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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, 2021

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 3, 2021, the registrant had 132,042,538 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, 2020 (the "2020 Form 10-K") filed with the Securities and Exchange Commission (the "SEC") on March 4, 2021. 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, 2021	December 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 72,135	$ 6,227
Prepaid expenses and other current assets	1,422	1,707
Total Current Assets	73,557	7,934
Property and equipment, net	115	174
Right of use asset	1,426	279
Deposits and other assets	23	23
Total Assets	**$ 75,121**	**$ 8,410**
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable	$ 1,255	$ 886
Accrued expenses	1,009	925
Accrued employee benefits	721	868
Operating lease liability	175	287
Total Current Liabilities	3,160	2,966
Lease liability - long term	1,401	186
Total Liabilities	4,561	3,152
Commitments and Contingencies		
Series A Preferred Stock, $0.001 par value; 10,000,000 shares authorized; 0 and 120,000 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	-	12,798
Stockholders' Equity (Deficit):		
Series B Preferred Stock, $1,000 par value; 10,000,000 shares authorized, 0 issued and outstanding and 3,973 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	-	2,477
Common stock, $0.001 par value; 200,000,000 shares authorized, 132,044,866 issued and 132,042,538 outstanding at September 30, 2021 and 29,252,253 issued and 29,249,925 outstanding at December 31, 2020	132	29
Additional paid-in capital	339,223	240,821
Accumulated deficit	(266,021)	(248,094)
Total Synthetic Biologics, Inc. and Subsidiaries Equity (Deficit)	73,334	(4,767)
Non-controlling interest	(2,774)	(2,773)
Total Stockholders' Equity (Deficit)	70,560	(7,540)
Total Liabilities and Stockholders' Equity (Deficit)	**$ 75,121**	**$ 8,410**

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,	
	2021	2020	2021	2020
Operating Costs and Expenses:				
General and administrative	$ 1,303	$ 1,197	$ 3,988	$ 3,876
Research and development	1,972	914	5,021	4,152
Total Operating Costs and Expenses	3,275	2,111	9,009	8,028
Loss from Operations	(3,275)	(2,111)	(9,009)	(8,028)
Other Income:				
Interest income	2	-	4	44
Total Other Income	2	-	4	44
Net Loss	(3,273)	(2,111)	(9,005)	(7,984)
Net Loss Attributable to Non-controlling Interest	-	(8)	(1)	(50)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (3,273)**	**$ (2,103)**	**$ (9,004)**	**$ (7,934)**
Series A Preferred Stock Dividends	-	(64)	(24)	(189)
Effect of Series A Preferred Stock price adjustment	-	-	(7,402)	-
Series B Preferred Stock Dividends	-	(519)	(1,496)	(1,315)
Net Loss Attributable to Common Stockholders	**$ (3,273)**	**$ (2,686)**	**$ (17,926)**	**$ (9,438)**
Net Loss Per Share - Basic and Dilutive	$ (0.02)	$ (0.14)	$ (0.15)	$ (0.52)
Weighted average number of shares outstanding during the period - Basic and Dilutive	132,042,538	19,398,339	118,448,633	18,302,585

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 $0.001 Par Value		Series B Preferred			Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	APIC	Deficit	Interest	Deficit
Balance at December 31, 2020	29,249,925	$ 29	3,973	$ 2,477	$ 240,821	$ (248,094)	$ (2,773)	$ (7,540)
Stock-based compensation	-	-	-	-	101	-	-	101
Stock issued under "at-the-market" offering	78,685,315	79	-	-	65,881	-	-	65,960
Warrants Exercised	11,655,747	12	-	-	8,030	-	-	8,042
Series A Preferred Stock Dividends	-	-	-	-	-	(24)	-	(24)
Effect of Series A Preferred Stock price adjustment	-	-	-	-	7,402	(7,402)	-	-
Conversion of Series A Preferred Stock to Common	8,996,768	9	-	-	12,813	-	-	12,822
Conversion of Series B Preferred Stock to Common	3,454,783	3	(3,973)	(2,477)	3,971	(1,497)	-	-
Net loss	-	-	-	-	-	(2,536)	-	(2,536)
Non-controlling interest	-	-	-	-	-	-	(1)	(1)
Balance at March 31, 2021	**132,042,538**	**$ 132**	**-**	**$ -**	**$ 339,019**	**$ (259,553)**	**$ (2,774)**	**$ 76,824**
Stock-based compensation	-	-	-	-	102	-	-	102
Net loss	-	-	-	-	-	(3,195)	-	(3,195)
Balance at June 30, 2021	**132,042,538**	**$ 132**	**-**	**$ -**	**$ 339,121**	**$ (262,748)**	**$ (2,774)**	**$ 73,731**
Stock-based compensation	-	-	-	-	102	-	-	102
Net loss	-	-	-	-	-	(3,273)	-	(3,273)
Balance at September 30, 2021	**132,042,538**	**$ 132**	**-**	**$ -**	**$ 339,223**	**$ (266,021)**	**$ (2,774)**	**$ 70,560**

	Common Stock $0.001 Par Value		Series B Preferred			Accumulated	Non-Controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	APIC	Equity	Interest	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 ($0.03 per share)	1,199,131	1	(1,379)	(860)	1,378	(519)	-	-
Net loss	-	-	-	-	-	(2,103)	-	(2,103)
Non-controlling interest	-	-	-	-	-	-	(16)	(8)
Balance at September 30, 2020	**19,842,955**	**$ 20**	**4,146**	**$ 2,584**	**$ 236,320**	**$ (244,975)**	**$ (2,750)**	**$ (8,801)**

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,	
	2021	2020
Cash Flows from Operating Activities:		
Net loss	$ (9,005)	$ (7,984)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	305	251
Subsidiary stock issued to vendor	-	178
Depreciation	74	169
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	285	724
Right of use asset	123	103
Accounts payable	368	(1,324)
Accrued expenses	85	(788)
Accrued employee benefits	(147)	(182)
Operating lease liability	(168)	(183)
Net Cash Used in Operating Activities	(8,080)	(9,036)
Cash Flows from Investing Activities		
Purchase of property and equipment	(14)	(4)
Net Cash Used in Investing Activities	(14)	(4)
Cash Flows from Financing Activities		
Proceeds from "at the market" stock issuance	65,960	-
Proceeds from issuance of common stock for warrant exercises	8,042	-
Net Cash Provided by Financing Activities	74,002	-
Net increase (decrease) in cash and cash equivalents	65,908	(9,040)
Cash and cash equivalents at the beginning of the period	6,227	15,045
Cash and cash equivalents at the end of the period	**$ 72,135**	**$ 6,005**
Noncash Financing Activities:		
Effect of Series A Preferred Stock price adjustment	$ 7,402	$ -
Right of use asset from operating lease	$ 1,270	$ -
Conversion of Series B Preferred Stock	$ 2,477	$ 2,177
Deemed dividends for accretion of Series B Preferred Stock discount	$ 1,496	$ 1,315
In-kind dividends paid in preferred stock	$ 24	$ 189

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 Current Good Manufacturing Practice (cGMP) conditions and intended to treat both local GI and systemic diseases.

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 2020 Form 10-K.

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 Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (subtopic 815-40)*: *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). 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 earnings per share guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the impact of ASU 2020-06 on its consolidated financial statements.

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

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

Impairment of Long-Lived Assets

Long-lived assets include property, equipment and right-of-use assets. In accordance with ASC 360, *Property, Plant and Equipment* ("ASC 360"), management reviews the Company's 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 the fair value and the carrying value of the asset. During the three months ended March 31, 2020, the Company identified a new strain of coronavirus originating in Wuhan, China (the "COVID-19" outbreak) 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, 2021 and 2020.

2. Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") Topic 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, included in Level 1 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.

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

3. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	September 30, 2021	December 31, 2020
Prepaid clinical research organizations	$ 1,182	$ 470
Prepaid consulting, subscriptions and other expenses	157	90
Prepaid insurances	83	639
Stock sales receivable	-	469
Prepaid manufacturing expenses	-	39
Total	$ 1,422	$ 1,707

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

Property and equipment, net (in thousands)

	September 30, 2021	December 31, 2020
Computers and office equipment	$ 827	$ 813
Leasehold improvements	94	439
Software	11	11
	932	1,263
Less: accumulated depreciation and amortization	(817)	(1,089)
Total	$ 115	$ 174

Accrued expenses (in thousands)

	September 30, 2021	December 31, 2020
Accrued clinical consulting services	$ 756	$ 700
Accrued vendor payments	253	225
Total	$ 1,009	$ 925

Accrued employee benefits (in thousands)

	September 30, 2021	December 31, 2020
Accrued bonus expense	$ 543	$ 724
Accrued vacation expense	178	144
Total	$ 721	$ 868

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

4. 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 was determined by the compensation committee of the Board of Directors and could 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 stock 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, 2021, there were 5,145 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 85,714 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. From time to time the number of shares authorized for options was increased such that 4,000,000 million were authorized as of September 30, 2021. 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, 2021, there were 2,452,273 options issued and outstanding under the 2010 Stock Plan.

On September 17, 2020, the stockholders approved and adopted the 2020 Stock Incentive Plan ("2020 Stock Plan") for the issuance of up to 4,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. As of September 30, 2021, there were 1,540,000 options issued and outstanding under the 2010 Stock Plan.

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

The Company has applied fair value accounting for all stock-based payment awards at the grant date. The fair value of each option granted 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, 2021 and 2020.

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

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

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

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

4. Stock-Based Compensation – (continued)

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

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 one-year anniversary date of the grant date,
- half vesting immediately and the remaining over three years,
- quarterly over three years,
- annually over three years,
- one-third immediate vesting and the remaining annually over two years,
- one-half immediate vesting and the remaining over nine months,
- one-quarter immediate vesting and the remaining over three years,
- one-quarter immediate vesting and the remaining over 33 months,
- monthly over one year, and
- monthly over three years.

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

4. Stock-Based Compensation – (continued)

A summary of stock option activity for the nine months ended September 30, 2021 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance - December 31, 2020	3,997,418	$ 2.35	6.09 years	-
Granted	-	-		
Exercised	-	-		
Expired	-	-		
Forfeited	-	-		
Balance - September 30, 2021 - outstanding	3,997,418	$ 2.35	5.03 years	$ 135,792
Balance - September 30, 2021 - exercisable	2,296,662	$ 3.79	4.50 years	$ 66,093
Grant date fair value of options granted – nine months ended September 30, 2021		$ -		
Weighted average grant date fair value –nine months ended September 30, 2021		$ -		
Grant date fair value of options granted – year ended December 31, 2020		$ 412,000		
Weighted average grant date fair value – year ended December 31, 2020		$ 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, 2021 was $34,000 and $101,000, respectively, and $41,000 and $120,000 for the three and nine months ended September 30, 2020, 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, 2021 was $16,000 and $47,000, respectively, and $14,000 and $45,000 for the three and nine months ended September 30, 2020, 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, 2021 was $49,000 and $147,000, respectively, and $26,000 and $79,000 for the three and nine months ended September 30, 2020, 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, 2021 was $3,000 and $10,000, respectively, and $1,000 and $7,000 for the three and nine months ended September 30, 2020.

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

4. Stock-Based Compensation – (continued)

As of September 30, 2021, total unrecognized stock-based compensation expense related to stock options was $380,000, which is expected to be expensed through May 2023.

The FASB's guidance for stock-based payments requires cash flows from excess tax benefits to be classified as a part of cash flows from operating activities. Excess tax benefits are realized tax benefits from tax deductions for exercised options in excess of the deferred tax asset attributable to stock compensation costs for such options. The Company did not record any excess tax benefits during the three and nine months ended September 30, 2021 and 2020.

5. Stock Warrants

On October 15, 2018, the Company closed its underwritten public offering pursuant to which it received gross proceeds of approximately $18.6 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company and sold an aggregate of (i) 2,520,000 Class A Units (the "Class A Units"), with each Class A Unit consisting of one share of the common stock, and one five-year warrant to purchase one share of common stock at an initial exercise price of $1.38 per share, which subsequently was reduced to $0.69 per share (each a "Warrant" and collectively, the "Warrants"), with each Class A Unit to be offered to the public at a public offering price of $1.15, and (ii) 15,723 Class B Units (the "Class B Units", and together with the Class A Units, the "Units"), with each Class B Unit offered to the public at a public offering price of $1,000 per Class B Unit and consisting of one share of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock"), with a stated value of $1,000 and convertible into shares of common stock at the stated value divided by a conversion price of $1.15 per share, with all shares of Series B Preferred Stock convertible into an aggregate of 13,672,173 shares of common stock, and issued with an aggregate of 13,672,173 Warrants. On November 16, 2020, the exercise price of the Warrants was reduced from $1.38 per Warrant per full share of the Company's common stock, $0.001 par value per share (the "Common Stock"), to $0.69 per Warrant per full share of common stock in accordance with the anti-dilution terms of the Warrant. The reduction was the result of the issuance of shares of common stock by the Company through its "at the market offering" facility. The effect of the change in the exercise price of the warrants as a result of the triggering of the down round protection clause in the Warrants was recorded as a deemed dividend of $0.9 million during the year ended December 31, 2020, which reduces the income available to common stockholders. In addition, pursuant to the underwriting agreement that the Company had entered into with A.G.P./Alliance Global Partners (the "Underwriters"), as representative of the underwriters, the Company granted the Underwriters a 45 day option (the "Over-allotment Option") to purchase up to an additional 2,428,825 shares of common stock and/or additional Warrants to purchase an additional 2,428,825 shares of common stock. The Underwriters partially exercised the Over-allotment Option by electing to purchase from the Company additional Warrants to purchase 1,807,826 shares of common stock.

If, at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of common stock to the holder, then the Warrants may only be exercised through a cashless exercise. No fractional shares of common stock will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, the holder will receive an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares. The Company has concluded that the Warrants are required to be equity classified. The Warrants were valued on the date of grant using Monte Carlo simulations. During the nine months ended September 30, 2021, 11,655,747 warrants were exercised for cash proceeds of $8.0 million. There were no warrants exercised during the three months ended September 30, 2021.

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

5. Stock Warrants – (continued)

On November 18, 2016, the Company completed a public offering of 714,286 shares of common stock in combination with accompanying warrants to purchase an aggregate of 1,428,571 shares of the common stock. The stock and warrants were sold in combination, with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was $35.00. The shares of common stock were immediately separable from the warrants and were issued separately. The initial per share exercise price of the Series A warrants was $50.05 and the per share exercise price of the Series B warrants was $60.20, each subject to adjustment as specified in the warrant agreements. The Series A and Series B warrants could be exercised at any time on or after the date of issuance. The Series A warrants were exercisable until the four-year anniversary of the issuance date. The Series B warrants expired December 31, 2017 and none were exercised prior to expiration. The Series A warrants expired November 18, 2020 and none were exercised prior to expiration. The warrants included a provision, that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder for cash. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date of $15.7 million and changes in estimated fair value will be recorded as non-cash income or expense in the Company's Statement of Operations at each subsequent period. At November 18, 2020, the fair value of the warrant liability was $100. The warrants were valued on the date of grant and on each remeasurement period.

A summary of all warrant activity for the Company for the nine months ended September 30, 2021 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2020	18,000,713	$ 0.69
Granted	-	-
Exercised	11,655,747	0.69
Forfeited	-	-
Balance at September 30, 2021	6,344,966	$ 0.69

A summary of all outstanding and exercisable common stock warrants as of September 30, 2021 is as follows:

Weighted Average Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life
$ 0.69	6,344,252	6,344,252	2.03 years
18.20	714	714	1.24 years
$ 0.69	6,344,966	6,344,966	2.03 years

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

6. 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 nine months ended September 30, 2021 excludes net loss attributable to non-controlling interest of $0.1 million and includes the accretion of the Series B preferred discount of $1.5 million as a result of converted shares and Series A preferred stock accrued dividends of $0.1 million and the deemed dividend of $7.4 million resulting from the effect of the Series A preferred stock price adjustment during the first quarter of 2021. 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. There were no 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, 2021 since all remaining Series B preferred stock were converted to common stock. A total of 3,605,217 shares of common stock underlying Series B preferred shares convertible to common stock were excluded from the computations of net loss per common share for the three and nine months ended September 30, 2020. The number of options and warrants for the purchase of common stock that were excluded from the computations of net loss per common share for the three and nine months ended September 30, 2021 were 3,997,418 and 6,344,966, respectively, and for the nine months ended September 30, 2020 were 2,460,325 and 18,714,999, respectively, because their effect is anti-dilutive.

7. 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 CSMC for an investigator-sponsored Phase 2b clinical study of SYN-010 to be co-funded by the Company and CSMC (the "Study"). The Study was to provide further evaluation of the efficacy and safety of SYN-010, the Company's modified-release reformulation of lovastatin lactone, which was exclusively licensed to the Company by CSMC. SYN-010 is designed to reduce methane production by certain microorganisms (*M. smithii*) in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). After the 2018 transaction with CSMC, the Company's equity interest in SYN Biomics is 83% and the non-controlling stockholder's interest is 17%. As of September 30, 2021 and 2020, the accumulated net loss attributable to the non-controlling interest is $2.8 million and $2.8 million, respectively.

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

7. Non-controlling Interest – (continued)

In consideration of the support provided by CSMC for the Study, the Company paid $328,000 to support the Study and the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company, upon the approval of the Study protocol by the Institutional Review Board (IRB): (i) issued to CSMC 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. ("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 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. There was no expense recorded related to this transaction during the three and nine months ended September 30, 2021.

The Agreement also provided 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 was unlikely to meet its primary endpoint by the time enrollment is completed.

On November 9, 2020, the Company and its subsidiary, SYN Biomics 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 informed the Company that it discontinued the ongoing Phase 2b investigator-sponsored clinical study of SYN-010 IBS-C patients.

8. 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.

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

8. Common and Preferred Stock – (continued)

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 conversion price of the Series B Preferred Stock and exercise price of the October 2018 Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the common stock. The exercise price of the Warrants is subject to adjustment in the event of certain dilutive issuances.

On November 16, 2020, the exercise price of the Warrants was reduced from $1.38 per Warrant per full share of common stock to $0.69 per Warrant per full share of common stock. The reduction was the result of the issuance of shares of Common Stock by the Company through its "at the market offering" facility. The effect of the change in the exercise price of the warrants as a result of the triggering of the down round protection clause in the Warrants was recorded as a deemed dividend in accumulated deficit of $0.9 million, which reduces the income available to common stockholders for the year ended December 31, 2020.

The October 2018 Warrants are immediately exercisable at a price of $0.69 per share of common stock (which was 120% of the public offering price of the Class A Units) and will expire on October 15, 2023. If, at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of common stock to the holder, then the October 2018 warrants may only be exercised through a cashless exercise. No fractional shares of common stock will be issued in connection with the exercise of any October 2018 warrants. In lieu of fractional shares, the holder will receive an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares.

Since the effective conversion price of the Series B Preferred Stock is less than the fair value of the underlying common stock at the date of issuance, there is a beneficial conversion feature ("BCF") at the issuance date. Because the Series B Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF is immediately charged to accumulated deficit as a "deemed dividend" and impacts earnings per share. During the nine months ended September 30, 2021 and 2020, 3,973 and 3,492 shares, respectively, were converted resulting in the recognition of deemed dividends of $1.5 million and $1.3 million, respectively, for the amortization of the Series B Preferred Stock discount upon conversion. During the three months ended September 30, 2020, 1,379 shares were converted resulting in the recognition of a deemed dividend of $0.5 million for the amortization of the Series B Preferred Stock discount upon conversion.

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

8. Common and Preferred Stock – (continued)

Series A Preferred Stock

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

The Series A Preferred Stock ranks senior to the shares of the Company's common stock, and any other class or series of stock issued by the Company with respect to dividend rights, redemption rights and rights to the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company. Holders of Series A Preferred Stock are entitled to a cumulative dividend at the rate of 2.0% per annum, payable quarterly in arrears, as set forth in the Certificate of Designation of Series A Preferred Stock classifying the Series A Preferred Stock. The Series A Preferred Stock is convertible at the option of the holders at any time into shares of common stock at an initial conversion price of $0.54 per share which was increased to $18.90 after taking into account the 2018 reverse stock split, subject to certain customary anti-dilution adjustments, and was decreased to $1.50 on January 27, 2021, as described below.

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

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

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

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

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

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

8. Common and Preferred Stock – (continued)

The Series A Preferred Stock was 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 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 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 months ended September 30, 2021, the Company did not record any Series A Preferred Stock dividends since all shares were converted to shares of common stock during the three months ended March 31, 2021. During the nine months ended September 30, 2021, the Company accrued dividends of $24,000. During the three and nine months ended September 30, 2020, the Company accrued dividends of $64,000 and $189,000, respectively.

On January 27, 2021, the Company filed an amendment to the Certificate of Designation for the Series A Preferred Stock to (i) lower the stated Conversion Price through September 30, 2021 and (ii) remove their change in control put, as an inducement for the holder to fully convert its Series A Preferred Stock. The Amendment to the Certificate of Designation for its Series A Convertible Preferred Stock (the "Certificate of Amendment") with the Secretary of State of the State of Nevada adjusted the conversion price from $18.90 per share to $1.50 per share and removed the redemption upon change of control. The Company received notice from the holder of the Series A Preferred Stock that it was increasing the Maximum Percentage as defined in the "Certificate of Designation" from 4.99% to 9.99%, such increase to be effective 61 days from the date thereof. There are no remaining shares of the Series A Convertible Preferred stock outstanding after these conversions. During January and February 2021, the Company issued 8,996,768 shares of its common stock upon the conversion effected on such date by the holder of 120,000 shares of its Series A Convertible Preferred Stock. The fair value of the consideration issued to the holder to induce conversion was accounted for as a deemed dividend and increased net loss available to common shareholders for purposes of calculating loss per share. The Company estimated the fair value of the inducement consideration of $7.4 million and as a result recorded a corresponding deemed dividend of $7.4 million during the nine months ended September 30, 2021.

B. Riley Securities Sales Agreement

On August 5, 2016, the Company entered into the B. Riley FBR Sales Agreement with FBR Capital Markets & Co. (now known as B. Riley Securities), which enables the Company to offer and sell shares of common stock from time to time through B. Riley Securities, Inc. as the Company's sales agent. Sales of common stock under the B. Riley Securities Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act. B. Riley Securities, Inc. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of the Common Stock sold on the Company's behalf. The Company did not sell any shares of common stock during the three and nine months ended September 30, 2020 through the Riley Securities Sales Agreement.

On February 9, 2021, the Company entered into an amended and restated sales agreement with B. Riley Securities, Inc. ("B. Riley") and A.G.P./Alliance Global Partners ("AGP") in order to include AGP as an additional sales agent for the Company's "at the market offering" program (the "Amended and Restated Sales Agreement").

During the nine months ended September 30, 2021, the Company sold through the At Market Issuance Sales Agreement and the Amended and Restated Sales Agreement approximately 78.7 million shares of the Company's common stock and received net proceeds of approximately $66.0 million. The Company did not sell any shares of common stock during the three months ended September 30, 2021 through the Amended and Restated Sales Agreement.

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

9. Related Party Transactions

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

In consideration of the support provided by CSMC for the Study, the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company: (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 owned by the Company, such that after such issuance CSMC owned an aggregate of seven million four hundred eighty thousand (7,480,000) shares of common stock of SYN Biomics, representing seventeen percent (17%) of the issued and outstanding shares of SYN Biomics' common stock.

The Agreement also provided 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 provided for tag-along rights in the event of the sale by the Company of its shares of SYN Biomics.

On September 30, 2020, CSMC MAST formally agreed to discontinue the ongoing Phase 2b investigator-sponsored clinical study of SYN-010 following the results of a planned interim futility analysis. Although it was concluded that SYN-010 was well tolerated, SYN-010 was unlikely to meet its primary endpoint by the time enrollment was completed.

On November 9, 2020, the Company and its subsidiary, SYN Biomics 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.

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

10. Commitments and Contingencies

Leases

All of the Company's existing leases as of September 30, 2021 are classified as operating leases. As of September 30, 2021, the Company has one operating lease for facilities with a remaining term expiring in 2027. During the quarter ended June 30, 2021, the Company renewed its facility lease by entering into a Second Lease Amendment which extends the lease term for 63 months beginning on September 1, 2022 and ending on December 31, 2027 at stated rental rates and including a 3 month rent abatement. The Second Amendment also has options for a Tenant Improvement Allowance and a Second Extension Term. The Second Amendment also gives the Company the right to expand their space by giving notice to the landlord before December 31, 2021. The Second Extension Term is offered at market rates and there is no economic incentive for the lessee, therefore the Company has determined that it is not part of the original lease term. There is an option in this Second Amendment to Lease for the Company to borrow funds for tenant improvements subject to an 8.5% interest rate. 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, 2021 approximated $77,000 and $195,000, respectively, and for the three and nine months ended September 30, 2020 approximated $50,000 and $151,000, respectively. For the three and nine months ended September 30, 2021, operating cash flows used for operating leases approximated $80,000 and $240,000, respectively, and for three and nine months ended September 30, 2020 approximated $77,000 and $231,000, respectively, and the right of use assets exchanged for operating the lease obligation was $1.3 million. The day one non-cash addition of right of use assets due to adoption of ASC 842 was $538,000.

A maturity analysis of our operating leases as of September 30, 2021 is as follows *(amounts in thousands of dollars)*:

Future undiscounted cash flow for the years ending September 30:	
2021	$ 81
2022	247
2023	327
2024	337
2025	347
2026	357
2027	368
Total	2,064
Discount factor	(488)
Lease liability	1,576
Lease liability – current	(175)
Lease liability – long term	$ 1,401

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

10. Commitments and Contingencies – (continued)

Risks and Uncertainties

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of 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.

As COVID-19 continued to spread around the globe, the Company experienced disruptions that impacted its business and clinical trials, including halting the postponement of clinical site initiation of the Phase 1b/2a clinical trial of SYN-004. The extent to which the COVID-19 pandemic impacts the Company's business, the clinical development of SYN-004 (ribaxamase) and SYN-020, the business of the Company's suppliers and other commercial partners, the Company's corporate development objectives and the value of and market for the Company's common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, especially in light of the new variants, 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.

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, 2020 included in our 2020 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 2020 Form 10-K.

Overview

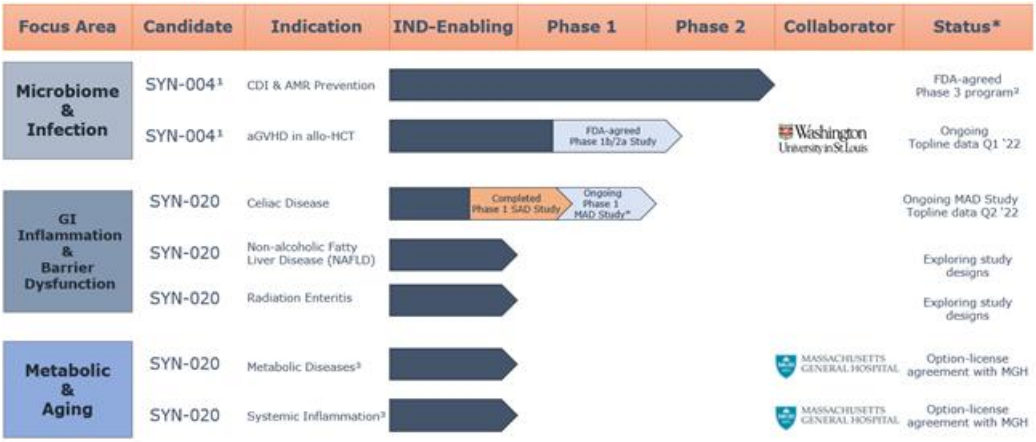
We are a diversified clinical-stage company developing therapeutics designed to treat gastrointestinal (GI) diseases in areas of high unmet need. Our lead clinical development candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta-lactam antibiotics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

We plan to explore and evaluate a range of strategic options, which may include: in-licensing opportunities; evaluation of potential acquisitions; or other potential strategic transactions. In the meantime, we remain focused on working with our clinical development partners to complete the ongoing Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT patients, and advancing the clinical development program for SYN-020 intestinal alkaline phosphatase (IAP) in multiple potential indications.

We are continuing to assess the potential impact of the COVID-19 pandemic. We are in close contact with our clinical development partners in order to assess the impact of COVID-19 on our studies and current timelines and costs. While we currently do not anticipate any interruptions in our operations due to COVID-19, it is possible that if the COVID-19 pandemic were to increase in severity for an extended period of time, we could once again experience delays in our clinical trials which could result in significant disruptions to our clinical development timelines due to the COVID-19 pandemic, which would adversely affect our business, financial condition, results of operations and growth prospects.

In response to the spread of COVID-19 as well as public health directives and orders, we have implemented a number of measures designed to ensure employee safety and business continuity. We have limited access to our offices and are allowing our administrative employees to continue their work outside of our offices in order to support the community efforts to reduce the transmission of COVID-19 and protect employees, complying with guidance from federal, state and local government and health authorities. The full extent to which the COVID-19 outbreak will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted. The effects of the governmental orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Our Product Pipeline:



Based on management's current beliefs and expectations
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 carbapenem 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.

Additional pipeline products with preclinical proof-of-concept include SYN-006 (carbapenemase) being designed to prevent aGVHD, microbiome damage and infection due to treatment with carbapenem antibiotics, and SYN-007 (ribaxamase) delayed release ("DR") being designed to prevent antibiotic associated diarrhea with oral β-lactam antibiotics.

Summary of Clinical and Preclinical Programs

Therapeutic Area	Product Candidate	Current Status
Prevention of microbiome damage, CDI, overgrowth of pathogenic organisms, AMR, and aGVHD in allogeneic HCT recipients (Degrade IV beta-lactam antibiotics)	SYN-004 (ribaxamase) (oral enzyme)	● Announced outcomes from End of Phase 2 meeting, including Food and Drug Administration (FDA)-proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval on the basis of a single Phase 3 clinical trial (Q4 2018) ● Clarified market/potential partner needs and identified potential additional indications in specialty patient populations such as allogeneic hematopoietic cell transplant (HCT) patients ● Announced clinical trial agreement (CTA) with Washington University School of Medicine to conduct a Phase 1b/2a clinical trial to evaluate safety, tolerability and pharmacokinetics in up to 36 evaluable adult allogeneic HCT recipients (Q3 2019) ● Received official meeting minutes from FDA Type-C meeting held on December 2, 2019 to discuss development in allogeneic HCT recipients who are administered IV beta-lactam antibiotics in response to fever (Q1 2020) ● Received written notification from the FDA informing the Company that the FDA determined the Phase 1b/2a clinical program in adult allogeneic hematopoietic cell transplant (HCT) recipients may proceed per the submitted clinical program protocol (Q3 2020) ● Washington University began enrollment and the first patient was dosed in the first of three antibiotic cohorts for the Phase 1b/2a clinical trial of SYN-004 in adult HCT recipients (Q2 2021)

Preserve gut barrier, treat local GI inflammation, and restore gut microbiome	SYN-020 (oral IAP enzyme)	● Generated high expressing manufacturing cell lines for intestinal alkaline phosphatase (IAP) (1H 2017) ● Identified basic Drug Supply manufacturing process and potential tablet formulation (2H 2017) ● Identified potential clinical indications with unmet medical need including enterocolitis associated with radiation therapy for cancer (Q1 2019) ● Completed pre-IND (Investigational New Drug) meeting with the FDA to clarify requirements for IND-enabling toxicology studies and manufacturing requirements (Q2 2019) ● Entered into an agreement with Massachusetts General Hospital ("MGH") granting the Company an option for an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age-related diseases (Q2 2020) ● Submitted IND application with U.S. FDA supporting an initial indication for the treatment of radiation enteropathy secondary to pelvic cancer therapy (Q2 2020) ● Received study-may-proceed letter from U.S. FDA to conduct a Phase 1 single ascending dose ("SAD") study in healthy volunteers, designed to evaluate SYN-020 for safety, tolerability, and pharmacokinetic parameters (Q3 2020) ● Commenced enrollment, dosing and observation in a Phase 1 SAD study of SYN-020 (Q2 2021) ● Announced that enrollment, dosing and observation has been completed in the Phase 1, open label, SAD clinical trial. Analyses of preliminary data demonstrated SYN-020 maintained a favorable safety profile and was well tolerated at all dose levels (Q2 2021) ● Commenced enrollment, dosing and observation in a Phase 1, multiple ascending dose ("MAD") clinical trial of SYN-020 in healthy, adult volunteers (Q3 2021). A data readout is anticipated during the second quarter of 2022

Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV carbapenem antibiotics)	SYN-006 (oral enzyme)	● Identified P2A as a potent carbapenemase that is stable in the GI tract ● Manufactured a formulated research lot for oral delivery (2017) ● Demonstrated microbiome protection in a pig model of ertapenem administration (Q1 2018) ● Reported supporting data demonstrating SYN-006 attenuated emergence of antibiotic resistance in a pig model, including encoded beta-lactamases and genes conferring resistance to a broad range of antibiotics such as aminoglycosides and macrolides (Q1 2019)
Prevention of antibiotic-associated diarrhea (AAD), 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 (combination amoxicillin/clavulanate), 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 Augmentin and also reduced the emergence of antibiotic resistance in a canine study (Q1 2020)
Prevention and treatment of pertussis	SYN-005 (monoclonal antibody therapies)	● Reported supportive preclinical data demonstrating that an extended half-life version of hu1B7, a component of SYN-005, provided protection from pertussis for five weeks in a neonatal non-human primate study (Q4 2017) ● Collaboration with UT Austin

Recent Developments

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.

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) for treatment of allogeneic HCT recipients who are administered IV beta-lactam antibiotics in response to fever. Under the terms of this agreement, we 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 serves 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.

The Phase 1b/2a clinical trial is 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 are being enrolled into three sequential cohorts administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 (ribaxamase) and four will receive placebo.

Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic. The 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.

On April 14, 2021, we announced that enrollment has commenced and the first patient of the first antibiotic cohort of this study had been dosed. At this time, enrollment remains ongoing and a data readout for the first antibiotic cohort is anticipated in Q1 2022.

Due to the unique challenges posed by the global COVID-19 pandemic, Washington University continues to evaluate non-essential activities which may have a direct impact on planned and ongoing clinical trials. Continuation of the Phase 1b/2a clinical trial including, but not limited to, the enrollment of new patients remains largely at the discretion of Washington University and is contingent upon their ability to conduct this clinical program free from the impact of COVID-19. We remain in close contact with Washington University and are actively monitoring the crisis caused by the spread of COVID-19 and its impact to the clinical development plans for our SYN-004 (ribaxamase) program.

SYN-020 — Oral Intestinal Alkaline Phosphatase

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 and systemic inflammation, tighten the gut barrier to diminish "leaky gut," and promote a healthy microbiome. Despite its broad therapeutic potential, a key hurdle to commercialization has been the high cost of IAP manufacture which is commercially available for as much as $10,000 per gram. We believe we have developed technologies to traverse this hurdle and now have the ability to produce more than 3 grams per liter of SYN-020 for roughly a few hundred dollars per gram at commercial scale. Based on the known mechanisms as well as our own supporting animal model data, we intended to initially develop SYN-020 to mitigate the intestinal damage caused by radiation therapy that is routinely used to treat pelvic cancers. While we believe SYN-020 may play a pivotal role in addressing acute and long-term complications associated with radiation exposure to the GI tract, we have also begun planning to develop SYN-020 in indications that may offer a more accelerated or streamlined pathway to registration while also addressing significant unmet medical needs. Such indications include celiac disease, non-alcoholic fatty liver disease ("NAFLD"), and indications to treat and prevent metabolic and inflammatory disorders associated with aging which are supported by our collaboration with Massachusetts General Hospital ("MGH"). Across the six major markets, the total prevalent cases of celiac disease are expected to increase from 5.8 million cases in 2013 to an expected 8.1 million cases in 2023, representing an annual growth rate of approximately 4%. During the same period, prevalent cases in the U.S. are expected to increase from 2.8 million in 2013 to an expected 4.3 million in 2023, representing a significant market opportunity.

On June 30, 2020, we submitted an IND application to the FDA in support of an initial indication for the treatment of radiation enteropathy secondary to pelvic cancer therapy. On July 30, 2020, we announced that we received a study-may-proceed letter from the FDA to conduct a Phase 1a single-ascending-dose ("SAD") study in healthy volunteers designed to evaluate SYN-020 for safety, tolerability and pharmacokinetic parameters. On April 1, 2021, we announced that enrollment had commenced in the Phase 1 SAD clinical trial of SYN-020. On June 29, 2021, we announced that enrollment, patient dosing and observation had been completed in its Phase 1, open-label, SAD study of SYN-020. The SAD study enrolled 6 healthy adult volunteers into each of four cohorts with SYN-020 given orally as single doses ranging from 5 mg to 150 mg. Analyses of preliminary data demonstrated that SYN-020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to the study drug. No serious adverse events were reported.

During the third quarter of 2021 we initiated a Phase 1 clinical study evaluating multiple ascending doses ("MAD") of SYN-020. On October 21, 2021 we announced that patient enrollment, dosing and observation commenced in the Phase 1 MAD of SYN-020. The ongoing Phase 1, placebo-controlled MAD study is intended to evaluate the safety, tolerability and biodistribution of SYN-020 upon repeated dosing and is expected to enroll 8 healthy adult volunteers into each of four cohorts (32 total study participants) with SYN-020 given orally twice daily for fourteen days as multiple ascending doses ranging from 5 mg to 75 mg. A safety review will be conducted at the end of each cohort to determine whether progression into the next higher dose cohort is permissible. At this time, the first cohort of 8 study participants is nearing completion and dosing of the second cohort of 8 study participants is expected to begin shortly thereafter, pending a safety review A topline data readout of the Phase 1 MAD clinical study is anticipated during the second quarter of 2022, pandemic conditions permitting. Both studies are intended to support the development of SYN-020 in multiple potential clinical indications including celiac disease, NAFLD, radiation enteritis, as well as indications supported by our collaboration with Massachusetts General Hospital. Following the completion of Phase 1 safety studies, we may consider conducting a placebo-controlled Phase 1b/2a gluten challenge study in as many as 40 celiac patients who present with predominantly GI symptoms followed by a Phase 2b proof-of-concept clinical trial in a similar patient population. We may also seek to initiate clinical trials of SYN-020 evaluating its potential therapeutic benefit in NAFLD patients.

During the second quarter of 2020, we announced that we entered into an agreement with Massachusetts General Hospital granting us an option for an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age-related diseases. During the second quarter of 2021, we announced an amendment to our option for an exclusive license agreement with MGH to include intellectual property and technology related to the use of SYN-020 to inhibit liver fibrosis in select diseases, including NAFLD. 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.

Intellectual Property

All of our programs are supported by growing patent estates. In total, we have over 80 U.S. and foreign patents and over 65 U.S. and foreign patents pending. The SYN-004 (ribaxamase) program is supported by IP that is assigned to Synthetic Biologics, namely U.S. patents and foreign patents (in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others) and U.S. and foreign patents pending in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others). For instance, U.S. Patent Nos. 8,894,994 and 9,587,234, which include claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004 (ribaxamase), have patent terms to at least 2031. Further, U.S. Patent 9,301,995 and 9,301,996, both of which will expire in 2031, cover various uses of beta-lactamases, including SYN-004 (ribaxamase), in protecting the microbiome, and U.S. Patent Nos. 9,290,754, 9,376,673, 9,404,103, 9,464,280, and 9,695,409 which will expire in at least 2035, covers further beta-lactamase compositions of matter related to SYN-004 (ribaxamase).

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

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

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 condensed 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 2020 Form 10-K.

Results of Operations

Three Months Ended September 30, 2021 and 2020

General and Administrative Expenses

General and administrative expenses increased by 9% to approximately $1.3 million for the three months ended September 30, 2021, from approximately $1.2 million for the three months ended September 30, 2020. This increase is primarily due to higher insurance costs, audit fees and registration fees offset by lower legal costs and vacation expense. The charge related to stock-based compensation expense was $83,000 for the three months ended September 30, 2021, compared to $67,000 for the three months ended September 30, 2020.

Research and Development Expenses

Research and development expenses increased by 116% to approximately $2.0 million for the three months ended September 30, 2021, from approximately $900,000 for the three months ended September 30, 2020. This increase is primarily the result of increased clinical trial expenses as we continued dosing patients in the Phase 1b/2a clinical trial of SYN-004 and by higher indirect program costs for the three months ended September 30, 2021, including an increase in manufacturing costs for SYN-020. We anticipate research and development expense to increase as our ongoing clinical trials continue to enroll patients. The charge related to stock-based compensation expense was $19,000 for the three months ended September 30, 2021, compared to $15,000 related to stock-based compensation expense for the three months ended September 30, 2020.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended September 30, 2021 and 2020. 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	September 30, 2021	September 30, 2020
Ribaxamase (SYN-004)	$ 457	$ 76
SYN-020	92	-
SYN-005	1	1
SYN-010	-	45
Total direct costs	550	122
Total indirect costs	1,422	792
Total Research and Development	$ 1,972	$ 914

Other Income/Expense

Other income was $2,000 for the three months ended September 30, 2021, compared to other income of $134 for the three months ended September 30, 2020. Other income for the three months ended September 30, 2021 and 2020 is primarily comprised of interest income.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was approximately $3.3 million, or $0.02 per basic and dilutive common share for the three months ended September 30, 2021, compared to a net loss of approximately $2.7 million, or $0.14 per basic common share and dilutive common share for the three months ended September 30, 2020. 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.

Nine Months Ended September 30, 2021 and 2020

General and Administrative Expenses

General and administrative expenses increased by 3% to approximately $4.0 million for the nine months ended September 30, 2021, from approximately $3.9 million for the nine months ended September 30, 2020. The movement for the period primarily consisted of increased insurance costs, audit fees and registration fees offset by lower legal costs related to business development, patent execution and employee contract matters, vacation expense and travel. The charge related to stock-based compensation expense was $248,000 for the nine months ended September 30, 2021, compared to $193,000 for the nine months ended September 30, 2020.

Research and Development Expenses

Research and development expenses increased by 21% to $5.0 million for the nine months ended September 30, 2021, from $4.1 million for the nine months ended September 30, 2020. This increase is primarily the result of the clinical trial expenses as we began dosing patients in the Phase 1b/2a clinical trial of SYN-004 and Phase 1 SAD clinical trial of SYN-020 offset by lower indirect program costs for the nine months ended September 30, 2021, including salary and related expense reductions, a decrease in clinical contract service costs for SYN-004 and market research. In addition, as a result of the global COVID-19 pandemic, our clinical development partner (Washington University) reduced their operating capacity during 2020 to include only essential activities as part of their pandemic response, which delayed the start of our clinical trial until 2021. We anticipate research and development expense to increase as our ongoing clinical trials continue to enroll patients. Research and development expenses also include a charge relating to stock-based compensation expense of $57,000 for the nine months ended September 30, 2021, compared to $52,000 for the nine months ended September 30, 2020.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the nine months ended September 30, 2021 and 2020. 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	September 30, 2021	September 30, 2020
SYN-020	$ 961	$ -
Ribaxamase	937	181
SYN-010	3	293
SYN-005	1	30
Total direct costs	1,902	504
Total indirect costs	3,119	3,648
Total Research and Development Expenses	$ 5,021	$ 4,152

Other Income/Expense

Other income was $4,000 for the nine months ended September 30, 2021, compared to other income of $44,000 for the nine months ended September 30, 2020. Other income for the nine months ended September 30, 2021 and 2020 is primarily comprised of interest income.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was approximately $17.9 million, or $0.15 per basic and dilutive common share for the nine months ended September 30, 2021, compared to a net loss of approximately $9.4 million, or $0.52 per basic common share and dilutive common share for the nine months ended September 30, 2020. Net loss attributable to common stockholders for the nine months ended September 30, 2021 excludes net loss attributable to non-controlling interest of $1,000 and includes the accretion of the Series B preferred discount of $1.5 million on converted shares, Series A Preferred Stock accrued dividends of $24,000 and the deemed dividend for the effect of the Series A preferred shares price adjustment of $7.4 million. 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.

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 approximately $266 million as of September 30, 2021 and expect to continue to incur losses in the foreseeable future. During the nine months ended September 30, 2021, our operating activities used net cash of approximately $8.1 million. Our cash and cash equivalents totaled approximately $72.1 million as of September 30, 2021, an increase of approximately $65.9 million from December 31, 2020. During the three and nine months ended September 30, 2021, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of approximately $3.3 million and approximately $9.0 million for the three and nine months ended September 30, 2021, respectively.

Historically, we have financed our operations primarily through public and private sales of our securities, and we expect to continue to seek and obtain additional capital in a similar manner. During the year ended December 31, 2020, our only source of financing was from sales of approximately 9.2 million shares of our common stock utilizing our at-the-market offering program through the Original ATM Sales Agreement (as defined below) pursuant to which we received net proceeds of approximately $3.4 million. During the nine months ended September 30, 2021, we raised approximately $74.0 million, of which (i) approximately $8.0 million was raised from cash received from the issuance of approximately 11.6 million shares of our common stock upon the exercise of approximately 65% of the 2018 Warrants during the three months ended March 31, 2021 and (ii) approximately $66.0 million of net proceeds was raised from the sale of approximately 78.7 million shares of our common stock during the three months ended March 31, 2021 in “at the market” offerings pursuant to the Sales Agreement that we had entered into in 2016 with FBR Capital Markets & Co. (now known as B. Riley Securities) (the “Original ATM Sales Agreement”) and the Amended and Restated ATM Sales Agreement. During the three months ended September 30, 2021, we did not sell any of our common stock through the Original ATM Sales Agreement and the Amended and Restated ATM Sales Agreement. We believe that our cash and cash equivalents at September 30, 2021 will be sufficient to fund our operations through at least the end of the first quarter of 2023.

The Amended and Restated ATM Sales Agreement enables us to offer and sell shares of our common stock from time to time through B. Riley and AGP as our sales agents. Sales of common stock under the Amended and Restated ATM Sales Agreement are made in sales deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act. B. Riley and AGP are entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of our common stock sold on our behalf. There can be no assurance that we will be able to continue to raise funds through the sale of shares of common stock through the Amended and Restated ATM Sales Agreement. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain funding for future clinical trials when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of future clinical trials until such time as we obtain adequate financing.

We have committed, and expect to continue to commit, substantial capital in order to implement our business strategy, including our planned product development efforts, preparation for our planned clinical trials, and performance of clinical trials and our research and discovery efforts. We believe our cash position of $72.1 million as of September 30, 2021 is sufficient to fund our operations through at least the end of the first quarter of 2023, including continuation of our ongoing Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients for the prevention of aGVHD, as well as our ongoing Phase 1 MAD study and Phase 2 clinical programs for SYN-020.

Following the anticipated completion of our ongoing Phase 1b/2a clinical study of SYN-004 (ribaxamase) in allogeneic HCT recipients, the ongoing Phase 1 MAD study and planned Phase 2a clinical trial of SYN-020, we may need to obtain additional funds for future clinical trials, the amount of which will depend upon the trial size and number of clinical sites. We anticipate that our future clinical trials will be much larger in size and require larger cash expenditures than the aforementioned clinical programs. We do not have any committed sources of financing for future clinical trials at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all.

As a result of the global COVID-19 pandemic, our clinical development partner (Washington University) reduced their operating capacity during 2020 and the first quarter of 2021 to include only essential activities as part of their pandemic response. These delays impacted the timelines for our clinical programs, which included delaying commencement of the Phase 1b/2a clinical trial of SYN-004 until the second quarter of 2021. These delays also resulted in a decrease in anticipated expenses as no clinical trials had yet commenced during that period. If enrollment in our ongoing Phase 1b/2a clinical trial being conducted by Washington University is halted due to COVID-19 developments, we may experience reduced expenses until such time as enrollment resumes.

As the COVID-19 coronavirus continues to spread around the globe, we have experienced disruptions that impacted our business and clinical trials, including postponement of commencement of the now ongoing Phase 1b/2a clinical trial of SYN-004. Although we are currently experiencing limited, if any, adverse impact to our financial stability stemming from the global economic slowdown, the overall disruption of global healthcare systems and other risks and uncertainties associated with the COVID-19 pandemic, including uncertainty regarding our clinical timelines, our business, financial condition, results of operations and growth prospects could be materially adversely affected. 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, 2021, 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, 2021, 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, 2021, 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, 2021, 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, 2021 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, 2021 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 2020 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2020 Form 10-K.

RISKS RELATING TO OUR BUSINESS

We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts. In addition, potential capital raises and strategic opportunities may require the issuance of additional securities.

During the nine months ended September 30, 2021, our operating activities used net cash of approximately $8.1 million and our cash and cash equivalents were approximately $72.1 million as of September 30, 2021. 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, 2021, our accumulated deficit totaled approximately $266 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended 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, if ever. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct later stage clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Any failure to raise additional capital as and when needed, as a result of insufficient authorized shares or otherwise, could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. Based on our current plans, our cash and cash equivalents will be sufficient to complete our ongoing Phase 1a/2a clinical trial of SYN-004, our ongoing Phase 1 multiple ascending dose clinical trial of SYN-020, and a potential Phase 2a clinical trial of SYN-020 but, may not be sufficient for post-Phase 2a future clinical programs for SYN-020 or additional trials of SYN-004, which are expected to require significant cash expenditures. In addition, based on the significant anticipated cost of a Phase 3 clinical program in a broad indication for SYN-004, we expect it will not be feasible for us to initiate and complete this trial at this time without a partner given the capital constraints tied to our current market cap and share price. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. We may also issue shares of our common stock in connection with strategic opportunities. However, our remaining authorized and unissued shares of common stock available may be insufficient to complete potential future equity financing transactions and/or strategic transactions we may seek to undertake. At our 2021 Annual Meeting of Shareholders, we sought shareholder approval of an amendment to our Articles of Incorporation, as amended, to increase our authorized number of shares of common stock, which approval was not obtained. Accordingly, we anticipate taking steps, when appropriate, to increase our number of available shares which may have the effect of facilitating such transactions; however, there can be no assurance that we will be successful in obtaining the required approval for any such action. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and also have a dilutive effect on our stockholders. A failure otherwise to secure additional funds when needed in the future whether through an equity or debt financing or a sufficient amount of capital without a strategic partnership could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

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

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. By way of example, on February 8, 2021, the price of our common stock closed at $1.17 per share while on October 18, 2021, our stock price closed at $0.4362 per share with no discernable announcements or developments by the company or third parties. On February 9, 2021, the intra-day sales price of our common stock fluctuated between a reported low sale price of $0.91 and a reported high sales price of $1.19. On October 18, 2021, the intra-day sales price of our common stock fluctuated between a reported low sale price of $0.43 and a reported high sales price of $0.44. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects. In addition, the recent outbreak of the novel strain of coronavirus (COVID-19) has caused broad stock market and industry fluctuations. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- investor reaction to our business strategy;
- the success of competitive products or technologies;
- our continued compliance with the listing standards of the NYSE American;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- results of our clinical trials;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations or partners;
- developments or disputes concerning patents or other proprietary rights, including litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- declines in the market prices of stocks generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and

- other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, public health issues including health epidemics or pandemics, such as the recent outbreak of the novel coronavirus (COVID-19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

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

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

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

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as consideration for acquisitions or part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. We are authorized to issue 200,000,000 shares of common stock, of which 132,042,548 shares of common stock were issued and outstanding as of November 3, 2021. At November 3, 2021, we had reserved 10,342,384 shares of common stock for issuance upon exercise of our outstanding options and warrants. In addition, at such date, we had 2,460,000 shares of our common stock reserved for future issuance under our equity incentive plans. If all of these securities were to be exercised, the total number of shares of our common stock that we would be required to issue is 12,802,384, which in addition to the 132,042,548 shares issued and outstanding, would leave 55,155,079 authorized but unissued shares of common stock. As a result of our limited number of authorized and unissued shares of common stock, we may have insufficient shares of common stock available to issue in connection with any future equity financing transactions or strategic transactions we may seek to undertake. At our 2021 Annual Meeting of Shareholders we sought shareholder approval of an amendment to our Articles of Incorporation, as amended, to increase our authorized number of shares of common stock, which approval was not obtained. Accordingly, we anticipate taking steps, when appropriate, to increase our number of available shares which may have the effect of facilitating such transactions; however, there can be no assurance that we will be successful in obtaining the required approval for any such action.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by existing stockholders, thereby subjecting such stockholders to dilution. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock.

We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. In the event that we sell shares or other securities at prices below the exercise price of the warrants that we issued in our October 2018 offering, the price protection anti-dilution provisions of the warrant provide that the exercise price of the warrants sold in our October 2018 offering is to be reduced which may result in additional warrant exercises and additional dilution to stockholders as was the case in 2020 and during the first quarter of 2021 when we utilized our at-the-market facility and the warrant exercise price was reduced. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by existing stockholders.

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.

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

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

On May 25, 2021, we received notification from the NYSE American that the Company had regained compliance with all of the continued listing standards set forth in Part 10, Section 1003 of the NYSE American Company Guide (the "Company Guide") relating to the Exchange's continued listing requirements.

We previously received notification from the NYSE American citing failure to comply with the minimum stockholders' equity continued listing standard as set forth in Part 10, Section 1003 of the Company Guide. As a result of management's efforts to regain compliance, the Exchange has informed the Company that it has cured the previously cited deficiencies and is in full compliance with the continued listing standards set forth in Part 10, Sections 1003 (i), (ii), and (iii) of the Company Guide. However, there can be no assurance that we will continue to meet the NYSE American continued listing requirements.

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

We did not sell any equity securities during the quarter ended September 30, 2021 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.

Not applicable

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

Date: November 3, 2021

EXHIBIT INDEX

Exhibit Number	Exhibit Title
1.1	Amended and Restated At Market Issuance Sales Agreement dated February 9, 2021 by and among Synthetic Biologics, Inc. and B. Riley Securities, Inc. and A.G.P./Alliance Global Partners (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed February 10, 2021, File No. 001-12584.)
3.1	Certificate of Incorporation, as amended (Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, File No. 001-12584, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001, File No. 001-12584; and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998, File No. 001-12584.)
3.2	Articles of Merger (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.3	Certificate of Merger filed with the Secretary of State of Delaware (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.4	Articles of Incorporation filed with the Nevada Secretary of State (Incorporated by reference to Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009, File No. 001-12584.)
3.5	Amended and Restated Bylaws Adopted and Effective October 31, 2011 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed November 2, 2011, File No. 001-12584.)
3.6	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 16, 2012, File No. 001-12584.)
3.7	Certificate of Amendment to Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed May 18, 2015, File No. 001-12584.)
3.8	Certificate of Amendment to Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 8, 2017, File No. 001-12584.)
3.9	Certificate of Designations for Series A Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 12, 2017, File No. 001-12584.)
3.10	Certificate of Change Pursuant to NRS 78. 209 (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed August 13, 2018, File No. 001-12584.)
3.11	Certificate of Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed September 26, 2018, File No. 001-12584.)
3.12	Certificate of Designations for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)
3.13	Certificate of Amendment to Certificate of Designations for Series B Preferred Stock to Certificate of Incorporation (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 15, 2018, File No. 001-12584.)

3.14	Certificate of Amendment to the Certificate of Designation for the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K/A filed on February 1, 2021 File No. 001-12584.)
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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)*

*Filed herewith.

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 3, 2021

By: /s/ Steven A. Shallcross
Name: Steven A. Shallcross
Chief Executive Officer and 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, 2021 (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 3, 2021

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