at all. We do not anticipate that we will generate revenue from product sales for at least several years, if at all. If we are unable to generate revenue from product sales, we will not become profitable, and we may be unable to continue our operations.

Our research and development efforts may not succeed in developing commercially successful products and technologies, which may limit our ability to achieve profitability. We are largely dependent on the success of our lead product candidates, SYN-004 and SYN-020, which require significant additional clinical testing before we can seek

regulatory approval and we cannot be certain that these product candidates will receive regulatory approval or be successfully commercialized.

We must continue to explore opportunities that may lead to new products and technologies. To accomplish this, we must commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. Any such expenditures that we make will be made without any assurance that our efforts will be successful. Failure can occur at any point in the process, including after significant funds have been invested.

The success of our business currently depends on our development, approval and commercialization of our lead product candidates, SYN-004 (ribaxamase) and SYN-020. Our planned Phase 1b/2a clinical trial of SYN-004 for the prevention of aGVHD in allogeneic HCT recipients and planned Phase 1 single ascending and multiple ascending dose studies of SYN-020 are not designed as registrational clinical trials and we currently do not have the necessary funding to complete any registrational clinical trials. There are many uncertainties known and unknown that may affect the outcome of future clinical trials. All of our product candidates, including SYN-004 (ribaxamase) and SYN-020, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Regardless of whether our clinical trials are deemed to be successful, promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals or satisfy regulatory criteria, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others. Failure to obtain regulatory approvals of SYN-004 (ribaxamase) or SYN-020 in a timely manner would have a material adverse impact on our business. Even if we successfully develop SYN-004 (ribaxamase) or SYN-020 or other new products or enhancements, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be quickly accepted in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire drug candidates or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, which may limit our ability to achieve profitability.

We are actively seeking and may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We are actively seeking and may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our

business prospects, financial condition and results of operations.

We may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products.

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We entered into an option agreement with MGH to enter into 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. There can be no assurance that we will be able to reach agreement on license terms or that the terms will be favorable to us. This license agreement is expected to require us to meet certain diligence requirements and timelines in order to keep the license agreement in effect. In addition, certain license agreements, including the one that may potentially be entered into with MGH, typically contain provisions requiring royalty free non-exclusive licenses to the U.S government if any federal funding was used to invent any of the patents being licensed. In the event we or our sublicensee are not able to meet our diligence requirements contained in the license agreement with MGH or any other license agreement, we may not be able to retain the rights granted under our agreement or renegotiate with our arrangement institution on reasonable terms, or at all. If any license were to terminate and we were to lose the right to commercialize our products, our business opportunity would be adversely affected. Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies. Our ECC agreement with Intrexon provides that Intrexon may terminate an agreement if we do not perform certain specified requirements, including developing therapies considered superior. Our agreement with UT Austin allows UT Austin to terminate its agreement if we fail to comply with the terms of the agreement.

We can give no assurances that any of our issued patents licensed to us or any of our other patent applications will provide us with significant proprietary protection or be of commercial benefit to us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, nor does the issuance of a patent provide the patent holder with freedom to operate without infringing the patent rights of others.

We may incur additional expenses in connection with our licenses and collaboration arrangements and our development of our product candidates.

Our agreements with Washington University and MGH may require that we initiate certain studies and file or have accepted an NDA within a certain amount of time, each of which are costly and will require additional expenditures. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. Due to our corporate restructuring plan to reduce cost that was implemented in 2018, we have a reduced work force and expect in future years to require additional personnel to support our later stage research and development efforts. In addition, we intend to commence manufacturing of SYN-004 (ribaxamase) and SYN-020 materials to support potential future clinical studies which will require us to incur additional expenses.

Because development activities in our collaborations are sometimes determined pursuant to joint steering committees, future development costs associated with these programs may be difficult to anticipate and may exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, enrollment challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or

discontinue development.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries, including the monoclonal antibody industry, are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of our competitors have drugs that have already been commercialized and therefore benefit from being first to market their products. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing. Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us, including for different indications of the same active ingredients that comprise our pipeline products. These competitors will compete with us in product sales as well as recruitment and retention of qualified scientific and management personnel, establishment of clinical trial sites and patient enrollment for clinical trials, as well as in the acquisition of technologies and technology licenses complementary to our programs or advantageous to our business. Companies that currently sell or are developing proprietary products for the prevention and treatment of *C. difficile* infection include: Actelion Pharmaceutical Ltd., Artugen Therapeutics, Inc., AzurRx, Inc., Da Volterra, Deinove, Merck & Co. Inc., Merus B.V., Pfizer Inc., Rebiotix, Inc., Seres Therapeutics, Inc., Summit Therapeutics plc., and Vedanta Biosciences, Inc. Companies that sell or are developing products for the treatment or prevention of acute graft-versus-host-disease (aGVHD) include: Amgen, Inc., Astellas Pharma, Janssen Biotech, Inc., Mallinckrodt plc, Novartis International AG, Pfizer, Inc., Roche AG and Takeda Pharmaceutical Company Ltd. Companies that currently sell or are developing proprietary products for pertussis include: GlaxoSmithKline plc, Mitsubishi Tanabe Pharma Corporation and Sanofi S.A. AG. The infectious disease market is highly competitive with many generic and proprietary intravenous and oral formulations available to physicians and their patients. For our monoclonal antibodies, we currently do not expect to be able to deliver our infectious disease candidates via the oral route and may thus be limited to the in-patient and/or acute treatment setting. In addition, academic research centers may develop technologies that compete with our SYN-004, SYN-020, and SYN-005 products and our other technologies. Should clinicians or regulatory authorities view alternative therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid, hospitals and private insurers.

We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our clinical product candidates will require substantial additional cash to fund expenses. For some of our product candidates (such as our planned phase 3 clinical trial of SYN-004) we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the

costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with our product candidate.

If the parties we depend on for supplying substance raw materials for our product candidates and certain manufacturing-related services do not timely supply these products and services in sufficient quality or quantity, it may delay or impair our ability to develop, manufacture and market our product candidates.

We rely on suppliers for the substance raw materials of our product candidates and third parties for manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of study material, which may be difficult or uneconomical to procure or manufacture and there can be no assurance that we will successfully procure such study material or even if procured, that we can do so in quantities and in a timely manner to allow our clinical trials to proceed as planned. We and our suppliers and vendors may not be able to (i) produce our study material to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us, or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or manufacturer which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

The third-party manufacturers of the active pharmaceutical ingredient (API) and drug product for our lead product candidates, SYN-004 (ribaxamase) and SYN-020, are established cGMP manufacturers. For all other therapeutic areas, we have not yet established cGMP manufacturers for our biologic and drug candidates. We do not currently have a definitive agreement with any third-party vendors for the manufacture of additional quantities of SYN-004 or SYN-020 and we currently have only one manufacturer for each of our lead product candidates. Although we believe additional manufacturers are available, if either of our manufacturers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time our production could be delayed. Any curtailment in the availability of SYN-004 (ribaxamase) or SYN-020 could have a material adverse effect on our business, financial position and results of operations. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

The manufacture of our product candidates requires significant expertise and manufacturers may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. We may experience longer than expected lead times with respect to the manufacture of clinical drug supply, which may result from the increase in manufacturing scale necessary to conduct our anticipated late stage clinical trials and result in trial delays. Furthermore, due to the COVID-19 pandemic, many manufacturers have been prioritizing the manufacture of COVID-19 related products, increasing the manufacturing lead times for non-COVID-19 related products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We are responsible for ensuring that each of our contract manufacturers comply with the cGMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. While we oversee compliance, we do not have control over our manufacturers and their compliance with regulatory requirements. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with cGMP requirements. We are responsible for regularly assessing a contract manufacturer's compliance with cGMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations.

A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.

As of March 3, 2021, we employed 10 full-time employees. We have also engaged clinical consultants to advise us on our clinical programs and regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Due to our corporate restructuring plan to reduce cost that was implemented in 2018, we have reduced our work force and expect in future years to require additional personnel to support our later stage research and development efforts. We have been and may be required to retain additional consultants and employees in order to fulfill our obligations under our licenses and collaborations for our development of SYN-004, SYN-020 and our agreements with Washington University and other collaborators. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop an effective working relationship among senior management.

Certain of our directors, scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies that might be developing competitive products to ours. Other than corporate opportunities, none of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the drug and biologic development areas, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

We rely on independent organizations, advisors, and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis when we need them.

We rely extensively on our information technology systems and are vulnerable to damage and interruption.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. Likewise, data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds

or intellectual property. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

Any failure to maintain the security of information relating to our customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

In connection with the pre-clinical and clinical development, sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

REGULATORY RISKS

If we do not obtain the necessary regulatory approvals in the U.S. and/or other countries we will not be able to sell our product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates or any product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. We will be required to conduct clinical trials that will be costly and we currently do not have the funding to complete any registrational clinical trials. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may prevent or delay commercialization of, and our ability to derive product revenues from our product candidates; and diminish any competitive advantages that we may otherwise believe that we hold.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs or BLAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In addition, the FDA may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product. The results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the

side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products.

In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any products, which can be time consuming and costly. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. There can be no assurance that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States.

If the FDA approves any of our product candidates, the labeling, manufacturing, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. Our drug manufacturers and subcontractors that we retain will be required to comply with FDA and other regulations. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, suspension of regulatory approval, suspension of production, injunctions or civil or criminal sanctions. The subsequent discovery of previously unknown problems with any marketed product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

Clinical trials are very expensive, time-consuming, and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials for our product candidates would take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Commencement and completion of clinical trials may be delayed by several factors, including:

- obtaining an IND application with the FDA to commence clinical trials;
- identification of, and acceptable arrangements with, one or more clinical sites;
- obtaining IRB approval to commence clinical trials;
- unforeseen safety issues;
- determination of dosing;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- inability to obtain supply of our drug candidate in a timely manner;
- inability or unwillingness of medical investigators to follow our clinical protocols; and

- unwillingness of the FDA or IRBs to permit the clinical trials to be initiated.

In addition, we, IRBs or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if IRBs or the FDA finds deficiencies in our submissions or conduct of our trials.

The results of our clinical trials may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials as was the case with SYN-010. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Success of our predecessor P1A clinical product or positive topline data from our previous SYN-004 (ribaxamase) Phase 1 and Phase 2 clinical trials, does not ensure success of SYN-004 (ribaxamase),. Furthermore, the FDA could determine that SYN-004 (ribaxamase) has not demonstrated safety and require additional clinical trials and safety data, despite positive results from our SYN-004 (ribaxamase) Phase 2b clinical trial and the determination by clinical sites investigators and an independent third party that the serious adverse events that occurred in the group that received SYN-004 in our Phase 2b clinical trial were not drug related. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing nor that they would satisfy the requirements of the FDA or other regulatory agencies. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products. Any such failure could cause us or our sublicensee to abandon a product candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Difficulties enrolling patients in our clinical trials or delays in enrollment are expected to result in our clinical development activities being delayed or otherwise adversely affected.

Delays in patient enrollment may result in increased cost or may adversely affect timing or outcome of planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. This can lead to delays in completion of clinical trials as well as additional expense for recruitment of patients. In addition, the COVID-19 pandemic may result in fewer technicians being available to conduct clinical testing for patients currently enrolled in our clinical trial.

Patients who are administered our product candidates may experience unexpected side effects or other safety risks that could cause a halt in their clinical development, preclude approval of our product candidates or limit their commercial potential.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients. For example, the FDA could determine that SYN-004 has not demonstrated safety, that adverse events are drug related and require additional clinical trials and safety data, despite positive results from our SYN-004 Phase 2b clinical trial and the determination by clinical sites investigators and an independent third party that the adverse events that

occurred in the group that received SYN-004 in our Phase 2b clinical trial were not drug related.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials. Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase commercialization costs.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies;
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

We depend on third parties, including researchers and sublicensees, who are not under our control. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates.

We have in-licensed some of our product candidates, have sublicensed a product candidate, and have collaboration agreements for the development of other product candidates. As a result, we depend upon our sublicensee and independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to advise us and to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors/advisors or those of our sublicensee become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we or our sublicensee may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors could harm our competitive position.

With respect to our product candidate for pertussis in collaboration with UT Austin, we are dependent on its research laboratories as we have no such facilities or capabilities of our own. If any of the foregoing were to become inaccessible or terminated, it would be difficult for us to develop and commercialize our synthetic biologic product candidates.

We have in the past and expect to have in the future agreements with third-party contract research organizations (CROs) under which we have delegated to the CROs the responsibility to coordinate and monitor the conduct of our SYN-004 and SYN-020 clinical trials and to manage data for our clinical programs. Our planned Phase 1b/2a clinical trial of SYN-004 and planned Phase 1 clinical trials of SYN-020 will be conducted by clinical sites over which we have little direct control. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or cGCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. If our CROs or investigator-sponsored clinical sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

We currently have no marketing, sales or distribution organization and have no experience in marketing products as a company. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no marketing, sales or distribution capabilities and have no experience in marketing products. We may develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payors pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of our products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing continued healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care

costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates and will face an even greater risk if we sell our product candidates commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- initiation of investigations by regulators;
- substantial monetary awards to patients or other claimants;
- distraction of management's attention from our primary business;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

We have clinical trial liability insurance. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

INTELLECTUAL PROPERTY RISKS

We rely on patent applications and various regulatory exclusivities to protect some of our product candidates and

our ability to compete may be limited or eliminated if we are not able to protect our products.

The patent positions of pharmaceutical companies are uncertain and may involve complex legal and factual questions. We may incur significant expenses in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expenses and divert the attention of our management. Even for our issued patents, we do not have a guarantee of patent term restoration and marketing exclusivity of the ingredients for our drugs under the Hatch-Waxman Amendments, even if we are granted FDA approval of our products.

Others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible.

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. Some of our current or former employees, consultants, scientific advisors, current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, as well as costs associated with lawsuits.

If any other person files patent applications, or is issued patents, claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. We, or our licensors, may also need to participate in interference proceedings involving our issued patents and pending applications of another entity.

The intellectual property environment in the monoclonal antibody field is particularly complex, constantly evolving and highly fragmented. We have not conducted freedom-to-use patent searches on all aspects of our product candidates or potential product candidates, and we may be unaware of relevant patents and patent applications of third parties. In addition, the freedom-to-use patent searches that have been conducted may not have identified all relevant issued patents or pending patents. We cannot provide assurance that our proposed products in this area will not ultimately be held to infringe one or more valid claims owned by third parties which may exist or come to exist in the future or that in such case we will be able to obtain a license from such parties on acceptable terms.

We cannot guarantee that the practice of our technologies will not conflict with the rights of others. In some foreign jurisdictions, we could become involved in opposition proceedings, either by opposing the validity of another's foreign patent or by persons opposing the validity of our foreign patents.

We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost to us of any litigation or other proceeding relating to these areas, even if deemed frivolous or resolved in our favor, could be substantial and could distract management from our business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

If we infringe the rights of others, we could be prevented from selling products or forced to pay damages.

If our products, methods, processes, and other technologies are found to infringe the proprietary rights of other parties, we could be required to pay damages, or we may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms.

RISKS RELATING TO OUR SECURITIES

We cannot assure you that our common stock will be liquid or that it will remain listed on the NYSE American. A failure to regain compliance with the NYSE American stockholders' equity listing requirements or failure to continue to meet the other listing requirements could result in a de-listing of our common stock.

Our common stock is listed on the NYSE American. The NYSE American's listing standards generally mandate that we meet certain requirements relating to stockholders' equity, stock price, market capitalization, aggregate market value of publicly held shares and distribution requirements. We cannot assure you that we will be able to maintain the continued listing standards of the NYSE American. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of $6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Company Guide. At December 31, 2020, we had a stockholders' deficit of $7.5 million. The NYSE American Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer if it is in compliance with all of the following:a total value of market capitalization of at least $50.0 million; 1,100,000 publicly-held shares; a market value of publicly held shares of at least $15.0 million; and 400 round lot shareholders. Although we have more than 1,100,000 shares publicly held and 400 round lot shareholders, our stock price is volatile and, during 2019 and 2020, the price of our common stock experienced a sustained decrease resulting in a period where our market capitalization fell below $50.0 million. Our market capitalization is currently above $50.0 million.

If our common stock falls below $0.20 per share on a 30-trading-day average it will become subject to the continued listing evaluation and follow-up procedures set forth in Section 1009 of the NYSE American Company Guide which could, among other things, result in initiation of immediate delisting procedures. In the event that we were to fail to meet the requirements of NYSE American per share price requirement or stockholders' equity requirement and we could not timely cure such deficiency, our listing could become subject to NYSE American continued listing evaluation and follow-up procedures, which could result in delisting procedures.

On November 25, 2019, we announced that we received written communication from the NYSE American stating we were no longer in compliance with certain continued listing standards as set forth in the NYSE American Company Guide relating to stockholders' equity as of September 30, 2019. Specifically, the Deficiency Letter stated that we were not in compliance with Section 1003(a)(iii) (requiring stockholders' equity of $6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years). The Deficiency Letter noted that the Company had a stockholders' equity of $4.9 million as of September 30, 2019, and had reported net losses in its five most recent fiscal years. On December 20, 2019, we submitted a plan of compliance to the NYSE American outlining our plan to regain compliance with certain continued listing standards as set forth in Part 10, Section 1003(iii) of the NYSE American Company Guide by November 25, 2020, the conclusion of the compliance plan period. On February 7, 2020, we received notice from the NYSE American that it had accepted our plan and granted a plan period through November 25, 2020 to regain compliance. On July 30, 2020 we received written communication from NYSE American stating that in addition to Section 1003(iii), we were also not in compliance with Section 1003(i) and Section 1003(ii) of the NYSE American Company Guide since we reported a

stockholders' deficit of ($4.0) million as of March 31, 2020 and losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2019. As a result, the Company is now subject to the procedures and requirements set forth in Section 1009 of the Company Guide. We remain subject to the conditions set forth in the Exchange's letter dated November 25, 2019 for the initial equity noncompliance. The NYSE Regulation staff will review our company periodically for compliance with the initiatives outlined in the plan. If we are not in compliance with the continued listing standards by November 25, 2020 or if we do not make progress consistent with the plan during the plan period, NYSE Regulation staff may initiate delisting proceeding as appropriate. On November 23, 2020 we received written communication from NYSE American notifying us that we have had been granted an extension until May 25, 2021 to regain compliance with certain continued listing standards as set forth in Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide. We will remain subject to periodic review by NYSE American staff during the extension period. Failure to make progress consistent with the plan or regain compliance with the continued listing standards by the end of the extension period could result in the Company being delisted from the NYSE American.

There can be no assurance that we can regain compliance with the listing standards of the NYSE American, or that the NYSE American will continue to list our common stock if we regain compliance, or if we continue to fail to maintain the minimum stockholders' equity. In addition, in the future we may not be able to maintain such minimum stockholders' equity and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE American. If we are delisted from the NYSE American then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE American could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities we cannot assure you that our common stock will be liquid or that it will remain listed on the NYSE American. A failure to regain compliance with the NYSE American stockholders' equity requirements or failure to continue to meet the other listing requirements could result in a de-listing of our common stock.

We expect to seek to raise additional capital in the future, which may be dilutive to stockholders or impose operational restrictions.

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by existing stockholders, thereby subjecting such stockholders to dilution. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. In the event that we sell shares or other securities at prices below the exercise price of the warrants that we issued in our October 2018 offering, the price protection anti-dilution provisions of the warrant provide that the exercise price of the warrants sold in our October 2018 offering is to be reduced which may result in additional warrant exercises and additional dilution to stockholders as was the case in 2020 and during the first quarter of 2021 when we utilized our at-the-market facility and the warrant exercise price was reduced. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by existing stockholders.

Holders of our warrants issued in our October 2018 offering have no rights as common stockholders until they exercise their warrants and acquire our common stock.

Until the holders of the warrants we issued in our October 2018 offering acquire shares of our common stock by exercising their warrants, the holders of the warrants have no rights as a stockholder with respect to the shares of common stock underlying their securities. Upon exercise of the warrants they will be entitled to the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Whether the outstanding warrants will have any value will depend on the market conditions for, and the price of, our common stock, which conditions will depend on factors related and unrelated to the success of our clinical development program, and cannot be predicted at this time. If our common stock price does not increase to an amount sufficiently above the exercise price of the warrants during the periods the warrants are exercisable, holders of warrants will be unable to recover any of their investment in the warrants

Because there is no established public trading market for the October 2018 warrants we issued, the liquidity of each such security is limited. We do not expect a market to develop, nor do we intend to apply to list the warrants on any securities exchange. Upon exercise of the warrants, our stockholders will experience dilution.

The market price of our common stock has been and may continue to be volatile and adversely affected by various factors.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. By way of example, on October 2, 2020, the price of our common stock closed at $0.32 per share while on February 9, 2021, our stock price closed at $1.10 per share with no discernable announcements or developments by the company or third parties. On January 5, 2021, the intra-day sales price of our common stock fluctuated between a reported low sale price of $0.93 and a reported high sales price of $1.70. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects. In addition, the recent outbreak of the novel strain of coronavirus (COVID-19) has caused broad stock market and industry fluctuations. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- investor reaction to our business strategy;
- the success of competitive products or technologies;
- our continued compliance with the listing standards of the NYSE American;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- results of our clinical trials;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;

- developments concerning our collaborations or partners;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- declines in the market prices of stocks generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, public health issues including health epidemics or pandemics, such as the recent outbreak of the novel coronavirus (COVID-19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Further, recent increases are significantly inconsistent with any improvements in actual or expected operating performance, financial condition or other indicators of value. Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. There can be no guarantee that our stock price will remain at current prices or that future sales of our common stock will not be at prices lower than those sold to investors.

Additionally, recently, securities of certain companies have experienced significant and extreme volatility in stock price due short sellers of shares of common stock, known as a "short squeeze." These short squeezes have caused extreme volatility in those companies and in the market and have led to the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. While we have no reason to believe our shares would be the target of a short squeeze, there can be no assurance that we won't be in the future, and you may lose a significant portion or all of your investment if you purchase our shares at a rate that is significantly disconnected from our underlying value.

Our articles of incorporation and bylaws and Nevada law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our articles of incorporation, as amended, our amended and restated bylaws and Nevada law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. The Board of Directors could authorize the issuance of an additional series of preferred stock that would grant holders preferred rights to our assets upon liquidation, special voting rights, the right to receive dividends before dividends

would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue additional preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

Provisions of our articles of incorporation, as amended and our amended and restated bylaws may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our articles of incorporation, as amended, and amended and restated bylaws, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Our failure to fulfill all of our registration requirements may cause us to suffer liquidated damages, which may be very costly.

Pursuant to the terms of the registration rights agreement that we entered into with Intrexon and an affiliated entity, we were required to file a registration statement with respect to securities issued and are required to maintain the effectiveness of such registration statement. The failure to do so could result in the payment of damages by us. There can be no assurance that we will be able to maintain the effectiveness of any registration statement, and therefore there can be no assurance that we will not incur damages with respect to such agreements.

We do not intend to pay dividends in the foreseeable future on our common stock.

We have never paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and currently do not plan to pay any cash dividends in the foreseeable future. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the market price of our common stock price appreciates. Our Series A Preferred Stockholders rank senior to our common stockholders with respect to dividends.

Resales of our common stock in the public market by our stockholders may cause the market price of our common stock to fall.

We may issue common stock from time to time in connection with future offerings. Any issuance from time to time of new shares of our common stock, or our ability to issue shares of common stock in future offerings, could result in resales of our common stock by our current stockholders concerned about the potential dilution of their holdings. In turn, these resales could have the effect of depressing the market price for our common stock.

The shares of common stock offered under our current Amended and Restated At Market Issuance Sales Agreement may be sold in "at the market" offerings, and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares that are sold under our current Amended and Restated At Market Issuance Sales Agreement at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price.

Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our corporate headquarters are located in Rockville, Maryland, where we occupy approximately 10,363 square feet of office space under a lease agreement expiring July 31, 2022, with monthly rent of $23,820.

We do not own any real property. We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed.

Item 3. *Legal Proceedings*

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. *Mine Safety Disclosures*

Not applicable.

PART II

Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

Market Information

Our common stock has traded on the NYSE American under the symbol "SYN" since February 16, 2012. Prior to February 16, 2012, our common stock traded under the symbol "AEN" since October 16, 2008. The last price of our common stock as reported on the NYSE American on March 3, 2021 was $0.6445 per share.

Dividend Policy

We have never paid or declared any cash dividends on our common stock to date, and do not anticipate paying such cash dividends on our common stock in the foreseeable future. Whether we declare and pay dividends is determined by our Board of Directors at their discretion, subject to certain limitations imposed under Nevada corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our Board of Directors.

The Series A Preferred Stock, none of which remains outstanding, ranked senior to the shares of our common stock and shares of our Series B Preferred Stock with respect to dividend rights and holders of Series A Preferred Stock were entitled to a cumulative dividend at the rate of 2.0% per annum, payable quarterly in arrears, as set forth in the Certificate of Designation of Series A Convertible Preferred Stock.

Holders

As of March 3, 2021, we had approximately 343 stockholders of record of our common stock. This number does not include stockholders for whom shares are held in a "nominee" or "street" name.

Stock Performance Graph

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Equity Compensation Plan Information

See Part II–Item 12 under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Equity Compensation Plan Information" of this Annual Report on Form 10-K for equity compensation plan information.

Recent Sales of Unregistered Securities

We did not sell any equity securities during the quarter ended December 31, 2020 in transactions that were not registered under the Securities Act, other than as previously disclosed in our filings with the SEC.

Issuer Purchases of Equity Securities

There were no issuer purchases of equity securities during the year ended December 31, 2020.

Item 6. *Selected Financial Data*

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion of our financial condition and results of operations should be read in conjunction with our audited financial statements and notes thereto for the years ended December 31, 2020 and 2019 included elsewhere in this Annual Report. In addition to historical information, the following discussion contains certain forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results 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 under "Risk Factors" in Part I, Item 1A of this Annual Report.

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 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.

We are continuing to assess the potential impact of the COVID-19 pandemic. We are in close contact with our clinical development partners in order to assess the impact of COVID-19 on our studies and current timelines and costs. While we currently do not anticipate any interruptions in our operations due to COVID-19, it is possible that if the COVID-19 pandemic persists, for an extended period of time, we could experience significant disruptions to our clinical development timelines due to the COVID-19 pandemic, 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 full extent to which the COVID-19 outbreak will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted. 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; allogeneic-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) designed to prevent aGVHD and infection by vancomycin resistant enterococci and SYN-007 (ribaxamase) DR designed 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 Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Current Status
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 Food and Drug Administration (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) · Clarified market/potential partner

		needs and identified potential additional indications in specialty patient populations such as allogeneic hematopoietic cell transplant (HCT) 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) ·Washington University has begun screening patients for enrollment of the first of three antibiotic cohorts for the Phase 1b/2a clinical trial of SYN-004 in adult HCT recipients (Q1 2021)

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 formulation (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) ·A Phase 1 single-ascending-dose (SAD) study is expected to commence during the second quarter of 2021. A topline data readout is anticipated during the third quarter of 2021, pandemic conditions permitting.
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 in a pig model, including encoded 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) · Collaboration with UT Austin

Financial Developments

B Riley and AGP Securities Sales Agreement

During the year ended December 31, 2020, we sold an aggregate of 9.2 million shares of our common stock and received net proceeds of approximately $3.4 million before deducting issuance expenses pursuant to that certain At Market Issuance Sales Agreement, dated August 5, 2016, with B. Riley Securities, Inc. (formerly known as B. Riley FBR, Inc.), as amended by amendment no. 1 thereto, dated May 7, 2018 (the "Original ATM Sales Agreement").

We entered into an Amended and Restated At Market Issuance Sales Agreement, dated February 9, 2021, with B. Riley Securities, Inc., or B. Riley, and A.G.P./Alliance Global Partners, or AGP and together with B. Riley, the sales agents (the "Amended and Restated ATM Sales Agreement"), which replaced the Original ATM Sales Agreement.

Subsequent to year end through March 3, 2021, we have sold approximately 76.3 million shares of our common stock and received net proceeds of approximately $63.8 million, pursuant to the Original ATM Sales Agreement and the Amended and Restated ATM Sales Agreement.

Stock Warrants

On November 16, 2020, the exercise price of warrants issued by us in October 2018 (the "2018 Warrants") was reduced from $1.38 per Warrant per full share of the Company's common stock, $0.001 par value per share (the "Common Stock"), to $0.69 per 2018 Warrant per full share of Common Stock pursuant to the terms of the Warrants. The reduction was the result of the issuance of shares of common stock by the us through its "at the market offering" facility. An entry to reduce the income available to common shareholders was recorded for $880,000 to recognize the value of the effect of the change in exercise price. During January and February 2021, 11,655,747 2018 Warrants were exercised for cash proceeds of $8.0 million.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosures. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

There are accounting policies that we believe are significant to the presentation of our consolidated financial

statements. The most significant accounting policies relate to stock-based compensation, warrants, grants and research and development costs.

Stock-Based Compensation

We recognize stock-based compensation expense under the provisions of ASC 718, *Compensation—Stock Compensation ("ASC 718")*. The fair value of stock options granted is the fair market value on the grant date. We apply the Black-Scholes option pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of our stock options using the weighted average life between the dates that options become fully vested and the maximum life of options granted. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates, however these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we only recognize expense for those stock options expected to vest over the service period.

Warrants

We have issued common stock warrants in connection with the execution of certain equity financings. The fair value of certain warrants, deemed to be derivative instruments, is recorded as a derivative liability under the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 815, *Derivatives and Hedging* ("ASC 815"), upon issuance. Subsequently, the liability is adjusted to fair value as of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption "Change in fair value of warrant liability."

The fair value of warrants deemed to be derivative instruments is determined using Monte Carlo simulations using varying assumptions regarding volatility of our common share price, remaining life of the warrant and risk-free interest rates at each period end. We thus use model-derived valuations where significant value drivers are unobservable to third parties to determine the fair value and accordingly classify such warrants as Level 3 per ASC 820, *Fair Value Measurement (Topic 820).* In 2020 and 2019, the Monte Carlo simulations were not used as the value of the warrants were deemed to be minimal based on the historical fair value of the warrants and the Company's current stock price.

Research and Development Costs

We expense research and development costs associated with developmental products not yet approved by the FDA to research and development expense as incurred. Research and development costs consist primarily of license fees (including upfront payments), milestone payments, manufacturing costs, salaries, stock-based compensation and related employee costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of our product candidates. Research and development expenses include external contract research organization ("CRO") services. We make payments to the CROs based on agreed upon terms and may include payments in advance of study services. We review and accrue CRO expenses based on services performed and rely on estimates of those costs applicable to the stage of completion of study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. At December 31, 2020 and 2019, we have accrued CRO expenses of $0.7 million that are included in accrued expenses. As of December 31, 2020, and 2019, we have prepaid CRO costs of $470,000 and $48,000, respectively.

Results of Operations

Years Ended December 31, 2020 and 2019

General and Administrative Expenses

General and administrative expenses increased to $5.0 million for the year ended December 31, 2020, from $4.6 million for the year ended December 31, 2019. This increase of 8.7% is due to increased legal costs related to business development, patent execution, employee contract matters, vacation expense, insurance costs and registration fees. The charge relating to stock-based compensation expense was $0.3 million for the year ended December 31, 2020, compared to $0.3 million for the year ended December 31, 2019.

Research and Development Expenses

Research and development expenses decreased to $5.1 million for the year ended December 31, 2020, from $11.1 million for the year ended December 31, 2019. This decrease of 54.1% is primarily due to a reduction in preclinical and manufacturing activity of SYN-020 IAP and 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 the SYN-010 clinical trial and to a lesser extent the discontinuation of the Phase 2b investigator sponsored clinical trial of SYN-010. Research and development expenses also include a charge relating to non-cash stock-based compensation expense of $66,000 for the year ended December 31, 2020, compared to $75,000 for the year ended December 31, 2019.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the years ended December 31, 2020 and 2019. These direct expenses were external costs associated with preclinical studies and clinical trials. Indirect research and development costs related to employee costs, facilities, manufacturing, stock-based compensation and research and development support services are not directly allocated to specific drug candidates.

Therapeutic Areas	December 31, 2020 (in thousands)	December 31, 2019 (in thousands)
SYN-010	$ 430	$ 450
SYN-004	245	254
Other therapeutic areas	40	30
Total direct costs	715	734
Total indirect costs	4,416	10,349
Total Research and development	$ 5,131	$ 11,083

Total Other Income

Total other income was $44,000 for the year ended December 31, 2020, compared to other income of $283,000 for the year ended December 31, 2019. Total other income for the year ended December 31, 2020 and 2019 is primarily comprised of interest income from investments.

Net Loss

Our net loss for the year ended December 31, 2020 was $10.1 million, or $0.66 per common share, compared to $15.4 million, or $0.98 per common share for the year ended December 31, 2019. Net loss attributable to common

stockholders for the year ended December 31, 2020 excludes net loss attributable to non-controlling interest of $73,000 and includes the accretion of the Series B preferred stock deemed dividends of $1.4 million on converted shares and Series A preferred stock accrued dividends of $254,000. Net loss attributable to common stockholders for the year ended December 31, 2019 excludes net loss attributable to non-controlling interest of $77,000 and includes the accretion of the Series B preferred stock deemed dividends of $524,000 on converted shares and Series A preferred stock accrued dividends of $248,000.

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 $248.1 million as of December 31, 2020 and expect to continue to incur losses in the foreseeable future.

Our cash and cash equivalents totaled $6.2 million as of December 31, 2020, a decrease of $8.8 million from December 31, 2019. During the year ended December 31, 2020, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $10.1 million for the year ended December 31, 2020. Subsequent to year end through March 3, 2021, we have raised approximately $71.8 million from cash received via the exercise of the 2018 Warrants and sales of our common stock through the Original ATM Sales Agreement and the Amended and Restated ATM Sales Agreement. With the cash available in early March 2021 of $72.6 million, we believe these resources will be sufficient to fund our operations through at least the end of the first quarter of 2023.

As a result of the global COVID-19 pandemic, management was able to extend the Company's cash runway in 2020 since our clinical development partners (CSMC and Washington University) reduced their operating capacity to include only essential activities as part of their response to the pandemic. These delays impacted the timelines for our clinical programs, which included delaying commencement of the Phase 1b/2a clinical trial of SYN-004, as well as a temporary halting of enrollment for the since discontinued clinical trial of SYN-010. If enrollment in our ongoing Phase 1b/2a clinical trial being conducted by Washington University is further postponed due to COVID-19 developments, we expect to continue to experience reduced expenses until such time as enrollment resumes. 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.

Although we are experiencing limited, if any, adverse impact to our financial stability stemming from the global economic slowdown, the overall disruption of global healthcare systems and 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 and obtain additional capital in a similar manner. During the year ended December 31, 2020, our only source of financing other than warrant exercises was from sales of 9.2 million shares of our common stock utilizing our at-the-market offering program through the Original ATM Sales Agreement pursuant to which we received net proceeds of approximately $3.4 million. Subsequent to year end through March 3, 2021, the Company sold approximately 76.3 million shares of the Company's common stock for net proceeds of approximately $63.8 million pursuant to the Original ATM Sales Agreement and the Amended and Restated ATM Sales Agreement.

During the year ended December 31, 2019, we did not engage in financing activities as capital raised via a public offering of our common stock during the year ended December 31, 2018 was sufficient to satisfy our cash needs in 2019 and 2020. The Amended and Restated ATM Sales Agreement enables us to offer and sell shares of our common stock from time to time through B Riley and AGP as our sales agents. Sales of common stock under the Amended and Restated ATM Sales Agreement are made in sales deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act. B Riley and AGP are 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.

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 Amended and Restated ATM Sales Agreement. 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.

We have committed, and expect to continue to commit, substantial capital in order to implement our business strategy, including our planned product development efforts, preparation for our planned clinical trials, and performance of clinical trials and our research and discovery efforts. We believe our cash position of $72.6 million in early March 2021 is sufficient to fund our operations through at least the end of the first quarter of 2023, including continuation of our ongoing Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients for the prevention of aGVHD, as well as our planned Phase 1 and Phase 2s clinical programs for SYN-020.

Following the anticipated completion of our ongoing Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients, the planned Phase 1 SAD and MAD studies and planned Phase 2a clinical trial 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 aforementioned clinical programs. 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.

As the COVID-19 coronavirus continues to spread around the globe, we have experienced disruptions that impacted 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.

License and Contractual Agreement Obligations

We have entered into several license and collaborative agreements for the right to use research, technology and patents. Some of these license and collaborative agreements may contain milestones. The specific timing of such milestones cannot be predicted and are dependent on future developments as well as regulatory actions which cannot be predicted with certainty (including actions which may never occur). Further, under the terms of certain licensing agreements, we may have the obligation to pay certain milestones contingent upon the achievement of specific levels of sales.

Off-Balance Sheet Arrangements

During the years ended December 31, 2020 and 2019, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Contractual Obligations

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Consulting Fees

In November 2017, we engaged a regulatory consultant to assist in our efforts to prepare, file and obtain FDA approval for ribaxamase. The term of the engagement was on a monthly basis, provided that either party may terminate the agreement at any time by providing the other party a six-month notice period. We are obligated to pay the consultant a monthly retainer in addition to the success fee payments of up to an aggregate of $4,500,000 for attainment of certain regulatory milestones. We do not deem the contingent fee is probable at this time.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 8. *Financial Statements and Supplementary Data*

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Synthetic Biologics, Inc.
Rockville, Maryland

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Synthetic Biologics, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of Liquidity

As described in Note 1 to the consolidated financial statements, the Company has a significant accumulated deficit and, with the exception of the three months ended June 30, 2010 and the three months ended December 31, 2017, the Company has experienced significant losses and incurred negative cash flows since inception. The Company expects to continue incurring losses for the foreseeable future. Further, the Company has spent, and expects to continue to spend, a substantial amount of funds in connection with implementing its business strategy, including planned product development efforts, clinical trials and research and discovery efforts. The Company is dependent on its ability to raise additional funding from the capital markets in order to continue to fund its operations.

We identified management's evaluation of the Company's liquidity as a critical audit matter due to the significant judgments and assumptions used by management in (i) preparing its forecast of cash expenditures to support the Company's drug development and clinical trials, and (ii) providing complete and accurate disclosures related to the Company's liquidity. Auditing these judgments and assumptions involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Testing the completeness and accuracy of underlying data used in the forecasted cash expenditures by (i) inspecting contractual arrangements with third-party clinical research organizations and suppliers, and (ii) considering current and past expenditures in evaluating the forecasted fixed and variable costs.

- Assessing the reasonableness of management's key assumptions in forecasting cash expenditures by (i) performing a retrospective review of historical forecasts, (ii) comparing information related to the Company's ongoing and anticipated clinical trials and drug development pipeline to management's assumptions, and (iii) assessing the impact of proceeds received from equity financing activities subsequent to year-end on the Company's planned expenditures.

- Evaluating the adequacy of management's disclosure in the consolidated financial statements regarding the Company's liquidity by comparing to other audit evidence obtained to determine whether such information is consistent with or contradictory to the Company's liquidity disclosure.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.

Potomac, Maryland

March 4, 2021

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Balance Sheets
(In thousands except share and par value amounts)

	December 31, 2020	December 31, 2019
Assets		
Current Assets		
Cash and cash equivalents	$ 6,227	$ 15,045
Prepaid expenses and other current assets	1,707	1,381
Total Current Assets	7,934	16,426
Property and equipment, net	174	367
Right of Use Asset	279	419
Deposits and other assets	23	23
Total Assets	$ 8,410	$ 17,235
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 886	$ 2,315
Accrued expenses	925	1,776
Accrued employee benefits	868	935
Lease liability	287	249
Total Current Liabilities	2,966	5,275
Lease liability - Long term	186	473
Total Liabilities	3,152	5,748
Commitments and Contingencies	-	-
Series A convertible preferred stock, $0.001 par value; 10,000,000 shares authorized; 120,000 issued and outstanding	12,798	12,544
Stockholders' Deficit:		
Series B convertible preferred stock, $0.0001 par value; 10,000,000 shares authorized, 3,973 issued and outstanding at December 31, 2020 and 7,638 issued and outstanding at December 31, 2019	2,477	4,761
Common stock, $0.001 par value; 200,000,000 shares authorized, 29,252,253 issued and 29,249,925 outstanding at December 31, 2020 and 16,808,758 issued and 16,806,430 outstanding at December 31, 2019	29	17
Additional paid-in capital	240,821	232,580

Accumulated deficit	(248,094)	(235,537)
Total Synthetic Biologics, Inc. and Subsidiaries (Deficit) Equity	(4,767)	1,821
Non-controlling interest	(2,773)	(2,878)
Total Stockholders' Deficit	(7,540)	(1,057)
Total Liabilities and Stockholders' Deficit	$ 8,410	$ 17,235

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	For the year ended December 31,	
	2020	2019
Operating Costs and Expenses:		
General and administrative	$ 5,029	$ 4,580
Research and development	5,131	11,083
Total Operating Costs and Expenses	10,160	15,663
Loss from Operations	(10,160)	(15,663)
Other Income:		
Interest income	44	283
Total Other Income	44	283
Net Loss	(10,116)	(15,380)
Net Loss Attributable to Non-controlling Interest	(73)	(77)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	$ (10,043)	$ (15,303)
Series A Preferred Stock Dividends	(254)	(248)
Series B Preferred Stock Dividends	(1,380)	(525)
Effect of Warrant exercise price adjustment	(880)	-
Net Loss Attributable to Common Stockholders	$ (12,557)	$ (16,076)
Net Loss Per Share - Basic and Dilutive	$ (0.66)	$ (0.98)
Weighted average number of shares outstanding during the period - Basic and Dilutive	19,011,362	16,438,201

See accompanying notes to consolidated financial statements

Consolidated Statements of Stockholders Deficit
(In thousands, except share and par value amounts)

	Common Stock		Series B Preferred					
	Shares	Amount	Shares	Amount	APIC	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Deficit
Balance at December 31, 2018	15,482,083	$ 15	9,161	$ 5,760	$ 230,754	$ (219,461)	$ (2,909)	$ 14,159
Stock-based compensation	-	-	-	-	340	-	-	340
Series A Preferred Stock Dividends	-	-	-	-	-	(248)	-	(248)
Issuance of SYN Biomics Stock	-	-	-	-	(36)	-	108	72
Conversion of Series B Preferred Stock to Common	1,324,347	2	(1,523)	(999)	1,522	(525)	-	-
Net Loss	-	-	-	-	-	(15,303)	-	(15,303)
Non-controlling interest	-	-	-	-	-	-	(77)	(77)
Balance at December 31, 2019	16,806,430	$ 17	7,638	$ 4,761	$ 232,580	$ (235,537)	$ (2,878)	$ (1,057)
Stock-based compensation	-	-	-	-	350	-	-	350
Stock issued under "at-the-market" offering	9,256,535	9	-	-	3,350	-	-	3,359
Series A Preferred Stock Dividends	-	-	-	-	-	(254)	-	(254)
Issuance of SYN Biomics Stock	-	-	-	-	-	-	178	178
Effect of Warrant exercise price adjustment	-	-	-	-	880	(880)	-	-
Conversion of Series B Preferred Stock to Common	3,186,960	3	(3,665)	(2,284)	3,661	(1,380)	-	-
Net Loss	-	-	-	-	-	(10,043)	-	(10,043)
Non-controlling interest	-	-	-	-	-	-	(73)	(73)
Balance at December 31, 2020	29,249,925	$ 29	3,973	$ 2,477	$ 240,821	$ (248,094)	$ (2,773)	$ (7,540)

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows
(In thousands)

	For the year ended December 31,	
	2020	2019
Cash Flows From Operating Activities:		
Net loss	$ (10,116)	$ (15,380)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	350	340
Subsidiary stock issuances to vendor	178	72
Depreciation	201	240
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(326)	(788)
Right of use asset	141	118
Accounts payable	(1,429)	1,282
Accrued expenses	(851)	857
Accrued employee benefits	(67)	(397)
Lease liability	(249)	(217)
Net Cash Used In Operating Activities	(12,168)	(13,873)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(9)	-
Net Cash Used In Investing Activities	(9)	-
Cash Flows From Financing Activities:		
Proceeds from "at-the-market" stock issuance	3,359	-
Net Cash Provided By Financing Activities	3,359	-
Net decrease in cash	(8,818)	(13,873)
Cash and cash equivalents at beginning of year	15,045	28,918
Cash and cash equivalents at end of year	$ 6,227	$ 15,045
NONCASH FINANCING ACTIVITIES:		
Conversion of Series B Preferred Stock	$ 2,284	$ 999
Deemed dividends for accretion of Series B Preferred Stock discount	$ 1,380	$ 525
Effect of Warrant exercise price adjustment	$ 880	$ -
In-kind dividends in preferred stock	$ 254	$ 248
Right of use assets from operating lease	$ -	$ 537

See accompanying notes to consolidated financial statements

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a diversified clinical-stage company developing therapeutics designed to prevent and treat gastrointestinal (GI) diseases in areas of high unmet need. The Company's lead clinical development candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent (a) microbiome damage, (b) *Clostridioides difficile* infection (CDI), (c) overgrowth of pathogenic organisms, (d) the emergence of antimicrobial resistance (AMR) and (e) 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 Current Good Manufacturing Practice (cGMP) conditions and intended to treat both local GI and systemic diseases.

The Company was 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 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.

Corporate Structure and Basis of Presentation

As of December 31, 2020, the Company had eight subsidiaries, Pipex Therapeutics, Inc. ("Pipex Therapeutics"), Effective Pharmaceuticals, Inc. ("EPI"), Solovax, Inc. ("Solovax"), CD4 Biosciences, Inc. ("CD4"), Epitope Pharmaceuticals, Inc. ("Epitope"), Healthmine, Inc. ("Healthmine"), Putney Drug Corp. ("Putney") and Synthetic Biomics, Inc. ("SYN Biomics"). Pipex Therapeutics, EPI, Healthmine and Putney are wholly owned, and Solovax, CD4, Epitope and SYN Biomics are majority-owned.

For financial reporting purposes, the outstanding common stock of the Company is that of Synthetic Biologics, Inc. All statements of operations, (deficit) equity and cash flows for each of the entities are presented as consolidated. All subsidiaries were formed under the laws of the State of Delaware on January 8, 2001, except for EPI, which was incorporated in Delaware on December 12, 2000, Epitope which was incorporated in Delaware in January of 2002, Putney which was incorporated in Delaware in November of 2006, Healthmine which was incorporated in Delaware in December of 2007 and SYN Biomics which was incorporated in Nevada in December of 2013.

1. Organization and Nature of Operations and Basis of Presentation – (continued)

Liquidity

As of December 31, 2020, the Company has a significant accumulated deficit, and with the exception of the three months ended June 30, 2010 and the three months ended December 31, 2017, the Company has experienced significant losses and incurred negative cash flows since inception. The Company expects to continue incurring losses for the foreseeable future, with the recognition of revenue being contingent on successful phase 3 clinical trials and requisite approvals by the FDA. Historically, the Company has financed its operations primarily through public and private sales of its common stock and a private placement of its preferred stock, and it expects to continue to seek to obtain required capital in a similar manner. The Company has spent, and expects to continue to spend, a substantial amount of funds in connection with implementing its business strategy, including planned product development efforts, clinical trials and research and discovery efforts.

Cash and cash equivalents totaled approximately $6.2 million as of December 31, 2020, which includes the net proceeds of approximately $3.4 million from sales of its Common Stock in "at-the-market" (ATM) equity offerings during 2020. Subsequent to year end through March 3, 2021, the Company received cash proceeds of approximately $8.0 million through the exercise of a portion of the October 2018 warrants and approximately $63.8 million from sales of its Common Stock in "at-the-market" (ATM) equity offerings, see Note 10. With these additional sources of liquidity, the Company believes it will be able to fund its operations through the next twelve months from the issuance date of these financial statements. Management believes its plan, which includes the further development of SYN-020 and additional testing of SYN-004 (ribaxamase), will allow the Company to meet its financial obligations, further advance key products, and maintain the Company's planned operations for at least one year from the issuance date of these consolidated financial statements. If necessary, the Company may attempt to utilize the ATM or seek to raise additional capital on the open market, neither of which is guaranteed. Use of the ATM is limited by certain restrictions and management's plan does not rely on additional capital from either of these sources. If the Company is not able 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 any later stage clinical trial will require significant financing or a significant partnership.

2. Summary of Significant Accounting Policies

Principles of Consolidation

All intercompany transactions and accounts have been eliminated in consolidation.

Immaterial Revision

In 2020, the Company completed an Internal Revenue Code Section 382 analysis of its historical net operating loss carry-forward amount. As a result, the prior year net operating loss carry-forward was determined to be limited. See Note 8 for further details.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such estimates and assumptions impact, among others, the following: the estimated useful lives for property and equipment, fair value of warrants, preferred stock and stock options granted for services or compensation, respectively, and the valuation allowance for deferred tax assets due to continuing and expected future operating losses.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of consolidated financial statements, which management considered in formulating its estimate could change in the near term due to one or more future confirming events. Accordingly, actual results could differ from those estimates.

Non-controlling Interest

The Company's non-controlling interest represents the minority stockholder's ownership interest related to the Company's subsidiary, SYN Biomics. The Company reports its non-controlling interest in subsidiaries as a separate

component of equity in the Consolidated Balance Sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company's common stockholders on the face of the Consolidated Statements of Operations. On September 5, 2018, the Company entered into an agreement with the minority stockholder for an investigator-sponsored Phase 2 clinical study of SYN-010. Prior to this agreement and IRB approval in December 2018, the Company's equity interest in SYN Biomics was 88.5% and the non-controlling stockholder's interest was 11.5%. In consideration of the support, the Company issued additional shares of stock to the minority stockholder. The Company's equity interest in SYN Biomics is now 83.0% and the non-controlling stockholder's interest is 17.0%. This is reflected in the Consolidated Statements of Equity (Deficit).

Risks and Uncertainties

The Company's operations could be subject to significant risks and uncertainties including financial, operational and regulatory risks and the potential risk of business failure. These conditions may not only limit the Company's access to capital, but also make it difficult for its customers, its vendors and its ability to accurately forecast and plan future business activities.

2. Summary of Significant Accounting Policies – (continued)

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less.

Property and Equipment

Property and equipment is recorded at cost and depreciated or amortized using the straight-line method over the estimated useful life of the asset or the underlying lease term for leasehold improvements, whichever is shorter. The estimated useful life by asset description is noted in the following table.

Asset Description	Estimated Useful Life
Office equipment and furniture	3 – 5 years
Leasehold improvements and fixtures	Lesser of estimated useful life or lease term

Depreciation and amortization expense was approximately $201,000 and $240,000 for the years ended December 31, 2020 and 2019, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts with any gain or loss reported in the consolidated statement of operations. Repairs and maintenance are charged to expense as incurred.

The Company reviews property and equipment for impairment to determine if assets are impaired due to obsolescence. As a result of this review, there was no impairment recognized for the years ended December 31, 2020 and 2019.

Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such an event or change in circumstances occurs and potential impairment is indicated because the carrying values exceed the estimated future undiscounted cash

flows of the asset, the Company will measure the impairment loss as the amount by which the carrying value of the asset exceeds its fair value.

Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding including the effect of common share equivalents. Diluted net loss per share assumes the issuance of potential dilutive common shares outstanding for the period and adjusts for any changes in income and the repurchase of common shares that would have occurred from the assumed issuance, unless such effect is anti-dilutive. Net loss attributable to common stockholders for the year ended December 31, 2020 excludes net loss attributable to non-controlling interest of $0.1 million and includes the accretion of Series B preferred discount of $1.4 million on converted shares and Series A preferred stock accrued dividends of $0.3 million. Net loss attributable to common stockholders for the year ended December 31, 2019 excludes net loss attributable to non-controlling interest of $0.1 million and includes the accretion of Series B preferred discount of $0.5 million on converted shares and Series A preferred stock accrued dividends of $0.2 million. The number of shares of common stock underlying Series A Preferred shares convertible to common stock that were excluded from the computations of net loss per common share for the years ended December 31, 2020 and 2019 were 678,258 and 664,798, respectively. The number of shares of common stock underlying Series B Preferred shares convertible to common stock that were excluded from the computations of net loss per common share and for the years ended December 31, 2020 and 2019 were 3,454,783 and 6,641,736, respectively. The number of options and warrants for the purchase of common stock that were excluded from the computations of net loss per common share for the year ended December 31, 2020 were 3,997,418 and 18,000,713, respectively, and for the year ended December 31, 2019 were 2,502,012 and 18,714,999, respectively, because their effect is anti-dilutive.

2. Summary of Significant Accounting Policies – (continued)

Research and Development Costs

The Company expenses research and development costs associated with developmental products not yet approved by the FDA to research and development expense as incurred. Research and development costs consist primarily of license fees (including upfront payments), milestone payments, manufacturing costs, salaries, stock-based compensation and related employee costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of our product candidates. Research and development expenses include external contract research organization ("CRO") services. The Company makes payments to the CROs based on agreed upon terms and may include payments in advance of study services. The Company reviews and accrues CRO expenses based on services performed and relies on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Accrued CRO costs are subject to revisions as such studies progress to completion. At December 31, 2020 and 2019, the Company has accrued CRO expenses of "$0.7 million and $0.7 million", that are included in accrued expenses. The Company has prepaid CRO costs at December 31, 2020 and 2019 of $470,000 and $48,000, respectively.

Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") 820, *Fair Value Measurement*, defines fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As

such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are classified on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices, that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

The carrying amounts of the Company's short-term financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities approximate fair value due to the relatively short period to maturity for these instruments.

Cash and cash equivalents include money market accounts of $114,000 and $98,000 as of December 31, 2020 and 2019, respectively, that are measured using Level 1 inputs.

The Company uses Monte Carlo simulations to estimate the fair value of the warrants. In using this model, the fair value is determined by applying Level 3 inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different. In 2020 and 2019, the Monte Carlo simulations were not used as the value of the warrants were deemed to be minimal based on the historical fair value of the warrants and the Company's current stock price.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, warrants, restricted stock grants and stock appreciation rights are measured at their fair value on the awards' grant date typically using the Black-Scholes option pricing model, based on the estimated number of awards that are ultimately expected to vest.

2. Summary of Significant Accounting Policies – (continued)

Stock based compensation awards issued to non-employees for services rendered are recorded at either the fair value of the services rendered or the fair value of the stock-based payment, whichever is more readily determinable. The expense resulting from stock-based payments is recorded in research and development expense or general and administrative expense in the Consolidated Statements of Operations, depending on the nature of the services provided.

Derivative Instruments

The warrants issued in conjunction with the public offering of the Company's securities in November 2016 include a

provision that if the Company were to enter into a certain transaction, as defined in the warrant agreement, the warrants would be purchased from the holder for cash. The provisions of these warrants preclude equity accounting treatment under ASC 815, *Derivatives and Hedging,* Accordingly, the Company is required to record the warrants as liabilities at their fair value upon issuance and re-measure the fair value at each period end with the change in fair value recorded in the Consolidated Statement of Operations. When the warrants are exercised or cancelled, they are reclassified to equity. The Company uses Monte Carlo simulations to estimate the fair value of the warrants. In November 2020, all liability-classified warrants expired. In 2019, the Monte Carlo simulations were not used as the value of the warrants was deemed to be minimal based on the historical fair value of the warrants and the Company's current stock price.

Income Taxes

The Company recognizes deferred tax assets and liabilities based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities, using enacted tax rates in effect in the years the differences are expected to reverse. Deferred income tax benefit (expense) results from the change in net deferred tax assets or deferred tax liabilities. A valuation allowance is recorded when it is more likely than not that some or all deferred tax assets will not be realized.

Management assesses the need to accrue or disclose uncertain tax positions for proposed potential adjustments from various federal and state authorities who regularly audit the Company in the normal course of business. In making these assessments, management must often analyze complex tax laws of multiple jurisdictions. The Company records the related interest expense and penalties, if any, as tax expense in the tax provision. At December 31, 2020 and 2019, the Company did not record any liabilities for uncertain tax positions.

Recent Accounting Pronouncements and Developments

In August 2020, the FASB issued Accounting Standards Update (ASU) 2020-06 *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (subtopic 815-40)*: *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the impact of ASU 2020-06 on its consolidated financial statements.

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 or "COVID-19") 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.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was enacted. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States' economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. The Company has assessed the impact of the CARES Act and, based upon our initial assessment, the Company does not believe that it will have a significant effect on our financial position, results of operations or cash flows. The Company continues to evaluate its impact as new information becomes available.

3. Selected Balance Sheet Information

PREPAID EXPENSES AND OTHER CURRENT ASSETS (in thousands):

	December 31, 2020	December 31, 2019
Prepaid insurances	$ 639	$ 549
Prepaid clinical research organizations	470	48
Stock sales receivable	469	3
Prepaid consulting, subscriptions and other expenses	90	134
Prepaid manufacturing expenses	39	622
Prepaid conferences and travel	-	25
Total	$ 1,707	$ 1,381

Prepaid CRO expense is classified as a current asset. The Company makes payments to the CROs based on agreed upon terms that include payments in advance of study services.

PROPERTY AND EQUIPMENT (in thousands)

	December 31, 2020	December 31, 2019
Computers and office equipment	$ 813	$ 804
Leasehold improvements	439	439
Software	11	11
	1,263	1,254
Less: accumulated depreciation and amortization	(1,089)	(887)
Total	$ 174	$ 367

ACCRUED EXPENSES (in thousands)

	December 31, 2020	December 31, 2019
Accrued clinical consulting services	$ 700	$ 684
Accrued vendor payments	225	456
Accrued manufacturing costs	-	636
Total	$ 925	$ 1,776

3. Selected Balance Sheet Information – (continued)

ACCRUED EMPLOYEE BENEFITS (in thousands)

	December 31, 2020	December 31, 2019
Accrued bonus expense	$ 724	$ 858
Accrued vacation expense	144	77
Total	$ 868	$ 935

4. Stock-Based Compensation and Warrants

Stock Incentive Plan

On March 20, 2007, the Company's Board of Directors approved the 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 71,429 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. This plan was approved by the stockholders on November 2, 2007. The exercise price of stock options under the 2007 Stock Plan was determined by the compensation committee of the Board of Directors and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2007 plan shall not exceed 7,143. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of December 31, 2020, there were 5,145 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 85,714 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. On October 22, 2013, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of Company's common stock reserved for issuance under the Plan from 85,714 to 171,429; on May 15, 2015, increased the number of shares from 171,429 to 228,572; on August 25, 2016, increased the number of shares from 228,572 to 400,000; on September 7, 2017, increased the number of shares from 400,000 to 500,000; on September 24, 2018 increased the number of shares from 500,000 to 1,000,000; and on September 5, 2019, increased the number of shares from 1,000,000 to 4,000,000. The exercise price of stock options under the 2010 Stock Plan is determined by the compensation committee of the Board of Directors and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various period from the date of grant, and expire between five and ten years after the grant date. As of December 31, 2020, there were 2,452,273 options issued and outstanding under the 2010 Stock Plan.

On September 17, 2020, the stockholders approved and adopted the 2020 Stock Incentive Plan ("2020 Stock Plan") for the issuance of up to 4,000,000 shares of Common Stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. As of December 31, 2020, there were 1,540,000 options issued and outstanding under the 2010 Stock Plan.

4. Stock-Based Compensation and Warrants – (continued)

In the event of an employee's termination, the Company will cease to recognize compensation expense for that employee. Stock forfeitures are recognized as incurred. There is no deferred compensation recorded upon initial grant date. Instead, the fair value of the stock-based payment is recognized over the stated vesting period.

The Company has applied fair value accounting for all stock-based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option pricing model. The assumptions used for the years ended December 31, 2020 and 2019 are as follows:

	Year ended December 31,	
	2020	2019
Exercise price	$ 0.42	$ 0.42
Expected dividends	0%	0%
Expected volatility	88%	84%
Risk free interest rate	0.31%	1.61%
Expected life of option (years)	4.3	4.5

Expected dividends —The Company has never declared or paid dividends on its common stock and has no plans to do so in the foreseeable future.

Expected volatility—Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The expected volatility assumption is derived from the historical volatility of the Company's common stock over a period approximately equal to the expected term.

Risk-free interest rate—The assumed risk free rate used is a zero coupon U.S. Treasury security with a maturity that approximates the expected term of the option.

Expected life of the option—The period of time that the options granted are expected to remain unexercised. Options granted during the year have a maximum term of seven years. The Company estimates the expected life of the option term based on the weighted average life between the dates that options become fully vested and the maximum life of options granted.

4. Stock-Based Compensation and Warrants – (continued)

The Company records stock-based compensation based upon the stated vesting provisions in the related agreements. The vesting provisions for these agreements have various terms as follows:

- immediate vesting,
- in full on one-year anniversary date of grant date,
- half vesting immediately and remaining over three years,
- quarterly over three years,

- annually over three years,
- one-third immediate vesting and remaining annually over two years,
- one-half immediate vesting and remaining over nine months,
- one-quarter immediate vesting and remaining over three years,
- one-quarter immediate vesting and remaining over 33 months,
- monthly over one year, and
- monthly over three years.

During the years ended December 31, 2020 and 2019, the Company granted 1,540,000 and 1,725,000 options to employees and directors having an approximate fair value of $0.4 million and $0.5 million based upon the Black-Scholes option pricing model, respectively.

Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to employees for the years ended December 31, 2020 and 2019 was $213,000 and $295,000, respectively. Stock-based compensation expense included in general and administrative expenses and research and development expenses relating to stock options issued to consultants for the years ended December 31, 2020 and 2019 were $137,000 and $45,000, respectively.

A summary of stock option activity for the years ended December 31, 2020 and 2019 is as follows:

4. Stock-Based Compensation and Warrants – (continued)

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2018	938,982	$ 15.18	6.19 years	$ -
Granted	1,725,000	0.42		
Exercised	-	-		
Expired	(94,738)	58.25		
Forfeited	(67,232)	5.95		
Balance - December 31, 2019	2,502,012	3.62	6.51 years	153,353
Granted	1,540,000	0.42		
Exercised	-	-		
Expired	(14,944)	17.57		
Forfeited	(29,650)	0.55		
Balance -December 31, 2020 - outstanding	3,997,418	$ 2.35	6.09 years	$ -

Balance - December 31, 2020 - exercisable	1,319,412	$ 6.25	4.35 years	$ -
Grant date fair value of options granted - December 31, 2020		$ 412,000		
Weighted average grant date fair value - December 31, 2020		$ 0.27		
Grant date fair value of options granted - December 31, 2019		$ 470,000		
Weighted average grant date fair value - December 31, 2019		$ 0.27		

4. Stock-Based Compensation and Warrants – (continued)

The options outstanding and exercisable at December 31, 2020 are as follows:

Options Outstanding				Options Exercisable		
Range of Exercise Price	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$ 0.00 – $40.00	3,929,257	$ 0.99	4.42 years	1,251,251	$ 2.18	4.42 years
41.00 – $70.00	8,364	50.29	2.53 years	8,364	50.29	2.53 years
$71.00 – $102.00	59,797	$ 85.19	3.13 years	59,797	$ 85.19	3.13 years

As of December 31, 2020, total unrecognized stock-based compensation expense related to stock options was $686,000, which is expected to be expensed through February 2023.

The FASB's guidance for stock-based payments requires cash flows from excess tax benefits to be classified as a part of cash flows from operating activities. Excess tax benefits are realized tax benefits from tax deductions for exercised options in excess of the deferred tax asset attributable to stock compensation costs for such options. The Company did not record any excess tax benefits in 2020 or 2019. Cash received from option exercises under the Company's stock-based compensation plans for the years ended December 31, 2020 and 2019 was zero.

Also, during the years ended December 31, 2020 and 2019, the Company did not issue any shares of common stock in connection with the exercise of stock options.

Stock Warrants

On October 15, 2018, the Company closed its underwritten public offering pursuant to which it received gross proceeds of approximately $18.6 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company 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 the Common Stock, and one five-year warrant to purchase one share of Common Stock at an initial exercise price of $1.38 per share, which subsequently was reduced to $0.69 per share (each a "Warrant" and collectively, the "Warrants"), with each Class A Unit to be offered to the public at a public offering price of $1.15, and (ii) 15,723 Class B Units (the "Class B Units", and together with the Class A Units, the "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 the Company's 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 Warrants. On November 16, 2020, the exercise price of the Warrants was reduced from $1.38 per Warrant per full share of the Company's common stock, $0.001 par value per share (the "Common Stock"), to $0.69 per Warrant per full share of Common Stock in accordance with the anti-dilution terms of the Warrant. The reduction was the result of the issuance of shares of Common Stock by the Company through its "at the market offering" facility. The effect of the change in the exercise price of the warrants as a result of the triggering of the down round protection clause in the Warrants was recorded as a deemed dividend of $880,000, which reduces the income available to common stockholders. In addition, pursuant to the underwriting agreement that the Company had entered into with A.G.P./Alliance Global Partners (the "Underwriters"), as representative of the underwriters, the Company 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 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 the Company additional Warrants to purchase 1,807,826 shares of Common Stock.

The Warrants are immediately exercisable at a price of $1.38 ($0.69 effective November 16, 2020) per share of Common Stock (which was 120% of the public offering price of the Class A Units) and expire on October 15, 2023. If, at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of Common Stock to the holder, then the Warrants may only be exercised through a cashless exercise. No fractional shares of Common Stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, the holder will receive an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares. The Company has concluded that the Warrants are required to be equity classified. The Warrants were valued on the date of grant using Monte Carlo simulations. During January and February 2021, 11,655,747 warrants were exercised for cash proceeds of $8.0 million, see note 10.

4. Stock-Based Compensation and Warrants – (continued)

On November 18, 2016, the Company completed a public offering of 714,286 shares of common stock in combination with accompanying warrants to purchase an aggregate of 1,428,571 shares of the common stock. The stock and warrants were sold in combination, with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was $35.00. The shares of common stock were immediately separable from the warrants and were issued separately. The initial per share exercise price of the Series A warrants is $50.05 and the per share exercise price of the Series B warrants is $60.20, each subject to adjustment as specified in the warrant agreements. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four-year anniversary of the issuance date. The Series B warrants expired December 31, 2017 and none were exercised prior to expiration. The warrants include a provision, that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder for cash. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date of $15.7 million and changes in estimated fair value will be

recorded as non-cash income or expense in the Company's Statement of Operations at each subsequent period. At December 31, 2019, the fair value of the warrant liability was $100. The warrants were valued on the date of grant and on each remeasurement period. The Series A warrants expired November 18, 2020 and none were exercised prior to expiration.

4. Stock-Based Compensation and Warrants – (continued)

On October 10, 2014, the Company raised net proceeds of $19.1 million through the sale of 14,059,616 units at a price of $1.47 per unit to certain institutional investors in a registered direct offering. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.50 shares of common stock. The warrants, exercisable for an aggregate of 200,852 shares of common stock, have an exercise price of $61.25 per share and a life of five years. The warrants vested immediately and expired on October 10, 2019.

4. Stock-Based Compensation and Warrants – (continued)

A summary of all warrant activity for the Company for the years ended December 31, 2020 and 2019 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2018	18,915,851	$ 3.85
Granted	-	-
Exercised	-	-
Forfeited	(200,852)	61.25
Balance at December 31, 2019	18,714,999	3.24
Granted	-	-
Exercised	-	-
Forfeited	(714,286)	50.05
Balance at December 31, 2020	18,000,713	$ 0.69

On December 26, 2017, the Company entered into a consulting agreement for advisory services for a period of six months. As compensation for such services, the consultant was paid an upfront payment, is paid a monthly fee and on January 24, 2018 was issued a warrant exercisable for 714 shares of the Company's common stock on the date of issue. The warrant is equity classified and the fair value of the warrant approximated $9,000 and was measured using the Black-Scholes option pricing model.

A summary of all outstanding and exercisable warrants as of December 31, 2020 is as follows:

	Weighted Average

Exercise Price	Warrants Outstanding	Warrants Exercisable	Remaining Contractual Life
$ 0.69	17,999,999	17,999,999	2.78 years
18.20	714	714	1.99 years
$ 0.69	18,000,713	18,000,713	2.78 years

Synthetic Biologics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

5. Stockholders' Equity

Series B Preferred Stock

On October 15, 2018, the Company closed its underwritten public offering pursuant to which it received gross proceeds of approximately $18.6 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company and sold an aggregate of (i) 2,520,000 Class A Units, with each Class A Unit offered to the public at a public offering price of $1.15, and (ii) 15,723 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 the Company's 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. Since the above units are equity instruments, the proceeds were allocated on a relative fair value basis which created the Series B Preferred Stock discount.

In addition, pursuant to the Underwriting Agreement that the Company entered into with the Underwriters on October 10, 2018, the Company 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 warrants to purchase an additional 2,428,825 shares of Common Stock. Each Warrant is exercisable for one share of common stock. The Underwriters partially exercised the Over-allotment Option by electing to purchase from the Company additional Warrants to purchase 1,807,826 shares of Common Stock.

The Units were offered by the Company 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.

The conversion price of the Series B Preferred Stock and exercise price of the October 2018 Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Common Stock. The exercise price of the Warrants is subject to adjustment in the event of certain dilutive issuances. On November 16, 2020, the exercise price of the Warrants was reduced from $1.38 per Warrant per full share of common stock to $0.69 per Warrant per full share of common stock. The reduction was the result of the issuance of shares of Common Stock by the Company through its "at the market offering" facility. The effect of the change in the exercise price of the warrants as a result of the triggering of the down round protection clause in the Warrants was recorded as a deemed dividend of $880,000, which reduces the income available to common stockholders. During the years ended December 31, 2020 and 2019, 3,665 and 1,523, respectively, shares were converted resulting in the recognition of deemed dividends of $1.4 million and $525,000, respectively, for the amortization of the Series B Preferred Stock discount upon conversion. This is recorded as a deemed dividend in accumulated deficit.

The October 2018 Warrants are immediately exercisable at a price of $1.38 ($0.69 effective November 16, 2020) per share of common stock (which was 120% of the public offering price of the Class A Units) and will expire on October 15, 2023. If, at the time of exercise, there is no effective registration statement registering, or no current

prospectus available for, the issuance of the shares of common stock to the holder, then the October 2018 warrants may only be exercised through a cashless exercise. No fractional shares of common stock will be issued in connection with the exercise of any October 2018 warrants. In lieu of fractional shares, the holder will receive an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares.

5. Stockholders' Equity – (continued)

The Company may not effect, and holder will not be entitled to, exercise any Warrants or conversion of the Series B Preferred Stock, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of the Company's securities beneficially owned by the holder (together with its affiliates) to exceed 4.99% (or, at the election of the holder, 9.99%) of the combined voting power of all of the Company's securities then outstanding immediately after giving effect to the exercise or conversion, as such percentage ownership is determined in accordance with the terms of the October 2018 Warrants or Series B Preferred Stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to the Company. The holders of the Series B Preferred will participate, on an as-if-converted-to-common stock basis, in any dividends to the holders of common stock. Upon a defined Fundamental Transaction, the holders of the Series B Preferred Stock are entitled to the same consideration as are holders of common stock. The Series B Preferred Stock ranks junior to existing Series A preferred stock but on parity with common stock. Liquidation preference is equal to an amount pari passu with the common stock on an as converted basis (i.e., there is no preference to common stock).

Since the effective conversion price of the Series B Preferred Stock is less than the fair value of the underlying common stock at the date of issuance, there is a beneficial conversion feature ("BCF") at the issuance date. Because the Series B Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF is immediately charged to accumulated deficit as a "deemed dividend" and impacts earnings per share.

5. Stockholders' Equity – (continued)

Series A Preferred Stock

On September 11, 2017, the Company entered into a share purchase agreement (the "Purchase Agreement") with an investor (the "Investor"), pursuant to which the Company offered and sold in a private placement 120,000 shares of its Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock") for an aggregate purchase price of $12 million, or $100 per share.

The Series A Preferred Stock ranks senior to the shares of the Company's common stock, and any other class or series of stock issued by the Company with respect to dividend rights, redemption rights and rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company. Holders of Series A Preferred Stock are entitled to a cumulative dividend at the rate of 2.0% per annum, payable quarterly in arrears, as set forth in the Certificate of Designation of Series A Preferred Stock classifying the Series A Preferred Stock. The Series A Preferred Stock is convertible at the option of the holders at any time into shares of common stock at an initial conversion price of $0.54 per share which was increased to $18.90 after taking into account the Reverse Stock Split, subject to certain customary anti-dilution adjustments On January 27, 2021, the Company filed a Certificate of Amendment to the Certificate of Designation for its Series A Convertible Preferred Stock (the "Certificate of Amendment") with the Secretary of State of the State of Nevada that adjusted the conversion price from $18.90 per share to $1.50 per share and removed the redemption upon change of control see Note 10.

Any conversion of Series A Preferred Stock may be settled by the Company in shares of common stock only.

The holder's ability to convert the Series A Preferred Stock into common stock is subject to (i) a 19.99% blocker provision to comply with NYSE American Listing Rules, (ii) if so elected by the Investor, a 4.99% blocker provision that will prohibit beneficial ownership of more than 4.99% of the outstanding shares of the Company's common stock or voting power at any time, and (iii) applicable regulatory restrictions.

In the event of any liquidation, dissolution or winding-up of the Company, holders of the Series A Preferred Stock are entitled to a preference on liquidation equal to the greater of (i) an amount per share equal to the stated value plus any accrued and unpaid dividends on such share of Series A Preferred Stock (the "Accreted Value"), and (ii) the amount such holders would receive in such liquidation if they converted their shares of Series A Preferred Stock (based on the Accreted Value and without regard to any conversion limitation) into shares of the common stock immediately prior to any such liquidation, dissolution or winding-up (the greater of (i) and (ii), is referred to as the "Liquidation Value").

Except as otherwise required by law, the holders of Series A Preferred Stock have no voting rights, other than customary protections against adverse amendments and issuance of *pari passu* or senior preferred stock. Upon certain change of control events involving the Company, the Company will be required to repurchase all of the Series A Preferred Stock at a redemption price equal to the greater of (i) the Accreted Value and (ii) the amount that would be payable upon a change of control (as defined in the Certificate of Designation) in respect of common stock issuable upon conversion of such share of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into common stock immediately prior to the change of control.

On or at any time after (i) the VWAP (as defined in the Certificate of Designation) for at least 20 trading days in any 30 trading day period is greater than $70.00, subject to adjustment in the case of stock split, stock dividends or the like the Company has the right, after providing notice not less than 6 months prior to the redemption date, to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share of Series A Preferred Stock of $7,875.00, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Convertible Preferred Stock or (ii) the five year anniversary of the issue date, the Company shall have the right to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Convertible Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share equal to the Liquidation Value.

5. Stockholders' Equity – (continued)

The Series A Preferred Stock is classified as temporary equity due to the shares being redeemable based on contingent events outside of the Company's control. Since the effective conversion price of the Series A Preferred Stock is less than the fair value of the underlying common stock at the date of issuance, there is a beneficial conversion feature ("BCF") at the issuance date. Because the Series A Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF is immediately charged to accumulated deficit as a "deemed dividend" and impacts earnings per share. During the year ended December 31, 2017, the Company recorded a discount of $6.9 million. Because the Series A Preferred Stock is not currently redeemable, the discount arising from issuance costs was allocated to temporary equity and will not be accreted until such time that redemption becomes probable. The stated dividend rate of 2% per annum is cumulative and the Company accrues the dividend on a quarterly basis (in effect accreting the dividend regardless of declaration because the dividend is cumulative). During the years ended December 31, 2020 and 2019, the Company accrued dividends of $254,000 and $248,000, respectively. Once the dividend is declared, the Company will reclassify the declared amount from temporary equity to a dividends payable liability. When the redemption of the Series A Preferred Stock becomes probable, the temporary equity will be accreted to redemption value as a deemed dividend.

5. Stockholders' Equity – (continued)

B. Riley Securities *Sales Agreement*

On August 5, 2016, the Company entered into the B. Riley FBR Sales Agreement with FBR Capital Markets & Co. (now known as B. Riley Securities), which enables the Company to offer and sell shares of the Common Stock from time to time through B. Riley Securities, Inc. as the Company's sales agent. Sales of common stock under the B. Riley Securities Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act. B. Riley Securities, Inc. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of the Common Stock sold on the Company's behalf. For the year ended December 31, 2020, the Company sold through the B. Riley Securities Sales Agreement an aggregate of 9.3 million shares of Common Stock and received net proceeds of approximately $ 3.4 million. The Company did not sell any shares of common stock during 2019 through the B. Riley Securities Sales Agreement. Subsequent to year end through March 3, 2021, the Company sold approximately 76.3 million shares of the Company's common stock and received net proceeds of approximately $63.8 million.

6. Non-controlling Interest

On September 5, 2018, the Company entered into an agreement (the 'Stock Purchase Agreement") with Cedars-Sinai Medical Center (CSMC) for an investigator-sponsored Phase 2b clinical study of SYN-010 to be co-funded by the

Company and CSMC (the "Study"). The Study will provide further evaluation of the efficacy and safety of SYN-010, the Company's modified-release reformulation of lovastatin lactone, which is exclusively licensed to the Company by CSMC. SYN-010 is designed to reduce methane production by certain microorganisms (*M. smithii*) in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C).

In consideration of the support provided by CSMC for the Study, the Company paid $328,000 to support the Study and the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company, upon the approval of the Study protocol by the Institutional Review Board ("IRB") : (i) issued to CSMC 50,000 shares of Common Stock of the Company; and (ii) transferred to CSMC an additional 2,420,000 shares of common stock of its subsidiary SYN Biomics, Inc. ("SYN Biomics") owned by the Company, such that after such issuance CSMC owns an aggregate of 7,480,000 shares of common stock of SYN Biomics, representing 17% of the issued and outstanding shares of SYN Biomics' common stock. The services rendered are recorded to research and development expense in proportion with the progress of the study and are based overall on the fair value of the shares ($285,000) as determined at the date of IRB approval. During the years ended December 31, 2020 and 2019, research and development expense recorded related to this transaction approximated $225,000 and $198,000, respectively.

The Stock Purchase Agreement also provides CSMC with a right, commencing on the six month anniversary of issuance of the stock under certain circumstances in the event that the shares of stock of SYN Biomics are not then freely tradeable, and subject to NYSE American, LLC approval, to exchange its SYN Biomics shares for unregistered shares of Common Stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of the Company at the time of each exchange. The Stock Purchase Agreement also provides for tag-along rights in the event of the sale by the Company of its shares of SYN Biomics.

On September 30, 2020, CSMC MAST formally 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, SYN-010 was unlikely to meet its primary endpoint by the time enrollment is completed.

On November 9, 2020, the Company and its subsidiary, Synthetic Biomics, Inc. and CSMC mutually agreed to terminate the exclusive license agreement dated December 5, 2013 and all amendments thereto and the clinical trial agreement relating to SYN-010. The determination to terminate the SYN-010 license agreement was agreed following the completion of a planned interim futility analysis of the Phase 2b investigator-sponsored clinical trial of SYN-010. On September 30, 2020, CSMC (the Company's SYN-010 clinical development partner) informed the Company that it discontinued the ongoing Phase 2b investigator-sponsored clinical study of SYN-010 IBS-C patients.

On August 29, 2015, the Company, SYN Biomics and Mark Pimentel, M.D. entered into an amendment to the Pimentel Stock Purchase Agreement dated December 3, 2013, which accelerated the date upon which Dr. Pimentel could exchange his shares of common stock in SYN Biomics for shares of the Company's common stock. On August 29, 2015, Dr. Pimentel notified the Company of his intent to exchange all of the shares of common stock in SYN Biomics, 8.5%, owned by him for 38,572 shares of the Company's common stock in accordance with the terms of the Stock Purchase Agreement, as amended. On August 31, 2015, the Company issued 38,572 shares of the Company's common stock to Dr. Pimentel in exchange for all of the shares of common stock of SYN Biomics held by Dr. Pimentel.

In December 2013, through the Company's subsidiary, Synthetic Biomics, Inc., the Company entered into a worldwide exclusive license agreement with CSMC and acquired the rights to develop products for therapeutic and prophylactic treatments of acute and chronic diseases, including the development of SYN-010 to target IBS-C. The Company licensed from CSMC a portfolio of intellectual property comprised of several U.S. and foreign patents and pending patent applications for various fields of use, including IBS-C, obesity and diabetes. During the years ended December 31, 2020 and 2019, the Company did not owe and did not pay CSMC for milestone payments related this license agreement.

6. Non-controlling Interest – (continued)

The Company's non-controlling interest is accounted for under ASC 810, *Consolidation* ("ASC 810") and represents the minority stockholder's ownership interest related to the Company's subsidiary, SYN Biomics. In accordance with ASC 810, the Company reports its non-controlling interest in subsidiaries as a separate component of equity in the Consolidated Balance Sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company's common stockholders on the face of the Consolidated Statements of Operations. After the 2018 transaction with CSMC, the Company's equity interest in SYN Biomics is 83% and the non-controlling stockholder's interest is 17%. As of December 31, 2020, the accumulated net loss attributable to the non-controlling interest was $2.8 million. As of December 31, 2019, the accumulated net loss attributable to the non-controlling interest was $2.9 million and includes $77,000 of prior year losses attributable to minority stockholders including the reversal of Dr. Pimentel's 2015 losses of $505,000 associated with the exchange of his shares of common stock in SYN Biomics for shares of the Company's common stock.

7. License, Collaborative and Employment Agreements and Commitments

License and Collaborative Agreements

As described below, the Company has entered into several license and collaborative agreements for the right to use research, technology and patents. Some of these license and collaborative agreements may contain milestones. The specific timing of such milestones cannot be predicted and are dependent on future developments as well as regulatory actions which cannot be predicted with certainty (including actions which may never occur). Further, under the terms of certain licensing agreements, the Company may have the obligation to pay certain milestones contingent upon the achievement of specific levels of sales. Due to the long-range nature of such commercial milestone amounts, they are neither probable at this time nor predictable and consequently are not included in this disclosure.

Washington University School of Medicine in St. Louis Clinical Trial Agreement

In August 7, 2019, 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), 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.

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 SYN-004 (ribaxamase) 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.

Cedars-Sinai Medical Center ("CSMC") Agreement

On December 5, 2013, the Company, through its newly formed, majority owned subsidiary, SYN Biomics, entered into a worldwide exclusive License Agreement with CSMC for the development of new treatment approaches to

target non-bacterial intestinal microorganism life forms known as archaea that are associated with intestinal methane production and chronic diseases such as irritable bowel syndrome (IBS), obesity and type 2 diabetes. As part of the terms of the License Agreement the Company issued 9,569 unregistered shares of the Company's common stock to CSMC, paid $150,000 for the initial license fee and $220,000 for patent reimbursement fees. The License Agreement also provides that, commencing on the second anniversary of the License Agreement, SYN Biomics will pay an annual maintenance fee, which payment shall be creditable against annual royalty payments owed under the License Agreement. In addition to royalty payments which are a percentage of net sales of licensed and technology products, SYN Biomics is obligated to pay CSMC a percentage of any non-royalty sublicense revenues, as well as additional consideration upon the achievement of milestones (the first two of which are payable in cash or unregistered shares of Company stock at the Company's option). On December 5, 2013, the Company also entered into an option agreement with CSMC, which expired unexercised on December 31, 2014.

7. License, Collaborative and Employment Agreements and Commitments – (continued)

The License Agreement provided for termination: (i) automatically if SYN Biomics enters into a liquidating bankruptcy or other specified bankruptcy event or if the performance of any term, covenant, condition or provision of the License Agreement will jeopardize the licensure of CSMC, its participation in certain reimbursement programs, its full accreditation by the Joint Commission of Accreditation of Healthcare Organizations or any similar state organizations, its tax exempt status or is deemed illegal; (ii) upon 30 days notice from CSMC if SYN Biomics fails to make a payment or use commercially reasonable efforts to exploit the patent rights; (iii) upon 60 days notice from CSMC if SYN Biomics fails to cure any breach or default of any material obligations under the License Agreement; or (iv) upon 90 days notice from SYN Biomics if CSMC fails to cure any breach or default of any material obligations under the License Agreement. SYN Biomics also has the right to terminate the License Agreement without cause upon six months notice to CSMC; however, upon such termination, SYN Biomics is obligated to pay a termination fee with the amount of such fee reduced: (i) if such termination occurs after an Investigational New Drug submission to the FDA but prior to completion of a Phase 2 clinical trial, (ii) reduced further if such termination occurs after completion of Phase 2 clinical trial but prior to completion of a Phase 3 clinical trial; and (iii) reduced to zero if such termination occurs after completion of a Phase 3 clinical trial.

Prior to the execution of the CSMC License Agreement, SYN Biomics issued shares of common stock of SYN Biomics to each of CSMC and Mark Pimentel, M.D. (the primary inventor of the intellectual property), representing 11.5% and 8.5%, respectively, of the outstanding shares of SYN Biomics (the "SYN Biomics Shares"). The Stock Purchase Agreements for the SYN Biomics shares provide for certain anti-dilution protection until such time as an aggregate of $3.0 million in proceeds from equity financings are received by SYN Biomics as well as a right, under certain circumstances in the event that the SYN Biomics shares are not then freely tradable, and subject to NYSE American approval, as of the 18 and 36 month anniversary date of the effective date of the Stock Purchase Agreements, for each of CSMC and the Dr. Pimentel to exchange up to 50% of their SYN Biomics shares for unregistered shares of the Company's common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of the Company at the time of each exchange. The Stock Purchase Agreements also provide for tag-along rights in the event of the sale by the Company of its shares of SYN Biomics.

On August 29, 2015, the Company, SYN Biomics and Mark Pimentel, M.D. entered into an amendment to the Pimentel Stock Purchase Agreement, which accelerated the date upon which Dr. Pimentel can exchange his shares of common stock in SYN Biomics for shares of the Company's common stock. On August 29, 2015, Dr. Pimentel notified the Company of his intent to exchange all of the shares of common stock in SYN Biomics owned by him for 38,572 shares of the Company's common stock in accordance with the terms of the Pimentel Stock Purchase Agreement, as amended. On August 31, 2015, the Company issued 38,572 shares of the Company's common stock

to Dr. Pimentel in exchange for all of the shares of common stock of SYN Biomics held by Dr. Pimentel.

As of and during the years ended December 31, 2020 and 2019, the Company did not owe and did not pay CSMC for milestone payments related to this license agreement.

On September 5, 2018, the Company entered into an agreement with CSMC for an investigator-sponsored Phase 2 clinical study of SYN-010 to be co-funded by the Company and CSMC (the "Study"). The Study was to provide further evaluation of the efficacy and safety of SYN-010, the Company's modified-release reformulation of lovastatin lactone, which is exclusively licensed to the Company by CSMC. SYN-010 is designed to reduce methane production by certain microorganisms (*M. smithii*) in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C).

7. License, Collaborative and Employment Agreements and Commitments – (continued)

In consideration of the support provided by CSMC for the Study, the Company paid $441,000 and the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company, upon the approval of the Study protocol by the Institutional Review Board, (IRB) to: (i) issued to CSMC fifty thousand (50,000) shares of common stock of the Company; and (ii) transferred to CSMC an additional two million four hundred twenty thousand (2,420,000) shares of common stock of its subsidiary SYN Biomics, Inc. ("Synbiomics") owned by the Company, such that after such issuance CSMC owned an aggregate of seven million four hundred eighty thousand (7,480,000) shares of common stock of SYN Biomics, representing seventeen percent (17%) of the issued and outstanding shares of SYN Biomics' common stock. The services rendered are recorded to research and development expense in proportion with the progress of the study and based overall on the fair value of the shares ($285,000) as determined at the date of IRB approval. During the years ended December 31, 2020 and 2019, research and development expense related to this transaction approximated $225,000 and $198,000, respectively.

The Agreement also provides CSMC with a right, commencing on the six month anniversary of issuance of the stock under certain circumstances in the event that the shares of stock of Synbiomics are not then freely tradeable, and subject to NYSE American, LLC approval, to exchange its Synbiomics shares for unregistered shares of the Company's common stock, with the rate of exchange based upon the relative contribution of the valuation of Synbiomics to the public market valuation of the Company at the time of each exchange. The Stock Purchase Agreement also provides for tag-along rights in the event of the sale by the Company of its shares of Synbiomics.

On September 30, 2020, CSMC MAST formally 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, SYN-010 is unlikely to meet its primary endpoint by the time enrollment is completed.

On November 9, 2020, the Company and its subsidiary, SYN Biomics, Inc. and CSMC mutually agreed to terminate the exclusive license agreement dated December 5, 2013 and all amendments thereto and the clinical trial agreement relating to SYN-010. The determination to terminate the SYN-010 license agreement was agreed following the completion of a planned interim futility analysis of the Phase 2b investigator-sponsored clinical trial of SYN-010. On September 30, 2020, CSMC (the Company's SYN-010 clinical development partner) informed the Company that it discontinued the ongoing Phase 2b investigator-sponsored clinical study of SYN-010 IBS-C patients. The patent rights previously licensed to the Company covering the use of SYN-010 will remain the property of CSMC.

University of Texas Austin Agreement

On December 19, 2012, the Company entered into a License Agreement with UT Austin for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to pertussis antibodies. The License Agreement provides that UT Austin is entitled to payment of past patent expenses, an annual payment of $50,000 per year commencing on the effective date through December 31, 2014, a $25,000 payment on December 31, 2015 and milestone payments of $50,000 upon commencement of Phase 1 clinical trials, $100,000 upon commencement of Phase 3 clinical trials, $250,000 upon NDA submission in the U.S., $100,000 upon European Medicines Agency approval and $100,000 upon regulatory approval in an Asian country. In addition, UT Austin is entitled to a running royalty upon net sales. The License Agreement terminates upon the expiration of the patent rights; provided, however that the License Agreement is subject to early termination by the Company in its discretion and by UT Austin for a breach of the License Agreement by the Company.

In connection with the License Agreement, the Company and UT Austin also entered into a Sponsored Research Agreement pursuant to which UT Austin will perform certain research work related to pertussis. The Sponsored Research Agreement may be renewed annually, in the sole discretion of the Company, after the first year for two additional one year terms with a fixed fee for the first year of $303,287. The Sponsored Research Agreement was renewed for the second and third years for a fixed fee of $316,438 and $328,758 respectively, all payable in quarterly installments. The Sponsored Research Agreement expires January 17, 2023; provided, however, the Sponsored Research Agreement is subject to early termination upon the written agreement of the parties, a default in the material obligations under the Research Agreement which remain uncured for 60 days after receipt of notice, automatically upon the Company's bankruptcy or insolvency and by the Company in its sole discretion at any time after the one year anniversary of the date of execution thereof upon no less than 90 days' notice.

7. License, Collaborative and Employment Agreements and Commitments – (continued)

On October 22, 2015, the Company and UT Austin amended the Sponsored Research Agreement to extend the termination date from the initial termination date of December 31, 2015 to January 15, 2017, on September 2, 2016 to extend the agreement until January 15, 2018, on August 22, 2017 to extend the agreement until January 17, 2019, on August 24, 2018 to extend the agreement until January 17, 2021 and again on August 8, 2020 until January 17, 2023. All other terms and conditions of the Sponsored Research Agreement remain unchanged. No further or additional payments will be made to UT Austin as a result of this amendment.

Prev ABR LLC ("Prev") Agreement

On November 28, 2012, the Company entered into an agreement ("Prev Agreement") to acquire the C. diff program assets of Prev, including pre-Investigational New Drug (IND) package, Phase 1 and Phase 2 clinical data, manufacturing process data and all issued and pending U.S. and international patents. Upon execution and closing of the Prev Agreement, the Company paid Prev cash payments of $235,000 and issued 17,858 unregistered shares of its common stock to Prev. As set forth in the Prev Agreement, Prev may be entitled to receive additional consideration upon the achievement of certain milestones including: (i) commencement of an IND; (ii) commencement of a Phase 1 clinical trial; (iii) commencement of a Phase 2 clinical trial; (iv) commencement of a Phase 3 clinical trial; (v) filing a Biologic License Application (BLA) in the U.S. and for territories outside of the U.S. (as defined in the Prev Agreement); and (vi) approval of a BLA in the U.S. and for territories outside the U.S. With exception of the first milestone payment, the remaining milestones are payable 50% in cash and 50% in our stock, however, at Prev's option the entire milestone may be payable in shares of the Company's stock. As of December 31, 2015, the first three milestones have been met, and at Prev's option, Prev elected to receive 18,724 shares of the Company's common stock. No milestones were achieved or such payments were made during the years ended December 31, 2020 and 2019.

Intrexon Exclusive Channel Collaboration

On August 6, 2012, the Company entered into an Exclusive Channel Collaboration ("Infectious Disease ECC") with Intrexon that governs an "exclusive channel collaboration" arrangement in which the Company will use Intrexon's technology relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of monoclonal antibody therapies for the treatment of certain serious infectious diseases. Pursuant to the terms of the Second Stock Issuance Agreement with Intrexon, which was approved by the Company's stockholders on October 5, 2012, the Company issued 101,492 shares of its common stock, $0.001 par value, which issuance is also deemed paid in consideration for the execution and delivery of the Infectious Disease ECC, dated August 6, 2012, between the Company and Intrexon. In connection with the transactions contemplated by the Second Stock Issuance Agreement, and pursuant to the First Amendment to Registration Rights Agreement (the "First Amendment to Registration Rights Agreement") executed and delivered by the parties at the closing, which was declared effective on May 5, 2013. The Company filed a "resale" registration statement registering the resale of the shares issued under the Second Stock Issuance Agreement.

Subject to certain expense allocations and other offsets provided in the Infectious Disease ECC, the Company will pay Intrexon royalties on annual net sales of the Synthetic Products, calculated on a Synthetic Product-by-Synthetic Product basis. The Company has likewise agreed to pay Intrexon a percentage of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. No such payments were made during the years ended December 31, 2020 and 2019.

7. License, Collaborative and Employment Agreements and Commitments – (continued)

The Company also agreed upon the filing of an IND application with the FDA for a Synthetic Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency (both as applicable, the "IND Milestone Event"), to pay Intrexon either (i) $2.0 million in cash, or (ii) that number of shares of common stock (the "IND Milestone Shares") having a fair market value equaling $2.0 million where such fair market value is determined using published market data of the share price for common stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the IND Milestone Event.

Upon the first to occur of either first commercial sale of a Synthetic Product in a country or the granting of the regulatory approval of that Synthetic Product (both as applicable, the "Approval Milestone Event"), the Company agreed to pay to Intrexon either (i) $3.0 million in cash, or (ii) that number of shares of common stock (the "Approval Milestone Shares") having a fair market value equaling $3.0 million where such fair market value is determined using published market data of the share price for common stock at the close of market on the business day immediately preceding the date of public announcement of attainment of the Approval Milestone Event.

7. License, Collaborative and Employment Agreements and Commitments – (continued)

On August 10, 2015, the Company entered into an Exclusive Channel Collaboration Agreement (the "PKU ECC") with Intrexon that governs a "channel collaboration" arrangement in which the Company was granted a worldwide exclusive license to use the patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of biotherapeutic products for the treatment of PKU in humans by direct administration of a viral construct containing a gene to alter genetic expression of phenyalanine hydroxylase and/or administration of genetically modified bacteria that express an effector directed to the metabolic conversion of phenyalanine. The license was exclusive to both parties within the Field. On September 2, 2015, in accordance with the terms of the Intrexon Stock Issuance Agreement that the Company entered into in connection with the PKU ECC, the Company paid Intrexon a technology access fee by the issuance of 26,786 shares of common stock, having a value equal to $3.0 million as of August 7, 2015. Pursuant to the Second Amendment to Registration Rights Agreement, the Company filed a "resale" registration statement to register the shares issued under the Intrexon Stock Issuance Agreement, which was declared effective by the SEC on October 15, 2015.

On November 30, 2018, the Company received written notice from Intrexon stating that Intrexon and the Company had terminated by mutual agreement the PKU Exclusive Channel Collaboration Agreement. As a result of the mutually agreed upon November 30, 2018 termination, each party retains its own respective confidential information and intellectual property and all licenses between the parties granted under the ECC are terminated. The Company had also entered into the Exclusive Channel Collaboration Agreement, dated August 6, 2012 with Intrexon that governs a "channel collaboration" arrangement in which the Company intends to use Intrexon's technology relating to the identification, design and production of human antibodies and DNA vectors for the development and commercialization of a series of monoclonal antibody therapies for the treatment of Pertussis, remains in effect.

7. License, Collaborative and Employment Agreements and Commitments – (continued)

Employment Agreements

On December 6, 2018, the Company entered into a three-year employment agreement with Steven A. Shallcross, (the "Employment Agreement"), to serve as the Chief Executive Officer and to continue to serve as the Chief Financial Officer of the Company.

The Employment Agreement has a stated term of three years but may be terminated earlier pursuant to its terms. If Mr. Shallcross' employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated (i) by the Company without Cause or by Mr. Shallcross for Good Reason (as each is defined in the Employment Agreement) then in addition to paying the Accrued Obligations, (a) the Company will continue to pay his then current base salary and continue to provide benefits at least equal to those that were provided at the time of termination for a period of twelve (12) months and (b) he shall have the right to exercise any vested equity awards until the earlier of six (6) months after termination or the remaining term of the awards; or (ii) by reason of his death or Disability (as defined in the Employment Agreement), then in addition to paying the Accrued Obligations, Mr. Shallcross would have the right to exercise any vested options until the earlier of six (6) months after termination or the remaining term of the awards. In such event, if Mr. Shallcross commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-

provided plan, the medical and other welfare benefits to be provided by the Company as described herein would terminate.

7. License, Collaborative and Employment Agreements and Commitments – (continued)

On December 30, 2020, the Board of the Company awarded Steven A. Shallcross (i) a cash bonus equal to 62% of his prior base salary and (ii) an option to purchase 450,000 shares of the Company's common stock.

7. License, Collaborative and Employment Agreements and Commitments – (continued)

Operating Lease

All of the Company's existing leases as of December 31, 2020 are classified as operating leases. As of December 31, 2020, the Company has one material operating lease for facilities with a remaining term expiring in 2022. The existing lease has fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. The discount rate used in the calculation of the lease liability was 9.9%. The rates implicit within the Company's leases are generally not determinable, therefore, the Company's incremental borrowing rate is used to determine the present value of lease payments. The determination of the Company's incremental borrowing rate requires judgment. Because the Company currently has no outstanding debt, the incremental borrowing rate for each lease is primarily based on publicly-available information for companies within the same industry and with similar credit profiles. The rate is then adjusted for the impact of collateralization, the lease term and other specific terms included in the Company's lease arrangements. The incremental borrowing rate is determined at lease commencement, or as of January 1, 2019 for operating leases in existence upon adoption of ASC 842, *Leases* ("ASC 842"). The incremental borrowing rate is subsequently reassessed upon a modification to the lease arrangement. ROU assets are subsequently assessed for impairment in accordance with the Company's accounting policy for long-lived assets. Operating lease costs are presented as part of general and administrative expenses in the consolidated statements of operations, and for the years ended December 31, 2020 and 2019 approximated $209,000 and 201,000, respectively. For the years ended December 31, 2020 and 2019, operating cash flows used for operating leases approximated $309,000 and $300,000, respectively.

A maturity analysis of our operating leases as of December 31, 2020 is as follows *(amounts in thousands of dollars)*:

Future undiscounted cash flows:		
2021	$	321
2022		192
Total		513
Discount factor		(40)

Lease liability	473
Amount due within 12 months	(287)
Lease liability – long term	$ 186

Consulting Fees

In November 2017, the Company engaged a regulatory consultant to assist in the Company's efforts to prepare, file and obtain FDA approval for ribaxamase. The term of the engagement is on a monthly basis, provided that either party may terminate the agreement at any time by providing the other party a six-month notice period. The Company is obligated to pay the consultant a monthly retainer in addition to the success fee payments of up to an aggregate of $4,500,000 for attainment of certain regulatory milestones. The achievement of the milestones is not probable at this time.

Risks and Uncertainties

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 COVID-19 continued to spread around the globe, the Company experienced disruptions that impacted its business and clinical trials, including halting the postponement of clinical site initiation of the Phase 1b/2a clinical trial of SYN-004. The extent to which the COVID-19 pandemic impacts the Company's business, the clinical development of SYN-004 (ribaxamase) and SYN-020, the business of the Company's suppliers and other commercial partners, the Company's corporate development objectives and the value of and market for the Company's common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects. In addition, to the extent the ongoing COVID-19 pandemic adversely affects the Company's business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties which the Company faces.

8. Income Taxes

There was no income tax expense for the years ended December 31, 2020 and 2019 due to the Company's net losses. The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2020 and 2019. For 2020, the "expected" tax expense is computed by applying the Federal corporate statutory tax rate of 21% and a net, after Federal benefit state tax rate of 6.45% (state blended rate was 27.45%) to loss before taxes. For 2019, the "expected" tax expense is computed by applying the Federal corporate statutory tax rate of 21% and a net, after Federal benefit state tax rate of 4.74% (state blended rate was 24.74.%) to loss before taxes. These results are as follows (in thousands):

	2020	2019
Computed "expected" tax-benefit – Federal	$ (2,124)	$ (3,230)

Computed "expected" tax-benefit – State	(616)	(729)
Non-deductible stock-based compensation	32	864
State tax rate adjustment	(1,221)	-
Change in valuation allowance	3,929	3,095
	$ —	$ —

The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2020 and 2019 are as follows (*in thousands*):

	2020	2019
Deferred tax assets:		
Stock issued for services	$ 1,428	$ 1,223
Accrued compensation	42	20
Stock issued for acquisition of program	1,436	1,301
Stock issued for license agreement	1,574	1,574
Stock issued for milestone payment	262	255
Amortizable license fee	5	5
Net operating loss carry-forward	12,540	8,494
Total gross deferred tax assets	17,287	12,872
Less: valuation allowance	(17,287)	(12,872)
Total net deferred tax assets	$ —	$ —

At December 31, 2020, the Company has a gross Federal net operating loss carry-forward of approximately $43.3 million available to offset future taxable income. The Company's pre-2018 net operating losses expire on various dates through 2037. In 2020, the Company completed an Internal Revenue Code Section 382 analysis of its historical net operating loss carry-forward amount. As a result, the prior year net operating loss carry-forward of $188.6 million was determined to be limited by $155.6 million. The decrease in the prior year net operating loss carry-forward is attributable to change of control ownership shifts which were determined for the years 2013 and 2018 which caused the reduction in the value of the historical net operating loss carry-forward amounts. Since the limitation affected the prior period, the Company has determined that its 2019 tax footnote presentation was incorrect by overstating the gross net operating loss deferred tax asset and corresponding valuation allowance. However, there was no net impact to the net deferred tax asset and tax expense as the decrease in the net operating loss carry-forward was offset completely by a corresponding adjustment to the Company's overall valuation allowance. For comparative purposes, the Company's prior year tax footnote has been revised to reflect the adjustment to the net operating losses and valuation allowance.

After the change noted above to the Company's net operating loss carry-forward amounts, at December 31, 2020 the Company has a net operating loss carry-forward of approximately $43.3 million available to offset future taxable income. The December 31, 2020 net operating loss carry-forward consists of $33.0 million of pre-2020 net operating loss carry-forward and $10.3 million of current year net operating loss carry-forward. The Company's pre-2018 net operating losses expire on various dates through 2037 while the net operating loss carry-forward originating in the 2018 year and later carry-forward indefinitely and are subject to additional limitations based on taxable income.

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in March 2020. The CARES Act includes several U.S. income tax provisions related to, among other things, net operating loss carrybacks, alternative minimum tax credits, modifications to the net interest deduction limitations, and technical amendments regarding the income tax depreciation of qualified improvement property placed in service after December 31, 2017. The CARES Act is not expected to have a material impact on the Company's financial results.

In December 2019, the FASB issued ASU 2019-12, "Income Taxes Topic 740-Simplifying the Accounting for Income Taxes" ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application of Topic 740. This guidance is effective for fiscal years beginning after December 15, 2020, including interim periods therein, and early adoption is permitted. Based on the Company's preliminary analysis, adoption of Topic 740 in 2021 is not expected to have a material effect on the Company's consolidated financial statements.

The valuation allowance at December 31, 2020 was approximately $17.3 million. The net change in valuation allowance during the year ended December 31, 2020 was an increase of approximately $3.9 million primarily due to increases in gross federal and state deferred tax assets in 2020 and state tax rate change from the previous period. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2020.

9. Related Party Transactions

On September 5, 2018, the Company entered into an agreement with CSMC for an investigator-sponsored Phase 2b clinical study of SYN-010 to be co-funded by the Company and CSMC (the "Study"). The Study was to provide further evaluation of the efficacy and safety of SYN-010, the Company's modified-release reformulation of lovastatin lactone, which was exclusively licensed to the Company by CSMC. SYN-010 is designed to reduce methane production by certain microorganisms (M. smithii) in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C).

In consideration of the support provided by CSMC for the Study, the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company, upon the approval of the Study protocol by the Institutional Review Board, (IRB): (i) issued to CSMC fifty thousand (50,000) shares of common stock of the Company; and (ii) transferred to CSMC an additional two million four hundred twenty thousand (2,420,000) shares of common stock of its subsidiary Synthetic Biomics, Inc. ("SYN Biomics") owned by the Company, such that after such issuance CSMC will own an aggregate of seven million four hundred eighty thousand (7,480,000) shares of common stock of Synbiomics, representing seventeen percent (17%) of the issued and outstanding shares of SynBiomics' common stock.

The Agreement also provides CSMC with a right, commencing on the six month anniversary of issuance of the stock under certain circumstances in the event that the shares of stock of SYN Biomics are not then freely tradeable, and subject to NYSE American, LLC approval, to exchange its SYN Biomics shares for unregistered shares of the Company's common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of the Company at the time of each exchange. The Stock Purchase Agreement also provides for tag-along rights in the event of the sale by the Company of its shares of SYN Biomics.

On September 30, 2020, CSMC MAST formally 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, SYN-010 is unlikely to meet its primary endpoint by the time enrollment is completed.

In December 2013, through the Company's subsidiary, SYN Biomics, Inc. the Company entered into a worldwide exclusive license agreement with CSMC and acquired the rights to develop products for therapeutic and prophylactic treatments of acute and chronic diseases, including the development of SYN-010 to target IBS-C. The Company licensed from CSMC a portfolio of intellectual property comprised of several U.S. and foreign patents and pending patent applications for various fields of use, including IBS-C, obesity and diabetes. During the year ended December 31, 2016, the Company paid CSMC $350,000 for milestone payments related this license agreement. There

were no milestone payments made during the years ended December 31, 2020 and 2019.

On November 9, 2020, the Company and its subsidiary, Synthetic Biomics, Inc. and CSMC mutually agreed to terminate the exclusive license agreement dated December 5, 2013 and all amendments thereto and the clinical trial agreement relating to SYN-010. The determination to terminate the SYN-010 license agreement was agreed following the completion of a planned interim futility analysis of the Phase 2b investigator-sponsored clinical trial of SYN-010. The patent rights previously licensed to the Company covering the use of SYN-010 will remain the property of CSMC.

10. Subsequent Events

At December 31, 2020 there were 17,999,999 October 2018 Warrants outstanding. On November 16, 2020, the exercise price of the October 2018 Warrants was reduced from $1.38 per October 2018 Warrant per full share of the Company's common stock, $0.001 par value per share (the "Common Stock"), to $0.69 per Warrant per full share of Common Stock in accordance with the anti-dilution terms of the October 2018 Warrant. The reduction was the result of the automatic price adjustment provision of the October 2018 Warrant triggered by the issuance of shares of Common Stock by the Company through its "at the market offering" facility. During January and February 2021, 11,655,747 October 2018 Warrants were exercised for cash proceeds of $8.0 million.

10. Subsequent Events – (continued)

On January 27, 2021, the Company filed a Certificate of Amendment to the Certificate of Designation for its Series A Convertible Preferred Stock (the "Certificate of Amendment") with the Secretary of State of the State of Nevada that adjusted the conversion price from $18.90 per share to $1.50 per share and removed the redemption upon change of control. The Company received notice from the holder of the Series A Preferred Stock that it was increasing the Maximum Percentage as defined in the "Certificate of Designation" from 4.99% to 9.99%, such increase to be effective 61 days from the date hereof. During January and February 2021, all outstanding shares of Series A Convertible Preferred Stock were converted to approximately 9.0 million shares of the Company's common stock. There are no remaining shares of the Series A Convertible Preferred stock outstanding after these conversions. During January and February 2021, the Company issued 8,996,768 shares of its common stock upon the conversion effected on such date by a holder of 120,000 shares of its Series A Convertible Preferred Stock.

On February 9, 2021, the Company entered into an amended and restated the sales agreement with B. Riley Securities, Inc. ("B. Riley") and A.G.P./Alliance Global Partners ("AGP") in order to include AGP as an additional sales agent for the Company's "at the market offering" program (the "Amended and Restated Sales Agreement"). The Sales Agreement amended and restated the At Market Issuance Sales Agreement, dated August 5, 2016, with B. Riley Securities, Inc. (formerly known as B. Riley FBR, Inc.), as amended by amendment no. 1, dated May 7, 2018, to the At Market Issuance Sales Agreement.

Subsequent to year end through March 3, 2021, the Company sold through the At Market Issuance Sales Agreement and the Amended and Restated Sales Agreement approximately 76.3 million shares of the Company's common stock and received net proceeds of approximately $63.8 million.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

The Company has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified under the rules of the SEC. The Company's disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, the Company's management, including the Chief Executive Officer who also serves as its Chief Financial Officer, after evaluating the effectiveness of disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, has concluded that based on such evaluation, the Company's disclosure controls and procedures were effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's Chief Executive Officer who is also its Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Internal control over financial reporting is defined in Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act as a process designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of the Company's internal control over financial reporting as of December 31, 2020 based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on the assessment, management concluded that, as of December 31, 2020, the Company's internal control over financial reporting was effective at a reasonable assurance level based on those criteria.

The Company's management, including its Chief Executive Officer who is also its Chief Financial Officer, does not expect that the Company's disclosure controls and procedures and its internal control processes will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that the breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Changes in Internal Control Over Financial Reporting

The Company made changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) to assess the limitation of net operating loss carry-forward and its tax impact through an

Internal Revenue Code Section 382 analysis during our fiscal quarter ended December 31, 2020. There has been no other change in our internal control over financial reporting during our fiscal quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. *Other Information*

None.

PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

Below is certain information regarding our directors and executive officers.

Name	Age	Position
Steven A. Shallcross	59	Chief Executive Officer, Chief Financial Officer and Director
Jeffrey J. Kraws	56	Chairman
John Monahan	74	Director
Jeffrey Wolf, J.D.	57	Director

Steven A. Shallcross. Mr. Shallcross has been a member of our Board of Directors since December 6, 2018 and currently serves as our Chief Executive Officer, a position he was appointed to on December 6, 2018, and our Chief Financial Officer. Mr. Shallcross was appointed as our Interim Chief Executive Officer on December 5, 2017 and has served as our Chief Financial Officer, Treasurer and Secretary since joining us in June 2015. Mr. Shallcross brings to our company operational, financial and international biotech industry experience, as well as an established track record at leading the financial development and strategy for several publicly traded biotech companies. From May 2013 through May 2015, Mr. Shallcross served as Executive Vice President and Chief Financial Officer of Nuo Therapeutics, Inc. (formerly Cytomedix, Inc.). In January 2016, Nuo Therapeutics, Inc. filed a voluntary petition for relief under Chapter 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware and on April 25, 2016, the Bankruptcy Court entered an order granting approval of Nuo's plan of reorganization. From July 2012 to May 2013, Mr. Shallcross held the offices of Executive Vice President, Chief Financial Officer and Treasurer of Empire Petroleum Partners, LLC, a motor fuel distribution company. From July 2011 to March 2012, Mr. Shallcross was Acting Chief Financial Officer of Senseonics, a privately-held medical device company located in Germantown, MD. From January 2009 to March 2011, he served as Executive Vice President and Chief Financial Officer of Innocoll AG (formerly privately held Innocoll Holdings, Inc.), a global, commercial-stage biopharmaceutical company specializing in the development and commercialization of collagen-based products. He also served for four years as the Chief Financial Officer and Treasurer of Vanda Pharmaceuticals, Inc., leading the company through its successful IPO and follow-on offering and previously served as the Senior Vice President and Chief Financial Officer of Middlebrook Pharmaceuticals, Inc. (formerly Advancis Pharmaceutical Corporation). In addition, Mr. Shallcross also served as the Chief Financial Officer of Bering Truck Corporation. Since June 2019, Mr. Shallcross has served on the board of directors of Elys Game Technology, Corp. (Nasdaq:ELYS), an international, vertically integrated commercial-stage company engaged in various aspects of the leisure gaming industry. He holds an MBA from the University of Chicago's Booth School of Business, a Bachelor of Science degree in Accounting from the University of Illinois, Chicago, and is a Certified Public Accountant in the State of Illinois.

Mr. Shallcross brings to the Board significant strategic, business and financial experience related to the business and financial issues facing biotechnology companies. Mr. Shallcross has a broad understanding of the financial markets, financial statements as well as generally accepted accounting principles. Through his services as our Chief Executive Officer and Chief Financial Officer, he developed extensive knowledge of our business.

Jeffrey J. Kraws. Mr. Kraws has been a member of the Company's Board of Directors since January of 2006, and was appointed independent, non-executive Chairman of the Board in May 2012. Since 2003, Mr. Kraws has served as Chief Executive Officer and co-founder of Crystal Research Associates and CRA Advisors, and since February 2012, he has served as partner and co-founder of TopHat Capital, LLC. Since August 2016, Mr. Kraws has served as the Co-President of Ra Medical Systems Inc. (NYSE RMED), a medical device company. Mr. Kraws is a partner at Grannus Securities Pty Ltd. (an Australian based private equity fund) since November 2015. Well known and respected on Wall Street, Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a "5-Star Rating" in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by Starmine.com. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. During 2006 through February of 2007, Mr. Kraws served as our Vice President of Business Development, on a part-time basis. Since December 2013, Mr. Kraws serves on the board of directors of Avivagen Inc. (TSX:VIV) and Saleen Automotive, Inc. (OTC Pink: SLNN . He holds an M.B.A. from Cornell University and a B.S. degree from State University of New York — Buffalo. Mr. Kraws brings a strong business background to us, having worked as a pharmaceutical analyst for over 22 years.

Mr. Kraws brings to the Board significant strategic, business and financial experience related to the business and financial issues facing pharmaceutical companies. Mr. Kraws has a broad understanding of the operational, financial and strategic issues facing pharmaceutical companies. His healthcare experience, executive and leadership experience further qualify him as a member of the Board.

John Monahan. Dr. Monahan has been a member of the Company's Board of Directors since November 11, 2020. Dr. Monahan has served on the board of directors of Heat Biologics, Inc. (Nasdaq: HTBX), a biopharmaceutical company primarily engaged in the development of immune therapies and vaccines, since November 2009, and also served on the board of directors of the biotech company Anixa Biosciences, Inc. (formerly known as ITUS Corporation)(Nasdaq: ANIX), a biotechnology company focused on using the body's immune system to diagnose, treat and prevent cancer, since 2016. He is also a board member of Cellix Ltd. (Ireland) and has served on a number of other public and private boards over the years. Dr. Monahan Co-Founded Avigen Inc. (Nasdaq: AVGN) in 1992, a company which has become a leader in its sector for the development of novel pharmaceutical products for the treatment of serious human diseases. Over a 12 year period as Chief Executive Officer of Avigen he raised over $235 million in several private and public financings including its initial public offering. From 1989-1992, he was Vice President of Research & Development at Somatix Therapy Corp., Alameda, CA and from 1985-1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc., Alameda, CA. Prior to that from 1982-1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche, Inc. Nutley, NJ, and from 1975 to 1977 he was an Instructor at Baylor College of Medicine, Houston TX. Dr. Monahan served as a scientific advisory consultant to the Company from 2015 to November 10, 2020 and from 2010 through 2015 he was the Company's Senior Executive Vice President of Research & Development. Dr. Monahan was also a Scientific Advisory Board member of Agilis Biotherapeutics (recently merged into PTC Therapeutics), from 2014 to 2019. Dr. Monahan received his Ph.D. in Biochemistry from McMaster University, Canada and his B.Sc. from University College Dublin, Ireland.

Dr. Monahan brings to our Board of Directors significant knowledge of and experience in the pharmaceutical and medical industries. He has extensive business, managerial, executive and leadership experience that further qualify him to serve as a member of the Board and a valuable understanding of biochemistry and our product candidates.

Jeffrey Wolf, J.D. Mr. Wolf, who has been a member of the Company's Board of Directors since 2006, has substantial experience in creating, financing, nurturing and growing new ventures based upon breakthrough research and technology. In August 2008, Mr. Wolf founded Heat Biologics, Inc. (NASDAQ: HTBX), a publicly traded company engaged in research and development of drugs focused on combating cancer and other diseases. Since April 2010, Mr. Wolf has served as the Chief Executive Officer and Chairman of the Board of Heat Biologics, Inc. Prior to founding Heat Biologics, Inc., from June 1997 to March 2011, Mr. Wolf has served as managing director at Seed-One Ventures, LLC a venture firm focused on launching and growing exceptional healthcare companies from the ground up. Since founding Seed-One, Mr. Wolf has founded and run several medical companies. Mr. Wolf's start-ups include Avigen, a San Francisco-based gene therapy company where he was a co-founder and director; TyRx Pharma, a Princeton-based company focused on the development of bio-compatible polymers where he was a co-founder and Chairman; EluSys Therapeutics, a New Jersey company focused on the development of novel technology to remove blood-borne pathogens where he was a cofounder, Chairman and Chief Executive Officer; and GenerationOne, a Miami-based company focused on mobile-based collaborative care, where he was the founder, Chairman and Chief Executive Officer. Mr. Wolf received his M.B.A. from Stanford Business School, his J.D. from New York University School of Law and his B.A. from the University of Chicago, where he graduated with honors in Economics. Mr. Wolf serves as a director of several Seed-One portfolio companies.

Mr. Wolf has extensive knowledge of the industry and in particular research and development. His legal and business background provide him with a broad understanding of the legal, operational, financial and strategic issues facing our company. Having served as a board member on other public company boards, Mr. Wolf has an extensive understanding of the operational, financial and strategic issues facing public companies.

Directors' Term of Office

Directors will hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by our Board of Directors and serve at the discretion of the Board of Directors.

Audit Committee

The Audit Committee is comprised of Mr. Wolf (Chairman), Mr. Kraws and Dr. Monahan. The Audit Committee is responsible for recommending our independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with our independent public accountants the scope and results of the audit engagement and the system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-K and Form 10-Q. Our Board has determined that all audit committee members are independent under applicable SEC regulations and NYSE American rules. Our Board of Directors has determined that each of Mr. Wolf and Mr. Kraws qualify as "audit committee financial experts" as that term is used in Section 407 of Regulation S-K. Our Audit Committee charter is located on our website *www.syntheticbiologics.com*.

Compensation Committee

Our Compensation Committee consists of Mr. Kraws (Chairman), Dr. Monahan and Mr. Wolf. This committee performs several functions, including reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation. Our Board has determined that all compensation committee members are independent under applicable SEC regulations and NYSE American rules. Our Compensation Committee charter is located on our website *www.syntheticbiologics.com*.

Nominations Committee

Our Nominations Committee consists of Dr. Monahan (Chairman), Mr. Kraws and Mr. Wolf. This committee performs several functions, including identifying qualified individuals to become members of the Board and recommending appointments to the Board and appointment of executive officers. The committee seeks individuals who have an inquisitive and objective perspective, practical wisdom and mature judgment, and the talent and expertise to understand, and provide sound and prudent guidance with respect to, our activities, operations and interests. Candidates must also be individuals who have the highest personal and professional integrity, who have demonstrated exceptional ability and judgment, and who are likely to be the most effective, in conjunction with the other members of the Board, in collectively serving the long-term interests of stockholders. Our Board has determined that all nominations committee members are independent under applicable SEC regulations and NYSE American rules. Our Nominations Committee charter is located on our website *www.syntheticbiologics.com*.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own more than 10 percent of a registered class of the Synthetic Biologics' equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Such officers, directors and persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file with the SEC.

Based solely on a review of the copies of such forms that were received by us, or written representations from certain reporting persons that no Forms 5 were required for those persons, we are not aware of any failures to file reports or report transactions in a timely manner during the year ended December 31, 2020.

Code of Ethics

We have long maintained a Code of Conduct which is applicable to all of our directors, officers and employees. In addition, we have adopted a Code of Ethics for Financial Management which applies to our Chief Executive Officer, Chief Financial Officer, Treasurer and Controller. Each of these codes is posted on our website at *www.syntheticbiologics.com*.

Item 11. *Executive Compensation*

We are a "smaller reporting company" and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules allow us to provide less detail about its executive compensation program, the Compensation Committee is committed to providing the information necessary to help stockholders understand its executive compensation-related decisions. Accordingly, this section includes supplemental narratives that describe the 2020 executive compensation program for our Named Executive Officer.

The following table summarizes all compensation awarded to, earned by or paid to Steven A. Shallcross, our Named Executive Officer, during the fiscal years presented below.

Name and Principal Position	Year	Salary ($)[1]	Bonus ($)	Options Awards ($)[2]	All Other Compensation ($)[3]	Total ($)
Steven Shallcross	2020	$ 565,000	$ 350,000[4]	$ 120,257	$ 26,992	$ 1,062,519
Chief Executive Officer and Chief Financial Officer	2019	$ 550,000	$ 412,500	$ 118,801	$ 27,308	$ 1,108,609

(1) Mr. Shallcross was appointed as our Chief Executive Officer on December 6, 2018. Mr. Shallcross' annual salary was $550,000 commencing December 6, 2018 and increased to $565,000 and $585,000 on December 5, 2019 and

December 30, 2020, respectively.

(2) Amount reflects the grant date fair value of the Named Executive Officer's stock options, calculated in accordance with FASB ASC Topic 718. For a discussion of the assumptions used in calculating these values, see Note 5 to our consolidated financial statements. In December 2020, Mr. Shallcross was issued an option to purchase 450,000 shares of common stock; the awards vest monthly over 36 months.

(3) The all other compensation column is comprised of vacation accrual paid, and the portion of medical, dental and vision premiums paid by us on behalf of our Named Executive Officers. These benefits are offered to all Synthetic Biologics' employees who work at least 17.5 hours per week.

(4) This bonus was earned in 2020 and paid in 2021.

Narrative Disclosure to Summary Compensation Table

Overview of Our Compensation Program

A. Philosophy and Objectives

The Compensation Committee seeks to attract and retain executive talent by offering competitive base salaries, bonuses and long-term incentives. The Compensation Committee's philosophy is to provide a compensation package that attracts and retains superior executive talent and delivers higher rewards for superior performance and consequences for underperformance. It is also the Compensation Committee's practice to provide a balanced mix of cash and equity-based compensation that aligns both the short and long-term interests of our executives with that of our stockholders. Our executive compensation program is based on the following philosophies and objectives:

- *Compensation Should Align with Stockholders' Interests* — The Compensation Committee believes that executives' interests should be aligned with those of the stockholders. Executives are granted stock options so that their total compensation is tied directly to the same value realized by our stockholders. Executive bonuses are tied directly to the value that we gain from an executive's contribution to our success as a whole.

- *Compensation is Competitive* — The Compensation Committee seeks to provide a total compensation package that attracts, motivates and retains the executive talent that we need in order to maximize its return to stockholders. To accomplish this objective, executive compensation is reviewed annually to ensure that compensation levels are competitive and reasonable given our level of performance and other comparable companies with which we compete for talent.

- *Compensation Motivates and Rewards the Achievement of Goals* — Our executive compensation program is designed to appropriately reward both individual and collective performance that meets and exceeds our annual, long-term and strategic goals. To accomplish this objective, a substantial percentage of total compensation is variable, "at risk", both through annual incentive compensation and the granting of long-term incentive awards.

B. Oversight of Executive Compensation

Role of the Compensation Committee

Pursuant to the terms of its charter, the Compensation Committee is responsible for the review of all aspects of our executive compensation program and makes decisions regarding the compensation of the Named Executive

Officers. Our sole Named Executive Officer for the year ended December 31, 2020 was Steven Shallcross, our Chief Executive Officer.

The Compensation Committee's responsibilities include but are not limited to the following:

- Establishing on an annual basis the performance goals and objectives for purposes of determining the compensation of our Chief Executive Officer and other senior executive officers.

- Evaluating the Chief Executive Officer's and other Named Executive Officer's performance at least annually in light of those goals and objectives, and based upon these evaluations setting the compensation level for those officers.

- Reviewing the competitive position of, and making recommendations to, the Board of Directors with respect to the cash-based and equity-based compensation plans and our programs relating to compensation and benefits.

- Overseeing administration of our stock option plan and incentive compensation plans, making recommendations to the Board of Directors regarding the granting of options and incentives and otherwise assisting the Board of Directors in administering awards under these plans.

- Reviewing the financial performance and operations of our major benefit plans.

Additional information regarding the Compensation Committee's responsibilities is set forth in its charter, which is posted on our website at *www.syntheticbiologics.com*.

Role of the Chief Executive Officer

Our Chief Executive Officer makes recommendations to the Compensation Committee regarding the compensation of our other Named Executive Officers, if any. The Chief Executive Officer does not participate in any discussions or processes concerning his own compensation and participates in a non-voting capacity in discussions or processes concerning the compensation of our other members of management. In addition to our Chief Executive Officer, our other Named Executive Officers, as well as members of our management and consultants also attend Compensation Committee meetings from time to time and may take part in discussions of executive compensation.

C. Program Design

The Compensation Committee uses a simple and straightforward approach in compensating our Named Executive Officers in which base salary, annual incentives and stock options are the principal components. In addition, executive officers generally participate in the same benefit programs as other full-time employees.

Our executive compensation program is designed to provide executives with a reasonable level of fixed compensation through base salary and benefits, and an opportunity to earn incentive compensation through the annual and long-term incentive programs based on a mix of individual and corporate performance, individual performance and the value of our stock. We do not currently have formal policies for allocating compensation among base salary, performance-based bonus and equity awards. Instead our Compensation Committee uses its judgment to establish a total direct compensation opportunity for each Named Executive Officer that is a mix of current, short-term and long-term incentive compensation and cash and non-cash compensation that it believes appropriate to achieve the goals of our executive compensation program and corporate objectives. Our target pay mix places a significant emphasis on performance based variable compensation. The incentive plans are designed to pay well when performance meets or exceeds expectations and pay little or no incentive if performance is below expectations.

In designing and implementing our executive compensation program, our Compensation Committee considers our company's operating and financial objectives, including our risk profile, and the effect that its executive compensation decisions will have on encouraging our executive officers to take an appropriate level of business risk consistent with our overall goal of enhancing long-term stockholder value. In particular, the Compensation Committee considers those business risks identified in our risk factors and the known trends and uncertainties identified in our management discussion and analysis and considers how our executive compensation program serves to achieve our operating and financial objectives while at the same time mitigating any incentives for our executive officers to engage in excessive risk-taking to achieve short-term results that may not be sustainable in the long-term.

Target compensation comprises base salary and performance based variable compensation, including targeted cash bonus amounts and equity-based compensation. As an executive's level of responsibility increases, the Compensation Committee generally targets a greater portion of the executive's compensation to be contingent upon performance in the form of variable compensation. For example, historically our Named Executive Officers have a higher percentage of compensation at risk (and thus greater upside and downside potential) relative to our other employees. The Compensation Committee believes this is appropriate because our Named Executive Officers have the greatest influence on our performance.

During 2020, the salary for our Chief Executive Officer who also serves as our Chief Financial Officer was 51% of his target compensation package and performance based variable compensation comprised 49% of his target compensation. Of the performance based variable compensation 22% was equity-based compensation and 78% was his target cash bonus.

D. Compensation Review Process

The Compensation Committee annually reviews compensation for our Named Executive Officers. The Compensation Committee considers the executive's role and responsibilities, corporate and individual performance, and industry-wide compensation practices and trends for other companies of similar size. This approach is used to set base salaries, bonuses, stock option award levels and the mix of compensation elements.

We strive to attract and retain the most highly qualified executive officers in an extremely competitive market. Our Compensation Committee believes that it is important when making its compensation decisions to be informed as to the competitive market for executive talent, including the current practices of comparable public companies with which we compete for such talent. Consequently, our Compensation Committee primarily reviewed a report from Meridian Compensation Partners, LLC that had been provided to the Compensation Committee. With respect to its analysis of the compensation of the Chief Executive Officer, the Compensation Committee took into account that our Chief Executive Officer also serves as our Chief Financial Officer, which is not typical for most companies.

While the Compensation Committee does take into consideration the data it reviewed, the Committee does not attempt to benchmark our executive compensation against any specific level, range, or percentile of compensation paid at any other companies, does not apply any specific measures of internal or external pay equity in reaching its conclusions, and does not employ tally sheets, wealth accumulation, or similar tools in its analysis. Rather, the Compensation Committee reviews compensation data from the survey and report mentioned above, as reference points in making executive compensation decisions especially in light of the fact that our Chief Executive Officer is also performing the role of Chief Financial Officer. The Compensation Committee's general aim is for our compensation to remain competitive with the market, falling above or below the median of the market data as appropriate based on corporate and individual executive performance, and other factors deemed to be appropriate. Competitive market positioning is only one of several factors, as described below, that the Compensation Committee considers in making compensation decisions, and therefore individual Named Executive Officer compensation may fall at varying levels as compared to the market data.

Our Compensation Committee values the opinion of our stockholders. At our 2019 Annual Meeting of Stockholders approximately 59% of the votes that were cast (excluding broker non-votes) were cast in favor of our say-on-pay proposal adopting a resolution approving the compensation paid to our Named Executive Officers as disclosed in our proxy statement for our 2019 Annual Meeting of Stockholders. In addition, at our 2019 Annual Meeting of Stockholders approximately the greatest number of votes were cast in favor of a three (3) year frequency for holding an advisory vote on executive compensation. Our Compensation Committee decided not to make any significant changes to the executive compensation policies; however, our Compensation Committee continues to monitor and evaluate our compensation program in light of our stockholders' views and our transforming business needs.

E. Components of Compensation

We provide four compensation components to Named Executive Officers:

- base salary;
- bonuses based on the achievement of specified goals and objectives;
- long-term incentives; and benefits

1. Base Salaries

We provide our Named Executive Officers a base salary commensurate with their position, responsibilities and experience. In setting the base salary, the Compensation Committee considers the scope and accountability associated with each Named Executive Officer's position and such factors as performance and experience of each Named Executive Officer. We design base pay to provide the essential reward for an employee's work that is required to be competitive in attracting talent. Once base pay levels are initially determined, increases in base pay may be provided to recognize an employee's specific performance achievements or expansion of responsibilities. The base salaries are targeted to be competitive with other similar biotechnology companies. Base salaries for the Named Executive Officers are set by their respective employment contracts and are reviewed annually by the Compensation Committee. Based on the analysis of the peer group and other comparative research performed by the Committee, the Committee was able to compare the base salary for the Chief Executive Officer who also serves as our Chief Financial Officer, including base salary, long-term incentives and bonuses. Upon the appointment of Mr. Shallcross to serve as our Chief Executive Officer in December 2018 and in light of the fact that he also serves as our Chief Financial Officer, it was determined that his overall compensation levels were not competitive with the peer group and therefore his annual base salary was increased to $550,000, which was the same annual base salary as that of our prior Chief Executive Officer. Mr. Shallcross' current employment agreement, dated December 6, 2018, was amended (the "Amended Employment Agreement") on December 5, 2019 to reflect a 3% merit adjustment to Mr. Shallcross' base salary, increasing his annual base salary to $565,000 and further amended on December 31, 2020 to reflect a 3.5% merit adjustment to Mr. Shallcross' base salary, increasing his annual base salary to $585,000.

The 2020 and current base salary for our Chief Executive Officer who also serves as our Chief Financial Officer is:

Named Executive Officer	2020 Base Salary	2021 Base Salary
Steven A. Shallcross, Chief Executive Officer and Chief Financial Officer	$ 565,000	$ 585,000

2. Bonuses

The Compensation Committee also makes recommendations to the full Board of Directors for determining bonuses.

The Compensation Committee also used information from the report and analysis discussed above in determining bonus as well as its own research of peer company compensation. For the year ended December 31, 2020, the Compensation Committee approved a $350,000 cash bonus and an option grant exercisable for 450,000 shares of our common stock for Mr. Shallcross.

The employment agreement with Mr. Shallcross that was in effect during 2020 provided that he was eligible for a bonus of up to seventy five percent (75%) of his base salary (a "Target Bonus") in cash or equity and Mr. Shallcross received a cash bonuses with a value equal to approximately eighty-three (83%) of his Target Bonus. The bonuses are to be rewarded in the discretion of the Compensation Committee and the Board of Directors, based on a review of achievements for the year. The Compensation Committee believes that the granting of a bonus is appropriate to motivate the Named Executive Officers. The Compensation Committee focuses on individual performance, which enables the Compensation Committee to differentiate among executives and emphasize the link between personal performance and compensation. Although the Compensation Committee does not use any fixed formula in determining bonuses, it does link bonuses to objectives the Compensation Committee deems important such as financings, reduction in burn rate and achievement of clinical milestones.

3. Long-Term Incentives

The Compensation Committee believes that a substantial portion of the Named Executive Officer's compensation should be awarded in equity-based compensation since equity-based compensation is directly linked to the interests of stockholders. The Compensation Committee has elected to grant stock options to the Named Executive Officers and other key employees as the primary long-term incentive vehicle. In making this determination, the Compensation Committee considered a number of factors including: the accounting impact, potential value of stock option grants versus other equity instruments and cash incentives, and the alignment of equity participants with stockholders. The Compensation Committee determined to grant stock options to:

- enhance the link between the creation of stockholder value and executive compensation;
- provide an opportunity for equity ownership;
- act as a retention tool; and
- provide competitive levels of total compensation.

Each of Mr. Shallcross' 2019 and 2020 bonuses included a grant of options exercisable for 450,000 shares of common stock. The stock options granted vest in equal monthly installments over a three-year term and are subject to the recipient's continued employment, therefore acting as a significant retention incentive.

The Compensation Committee reviews the performance, potential burn rates and dilution levels to create an option pool that may be awarded to employee participants. Grants to the Named Executive Officers are determined by the Compensation Committee after reviewing market data, including the reports and analysis discussed above and after considering each executive's performance, role and responsibilities.

The Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Option grants are effective on the date the award determination is made by the Compensation Committee and the exercise price of options is the closing market price of our common stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

4. Benefits

Named Executive Officers are eligible to participate in our standard medical, dental, vision, disability insurance, life insurance plans and other health and welfare plans provided to other full-time employees.

Each of our Named Executive Officers are entitled to participate in our 401(k) contributory defined contribution plan.

Pension Benefits

We do not currently provide pension arrangements or post-retirement health coverage for our employees, although we may consider such benefits in the future.

Retirement Benefits

Each of our Named Executive Officers are eligible to participate in our 401(k) contributory defined contribution plan. Pursuant to our 401(k) plan, all eligible employees, including our Named Executive Officers, are provided with a means of saving for their retirement. We currently match all participating employee contributions up to maximum of 4 percent of compensation which vest immediately.

Nonqualified Deferred Compensation

We do not provide any nonqualified deferred compensation plans to our employees, although we may consider such benefits in the future.

Conclusion

Attracting and retaining talented and motivated management and key employees is essential to creating long-term stockholder value. Offering a competitive, performance-based compensation program with a substantial equity component helps to achieve this objective by aligning the interests of the executive officers and other key employees with those of stockholders. We believe that our compensation program met these objectives and that our 2020 compensation program was appropriate in light of the challenges we and our employees face.

Risk Analysis of Our Compensation Program

Our Compensation Committee has reviewed our compensation policies as generally applicable to our employees and believes that our policies do not encourage excessive or inappropriate risk taking and that the level of risk that they do encourage is not reasonably likely to have a material adverse effect on us. As part of its assessment, the Compensation Committee considered, among other factors, the allocation of compensation among base salary and short- and long-term compensation, and our approach to establishing company-wide and individual financial, operational and other performance goals.

Outstanding Equity Awards at Fiscal Year End

The table below reflects all outstanding equity awards made to each of the Named Executive Officers that are outstanding at December 31, 2020. We currently grant stock-based awards pursuant to our 2020 Stock Incentive Plan (the "2020 Stock Plan") and have outstanding awards under our 2001 Stock Incentive Plan (the "2001 Stock Plan"), 2007 Stock Incentive Plan (the "2007 Stock Plan") and 2010 Stock Incentive Plan (the "2010 Stock Plan").

Name	Grant Date[1]	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date
Steven Shallcross	12/30/20	-	450,000	$ 0.42	12/30/27
	12/06/19	150,000	300,000	$ 0.42	12/04/26
	12/20/18	133,333	66,667	$ 0.69	12/06/25
	12/20/17	15,716	-	$ 18.20	12/20/24
	11/30/16	14,286	-	$ 28.00	11/30/23
	12/04/15	2,858	-	$ 96.60	12/04/22
	06/01/15	25,715	-	$ 75.60	06/01/25

(1) Shallcross Options will vest pro rata, on a monthly basis, over 36 months.

Employment Agreements

Steven A. Shallcross, Chief Executive Officer, Chief Financial Officer

On December 6, 2018, we entered into a three-year employment agreement with Mr. Shallcross (the "Shallcross Employment Agreement"), to serve as the Chief Executive Officer and to continue to serve as our Chief Financial Officer. Mr. Shallcross has served as our Chief Financial Officer since June 1, 2015, initially pursuant to the terms of a two year employment agreement that we entered with him on April 28, 2015 (the "Initial Shallcross Employment Agreement"). The Shallcross Employment Agreement replaced the Initial Shallcross Employment Agreement. In addition, on December 6, 2018 Mr. Shallcross was appointed as a director of the Company. Mr. Shallcross does not receive additional compensation for service as our director. The material terms of the Shallcross Employment Agreement are set forth below.

Pursuant to the Shallcross Employment Agreement, as amended, Mr. Shallcross is entitled to an annual base salary of $585,000 and an annual performance bonus of up to seventy five percent (75%) of his annual base salary. The annual bonus will be based upon the assessment of the Board of Mr. Shallcross's performance. The Shallcross Employment Agreement also includes confidentiality obligations and inventions assignments by Mr. Shallcross and non-solicitation and non-competition provisions.

The Shallcross Employment Agreement has a stated term of three years but may be terminated earlier pursuant to its terms. If Mr. Shallcross's employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated (i) by us without Cause or by Mr. Shallcross for Good Reason (as each is defined in the Shallcross Employment Agreement) then in addition to paying the Accrued Obligations, (a) we will continue to pay his then current base salary and continue to provide benefits at least equal to those that were provided at the time of termination for a period of twelve (12) months and (b) he shall have the right to exercise any vested equity awards until the earlier of six (6) months after termination or the remaining term of the awards; or (ii) by reason of his death or Disability (as defined in the Shallcross Employment Agreement), then in addition to paying the Accrued Obligations, Mr. Shallcross would have the right to exercise any vested options until the earlier of six (6) months after termination or the remaining term of the awards. In such event, if Mr. Shallcross commenced employment with another employer and becomes eligible to receive medical or other welfare benefits under another employer-provided plan, the medical and other welfare benefits to be provided by us as described herein would terminate.

The Shallcross Employment Agreement provides that upon the closing of a "Change in Control" (as defined in the Shallcross Employment Agreement), all unvested options shall immediately vest and the time period that Mr. Shallcross will have to exercise all vested stock options and other awards that Mr. Shallcross may have will be equal to the shorter of: (i) six (6) months after termination, or (ii) the remaining term of the award(s). If within one (1) year after the occurrence of a Change in Control, Mr. Shallcross terminates his employment for "Good Reason" or we terminate Mr. Shallcross's employment for any reason other than death, disability or Cause, Mr. Shallcross will be entitled to receive: (i) the portion of his base salary for periods prior to the effective date of termination accrued but unpaid (if any); (ii) all unreimbursed expenses (if any); (iii) an aggregate amount (the "Change in Control Severance Amount") equal to two (2) times the sum of his base salary plus an amount equal to the bonus that would be payable if the "target" level performance were achieved under the Company's annual bonus plan (if any) in respect of the fiscal year during which the termination occurs (or the prior fiscal year if bonus levels have not yet been established for the year of termination); and (iv) the payment or provision of any other benefits. If within two (2) years after the occurrence of a Change in Control, Mr. Shallcross terminates his employment for "Good Reason" or we terminate Mr. Shallcross's employment for any reason other than death, disability or Cause, Mr. Shallcross will be entitled to also receive for the period of two (2) consecutive years commencing on the date of such termination of his employment, medical, dental, life and disability insurance coverage for him and the members of his family that are not less favorable to him than the group medical, dental, life and disability insurance coverage carried by us for him.

The Change in Control Severance Amount is to be paid in a lump sum if the Change in Control event constitutes a "change in the ownership" or a "change in the effective control" of the Company or a "change in the ownership of a substantial portion of a corporation's assets" (each within the meaning of Section 409A of the Internal Revenue Code ("Rule 409A")), or in 48 substantially equal payments, if the Change in Control event does not so comply with Section 409A.

On December 30, 2020, the Board awarded Steven A. Shallcross, the Company's Chief Executive Officer and Chief Financial Officer, (i) a cash bonus equal to 62% of his prior base salary and (ii) an option to purchase 450,000 shares of our common stock. The stock option granted to Mr. Shallcross has an exercise price of $0.42 per share, which is the closing price of the Common Stock on the date of the grant (December 30, 2020), vests pro rata, on a monthly basis, over 36 consecutive months and expires in seven (7) years from the date of the grant, unless terminated earlier. The stock option was granted pursuant to our 2020 Stock Incentive Plan, as amended, and our effective registration statement on Form S-8 for the 2020 Stock Incentive Plan. In addition, the Shallcross Employment Agreement was amended on December 5, 20120 to reflect a 3.5% merit adjustment to Mr. Shallcross' base salary, increasing his annual base salary to $585,000.

Former Chief Medical Officer Compensation

Joseph Sliman, served as our Chief Medical Officer from February 3, 2012 until the expiration of his employment agreement on January 16, 2019. Prior to the expiration date, he was compensated in accordance with his employment agreement and other benefits consistent with those provided to members of management. On October 9, 2018, we received a letter from Dr. Sliman, our Chief Medical Officer purporting to provide notice of a right to terminate his employment agreement, dated January 17, 2017, with us for "good reason", alleging a material reduction in his duties, authorities, and responsibilities as an executive of our company. Pursuant to the terms of his two year employment agreement that we entered into on January 17, 2017, Dr. Sliman served as our Chief Medical Officer and was entitled a base salary of $385,000, and he was eligible for a target bonus of 75% of his base salary. Dr. Sliman did not receive any performance based variable compensation in 2018. In 2019, Dr. Sliman received a prorated salary of $18,716. The agreement also provided that if Dr. Sliman 's employment was terminated for any reason, he or his estate as the case may be, would be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"): provided, however that if his employment were terminated (1) by us without Cause (as defined in the agreement) or by him for Good Reason (as defined in the agreement) then in addition to paying the Accrued Obligations, (x) we would be obligated to continue to pay his then current base salary and continue to provide benefits at least equal to those which were provided at the time of termination for a period of 12 months and (y) he would have the right to exercise any vested equity options until the earlier of six months after termination or the remaining term of the awards. In 2020, we paid Dr. Sliman a settlement payment of $385,000.

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2020 regarding the compensation of our directors who at December 31, 2020 were not also our Named Executive Officers.

Name	Fees Earned or Paid in Cash	Option Awards[1][2]	Other Compensation	Total
Jeffrey J. Kraws[3]	$ 176,250	$ 40,086	$ -	$ 216,336
Scott Tarriff[4]	$ 57,070	$ -	$ -	$ 57,070
John Monahan[5]	$ 9,251	$ 40,086	$ -	$ 49,337
Jeffrey Wolf	$ 73,750	$ 40,086	$ -	$ 113,836

(1) The amounts in the "Option Awards" column reflect the dollar amounts of the grant date fair value for the financial statement reporting purposes for stock options for the fiscal year ended December 31, 2020 in accordance with ASC 718. The fair value of the options was determined using the Black-Scholes model. For a discussion of the assumptions used in computing this valuation, see "Management's Discussion and Analysis of Financial Conditions and Results of Operations" and Note 5 of the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

(2) As of December 31, 2020, the following are the outstanding aggregate number of option awards held by each of our directors who were not also Named Executive Officers:

Name	Option Awards (#)
Jeffrey J. Kraws	497,324
Scott Tarriff	348,039
John Monahan	177,358
Jeffrey Wolf	497,324

During 2020, each non-employee member of the Board of Directors received an annual cash retainer of $43,000, our independent, non-executive Chairman of the Board of Directors receives an annual cash retainer of $150,000, all non-employee directors receive an annual cash fee of $7,500, $5,000 and $3,750 for service on the Audit, Compensation and Nominations Committees, respectively, and the Chairman of the Audit, Compensation and Nominations Committees receive an additional annual cash fee of $15,000, $10,000 and $7,500, respectively. In addition, each non-employee member of the Board of Directors was issued an option exercisable for 250,000 shares of our common stock, for a term of seven years, vesting monthly over one year of the date of grant. In setting 2020 compensation for directors, the Compensation Committee relied upon the report that was provided by Korn Ferry Hay Group in November 2017 to provide an assessment of our director compensation. In setting 2021 compensation for directors, the Compensation Committee relied on a report form Meridian Compensation Partners, LLC. Based on an analysis of director compensation set forth in the report, our financial performance, general market conditions and the interests of stockholders, it was determined that the annual cash retainer for serving on the board and the committee retainers would remain for 2021 the same as they were in 2020 and 2019.

(3) Mr. Kraws was appointed as our independent, non-executive Chairman of the Board of Directors in May 2012.

Pursuant to his agreement Mr. Kraws receives an annual retainer of $150,000 for serving as our Chairman.

(4) Mr. Tarriff resigned as a director on November 11, 2020. Upon his resignation, the Board of Directors accelerated vesting of his unvested options and extended the period for which he has the right to exercise vested options from three months to the earlier of December 31, 2022 and the original option exercise expiration date.

(5) Dr. Monahan was appointed as a director on November 11, 2020. Fees in the director compensation chart do not include $11,250 for consulting fees earned for services provided during 2020 prior to his appointment as a director.

Compensation Committee Interlocks

During the last fiscal year ended December 31, 2020, none of our executive officers served on the Board of Directors or Compensation Committee of any other entity whose officers served either on our Board of Directors or Compensation Committee.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The following table sets forth information, as of March 3, 2021, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons known to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock; (ii) each of our directors and our named executive officers named in the Summary Compensation Table; and (iii) all of our directors and our executive officer as a group.

	Shares Owned [1]	
Name and Address of Beneficial Ownership (2)	Number of Shares Owned	Percentages of Shares [3]
Jeffrey J. Kraws [4]	219,526	*
Steven Shallcross [5]	514,130	*
Jeffrey Wolf [6]	212,990	*
John Monahan [7]	63,469	*
All current officers and directors as a group (4 persons)	1,010,115	0.78%

* represents less than 1% of our common stock

(1) The address for each officer and directors is 9605 Medical Center, Suite 270, Rockville, Maryland 20850.

(2) Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. Except as indicated in the footnotes to the table, to the knowledge of the Company, the persons named in the table have sole voting and investment power with respect to all shares of common stock, options and/or warrants shown as beneficially owned by them, subject to community property laws, where applicable. Pursuant to the rules of the SEC, the number of shares of our common stock deemed outstanding includes shares issuable pursuant to options held by the respective person or group that are currently exercisable or may be exercised within 60 days of March 3, 2021.

(3) As of March 3, 2021, the Company had 129,654,575 shares of common stock outstanding.

(4) Includes 212,990 shares issuable upon exercise of options held by Mr. Kraws that are exercisable within the 60-day period following March 3, 2021. Does not include an additional 284,334 shares issuable upon exercise of options held by Mr. Kraws that are not exercisable within the 60-day period following March 3, 2021.

(5) Includes 464,130 shares issuable upon exercise of options held by Mr. Shallcross that are exercisable within the 60-day period following March 3, 2021. Does not include an additional 694,445 shares issuable upon exercise of options held by Mr. Shallcross that are not exercisable within the 60-day period following March 3, 2021.

(6) Includes 212,990 shares issuable upon exercise of options held by Mr. Wolf that are exercisable within the 60-day period following March 3, 2021. Does not include an additional 284,334 shares issuable upon exercise of options held by Mr. Wolf that are not exercisable within the 60-day period following March 3, 2021.

(7) Includes 63,469 shares issuable upon exercise of options held by Dr. Monahan that are exercisable within the 60-day period following March 3, 2021. Does not include an additional 113,889 shares issuable upon exercise of options held by Dr. Monahan that are not exercisable within the 60-day period following March 3, 2021.

Equity Compensation Plan Information

The following table sets forth information about the securities authorized for issuance under our equity compensation plans for the fiscal year ended December 31, 2020.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by stockholders:			
2001 Stock Incentive Plan	-	$ -	-
2007 Stock Incentive Plan	5,145	$ 69.52	-
2010 Stock Incentive Plan	2,452,273	$ 3.43	-
2020 Stock Incentive Plan	1,540,000	0.42	2,460,000
Equity compensation plans not approved by stockholders	N/A	N/A	.
Total	3,997,418	$ 2.35	2,460,000

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

Pursuant to our charter, our Audit Committee shall review on an on-going basis for potential conflicts of interest, and approve if appropriate, all our "Related Party Transactions" as required by Section 120 of the NYSE American Company Guide. For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404.

The Board of Directors has determined that Mr. Kraws, Dr. Monahan and Mr. Wolf are independent directors.

Except as disclosed under "Executive Compensation," there were no related party transactions during the two year's

ended December 31, 2020 or the current year.

Item 14. *Principal Accountant Fees and Services*

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2020 and 2019 by BDO USA, LLP.

	December 31,	
	2020	2019
Audit Fees and Expenses (1)	$ 282,000	$ 295,000
	$ 282,000	$ 295,000

(1) Audit fees and expenses were for professional services rendered for the audit and reviews of the consolidated financial statements of the Company, professional services rendered for issuance of consents and assistance with review of documents filed with the SEC.

Audit Committee Pre-Approval Policy

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the Public Company Accounting Oversight Board (PCAOB). The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by the Audit Committee.

PART IV

Item 15. *Exhibits and Financial Statement Schedules*

(a)(1) The following financial statements are included in this Annual Report on Form 10-K for the fiscal years ended December 31, 2020 and 2019.

1. Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2020 and 2019
3. Consolidated Statements of Operations for the years ended December 31, 2020 and 2019
4. Consolidated Statements of (Deficit) Equity for the years ended December 31, 2020 and 2019

5. Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019

6. Notes to Consolidated Financial Statements

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Consolidated Financial Statements or related notes.

(a)(3) Exhibits

EXHIBIT INDEX

The following exhibits are either filed as part of this report or are incorporated herein by reference:

1.1	At Market Issuance Agreement dated August 5, 2016 between Synthetic Biologics, Inc. and FBR Capital Markets & Co. (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed August 5, 2016, File No. 001-12584.)
1.2	Amendment No. 1 to At The Market Issuance Sales Agreement(Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed May 7, 2016, File No. 001-12584.)
1.3	Amended and Restated At Market Issuance Sales Agreement by and among Synthetic Biologics, Inc., B. Riley Securities, Inc. and A.G.P./Alliance Global Partners, dated February 9, 2021 (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed February 10, 2021), File No. 001-12584.)
1.4	Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, File No. 001-12584, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001, File No. 001-12584; and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998, File No. 001-12584.)
3.2	Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.3	Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.4	Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.5	Amended and Restated Bylaws Adopted and Effective October 31, 2011 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 2, 2011, File No. 001-12584.)

3.6	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 16, 2012, File No. 001-12584.)
3.7	Certificate of Amendment to Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed May 18, 2015, File No. 001-12584.)
3.8	Certificate of Amendment to Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 of the

	Registrant's Current Report on Form 8-K filed September 8, 2017, File No. 001-12584.)
3.9	Certificate of Designations for Series A Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 12, 2017, File No. 001-12584.)
3.10	Certificate of Change Pursuant to NRS 78. 209 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 13, 2018, File No. 001-12584.)
3.11	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 26, 2018, File No. 001-12584.)
3.12	Certificate of Designations for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
3.13	Certificate of Amendment to Certificate of Designations for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
3.14	Certificate of Amendment to the Certificate of Designation for the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K/A filed on February 1, 2021 File No. 001-12584.)
4.1	Specimen Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-3 filed on July 3, 2013, File No. 333-189794.)
4.2	Form of Warrant for Purchasers of Units (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on October 10, 2014, File No. 001-12584.)
4.3	Form of Series B Warrant to Purchase Common Stock issued November 18, 2016 (Incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on November 15, 2016, File No. 001-12584.)
4.4	Form of Warrant Agreement, dated November 18, 2016 between Synthetic Biologics, Inc. and Corporate Stock Transfer, Inc. (Incorporated by reference to Exhibit 4.3 of the Registrant's Current Report on Form 8-K filed on November 15, 2016, File No. 001-12584.)
4.5	Form of Warrant issued December 26, 2017 to InSite Communications (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 10-Q filed May 5, 2018, File No. 001-12584.)
4.6	Warrant Agency Agreement, dated October 15, 2018, by and between Synthetic Biologics, Inc. and Corporate Stock Transfer, Inc. (including the form of warrant certificate) (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
4.7	Description of Securities of Synthetic Biologics, Inc.(1)
10.1*	2007 Stock Incentive Plan (Incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-8 filed January 18, 2008, File No. 333-148764.)
10.2*	Form of Director/Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 6, 2009, File No. 001-12584.)
10.3*	2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-8 filed November 29, 2010, File No. 333-170858.)
10.4	Stock Purchase Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.2 of the

Registrant's Current Report on Form 8-K filed November 21, 2011, File No. 001-12584.)

10.5	Registration Rights Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed November 21, 2011, File No. 001-12584.)
10.6+	Exclusive Channel Collaboration Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed August 9, 2012, File No. 001-12584.)
10.7	Stock Purchase Agreement with Intrexon Corporation (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed August 9, 2012, File No. 001-12584.)
10.8	First Amendment to Registration Rights Agreement between Synthetic Biologics, Inc. and Intrexon Corporation (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed August 9, 2012, File No. 001-12584.)
10.10	Registration Rights Agreement dated October 25, 2012 with investors (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed October 31, 2012, File No. 001-12584.)
10.11	Joinder Agreement by and among Synthetic Biologics, Inc., NRM VII Holdings I, LLC and Intrexon Corporation (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed October 31, 2012, File No. 001-12584.)
10.12+	Patent License Agreement dated December 19, 2012 between Synthetic Biologics, Inc. and The University of Texas at Austin (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed December 21, 2012, File No. 001-12584.)
10.13	Sponsored Research Agreement dated December 19, 2012 between Synthetic Biologics, Inc. and The University of Texas at Austin (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed December 21, 2012, File No. 001-12584.)
10.14*	Amended and Restated 2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on November 15, 2013, File No. 333-192355.)
10.15+	Exclusive License Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013 (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.16	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013(Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.17	Stock Purchase Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedars-Sinai Medical Center dated December 5, 2013 (Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on December 10, 2013, File No. 001-12584.)
10.18*	Amended and Restated 2010 Stock Incentive Plan. (Incorporated by reference to Exhibit B to the Definitive Proxy Statement filed on April 13, 2015, File No. 001-12584.)
10.19	Stock Issuance Agreement by and between Synthetic Biologics, Inc., and Intrexon Corporation, dated August 10, 2015. (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 10, 2015, File No. 001-12584.)

10.20	Second Amendment to the Registration Rights Agreement by and between Synthetic Biologics, Inc. and Intrexon Corporation, dated as of August 10, 2015. (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed August 10, 2015, File No. 001-12584.)

10.21*	Synthetic Biologics, Inc. 2010 Stock Incentive Plan, as amended and restated on May 15, 2015. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on August 10, 2015, File No. 333-206268.)
10.22	Third Amendment to the License Agreement between Synthetic Biologics, Inc., Synthetic Biomics, Inc. and Cedar-Sinai Medical Center, dated September 4, 2015. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 filed November 5, 2015, File No. 001-12584.)
10.23*	Form of Stock Option Agreement. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed December 10, 2015, File No. 001-12584.)
10.24*	Synthetic Biologics, Inc. 2010 Stock Incentive Plan, as amended and restated on May 31, 2016. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on August 31, 2016, File No. 333-206268.)
10.25*	Employment Agreement by and between Synthetic Biologics, Inc. and Joseph Sliman dated as of January 17, 2017 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 19, 2017, File No. 001-12584.)
10.26*	Amendment to Employment Agreement dated May 31, 2017 between Synthetic Biologics, Inc. and Steven A. Shallcross (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed June 2, 2017, File No. 001-12584.)
10.27*	Amended and Restated 2010 Stock Incentive Plan (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed on September 8, 2017, File No. 333-220401.)
10.28	Share Purchase Agreement dated as of September 11, 2017 between Synthetic Biologics, Inc. and MSD Credit Opportunity Master Fund, L.P. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed September 12, 2017, File No. 001-12584.)
10.29	Registration Rights Agreement dated as of September 11, 2017 between Synthetic Biologics, Inc. and MSD Credit Opportunity Master Fund, L.P. (Incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on September 12, 2017, File No. 001-12584.)
10.30	Fourth Amendment to Exclusive License Agreement entered into February 16, 2017 between Synthetic Biologics, Inc. and Cedars-Sinai Medical Center. (Incorporated by reference to Exhibit 10.53 of the Registrant's Annual Report on Form 10-K filed on February 22, 2018, File No. 001-12584.)
10.31	Fifth Amendment dated August 22, 2017 to Sponsored Research Agreement dated December 19, 2012 between Synthetic Biologics, Inc. and The University of Texas at Austin (Incorporated by reference to Exhibit 10.54 of the Registrant's Annual Report on Form 10-K filed on February 22, 2018, File No. 001-12584.)
10.32	Stock Purchase Agreement entered into as of September 5, 2018 by and among Synthetic Biologics, Inc., Synthetic Biomics, Inc., and Cedars-Sinai Medical Center(Incorporated by reference to Exhibit 10.1 of the

	Registrant's Current Report on Form 8-K filed on September 6, 2018, File No. 001-12584.)
10.33*	Employment Agreement between Synthetic Biologics, Inc. and Steven A. Shallcross dated as of December 6, 2018 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 6, 2018), File No. 001-12584.
10.34*	Synthetic Biologics, Inc. 2010 Stock Incentive Plan, as amended (incorporated by reference to Appendix A to the Definitive Proxy Statement filed with the Securities and Exchange Commission on July 15, 2019, File No. 001-12584)
10.35+	Clinical Trial Agreement between Washington University School of Medicine in St. Louis and Synthetic Biologics, Inc. dated August 7, 2019 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 8, 2019, File No. 001-12584)

10.36*	Amendment to Employment Agreement with Steven A. Shallcross dated December 5, 2019 (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 5, 2019, File No. 001-12584)
10.37*	Synthetic Biologics, Inc. 2020 Stock Incentive Plan (Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed on August 4, 2020)
10.38*	Form of Incentive Stock Option Grant Agreement (Incorporated by reference to Exhibit 4.11 to the Registration Statement on Form S-8 filed on October 28, 2020)
10.39*	Form of Nonqualified Stock Option Grant Agreement (Incorporated by reference to Exhibit 4.12 to the Registration Statement on Form S-8 filed on October 28, 2020)
10.40*	Form of Restricted Stock Unit Award Agreement (Incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-8 filed on October 28, 2020)
10.41	Termination of Exclusive License Agreement, effective November 9, 2020, by and among Cedars- Sinai Medical Center, Synthetic Biologics, Inc. and Synthetic Biomics, Inc. (Incorporated by Reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed on November 10, 2020 File No. 001-12584)
21.1	List of Subsidiaries (1)
23.1	Consent of Independent Registered Public Accounting Firm (BDO USA, LLP) (1)
31.1	Certification of Steven A. Shallcross, Chief Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) (1)
31.2	Certification of Steven A. Shallcross, Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) (1)
32.1	Certification of Steven A. Shallcross, Chief Executive Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 (1)
32.2	Certification of Steven A. Shallcross, Chief Financial Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 (1)
101.INS	XBRL Instance Document (1)

101.SCH	XBRL Taxonomy Extension Schema Document (1)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (1)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (1)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (1)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (1)

(1) Filed herewith.

* Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.

\+ Confidential treatment has been requested as o certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Item 16. *Form 10-K Summary*

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Executive Officer, Chief Financial Officer and Director
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
Date: March 4, 2021

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Steven A. Shallcross, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 4, 2021

By : /s/ Steven A. Shallcross
Steven A. Shallcross
Chief Executive Officer, Chief Financial Officer and Director

(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: March 4, 2021

By : /s/ Jeffrey J. Kraws
Jeffrey J. Kraws
Chairman

Date: March 4, 2021

By: /s/ John J. Monahan
John J. Monahan
Director

Date: March 4, 2021

By: /s/ Jeffrey Wolf
Jeffrey Wolf
Director