UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-12584

SYNTHETIC BIOLOGICS, INC.

(Exact name of Registrant as Specified in Its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SYN	NYSE American

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

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

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Yes ☐ No ☒

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

SYNTHETIC BIOLOGICS, INC.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

NOTE REGARDING COMPANY REFERENCES

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

NOTE REGARDING TRADEMARKS

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

SYNTHETIC BIOLOGICS, INC.

FORM 10-Q

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PART I–FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

Synthetic Biologics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands except share and par value amounts)

	September 30, 2020	December 31, 2019
Assets		
Current Assets		
Cash and cash equivalents	$ 6,005	$ 15,045
Prepaid expenses and other current assets	657	1,381
Total Current Assets	6,662	16,426
Property and equipment, net	202	367
Right of use asset	316	419
Deposits and other assets	23	23
Total Assets	**$ 7,203**	**$ 17,235**
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 992	$ 2,315
Accrued expenses	988	1,776
Accrued employee benefits	752	935
Lease liability	278	249
Total Current Liabilities	3,010	5,275
Lease liability - Long term	261	473
Total Liabilities	3,271	5,748
Series A convertible preferred stock, $0.001 par value; 10,000,000 shares authorized; 120,000 issued and outstanding	12,733	12,544
Stockholders' Deficit:		
Series B convertible preferred stock, $1,000 par value; 10,000,000 shares authorized, 4,146 issued and outstanding and 7,638 issued and outstanding	2,584	4,761
Common Stock, $0.001 par value; 200,000,000 shares authorized, 19,845,283 and 16,808,758 issued and 19,842,955 and 16,806,430 outstanding	20	17
Additional paid-in capital	236,320	232,580
Accumulated deficit	(244,975)	(235,537)
Total Synthetic Biologics, Inc. and Subsidiaries Deficit	(6,051)	1,821
Non-controlling interest	(2,750)	(2,878)
Total Stockholders' Deficit	(8,801)	(1,057)
Total Liabilities and Stockholders' Deficit	**$ 7,203**	**$ 17,235**

See accompanying notes to unaudited condensed consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
Operating Costs and Expenses:				
General and administrative	$ 1,197	$ 1,098	$ 3,876	$ 3,297
Research and development	914	4,144	4,152	9,156
Total Operating Costs and Expenses	2,111	5,242	8,028	12,453
Loss from Operations	(2,111)	(5,242)	(8,028)	(12,453)
Other Income:				
Interest income	-	92	44	217
Total Other Income	-	92	44	217
Net Loss	(2,111)	(5,150)	(7,984)	(12,236)
Net Loss Attributable to Non-controlling Interest	(8)	(30)	(50)	(73)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (2,103)**	**$ (5,120)**	**$ (7,934)**	**$ (12,163)**
Series A Preferred Stock Dividends	(64)	(63)	(189)	(185)
Series B Preferred Stock Dividends	(519)	(70)	(1,315)	(585)
Net Loss Attributable to Common Stockholders	**$ (2,686)**	**$ (5,253)**	**$ (9,438)**	**$ (12,933)**
Net Loss Per Share - Basic and Dilutive	$ (0.14)	$ (0.31)	$ (0.52)	$ (0.79)
Weighted average number of shares outstanding during the period - Basic and Dilutive	19,398,339	16,805,257	18,302,585	16,313,326

See accompanying notes to unaudited condensed consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders Equity (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' Equity (Deficit)
Balance at December 31, 2019	16,806,430	$ 17	7,638	$ 4,761	$ 232,580	$ (235,537)	$ (2,878)	$ (1,057)
Stock-based compensation	-	-	-	-	83	-	-	83
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(62)	-	(62)
Issuance of SYN Biomics Stock	-	-	-	-		-	26	26
Conversion of Series B Preferred Stock to Common ($0.03 per share)	933,045	1	(1,073)	(669)	1,072	(404)	-	-
Net loss	-	-	-	-	-	(2,964)	-	(2,964)
Non-controlling interest	-	-	-	-	-	-	(26)	(26)
Balance at March 31, 2020	17,739,475	$ 18	6,565	$ 4,092	$ 233,735	$ (238,967)	$ (2,878)	$ (4,000)
Stock-based compensation	-	-	-	-	86	-	-	86
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(63)	-	(63)
Issuance of SYN Biomics Stock	-	-	-	-	-	-	10	10
Conversion of Series B Preferred Stock to Common ($0.03 per share)	904,349	1	(1,040)	(648)	1,039	(392)	-	-
Net loss	-	-	-	-	-	(2,867)	-	(2,867)
Non-controlling interest	-	-	-	-	-	-	(16)	(16)
Balance at June 30, 2020	18,643,824	$ 19	5,525	$ 3,444	$ 234,860	$ (242,289)	$ (2,884)	$ (6,850)
Stock-based compensation	-	-	-	-	82	-	-	82
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(64)	-	(64)
Issuance of SYN Biomics Stock	-	-	-	-	-	-	142	142
Conversion of Series B Preferred Stock to Common ($0.03 per share)	1,199,131	1	(1,379)	(860)	1,378	(519)	-	-
Net loss	-	-	-	-	-	(2,103)	-	(2,103)
Non-controlling interest	-	-	-	-	-	-	(8)	(8)
Balance at September 30, 2020	**19,842,955**	**$ 20**	**4,146**	**$ 2,584**	**$ 236,320**	**$ (244,975)**	**$ (2,750)**	**$ (8,801)**

	Common Stock		Series B Preferred					
	Shares	Amount	Shares	Amount	APIC	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity (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	-	-	-	-	64	-	-	64
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(61)	-	(61)
Issuance of SYN Biomics Stock	-	-	-	-	(36)	-	53	17
Conversion of Series B Preferred Stock to Common ($0.03 per share)	900,869	1	(1,036)	(638)	1,035	(398)	-	-
Net loss	-	-	-	-	-	(3,512)	-	(3,512)
Non-controlling interest	-	-	-	-	-	-	(16)	(16)
Balance at March 31, 2019	16,382,952	$ 16	8,125	$ 5,122	$ 231,817	$ (223,432)	$ (2,872)	$ 10,651
Stock-based compensation	-	-	-	-	91	-	-	91
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(61)	-	(61)
Issuance of SYN Biomics Stock	-	-	-	-	-	-	45	45
Conversion of Series B Preferred Stock to Common ($0.03 per share)	262,608	1	(302)	(187)	303	(117)	-	-
Net loss	-	-	-	-	-	(3,531)	-	(3,531)
Non-controlling interest	-	-	-	-	-	-	(27)	(27)
Balance at June 30, 2019	16,645,560	$ 17	7,823	$ 4,935	$ 232,211	$ (227,141)	$ (2,854)	$ 7,168
Stock-based compensation	-	-	-	-	91	-	-	91
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(63)	-	(63)
Issuance of SYN Biomics Stock	-	-	-	-	-	-	43	43
Conversion of Series B Preferred Stock to Common ($0.03 per share)	160,870		(185)	(113)	183	(70)	-	-
Net loss	-	-	-	-	-	(5,120)	-	(5,120)
Non-controlling interest	-	-	-	-	-	-	(30)	(30)
Balance at September 30, 2019	**16,806,430**	**$ 17**	**7,638**	**$ 4,822**	**$ 232,485**	**$ (232,394)**	**$ (2,854)**	**$ 2,089**

See accompanying notes to unaudited condensed consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	For the nine months ended September 30,	
	2020	**2019**
Cash Flows From Operating Activities:		
Net loss	$ (7,984)	$ (12,236)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	251	246
Subsidiary stock issued to vendor	178	104
Depreciation	169	182
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	724	(600)
Right of use asset	103	86
Accounts payable	(1,324)	1,419
Accrued expenses	(788)	1,403
Accrued employee benefits	(182)	(713)
Lease liability	(183)	(159)
Net Cash Used In Operating Activities	(9,036)	(10,268)
Cash Flows From Investing Activities		
Purchase of property and equipment	(4)	-
Net Cash Used In Investing Activities	(4)	-
Net Cash From Financing Activities	-	-
Net decrease in cash and cash equivalents	(9,040)	(10,268)
Cash and cash equivalents at beginning of period	15,045	28,918
Cash and cash equivalents at end of period	**$ 6,005**	**$ 18,650**
Noncash Financing Activities:		
Conversion of Series B Preferred Stock	$ 2,177	$ 938
Deemed dividends for accretion of Series B Preferred Stock discount	$ 1,315	$ 585
In-kind dividends paid in preferred stock	$ 189	$ 185
Right of use asset from operating lease	$ -	$ 538

See accompanying notes to unaudited condensed consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization, 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 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.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and notes required by Accounting Principles Generally Accepted in the United States of America ("U.S. GAAP") for complete financial statements. The accompanying condensed consolidated financial statements include all adjustments, comprised of normal recurring adjustments, considered necessary by management to fairly state the Company's results of operations, financial position and cash flows. The operating results for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's 2019 Form 10-K. The interim results for the three and nine months ended September 30, 2020 are not necessarily indicative of results for the full year.

The condensed consolidated financial statements are prepared in conformity with U.S. GAAP, which requires the use of estimates, judgments and assumptions that affect the amounts of assets and liabilities at the reporting date and the amounts of revenue and expenses in the periods presented. The Company believes that the accounting estimates employed are appropriate and the resulting balances are reasonable; however, due to the inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods.

Recent Accounting Pronouncements and Developments

In August 2020, the FASB issued Accounting Standards Update 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 our 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, we do 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.

Impairment of Long-Lived Assets

Long-lived assets include property, equipment and right-of-use assets. In accordance with Accounting Standards Codification ("ASC") 360 -*Property, Plant and Equipment* ("ASC 360"), management reviews the Company's recorded long-lived assets for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. The Company determines the extent to which an asset may be impaired based upon its expectation of the asset's future usability as well as whether there is reasonable assurance that the future cash flows associated with the asset will be in excess of its carrying amount. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset, a loss is recognized for the difference between fair value and the carrying value of the asset. During the quarter ending March 31, 2020 the Company identified COVID-19 as a triggering event and performed a qualitative assessment of the fair value of its long-lived assets. The results from this analysis determined that it is still more likely than not that the fair value of its long-lived assets remain higher than the carrying value of these assets. As a result, no impairment charges were recorded during the three and nine months ended September 30, 2020.

2. Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company continues to incur losses and, as of September 30, 2020, the Company had an accumulated deficit of approximately $245 million. Since inception, the Company has financed its activities primarily from the proceeds from the issuance of equity securities.

The Company does not have sufficient capital to fund its operations for the next twelve months following the issuance date of its Quarterly Report on Form 10-Q. The Company's ability to continue as a going concern, address its capital needs, and execute the required clinical trials, is therefore dependent upon the Company's ability to obtain capital through the issuance of debt and/or additional equity offerings. The Company is actively pursuing additional equity or debt financing in the form of either a private placement or a public offering and the Company continues ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. Included in these options is utilizing the "at-the-market" Issuance Sales Agreement (the "FBR Sales Agreement") that the Company entered into with B. Riley Securities (formerly FBR Capital Markets & Co.) in August 2016. Nonetheless, there can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company when and if needed or that the Company will meet the requirements for use of the FBR Sales Agreement.

If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, the Company's operating results and prospects will be adversely affected. These factors individually and collectively, including the Company's dependence on its ability to raise additional capital to fund its operations for the next twelve months following the issuance date of these financial statements raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

In January 2020, the World Health Organization declared a global pandemic for the novel strain of coronavirus, COVID-19. Since then, COVID-19 has spread to the United States and countries worldwide. As COVID-19 continues to spread around the globe, the Company has experienced disruptions that impact our business and clinical trials, including the temporary halt of the enrollment of new patients in its SYN-010 Phase 2b clinical study during the quarter ended June 30, 2020_and the postponement of clinical site initiation for its SYN-004 Phase 1b/2a clinical study. While the Company has experienced limited financial impact at this time, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, the Company's business, financial condition, results of operations and growth prospects could be materially adversely affected, including its ability to raise capital. To maximize patient participation and safeguard the trial's integrity and patient safety, initiation of the Company's Phase 1b/2a clinical study of SYN-004 to be conducted by Washington University in Allogeneic HCT Recipients is deferred until Q1 2021, pandemic conditions permitting.

At September 30, 2020, the Company had cash and cash equivalents of approximately $6.0 million. Management has been able to extend its cash runway since its clinical development partners CSMC and Washington University continued to limit non-essential activities during the third quarter, which included the SYN-010 Phase 2b clinical study and SYN-004 Phase 1b/2a clinical study. The Company anticipates its current cash will allow it to cover overhead costs, manufacturing costs for clinical supply, commercial scale up costs and limited research efforts, including funding requirements to initiate its planned Phase 1b/2a clinical study of SYN-004 in allogeneic HCT recipients and Phase 1-enabling assay development and manufacturing of drug supply in support of the planned Phase 1 single ascending dose (SAD) study of SYN-020 intestinal alkaline phosphatase (IAP).

The Company does not anticipate any additional expense related to the Phase 1b/2a SYN-004 (ribaxamase) clinical trial until the trial is cleared for commencement by Washington University (expected Q1 2021). Commencement of the FDA-agreed Phase 3 clinical trial of SYN-004 for the prevention of C. difficile infection in the future is subject to the Company's successful pursuit of opportunities that will allow it to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete its plan. The Company will be required to obtain additional funding in order to continue the development of its current product candidates beyond its planned Phase 1b/2a clinical study of SYN-004 in allogeneic HCT recipients, its planned Phase 1 SAD study of SYN-020 IAP in healthy volunteers, and to continue to fund operations at the current cash expenditure levels. Currently, the Company does not have commitments from any third parties to provide it with capital. If the Company fails to obtain additional funding for its clinical trials, it will not be able to fully execute its business plan as planned and will be forced to cease certain development activities until funding is received.

2. Going Concern – (continued)

Further, on September 30, 2020, the Company and 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. The Company anticipates additional reductions in clinical development expense during the remainder of 2020 as a result of the discontinuation of this clinical program.

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

- the progress of its research activities;
- the number and scope of its research programs;
- the ability to recruit patients for clinical studies in a timely manner;
- the progress of its preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements and amount of funding received from partners and collaborators;
- its ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- its ability to achieve milestones under licensing arrangements;
- the costs associated with manufacturing-related services to produce material for use in clinical trials;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals; and
- the ability to commence or complete clinical trials due to the ongoing impact of the COVID-19 global pandemic.

The Company has based its estimates of funding requirements on assumptions that may prove to be wrong. The Company may need to obtain additional funds sooner or in greater amounts than it currently anticipates.

If the Company raises funds by selling additional shares of Common Stock or other securities convertible into Common Stock, the ownership interest of the existing stockholders will be diluted. If the Company is not able to obtain financing when needed, it may be unable to carry out its business plan. As a result, the Company may have to significantly limit its operations and its business, financial condition and results of operations would be materially harmed.

3. Fair Value of Financial Instruments

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 rated 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, other current assets, 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 as of September 30, 2020 and $98,000 as of December 31, 2019 that are measured using Level 1 inputs.

4. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	September 30, 2020	December 31, 2019
Prepaid clinical research organizations	$ 471	$ 48
Prepaid consulting, subscriptions and other expenses	74	134
Prepaid insurances	73	549
Prepaid manufacturing expenses	39	622
Prepaid conferences, travel and other expenses	-	25
Other receivables	-	3
Total	$ 657	$ 1,381

Amounts prepaid to clinical research organizations (CROs) were classified as current assets. The Company makes payments to the CROs based on agreed upon terms that include payments in advance of study services.

4. Selected Balance Sheet Information – (continued)

Property and equipment, net (in thousands)

	September 30, 2020	December 31, 2019
Computers and office equipment	$ 808	$ 804
Leasehold improvements	439	439
Software	11	11
	1,258	1,254
Less: accumulated depreciation and amortization	(1,056)	(887)
Total	$ 202	$ 367

Accrued expenses (in thousands)

	September 30, 2020	December 31, 2019
Accrued clinical consulting services	$ 660	$ 684
Accrued vendor payments	309	456
Accrued manufacturing costs	18	635
Other accrued expenses	1	1
Total	$ 988	$ 1,776

Accrued employee benefits (in thousands)

	September 30, 2020	December 31, 2019
Accrued bonus expense	$ 594	$ 858
Accrued vacation expense	158	77
Total	$ 752	$ 935

5. Stock-Based Compensation

Stock Incentive Plans

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 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. 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 September 30, 2020, there were 7,052 options issued and outstanding under the 2007 Stock Plan.

5. Stock-Based Compensation – (continued)

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 Stock Plan to increase the number of shares of the Company's Common Stock reserved for issuance under the Plan from 85,714 to 171,429. On May 15, 2015, the stockholders approved and adopted an amendment to the Company's 2010 Stock Plan to increase the number of shares of the Company's Common Stock reserved for issuance under the Plan from 171,429 to 228,572. On August 25, 2016, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's Common Stock reserved for issuance under the 2010 Stock Plan from 228,572 to 400,000. On September 7, 2017, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's Common Stock reserved for issuance under the 2010 Stock Plan from 400,000 to 500,000. On September 24, 2018, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's Common Stock reserved for issuance under the 2010 Stock Plan from 500,000 to 1,000,000. On September 5, 2019, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Common Stock reserved for issuance under the 2010 Stock Plan 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 periods from the date of grant, and expire between five and ten years after the grant date. As of September 30, 2020, there were 2,453,273 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 September 30, 2020, there were no options issued and outstanding under the 2020 Stock Plan.

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 as compensation expense 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 is estimated on the date of grant using the Black-Scholes option pricing model. There were no options granted during the three and nine months ended September 30, 2020 and 2019.

5. Stock-Based Compensation – (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 the six-month anniversary of grant date;
- in full on one-year anniversary of grant date;
- quarterly over three years;
- annually over three years;
- one-third immediate vesting and remaining annually over two years; and
- monthly over three years.

5. Stock-Based Compensation – (continued)

A summary of stock option activity for the nine months ended September 30, 2020 and the year ended December 31, 2019 is as follows:

	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	-	-		
Exercised	-	-		
Expired	(12,037)	10.89		
Forfeited	(29,650)	0.55		
Balance – September 30, 2020 - outstanding	2,460,325	$ 3.62	5.79 years	$ 96,106
Balance – September 30, 2020 - exercisable	747,781	$ 10.80	5.14 years	$ 13,196
Grant date fair value of options granted – nine months ended September 30, 2020		$ -		
Weighted average grant date fair value – nine months ended September 30, 2020		$ -		
Grant date fair value of options granted – year ended December 31, 2019		$ 470,000		
Weighted average grant date fair value – year ended December 31, 2019		$ 0.27		

Stock-based compensation expense included in general and administrative expenses relating to stock options issued to employees for the three and nine months ended September 30, 2020 was $41,000 and $120,000, respectively, and $59,000 and $165,000 for the three and nine months ended September 30, 2019, respectively. Stock-based compensation expense included in research and development expenses relating to stock options issued to employees for the three and nine months ended September 30, 2020 was $14,000 and $45,000, respectively, and $22,000 and $52,000 for the three and nine months ended September 30, 2019, respectively.

Stock-based compensation expense included in general and administrative expenses relating to stock options issued to consultants for the three and nine months ended September 30, 2020 was $26,000 and $79,000, respectively, and $9,000 and $28,000 for the three and nine months ended September 30, 2019, respectively. Stock-based compensation expense included in research and development expenses relating to stock options issued to consultants for the three and nine months ended September 30, 2020 was $1,000 and $7,000, respectively, and $1,000 for the three and nine months ended September 30, 2019.

5. Stock-Based Compensation – (continued)

As of September 30, 2020, total unrecognized stock-based compensation expense related to stock options was $406,000, which is expected to be expensed through August 2022.

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 during the three and nine months ended September 30, 2020 and 2019.

6. 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 Common Stock, and one five-year warrant to purchase one share of Common Stock at an exercise price of $1.38 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. 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 per share of Common Stock (which is 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.

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 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 on 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 are being recorded as non-cash income or expense in the Company's Condensed Consolidated Statements of Operations at each subsequent period. At September 30, 2020 and September 30, 2019, the fair value of the warrant liability was nominal. 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.

6. Stock 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, had an exercise price of $61.25 per share and a life of five years. The warrants vested immediately and expired on October 10, 2019.

A summary of all warrant activity for the Company for the nine months ended September 30, 2020 and the year ended December 31, 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	-	-
Balance at September 30, 2020	18,714,999	$ 3.24

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, was 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 issuance. The warrant is equity classified and the fair value of the warrant approximated $9,000 on the date of grant and was measured using the Black-Scholes option pricing model. This entire expense was recorded in the quarter ended March 31, 2018.

A summary of all outstanding and exercisable warrants as of September 30, 2020 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life
$ 1.38	17,999,999	17,999,999	3.03 years
18.20	714	714	2.24 years
50.05	714,286	714,286	0.13 years
$ 3.24	18,714,999	18,714,999	2.92 years

7. Net 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 three and nine months ended September 30, 2020 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 and $1.3 million, respectively, on converted shares and Series A preferred stock accrued dividends of $0.1 million and $0.2 million, respectively. Net loss attributable to common stockholders for the three and nine months ended September 30, 2019 excludes net loss attributable to non-controlling interest of $0.1 million and includes the accretion of Series B preferred discount of $0.1 million and $0.6 million, respectively, on converted shares and Series A preferred stock accrued dividends of $0.1 million and $0.2 million, 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 for the three and nine months ended September 30, 2020 and 2019 were 3,605,217 and 6,641,739, 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 and for the three and nine months ended September 30, 2020 were 2,460,325 and 18,714,999, respectively, and for the three and nine months ended September 30, 2019 were 803,577 and 18,915,851, respectively, because their effect is anti-dilutive.

8. Non-controlling Interest

The Company's non-controlling interest is accounted for under ASC 810, *Consolidation* ("ASC 810"), and represents the minority shareholder's ownership interest related to the Company's subsidiary, Synthetic Biomics, Inc. ("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. On September 5, 2018, the Company entered into an 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 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 was 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). After the 2018 transaction with CSMC, the Company's equity interest in SYN Biomics was 83% and the non-controlling stockholder's interest is 17%. As of September 30, 2020, the accumulated net loss attributable to the non-controlling interest is $2.8 million.

In consideration of the support provided by CSMC for the Study, the Company agreed to pay $441,000 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 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 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 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 three and nine months ended September 30, 2020, research and development expense recorded related to this transaction approximated $134,000 and $225,000, respectively. During the three and nine months ended September 30, 2019, research and development expense recorded related to this transaction approximated $108,000 and $318,000, respectively. 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, it was also concluded that SYN-010 is unlikely to meet its primary endpoint by the time enrollment is completed. As a result, the Company anticipates additional reductions in clinical development expense during the remainder of 2020 resulting from the discontinuation of this clinical program.

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.

9. Common and Preferred Stock

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 are 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.

During the three and nine months ended September 30, 2020, 1,379 and 3,492 Series B shares, respectively, have been converted into common stock resulting in the recognition of $519,000 and $1,315,000, respectively, of unamortized discount from the conversion. During the three and nine months ended September 30, 2019, 185 and 1,523 Series B shares, respectively, have been converted into common stock resulting in the recognition of $71,000 and $585,000, respectively, of unamortized discount from the conversion. As of September 30, 2020, 11,577 shares have been converted resulting in the recognition of $4.4 million of unamortized discount. This is recorded as a deemed dividend in accumulated deficit.

The October 2018 Warrants are immediately exercisable at a price of $1.38 per share of common stock (which is 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.

The Company may not effect, and the 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).

9. Common and Preferred Stock – (continued)

Since the effective conversion price of the Series B Preferred Stock was less than the fair value of the underlying common stock at the date of issuance, there was a beneficial conversion feature ("BCF") at the issuance date. Because the Series B Preferred Stock had no stated maturity or redemption date and was 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, 2018, the Company recorded a discount of $9.1 million and immediately amortized the discount to record the deemed dividend.

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 upon 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. 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 $18.90 per share, subject to certain customary anti-dilution adjustments.

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

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, 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 issuance date, the Company has 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 (as defined in the Certificate of Designations).

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 three and nine months ended September 30, 2020, the Company accrued dividends of $64,000 and $189,000, respectively. During the three and nine months ended September 30, 2019, the Company accrued dividends of $63,000 and $185,000, 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.

9. Common and Preferred Stock – (continued)

B. Riley FBR 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 Company's common stock with an aggregate sales price of up to $40.0 million from time to time through B. Riley FBR, Inc. as the Company's sales agent. Sales of common stock under the B. Riley FBR Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act. B. Riley FBR, Inc. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of the Company's common stock sold on the Company's behalf. The Company has not sold any shares during 2020 and 2019 through the B. Riley FBR Sales Agreement.

10. 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 intended 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 was 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) 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 Synthetic Biomics, Inc. ("SYN Biomics") owned by the Company, 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 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. The Company anticipates additional reductions in clinical development expense during the remainder of 2020 and an acceleration of expense recognition of $141,000 as a result of the discontinuation of this clinical program.

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. An investigational team led by Mark Pimentel, M.D. at CSMC discovered that these products may reduce the production of methane gas by certain GI microorganisms. During the three and nine months ended September 30, 2020 and 2019, the Company did not owe and did not pay CSMC for milestone payments related this license agreement.

11. Commitments and Contingencies

Leases

All of the Company's existing leases as of September 30, 2020 are classified as operating leases. As of September 30, 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 condensed consolidated statements of operations, and for the three and nine months ended September 30, 2020 approximated $50,000 and $151,000, respectively, and for three and nine months ended September 30, 2019 approximated $50,000 and $151,000, respectively. For the three and nine months ended September 30, 2020, operating cash flows used for operating leases approximated $77,000 and $231,000, respectively, and for three and nine months ended September 30, 2019 approximated $75,000 and $224,000, respectively.

A maturity analysis of our operating leases as of September 30, 2020 is as follows*(amounts in thousands of dollars)*:

Future undiscounted cash flow for the years ending December 31:	
2020	$ 79
2021	321
2022	192
Total	592
Discount factor	(53)
Lease liability	539
Amount due within 12 months	(278)
Lease liability – long term	$ 261

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 the COVID-19 continued to spread around the globe, the Company experienced disruptions that impact 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.

12. Subsequent Events

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. 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. The patent rights previously licensed to the Company covering the use of SYN-010 will remain the property of CSMC.

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

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

Overview

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

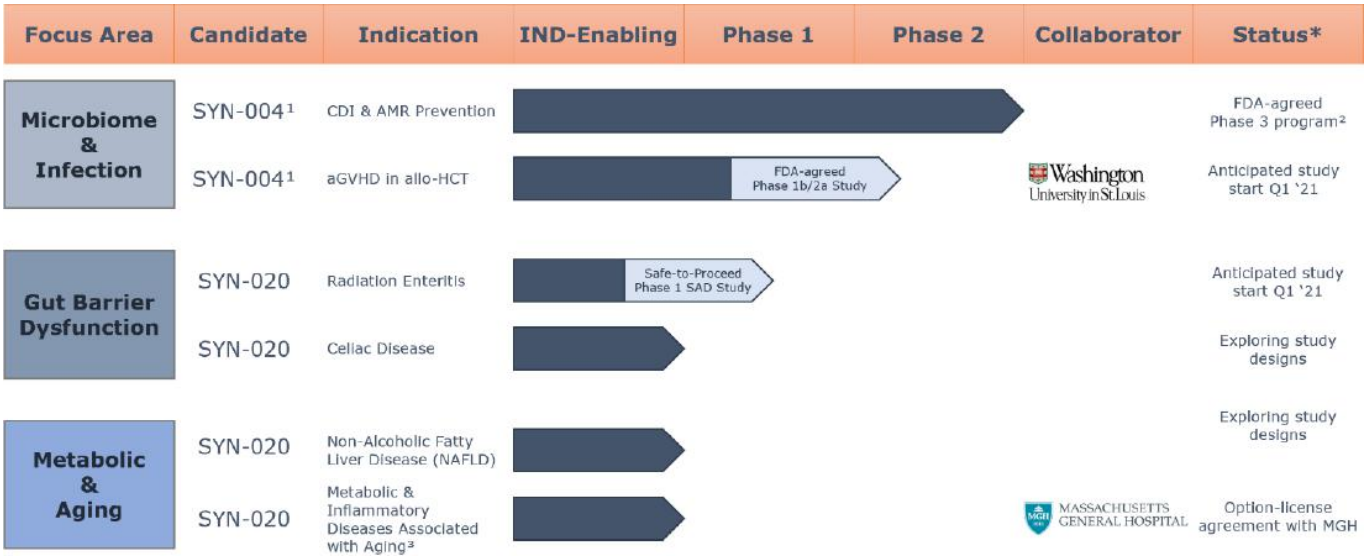
We were also developing SYN-010 to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). On September 30, 2020, Cedars Sinai Medical Center's (CSMC) (the Company's SYN-010 clinical development partner) informed the Company that it agreed to discontinue the ongoing Phase 2b investigator-sponsored clinical study of SYN-010 in IBS-C patients. Based on the results of a planned interim futility analysis, it was concluded that although SYN-010 was well tolerated, it was unlikely to meet its primary endpoint by the time enrollment is completed.

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

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

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

Our Product Pipeline:



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

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

Summary of Current Clinical and Preclinical Programs

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

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

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

Our Gastrointestinal (GI) and Microbiome-Focused Pipeline

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

Recent Developments

Clinical and Pre-Clinical Update

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

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

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

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

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

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

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

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

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

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

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

SYN-020 — Oral Intestinal Alkaline Phosphatase

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

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

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

Intellectual Property

All of our programs are supported by growing patent estates that we either own or exclusively license. Each potential product has issued patents that provide protection. In total, we have over 110 U.S. and foreign patents and over 100 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-010 program is supported by IP that is exclusively licensed to (and, in some cases co-owned by) Synthetic Biologics, namely U.S. patents and foreign patents (in most major markets, e.g. Europe (including Germany, Great Britain and France), 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 No. 9,192,618, which expires in at least 2023, includes claims that cover use of statins, including SYN-010, for the treatment of IBS-C. U.S. Patent No. 9,289,418, which expires in at least 2033, includes claims that cover the use of a variety of compounds, including the active agent of SYN-010, to treat constipation in certain screened patients. U.S. Patent No. 9,744,208 covers methods of use of the active agent of SYN-010 for the treatment of constipation until at least 2034. U.S. Patent No. 9,956,292 includes claims related to composition of matter of anti-methanogenic compositions that find use in treating IBS-C and will expire in at least 2035. Further, U.S. Patent No. 10,328,151, covers the composition of matter of the SYN-010 clinical agent and U.S. Patent10,519,515 covers methods of treating IBS-C with a statin, inclusive of SYN-010, in a selected patient population.

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

Critical Accounting Policies

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

Results of Operations

Three Months Ended September 30, 2020 and 2019

General and Administrative Expenses

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

Research and Development Expenses

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

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

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

Other Income/Expense

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

Net Loss Attributable to Common Stockholders

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

Nine Months Ended September 30, 2020 and 2019

General and Administrative Expenses

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

Research and Development Expenses

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

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

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

Other Income

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

Net Loss Attributable to Common Stockholders

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

Liquidity and Capital Resources

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

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

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

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

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

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

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

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

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

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

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

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

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

Off-Balance Sheet Arrangements

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

Contractual Obligations

Leases

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2020, our cash and cash equivalents consisted primarily of investments in treasury securities. We do not engage in any hedging activities against changes in interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio. We may, however, require additional financing to fund future obligations and no assurance can be given that the terms of future sources of financing will not expose us to material market risk.

ITEM 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures

The Company has adopted and maintains disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is collected, recorded, processed, summarized and reported within the time periods specified in 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 the Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures as of September 30, 2020, the end of the period covered by this Quarterly Report on Form 10-Q, has concluded that based on such evaluation, the Company's disclosure controls and procedures are effective as of September 30, 2020 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 and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting

There have not been any changes in our internal controls over financial reporting during the three months ended September 30, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II–OTHER INFORMATION

ITEM 1. 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 1A. RISK FACTORS.

The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, "Risk Factors," contained in our 2019 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2019 Form 10-K.

RISKS RELATING TO OUR BUSINESS

Our auditor's report on our consolidated financial statements for the years ended December 31, 2019 and 2018 contains an explanatory paragraph regarding our ability to continue as a going concern and the notes to our financial statements for the quarter ended September 30, 2020 mention there being substantial doubt about our ability to continue as a going concern.

Our consolidated financial statements as of December 31, 2019 have been prepared under the assumption that we will continue as a going concern for the next twelve months. In addition, our independent registered public accounting firm has issued a report that includes an explanatory paragraph referring to our recurring losses from operations (anticipated continued losses in the future) and net capital deficiency that raise substantial doubt about our ability to continue as a going concern without additional capital becoming available. Our consolidated financial statements as of December 31, 2019 did not include any adjustments that might result from the outcome of this uncertainty.

The consolidated financial statements for the quarter ended September 30, 2020 have been prepared assuming we will continue as a going concern. We continue to incur losses and, as of September 30, 2020, we had an accumulated deficit of approximately $245 million. Our consolidated financial statements as of September 30, 2020 do not include any adjustments that might result from the outcome of this uncertainty.

Our ability to continue as a going concern is dependent upon our ability to raise additional debt and equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us. These factors raise substantial doubt about our ability to continue as a going concern.

We 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 nine months ended September 30, 2020, our operating activities used net cash of approximately $9.0 million and our cash and cash equivalents were $6.0 million as of September 30, 2020. 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 and have a significant accumulated deficit. As of September 30, 2020, our accumulated deficit totaled approximately $245 million on a consolidated basis. We do not have sufficient capital to fund our operations beyond twelve months following the issuance date of this Quarterly Report on Form 10-Q. 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 September 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, recommence clinical trials that have been postponed 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 we 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 not be sufficient to complete our planned Phase 3 clinical trial for SYN-004 or post-Phase 1 future clinical programs for SYN-020, which are expected to require significant cash expenditures. In addition, based on the anticipated significant 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. Our ability to raise capital through the sale of securities is currently limited by the rules of the SEC and NYSE American that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on registration statement Form S-3 will be limited until such time the market value of our voting securities held by non-affiliates is $75 million or more. 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 in clinical site initiation for our SYN-004 clinical study;
- postponement of the initiation of our SYN-020 single ascending dose (SAD) study
- 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;
- 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 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 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.

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. In some cases, generating meaningful clinical data may require rigorous screening criteria which may result in unintended and higher than anticipated patient-related screen-fail rates, as had occurred with our current investigator-sponsored Phase 2b clinical study conducted by CSMC. 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.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We recently have experienced delays in clinical testing of our product candidates due to COVID-19 and may in the future experience other delays. We do not know when the planned SYN-004 clinical trial or planned SYN-020 SAD study will initiate. 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. 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.

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. More specifically, 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 September 30, 2020, we had a stockholders' deficit of $8.8 million. The NYSE American Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer with total value of market capitalization of at least $50.0 million and 1,100,000 shares publicly held, 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 the first two quarters of 2018, 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 below $50.0 million

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 the Company 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 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. The Company remains 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 a delisting proceeding as appropriate.

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 should 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. If our Common Stock is delisted from the NYSE American due to our failure to regain compliance with the listing standards by the end of the compliance period or for any other reason, and the market value of our shares of Common Stock held by non-affiliates remains below $75 million, we will likely no longer be eligible to sell Common Stock pursuant to the B. Riley FBR Sales Agreement or otherwise utilize our shelf registration statement. 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

We did not sell any equity securities during the three and nine months ended September 30, 2020 in transactions that were not registered under the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

On November 9, 2020, we and CSMC mutually agreed to terminate the exclusive license agreement that we and our subsidiary, Synthetic Biomics, Inc. entered into with CSMC date December 5, 2013 and all amendments thereto and the clinical trial agreement relating to SYN-010. 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 informed us that it discontinued 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. The patent rights previously licensed to us covering the use of SYN-010 will remain the property of CSMC.

ITEM 6. EXHIBITS

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SYNTHETIC BIOLOGICS, INC.

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

Date: November 10, 2020

EXHIBIT INDEX

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

*Filed herewith.

EXHIBIT 10.1

TERMINATION OF EXCLUSIVE LICENSE AGREEMENT

This Termination of Exclusive License Agreement, effective November 9, 2020 (the "Termination Effective Date") is entered into by and among CEDARS-SINAI MEDICAL CENTER, a California nonprofit public benefit corporation ("CSMC"), SYNTHETIC BIOLOGICS, INC., a Nevada corporation ("SYN") and SYNTHETIC BIOMICS, INC., a Nevada corporation ("Licensee").

Reference made is to that certain Exclusive License Agreement, effective December 5, 2013, by and among CSMC, SYN and Licensee, as amended on December 5, 2013, August 11, 2014, September 4, 2015, and February 16, 2018 (the "License Agreement"). All terms used herein without definition shall have the meanings ascribed in the License Agreement.

1. Pursuant to Section 6.2(g) of the License Agreement, by mutual agreement, CSMC, SYN and Licensee hereby agree to terminate the License Agreement as of the Termination Effective Date.

2. From and after the Termination Effective Date, Licensee and/or SYN shall have no further obligations to CSMC under the License Agreement other than those obligations which survive termination and payment obligations as set forth below with respect to Patent Rights Prosecution.

3. All unreimbursed Prosecution Costs incurred prior to the Termination Effective Date with respect to the Prosecution of the Patent Rights (the "Pre-Termination Prosecution Costs") shall be paid by Licensee and/or SYN to CSMC's patent counsel, Nixon Peabody LLP, within thirty (30) days of the Termination Effective Date and all Prosecution Costs incurred by CSMC after the Termination Effective Date with respect to the Prosecution of the Patent Rights shall be paid by CSMC.

4. Licensee and/or SYN hereby agrees to provide reasonable assistance, as requested by CSMC, with respect to the preparation of a final clinical study report with respect to the investigator-sponsored Phase 2b clinical study of SYN-010 conducted by CSMC (the "Study").

5. Within thirty (30) days of the Termination Effective Date, Licensee and/or SYN agrees to transfer to CSMC the ownership of all Study drug in its possession, the cost of such transfer to be equally paid by SYN and CSMC.

6. Within thirty (30) days of the Termination Effective Date, Licensee and/or SYN agrees to transfer to CSMC (i) copies of all files, documents and FDA correspondence contained in United States Investigational New Drug Application IND 12471; and (ii) copies of all other clinical and clinical reports related to the development of SYN-010 that aren't included in the IND.

7. Within thirty (30) days of the Termination Effective Date, Licensee and/or SYN shall return all of CSMC's Confidential Information to CSMC.

8. Within thirty (30) days of the Termination Effective Date, Licensee and/or SYN shall provide CSMC with copies of all data, including submissions to the United States Food and Drug Administration, obtained or generated by or on behalf of Licensee in the course of conducting research and developing Licensed Products and Licensed Technology Products using the Patent Rights and the Technical Information (the "Licensee Data"). CSMC hereby agrees to indemnify SYNand each of its officers, directors and employees (the "Indemnified Parties") from and against any and all claims, damages, losses, liabilities, costs and expenses (including reasonable attorneys' fees and expenses and costs of investigation, whether or not suit is filed) suffered or incurred by any of the Indemnified Parties in any action, suit, litigation, arbitration or dispute of any kind arising or resulting from CSMC's use of such Licensee Data following the Termination Effective Date.

SYNTHETIC BIOLOGICS, INC.

By: /s/ Steve Shallcross
Name: Steve Shallcross
Title: Chief Executive Officer

SYNTHETIC BIOMICS, INC.

By: /s/ Steve Shallcross
Name: Steve Shallcross
Title: Chief Executive Officer

CEDARS-SINAI MEDICAL CENTER

By: /s/ James D. Laur, JD
Name: James D. Laur, JD
Title: Vice President, Intellectual Property

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EXHIBIT 31.1

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

I, Steven A. Shallcross, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Synthetic Biologics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2020

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

EXHIBIT 32.1

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

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

(1) the accompanying Quarterly Report on Form 10-Q of the Registrant for the quarter ended September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: November 10, 2020

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