UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2019

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 x No ¨

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

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

Large Accelerated Filer	¨	Accelerated Filer	¨
Non-accelerated Filer	x	Smaller Reporting Company	x
		Emerging growth company	¨

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ¨ No x

As of August 6, 2019, the registrant had 16,806,430 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, 2018 filed with the Securities and Exchange Commission (the "SEC") on February 27, 2019, as amended by the Form 10-K/A (Amendment No. 1) for the year ended December 31, 2018 filed with the SEC on April 1, 2019 ("2018 Form 10-K"). 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 per share amounts)

	June 30, 2019	December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	$ 21,712	$ 28,918
Prepaid expenses and other current assets	1,298	593
Total Current Assets	23,010	29,511
Property and equipment, net	485	607
Right of Use Asset	481	-
Deposits and other assets	23	23
Total Assets	**$ 23,999**	**$ 30,141**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,523	$ 1,034
Accrued expenses	1,544	919
Accrued employee benefits	511	1,332
Deferred rent	-	99
Lease liability	233	-
Total Current Liabilities	3,811	3,384
Long term deferred rent	-	302
Lease liability - Long term	601	-
Total Liabilities	4,412	3,686
Series A convertible preferred stock, $0.001 par value; 10,000,000 shares authorized; 120,000 issued and outstanding	12,419	12,296
Stockholders' Equity:		
Series B Convertible Preferred stock, $1,000 par value; 10,000,000 shares authorized, 7,823 issued and outstanding and 9,161 issued and outstanding	4,935	5,760
Common stock, $0.001 par value; 200,000,000 shares authorized, 16,647,888, issued and 16,645,560 outstanding and 15,484,411, issued and 15,482,083 outstanding	17	15
Additional paid-in capital	232,211	230,754
Accumulated deficit	(227,141)	(219,461)
Total Synthetic Biologics, Inc. and Subsidiaries Equity	10,022	17,068
Non-controlling interest	(2,854)	(2,909)
Total Stockholders' Equity	7,168	14,159
Total Liabilities and Stockholders' Equity	**$ 23,999**	**$ 30,141**

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 June,		For the six months ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating Costs and Expenses:				
General and administrative	$ 1,044	$ 1,431	$ 2,199	$ 3,051
Research and development	2,594	3,572	5,012	6,942
Total Operating Costs and Expenses	3,638	5,003	7,211	9,993
Loss from Operations	(3,638)	(5,003)	(7,211)	(9,993)
Other Income:				
Change in fair value of warrant liability	-	783	-	3,438
Interest income	80	6	125	15
Total Other Income	80	789	125	3,453
Net Loss	(3,558)	(4,214)	(7,086)	(6,540)
Net Loss Attributable to Non-controlling Interest	(27)	(17)	(43)	(26)
Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries	**$ (3,531)**	**$ (4,197)**	**$ (7,043)**	**$ (6,514)**
Series A Preferred Stock Dividends	(61)	(61)	(122)	(120)
Series B Preferred Stock Dividends	(117)	**-**	(515)	-
Net Loss Attributable to Common Stockholders	**$ (3,709)**	**$ (4,258)**	**$ (7,680)**	**$ (6,634)**
Net Loss Per Share - Basic and Dilutive	$ (0.23)	$ (1.16)	$ (0.48)	$ (1.80)
Weighted average number of shares outstanding during the period - Basic and Dilutive	16,465,314	3,683,383	16,063,283	3,678,389

See accompanying notes to unaudited condensed consolidated financial statements.

Synthetic Biologics, Inc. and Subsidiaries
Consolidated Statements of Stockholders Equity (Deficit)
(In thousands, except share amounts)

	Common Stock $0.001 Par Value		Series B Preferred					
	Shares	Amount	Shares	Amount	APIC	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2018	15,482,083	$ 15	9,161	$ 5,760	$ 230,754	$ (219,461)	$ (2,909)	$ 14,159
Stock-based compensation	-	-	-	-	64	-	-	64
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(61)	-	(61)
Issuance of SYN Biomics Stock	-	-	-	-	(36)	-	53	17
Conversion of Series B Preferred Stock to Common ($0.03 per share)	900,869	1	(1,036)	(638)	1,035	(398)	-	-
Net loss	-	-	-	-	-	(3,512)	-	(3,512)
Non-controlling interest	-	-	-	-	-	-	(16)	(16)
Balance at March 31, 2019	16,382,952	$ 16	8,125	$ 5,122	$ 231,817	$ (223,432)	$ (2,872)	$ 10,651
Stock-based compensation	-	-	-	-	91	-	-	91
Series A Preferred Stock Dividends ($0.01 per share)	-	-	-	-	-	(61)	-	(61)
Issuance of SYN Biomics Stock	-	-	-	-	-	-	45	45
Conversion of Series B Preferred Stock to Common ($0.03 per share)	262,608	1	(302)	(187)	303	(117)	-	-
Net loss	-	-	-	-	-	(3,531)	-	(3,531)
Non-controlling interest	-	-	-	-	-	-	(27)	(27)
Balance at June 30, 2019	**16,645,560**	**$ 17**	**7,823**	**$ 4,935**	**$ 232,211**	**$ (227,141)**	**$ (2,854)**	**$ 7,168**

	Common Stock $0.001 Par Value		Series B Preferred					
	Shares	Amount	Shares	Amount	APIC	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' (Deficit)
Balance at December 31, 2017	3,671,014	$ 4	-	$ -	$ 192,670	$ (194,170)	$ (1,914)	$ (3,410)
Stock-based compensation	-	-	-	-	676	-	-	676
Fair Value of Warrants issued	-	-	-	-	9	-	-	9
Series A Preferred Stock Dividends ($0.02 per share)	-	-	-	-	-	(59)	-	(59)
Net loss	-	-	-	-	-	(2,316)	-	(2,316)
Non-controlling interest	-	-	-	-	-	-	(9)	(9)
Balance at March 31, 2018	3,671,014	$ 4	-	$ -	$ 193,355	$ (196,545)	$ (1,923)	$ (5,109)
Stock-based compensation	-	-	-	-	557	-	-	557
Series A Preferred Stock Dividends ($0.02 per share)	-	-	-	-	-	(61)	-	(61)
Stock issued under "at-the-market" offering	49,490		-	-	400	-	-	400
Net loss	-	-	-	-	-	(4,197)	-	(4,197)
Non-controlling interest	-	-	-	-	-	-	(17)	(17)
Balance at June 30, 2018	**3,720,504**	**$ 4**	**-**	**$ -**	**$ 194,312**	**$ (200,803)**	**$ (1,940)**	**$ (8,427)**

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

Consolidated Statements of Cash Flows

	For the Six Months Ended June 30,	
	2019	**2018**
Cash Flows From Operating Activities:		
Net loss	$ (7,086)	$ (6,540)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	155	1,233
Subsidiary stock issued to consultant	62	-
Warrant issued to consultant	-	9
Change in fair value of warrant liabilities	-	(3,438)
Depreciation and amortization	122	141
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(706)	292
Right of use asset	56	-
Accounts payable	490	(803)
Accrued expenses	627	(526)
Accrued employee benefits	(821)	(711)
Lease liability	(105)	-
Deferred rent	-	(44)
Net Cash Used In Operating Activities	(7,206)	(10,387)
Net Cash Used In Investing Activities	-	-
Cash Flows From Financing Activities:		
Proceeds from issuance ATM offering, net of issuance costs	-	400
Net Cash Provided By Financing Activities	-	400
Net decrease in cash	(7,206)	(9,987)
Cash and cash equivalents at beginning of period	28,918	17,116
Cash and cash equivalents at end of period	**$ 21,712**	**$ 7,129**
Noncash Financing Activities:		
Right of use asset from operating lease	$ 538	$ -
Conversion of Series B Preferred Stock	$ 825	$ -
Deemed dividends for beneficial conversion features	$ 515	$ -
In-kind dividends paid in preferred stock	$ 122	$ 120

See accompanying notes to unaudited condensed consolidated financial statements.

1. Organization, Nature of Operations and Basis of Presentation

Description of Business

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a clinical-stage company focused on developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. The Company's lead 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-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). The Company is also advancing SYN-020, an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) 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 2018 Form 10-K. The interim results for the three and six months ended June 30, 2019 are not necessarily indicative of results for the full year.

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

Liquidity

As of June 30, 2019, the Company has a significant accumulated deficit and with the exception of the three months ended September 30, 2010 and December 31, 2017, the Company has experienced significant losses and incurred negative cash flows since inception. The Company expects to continue incurring losses for the foreseeable future, with the recognition of revenue being contingent on successful phase 3 clinical trials and requisite approvals by the FDA. Historically, the Company has financed its operations primarily through public and private sales of its common stock and a private placement of its preferred stock, and it expects to continue to seek to obtain required capital in a similar manner. The Company has spent, and expects to continue to spend, a substantial amount of funds in connection with implementing its business strategy including, planned product development efforts, clinical trials and research and discovery efforts.

Cash and cash equivalents totaled approximately $20.1 million as of early August 2019, which includes the net proceeds of approximately $16.7 million from the sale of securities in October 2018 (the Offering) and net proceeds of approximately $12.2 million from sales of its Common Stock in "at-the-market" (ATM) equity offerings during 2018. With the cash available in early August 2019, the Company believes these resources will be sufficient to fund its operations through at least the end of the third quarter of 2020. Management believes its plan, which includes the further development of SYN-020 and additional testing of SYN-004 (ribaxamase) and SYN-010, will allow the Company to meet its financial obligations, further advance key products, and maintain the Company's planned operations for at least one year from the issuance date of these consolidated financial statements, while not sacrificing the strategic direction of the Company. If necessary, the Company may attempt to utilize the ATM or seek to raise additional capital on the open market, neither of which is guaranteed. Use of the ATM is limited by certain restrictions and management's plan does not rely on additional capital from either of these sources. If the Company is not able to obtain additional capital (which is not assured at this time), the Company's long term business plan may not be accomplished and the Company may be forced to cease certain development activities. More specifically, the completion of a Phase 3 clinical trial will require significant financing or a significant partnership.

Reverse Stock Split

On August 10, 2018, the Company effected a one for thirty-five reverse stock split (the "Reverse Stock Split") of its authorized, issued and outstanding common stock. Unless otherwise noted, all references to share amounts in these financial statements reflect the Reverse Stock Split.

Every thirty-five shares of issued and outstanding Common Stock were automatically combined into one issued and outstanding share of Common Stock, without any change in the par value per share of Common Stock. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

The Reverse Stock Split affected all issued and outstanding shares of Common Stock, as well as Common Stock underlying stock options, warrants and convertible instruments outstanding immediately prior to the effectiveness of the Reverse Stock Split. The Reverse Stock Split reduced the total number of shares of Common Stock outstanding from approximately 128.5 million to approximately 3.7 million.

Recent Accounting Pronouncements and Developments

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective transition approach and provides for certain practical expedients. We adopted this guidance effective January 1, 2019 using the modified retrospective transition approach wherein we applied the guidance to each lease that had commenced as of January 1, 2019 (the beginning of effective date) with a cumulative effect adjustment as of that date. The prior comparative period was not adjusted under this method and we have provided the required disclosures under Accounting Standards Codification (ASC) 840 for the comparative period to which ASC 840 is applied. We have also elected to adopt the following package of practical expedients:

- we did not reassess if any expired or existing contracts are or contain leases.
- we did not reassess the initial direct costs for existing leases.
- we did not reassess the classification of any expired or existing leases.

Additionally, we made ongoing accounting policy elections whereby we (i) do not recognize right of use ("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. The determination of whether an arrangement contains a lease and the classification of a lease, if applicable, is made at lease commencement.

Upon adoption of the new guidance on January 1, 2019, we recorded a ROU asset of approximately $537,000 (net of taxes and existing deferred rent liability) and recognized a lease liability of approximately $939,000.

2. Fair Value of Financial Instruments

Fair Value of Financial Instruments

ASC 820, *Fair Value Measurement*, defines fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- **Level 1 inputs:** Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- **Level 2 inputs:** Inputs, other than quoted prices, 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.

Cash and cash equivalents include money market accounts of $98,000 as of June 30, 2019 and December 31, 2018 that are measured using Level 1 inputs.

The Company uses Monte Carlo simulations to estimate the fair value of its stock warrants. In using this model, the fair value is determined by applying Level 3 inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

3. Selected Balance Sheet Information

Prepaid expenses and other current assets (in thousands)

	June 30, 2019	December 31, 2018
Prepaid manufacturing expenses	$ 1,001	$ -
Prepaid insurance	197	419
Prepaid consulting, subscriptions and other expenses	96	132
Other receivable	4	-
Prepaid conferences, travel	-	42
Total	$ 1,298	$ 593

Property and equipment, net (in thousands)

	June 30, 2019	December 31, 2018
Computers and office equipment	$ 852	$ 852
Leasehold improvements	439	439
Software	11	11
	1,302	1,302
Less: accumulated depreciation and amortization	(817)	(695)
Total	$ 485	$ 607

Accrued expenses (in thousands)

	June 30, 2019	December 31, 2018
Accrued clinical consulting services	$ 726	$ 674
Accrued manufacturing costs	670	83
Accrued vendor payments	140	150
Other accrued expenses	8	12
Total	$ 1,544	$ 919

Accrued employee benefits (in thousands)

	June 30, 2019	December 31, 2018
Accrued bonus expense	$ 405	$ 907
Accrued vacation expense	106	118
Accrued severance	-	307
Total	$ 511	$ 1,332

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 is determined by the compensation committee of the Board of Directors and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2007 plan shall not exceed 7,143. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of June 30, 2019, there were 11,737 options issued and outstanding under the 2007 Stock Plan.

On November 2, 2010, the Board of Directors and stockholders adopted the 2010 Stock Incentive Plan ("2010 Stock Plan") for the issuance of up to 85,714 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. On October 22, 2013, the stockholders approved and adopted an amendment to the Company's 2010 Stock Plan to increase the number of shares of Company's common stock reserved for issuance under the Plan from 85,714 to 171,429. On May 15, 2015, the stockholders approved and adopted an amendment to the Company's 2010 Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the Plan from 171,429 to 228,572. On August 25, 2016, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the 2010 Stock Plan from 228,572 to 400,000. On September 7, 2017, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the 2010 Stock Plan from 400,000 to 500,000. On September 24, 2018, the stockholders approved and adopted an amendment to the 2010 Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the 2010 Stock Plan from 500,000 to 1,000,000. 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 June 30, 2019, there were 831,382 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. There is no deferred compensation recorded upon initial grant date. Instead, the fair value of the stock-based payment is recognized as compensation expense over the stated vesting period.

The Company has applied fair value accounting for all stock-based payment awards since inception. The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model. There were no options granted during the three and six months ended June 30, 2019 and 2018. The assumptions used for the awards during the year ended December 31, 2018 are as follows:

Exercise price	$ 0.69
Expected dividends	0%
Expected volatility	86%
Risk-free interest rate	2.75%
Expected life of option	4 years

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.

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

Expected life of the option—The period of time that the options granted are expected to remain unexercised. Options granted during 2018 have a maximum term of seven years. The Company estimates the expected life of the option 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;
- half vesting immediately and remaining over three years;
- in full on one-year anniversary date of grant date;
- quarterly over three years;
- annually over three years;
- one-third immediate vesting and remaining annually over two years;
- one-half immediate vesting and remaining over nine months;
- one quarter immediate vesting and remaining over three years;
- one quarter immediate vesting and remaining over 33 months; and
- monthly over three years.

A summary of stock option activity for the six months ended June 30, 2019 and the year ended December 31, 2018 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Balance - December 31, 2017	359,076	$ 53.93	4.60	$ 1,800
Granted	671,500	$ 0.69		
Expired	(78,667)	$ 67.02		
Forfeited	(12,927)	$ 23.72		
Balance - December 31, 2018	938,982	$ 15.18	6.19	$ -
Expired	(52,419)	$ 68.96		
Forfeited	(43,444)	$ 8.30		
Balance - June 30, 2019 - outstanding	843,119	$ 12.19	5.85	$ -
Balance - June 30, 2019 - exercisable	289,660	$ 32.81	4.80	$ -
Grant date fair value of options granted - June 30, 2019		$ -		
Weighted average grant date fair value - June 30, 2019		$ -		
Grant date fair value of options granted - December 31, 2018		$ 301,000		
Weighted average grant date fair value - December 31, 2018		$ 0.45		

Stock-based compensation expense included in operating expenses related to stock options issued to employees and consultants for the three months ended June 30, 2019 and 2018 was $91,000 and $557,000 respectively, and $155,000 and $1.2 million for the six month ended June 30, 2019 and 2018, respectively.

As of June 30, 2019, total unrecognized stock-based compensation expense related to stock options was $422,000, which is expected to be expensed through March 2021.

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 six months ended June 30, 2019 and 2018.

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 Company's common stock, par value $0.001 per share (the "Common Stock"), and one five-year warrant to purchase one share of Common Stock at an exercise price of $1.38 per share (each a "Warrant" and collectively, the "Warrants"), with each Class A Unit to be offered to the public at a public offering price of $1.15, and (ii) 15,723 Class B Units (the "Class B Units", and together with the Class A Units, the "Units"), with each Class B Unit offered to the public at a public offering price of $1,000 per Class B Unit and consisting of one share of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock"), with a stated value of $1,000 and convertible into shares of Common Stock at the stated value divided by a conversion price of $1.15 per share, with all shares of Series B Preferred Stock convertible into an aggregate of 13,672,173 shares of Common Stock, and issued with an aggregate of 13,672,173 Warrants . In addition, pursuant to the underwriting agreement that the Company had entered into with A.G.P./Alliance Global Partners (the "Underwriters"), as representative of the underwriters, the Company granted the Underwriters a 45 day option (the "Over-allotment Option") to purchase up to an additional 2,428,825 shares of Common Stock and/or additional Warrants to purchase an additional 2,428,825 shares of Common Stock. The Underwriters partially exercised the Over-allotment Option by electing to purchase from the Company additional Warrants to purchase 1,807,826 shares of Common Stock.

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

The assumptions used by the Company are summarized in the following table:

	Issuance Date
Closing stock price	$ 0.88
Expected dividends	0%
Expected volatility	90%
Risk free interest rate	3.01%
Expected life of warrant (years)	5.00

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 per share exercise price of the Series A warrants is $50.05 and the per share exercise price of the Series B warrants is $60.20, each subject to adjustment as specified in the warrant agreements. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four-year anniversary of the issuance date. The Series B warrants expired December 31, 2017 and none were exercised prior to expiration. The warrants include a provision that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder for cash. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date of $15.7 million and changes in estimated fair value are being recorded as non-cash income or expense in the Company's Condensed Consolidated Statements of Operations at each subsequent period. At June 30, 2019, the fair value of the warrant liability was $100. At June 30, 2018, the fair value of the warrant liability was $624,000, which resulted in non-cash income of $714,000 and $3.0 million for the three and six months ended June 30, 2018, respectively. The warrants were valued on the date of grant and on each remeasurement period using Monte Carlo simulations. A third party valuation was not obtained for these warrants as of June 30, 2019 due to the nominal value of the warrants as of December 31, 2018 and the Company's continued low stock price.

The assumptions used by the Company are summarized in the following table:

	December 31, 2018	Series A December 31, 2017	November 18, 2016
Closing stock price	$ 0.56	$ 17.85	$ 31.15
Expected dividends	0%	0%	0%
Expected volatility	92.5%	80%	85%
Risk free interest rate	2.50%	1.97%	1.58%
Expected life of warrant	1.9 years	2.9 years	4.0 years

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

The warrants issued in conjunction with the registered direct offering in October 2014 include a provision that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder at a premium. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date, which was $7.4 million, and changes in estimated fair value are being recorded as non-cash income or expense in the Company's Consolidated Statements of Operations at each subsequent period. At June 30, 2019, the fair value of the warrant liability was zero. At June 30, 2018, the fair value of the warrant liability was $21,000, which resulted in non-cash income of $69,000 and $395,000 for the three and six months ended June 30, 2018, respectively. The warrants were valued on the date of grant using the Black-Scholes valuation model which approximates the value derived using Monte Carlo simulations. The warrants were not valued during 2019 due the current minimal value and stock price. The assumptions used by the Company are summarized in the following table:

	December 31, 2018	December 31, 2017	October 10, 2014
Closing stock price	$ 0.56	$ 17.85	$ 61.25
Expected dividends	0%	0%	0%
Expected volatility	110%	80%	95%
Risk free interest rate	2.60%	1.86%	1.39%
Expected life of warrant	.79 years	1.79 years	5.0 years

The following table summarizes the estimated fair value of the warrant liability *(in thousands)*:

Balance at December 31, 2017	$ 4,083
Change in fair value of warrant liability	(4,083)
Balance at December 31, 2018	-
Change in fair value of warrant liability	-
Balance at June 30, 2019	$ -

A summary of all warrant activity for the Company for the six months ended June 30, 2019 and the year ended December 31, 2018 is as follows:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2017	915,138	$ 52.50
Granted	18,000,713	1.38
Exercised	-	-
Forfeited	-	-
Balance at December 31, 2018	18,915,851	3.85
Granted	-	-
Exercised	-	-
Forfeited	-	-
Balance at June 30, 2019	18,915,851	$ 3.85

On December 26, 2017, the Company entered into a consulting agreement for advisory services for a period of six months. As compensation for such services, the consultant was paid an upfront payment, is paid a monthly fee, and on January 24, 2018 was issued a warrant exercisable for 714 shares of the Company's common stock on the date of issuance. The warrant is equity classified and the fair value of the warrant approximated $9,000 on the date of grant and was measured using the Black-Scholes option pricing model. This entire expense was recorded in the quarter ended March 31, 2018.

The assumptions used by the Company are summarized in the following table:

	Issuance Date
Closing stock price	$ 18.55
Expected dividends	0%
Expected volatility	85%
Risk free interest rate	2.42%
Expected life of warrant (years)	4.92

A summary of all outstanding and exercisable warrants as of June 30, 2019 is as follows:

Exercise Price	Warrants Outstanding	Warrants Exercisable	Weighted Average Remaining Contractual Life
$ 1.38	17,999,999	17,999,999	4.29 years
18.20	714	714	3.49 years
50.05	714,286	714,286	1.39 years
61.25	200,852	200,852	0.28 years
$ 3.85	18,915,851	18,915,851	4.14 years

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. Included in net loss is the Series A preferred dividend from preferred shares issuance of $61,000 and $122,000 for the three and six months ended June 30, 2019 and $61,000 and $120,000 for the three and six months ended June 30, 2018, respectively. Net loss for the three and six months ended June 30, 2019 also includes the Series B deemed dividend of $117,000 and $515,000. The deemed dividend relates to the discount provided to preferred stockholders upon conversion of their preferred stock to common shares and is subtracted from net loss (see Note 8). 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 potentially 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. 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 six months ended June 30, 2019 were 843,119 and 18,915,851, respectively, and for the three and six months and ended June 30, 2018 were 12,168,515 and 32,054,809, respectively.

The following tables set forth the computation of diluted net loss per weighted average number of shares outstanding attributable to Synthetic Biologics, Inc. and Subsidiaries for the three and six months ended June 30, 2019 and 2018 *(in thousands except share and per share amounts)*:

	Three months ended June 30, 2019			Six months ended June 30, 2019		
	Net loss (Numerator)	Shares (Denominator)	Per Share Amount	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Net loss - Basic	$ (3,709)	16,465,314	$ (0.23)	$ (7,680)	16,063,283	$ (0.48)
Dilutive shares related to warrants	-	-	-	-	-	-
Net loss - Dilutive	$ (3,709)	16,465,314	$ (0.23)	$ (7,680)	16,063,283	$ (0.48)

	Three months ended June 30, 2018			Six months ended June 30, 2018		
	Net loss (Numerator)	Shares (Denominator)	Per Share Amount	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Net loss - Basic	$ (4,258)	3,683,383	$ (1.16)	$ (6,634)	3,678,389	$ (1.80)
Dilutive shares related to warrants	-	-	-	-	-	-
Net loss - Dilutive	$ (4,258)	3,683,383	$ (1.16)	$ (6,634)	3,678,389	$ (1.80)

7. Non-controlling Interest

The Company's non-controlling interest is accounted for under ASC 810, *Consolidation*, and represents the minority shareholder's ownership interest related to the Company's subsidiary, Synthetic Biomics, Inc. ("SYN Biomics"). In accordance with ASC 810, the Company reports its non-controlling interest in subsidiaries as a separate component of equity in the Consolidated Balance Sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company's common stockholders on the face of the Consolidated Statements of Operations. On September 5, 2018, the Company entered into an agreement with Cedars-Sinai Medical Center (CSMC) for an investigator-sponsored Phase 2b clinical study of SYN-010 to be co-funded by the Company and CSMC (the "Study"). The Study will provide further evaluation of the efficacy and safety of SYN-010, the Company's modified-release reformulation of lovastatin lactone, which is exclusively licensed to the Company by CSMC. SYN-010 is designed to reduce methane production by certain microorganisms (*M. smithii*) in the gut to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C).

In consideration of the support provided by CSMC for the Study, the Company will pay $441,000 to support the Study and the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company, upon the approval of the Study protocol by the Institutional Review Board (IRB) : (i) issued to CSMC 50,000 shares of common stock of the Company; and (ii) transferred to CSMC an additional 2,420,000 shares of common stock of its subsidiary SYN Biomics, Inc. ("Synbiomics") owned by the Company, such that after such issuance CSMC owns an aggregate of 7,480,000 shares of common stock of SYN Biomics, representing 17% of the issued and outstanding shares of SYN Biomics' common stock. The services rendered are recorded to research and development expense in proportion with the progress of the study and are based overall on the fair value of the shares ($285,000) as determined at the date of IRB approval. During 2019, research and development expense recorded related to this transaction approximated $119,000 and $174,000 for the three and six months ended June 30, 2019, respectively.

The Agreement also provides CSMC with a right, commencing on the six month anniversary of issuance of the stock under certain circumstances in the event that the shares of stock of 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.

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.

In addition, pursuant to the Underwriting Agreement that the Company entered into with the Underwriters on October 10, 2018, the Company granted the Underwriters a 45 day option (the "Over-allotment Option") to purchase up to an additional 2,428,825 shares of Common Stock and/or additional warrants to purchase an additional 2,428,825 shares of Common Stock. Each Warrant is exercisable for one share of common stock. The Underwriters partially exercised the Over-allotment Option by electing to purchase from the Company additional Warrants to purchase 1,807,826 shares of Common Stock.

The Units were offered by the Company pursuant to a registration statement on Form S-1 (File No. 333-227400), as amended, filed with the SEC, which was declared effective by the SEC on October 10, 2018.

The conversion price of the Series B Preferred Stock and exercise price of the October 2018 Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Common Stock. The exercise price of the Warrants is subject to adjustment in the event of certain dilutive issuances. During the three and six months ended June 30, 2019, 302 and 1,338 shares, respectively, have been converted resulting in the recognition of $117,000 and $515,000 of unamortized discount from the conversion, respectively. As of June 30, 2019, 7,900 shares have been converted resulting in the recognition of $3.0 million of unamortized discount. This is recorded as a deemed dividend in accumulated deficit.

The October 2018 Warrants are immediately exercisable at a price of $1.38 per share of common stock (which is 120% of the public offering price of the Class A Units) and will expire on October 15, 2023. If, at the time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares of common stock to the holder, then the October 2018 Warrants may only be exercised through a cashless exercise. No fractional shares of common stock will be issued in connection with the exercise of any October 2018 Warrants. In lieu of fractional shares, the holder will receive an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares.

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

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 year ended December 31, 2018, the Company recorded a discount of $9.1 million and immediately amortized the discount to record the deemed dividend.

Series A Preferred Stock

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

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

On or at any time after (i) the VWAP (as defined in the Certificate of Designation) for at least 20 trading days in any 30 trading day period is greater than $70.00, subject to adjustment in the case of stock split, stock dividends or the like the Company has the right, after providing notice not less than 6 months prior to the redemption date, to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share of Series A Preferred Stock of $7,875, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Convertible Preferred Stock, or (ii) the five year anniversary of the issuance date, the Company has the right to redeem, in whole or in part, on a pro rata basis from all holders thereof based on the number of shares of Series A Convertible Preferred Stock then held, the outstanding Series A Preferred Stock, for cash, at a redemption price per share equal to the Liquidation Value (as defined in the Certificate of Designations).

The Series A Preferred Stock is classified as temporary equity due to the shares being (i) redeemable based on contingent events outside of the Company's control, and (ii) convertible immediately and from time to time. 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 is a beneficial conversion feature ("BCF") at the issuance date. Because the Series A Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF is immediately charged to retained earnings as a "deemed dividend" and impacts earnings per share. Because the Series A Preferred Stock is not currently redeemable, the discount arising from issuance costs was allocated to temporary equity and will not be accreted until such time that redemption becomes probable. The stated dividend rate of 2% per annum is cumulative and the Company accrues the dividend on a quarterly basis (in effect accreting the dividend regardless of declaration because the dividend is cumulative). During the three and six months ended June 30, 2019, the Company accrued dividends of $61,000 and $122,000, respectively. During the three and six months ended June 30, 2018, the Company accrued dividends of $61,000 and $120,000, respectively. Once the dividend is declared, the Company will reclassify the declared amount from temporary equity to a dividends payable liability. When the redemption of the Series A Preferred Stock becomes probable, the temporary equity will be accreted to redemption value as a deemed dividend.

B. Riley FBR Sales Agreement

On August 5, 2016, the Company entered into the B. Riley FBR Sales Agreement with FBR Capital Markets & Co. (now known as B. Riley FBR, Inc.), which enables the Company to offer and sell shares of the Company's common stock with an aggregate sales price of up to $40.0 million from time to time through B. Riley FBR, Inc. as the Company's sales agent. Sales of common stock under the B. Riley FBR Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act. B. Riley FBR, Inc. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of the Company's common stock sold on the Company's behalf. For the year ended December 31, 2018, the Company sold through the B. Riley FBR Sales Agreement an aggregate of 3.5 million shares of the Company's common stock, and received net proceeds of approximately $12.2 million. For the three and six months ending June 30, 2018, the Company sold through the B. Riley FBR Sales Agreement an aggregate of 0 and 1.7 million shares of the Company's common stock, and received net proceeds of approximately $400,000. The Company has not sold any shares during 2019 through the B. Riley FBR Sales Agreement.

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

In consideration of the support provided by CSMC for the Study, the Company entered into a Stock Purchase Agreement with CSMC pursuant to which the Company: (i) issued to CSMC 50,000 shares of common stock of the Company; and (ii) transferred to CSMC an additional 2,420,000 shares of common stock of its subsidiary Synthetic Biomics, Inc. ("SYN Biomics") owned by the Company, such that after such issuance CSMC owns an aggregate of 7,480,000 shares of common stock of SYN Biomics, representing seventeen percent (17%) of the issued and outstanding shares of SYN Biomics' common stock.

The Agreement also provides CSMC with a right, commencing on the six month anniversary of issuance of the stock under certain circumstances in the event that the shares of stock of SYN Biomics are not then freely tradeable, and subject to NYSE American, LLC approval, to exchange its SYN Biomics shares for unregistered shares of the Company's common stock, with the rate of exchange based upon the relative contribution of the valuation of SYN Biomics to the public market valuation of the Company at the time of each exchange. The Stock Purchase Agreement also provides for tag-along rights in the event of the sale by the Company of its shares of SYN Biomics. As of June 30, 2019, CSMC has not exercised its right to exchange its SYN Biomics shares for the Company's common stock.

In December 2013, through the Company's subsidiary, Synthetic Biomics, Inc., the Company entered into a worldwide exclusive license agreement with CSMC and acquired the rights to develop products for therapeutic and prophylactic treatments of acute and chronic diseases, including the development of SYN-010 to target IBS-C. The Company licensed from CSMC a portfolio of intellectual property comprised of several U.S. and foreign patents and pending patent applications for various fields of use, including IBS-C, obesity and diabetes. An investigational team led by Mark Pimentel, M.D. at CSMC discovered that these products may reduce the production of methane gas by certain GI microorganisms. During the three and six months ended June 30, 2019 and 2018, the Company did not owe and did not pay CSMC for milestone payments related this license agreement.

10. Commitments and Contingencies

Leases

All of the Company's existing leases as of June 30, 2019 are classified as operating leases. As of June 30, 2019, the Company has one material operating lease for facilities with a remaining term expiring in 2022. The existing lease has fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. The discount rate used in the calculation of the lease liability was 9.9%. The rates implicit within the Company's leases are generally not determinable, therefore, the Company's incremental borrowing rate is used to determine the present value of lease payments. The determination of the Company's incremental borrowing rate requires judgment. Because the Company currently has no outstanding debt, the incremental borrowing rate for each lease is primarily based on publicly-available information for companies within the same industry and with similar credit profiles. The rate is then adjusted for the impact of collateralization, the lease term and other specific terms included in the Company's lease arrangements. The incremental borrowing rate is determined at lease commencement, or as of January 1, 2019, for operating leases in existence upon adoption of ASC 842. The incremental borrowing rate is subsequently reassessed upon a modification to the lease arrangement. ROU assets are subsequently assessed for impairment in accordance with the Company's accounting policy for long-lived assets. Operating lease costs are presented as part of the general and administrative expenses in the condensed consolidated statements of operations, and for the three and six months ended June 30, 2019 approximated $50,000 and $101,000, respectively. During the same period, operating cash flows used for operating leases approximated $75,000 and $149,000, respectively. During 2019 there were no ROU assets exchanged for operating lease obligations. The initial non-cash addition of ROU assets due to adoption of ASC 842 was $538,000.

A maturity analysis of our operating leases as of June 30, 2019 is as follows *(amounts in thousands of dollars)*:

Future undiscounted cash flows:		
2019	$	151
2020		309
2021		321
2022		192
Total	$	973
Discount factor	$	(139)
Lease liability	$	834
Amount due within 12 months	$	(233)
Non-current lease liability	$	601

As of December 31, 2018, the Company's future minimum lease payments were as follows *(in thousands)*:

	2019	2020	2021	2022	Total
Operating Lease	$ 300	$ 309	$ 321	$ 192	$ 1,122
Total	$ 300	$ 309	$ 321	$ 192	$ 1,122

11. Subsequent Events

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

The goal of the Study is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of 150 mg oral SYN-004 administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever. Study participants will be enrolled into three sequential cohorts administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 and four will receive placebo. Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic. The Study will also evaluate potential protective effects of SYN-004 on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 in allogeneic HCT recipients. Enrollment is expected to begin during the fourth quarter of 2019, contingent upon approval of the clinical study protocol by the Washington University School of Medicine's Institutional Review Board (IRB) and the U.S. Food & Drug Administration (FDA).

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

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

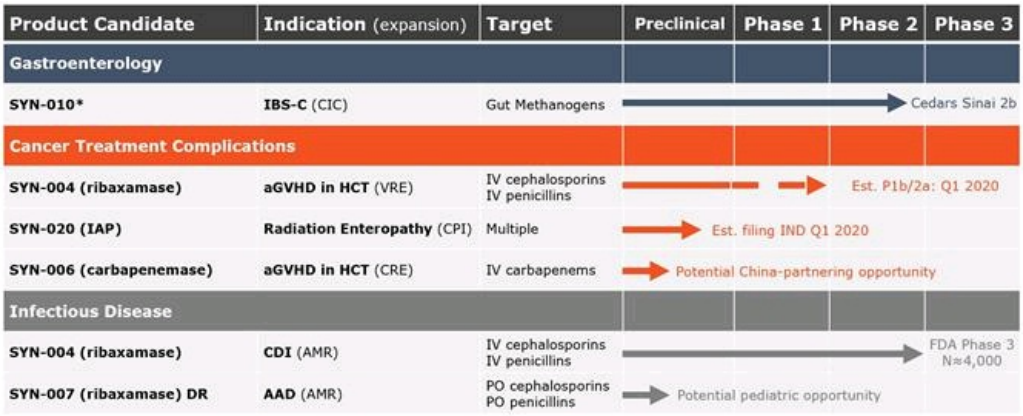
The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q, and our audited consolidated financial statements and notes thereto for the year ended December 31, 2018 included in our 2018 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 2018 Form 10-K. All share and per share numbers set forth in this Management's Discussion and Analysis of Financial

Conditions and Results of Operations reflect the one-for-thirty five reverse stock split effected August 10, 2018.

Overview

We are a clinical-stage company focused on developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. Our lead 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 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-010 which is intended to reduce the impact of methane-producing organisms in the gut microbiome to treat an underlying cause of irritable bowel syndrome with constipation (IBS-C). We are also advancing SYN-020, an early-stage oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases.

Our Product Pipeline:



AAD antibiotic associated diarrhea; **aGVHD** acute graft-vs-host disease; **AMR** antimicrobial resistance; **CDI** *Clostridioides difficile* infection; **CIC** chronic idiopathic constipation; **CPI** checkpoint inhibitor autoimmune enteropathy; **CRE** carbapenem resistant enterococci; **DR** delayed release; **Est.** estimated; **HCT** hematopoietic cell transplant patients; **IAP** intestinal alkaline phosphatase; **IBS-C** irritable bowel syndrome with constipation; **VRE** vancomycin resistant enterococci.

*SYN-010 Phase 2b investigator-sponsored clinical study is being conducted by the Medically Associated Science and Technology (MAST) Program at Cedars-Sinai Medical Center.

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 FDA-proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval on the basis of a single Phase 3 clinical trial (Q4 2018) · Anticipate initiation of the Phase 3 clinical program proposed by the FDA for the prevention of CDI only after securing additional potential funding via a strategic partnership · Clarified market/potential partner needs and identified potential additional indications in specialty patient populations such as allogeneic hematopoietic cell transplant patients · Announced clinical trial agreement with Washington University School of Medicine to conduct a Phase 1b/2a clinical trial to evaluate safety, tolerability and pharmacokinetics in up to 36 adult allogeneic HCT recipients (Q3 2019) · Anticipate initiation of Phase 1b/2a clinical trial to be conducted by Washington University in adult allogeneic HCT recipients in Q1 2020
Treatment of IBS-C	SYN-010 (oral modified-release lovastatin lactone)	· Confirmed key elements of Pivotal Phase 2b/3 clinical trial design pursuant to consultations with FDA (Q1 2017) · Entered into agreement with CSMC for an investigator-sponsored Phase 2b clinical study of SYN-010 to evaluate SYN-010 dose response and inform Phase 3 clinical development (Q3 2018) · Commenced enrollment in the Phase 2b investigator-sponsored clinical study of SYN-010 conducted by CSMC (Q1 2019) · Anticipate a data readout from investigator-sponsored Phase 2b clinical study (1H 2020)
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV carbapenem antibiotics)	SYN-006 (oral enzyme)	· Identified P2A as a potent carbapenemase that is stable in the GI tract · Manufactured a formulated research lot for oral delivery (2017) · Demonstrated microbiome protection in a pig model of ertapenem administration (Q1 2018)
Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade oral beta-lactam antibiotics)	SYN-007 (oral enzyme)	· Preclinical work ongoing to expand the utility of SYN-004 (ribaxamase) for use with oral beta-lactam antibiotics · Reported supportive data from a second canine animal model demonstrating that when co-administered with oral amoxicillin and oral Augmentin, oral SYN-007 did not interfere with systemic absorption of antibiotics but did diminish microbiome damage associated with these antibiotics (Q2 2018)

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) · Anticipated IND filing (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) · Collaborations with Intrexon and UT Austin

Recent Developments

Our Microbiome-Focused Pipeline

Our SYN-004 (ribaxamase) and SYN-010 clinical programs are focused on 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. Our plan remains focused on the advancement of our two lead clinical programs. We continue to actively manage resources in preparation for the clinical advancement of our two lead microbiome-focused clinical programs, SYN-004 (ribaxamase) and SYN-010, as well as our pre-IND program SYN-020, including our pursuit of opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete this plan.

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

On November 21, 2018, we announced results from our End-of-Phase 2 meeting with the FDA during which key elements of a Phase 3 clinical program were confirmed. Pursuant to the meeting, the FDA proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval of SYN-004 (ribaxamase) on the basis of a single Phase 3 clinical trial. The proposed SYN-004 (ribaxamase) Phase 3 clinical program comprises a single, global, event-driven clinical trial with a fixed maximum number of approximately 4,000 patients for total enrollment and will evaluate the potential efficacy and safety of ribaxamase in a broad patient population by enrolling patients with a variety of underlying infections treated with a range of IV beta-lactam antibiotics. We expect the clinical development costs to complete this trial to be in excess of $80 million and anticipate at this time initiating the Phase 3 clinical program only after securing additional potential financing via a strategic partnership or other financing activities, which we continue to aggressively pursue.

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

One such narrow patient population for SYN-004 (ribaxamase) is allogenic hematopoietic cell transplant (HCT) recipients, who have a very high risk of CDI, VRE colonization and potentially fatal bacteremia, and aGVHD. Published literature has demonstrated a strong association between these adverse outcomes and microbiome damage caused by IV beta-lactam antibiotics in these patients. Approximately 80-90% of HCT recipients receive IV beta-lactam antibiotics to treat febrile neutropenia. Penicillins and cephalosporins are first-line therapies in the USA and EU, whereas carbapenems are first-line in China. Antibiotic-mediated damage to the gut microbiome is strongly associated with aGVHD, bloodstream infections, VRE bacteremia, transplant relapse, and increased mortality in HCT recipients, raising concern over the spectrum of antibiotics used during HCT. CDI occurs in up to 31% of HCT patients and is associated with GVHD and increased mortality. aGVHD occurs in 40-60% of allogeneic HCT recipients and is recognized as a primary contributor to morbidity and mortality in this patient population. Approximately 8,500 allogeneic HCT procedures were conducted in the U.S. in 2016, compared to approximately 4,500 in China. First-line treatments for aGVHD fail in more than 50% of patients and 2-year survival in patients with steroid refractory aGVHD is only 20%. At least one U.S. study found allogeneic HCT recipients who developed aGVHD had 3-times higher in-hospital mortality and almost 2-fold higher median hospital costs than patients who did not develop aGVHD. It has been reported that in-patient costs for allogeneic HCT in the USA range from $180,000-$300,000 depending on the disease severity. In 2014, all-cause costs for allogeneic HCT in the USA were greater than $600,000 per patient (up to 12 months post-transplant). VRE infection is a persistent problem in HCT patients and VRE colonization after HCT has been associated with decreased patient survival.

In August 2019, we entered into a Clinical Trial Agreement (CTA) with Washington University School of Medicine (“Washington University”) to conduct a Phase 1b/2a clinical trial. The Phase 1b/2a single-center, randomized, double-blinded, placebo-controlled clinical trial is designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN-004 (ribaxamase) in up to 36 adult allogeneic HCT recipients. Under the terms of this agreement, Synthetic Biologics will serve as the sponsor of the study and supply SYN-004 (ribaxamase). Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University will serve as the principal investigator of the trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia.

The 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 administered to allogeneic HCT recipients who receive an IV beta-lactam antibiotic to treat fever. Study participants will be enrolled into three sequential cohorts administered a different study-assigned IV beta-lactam antibiotic. Eight participants in each cohort will receive SYN-004 and four will receive placebo. Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV beta-lactam antibiotic. The study will also evaluate potential protective effects of SYN-004 on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN-004 in allogeneic HCT recipients. Enrollment is expected to begin during the first quarter of 2020, contingent upon approval of the clinical study protocol by the Washington University School of Medicine’s Institutional Review Board (IRB) and the FDA. We anticipate that subsequent potential Phase 2/3 pivotal trial(s) in this patient population may consist of as many as 500 patients.

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

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

The Study will further evaluate the efficacy and safety of SYN-010. The data from this study will provide additional insights into potential SYN-010 clinical efficacy, including dose response and microbiome effects, ideally solidifying existing clinical outcomes data, and potentially simplifying and reducing costs for future Phase 3 clinical development. We believe the successful completion of the Study will allow us to re-engage with prospective partners, both domestically and abroad, who found the results from our previously completed Phase 2a study compelling and have indicated their interest in reviewing a more robust clinical data set.

The Phase 2b study is being conducted out of the Medically Associated Science and Technology (MAST) Program at CSMC and is a 12-week, placebo-controlled, double-blind, randomized clinical trial to evaluate two dose strengths of oral SYN-010 21 mg and 42 mg in approximately 150 patients diagnosed with IBS-C.

The primary objective for the Study is to determine the efficacy of SYN-010, measured as an improvement from baseline in the weekly average number of complete spontaneous bowel movements (CSBMs) during the 12-week treatment period for SYN-010 21 mg and 42 mg daily doses relative to placebo. Secondary efficacy endpoints for both dose strengths of SYN-010 will measure changes from baseline in abdominal pain, bloating, stool frequency as well as the use of rescue medication relative to placebo. Exploratory outcomes include Adequate Relief and quality of life measures using the well-validated EQ-5D-5L and PAC-SYM patient questionnaires. Enrollment in this study commenced in January 2019 and remains ongoing. After consulting with the investigators at Cedars-Sinai Medical Center, the study sponsor, we have elected to extend enrollment to accommodate the higher than anticipated screen-fail rates for patients who presented at screening with breath-methane levels below the protocol-required ten parts-per-million. In order to ensure the possibility of generating a meaningful data set of the highest quality, we are discussing with Cedars-Sinai the opportunity for a data read out in the first half of 2020.

SYN-020 — Oral Intestinal Alkaline Phosphatase

SYN-020 is a quality-controlled, recombinant version of Intestinal Alkaline Phosphatase (IAP) formulated for oral delivery. The published literature indicates that IAP functions to diminish GI inflammation, tighten the gut barrier to diminish “leaky gut,” and promote a healthy microbiome. Based on these known mechanisms as well as our own supporting animal model data, we are developing SYN-020 to mitigate the intestinal damage caused by radiation therapy that is routinely used to treat pelvic cancers. A key hurdle to commercialization has been the high cost of IAP manufacture. We believe we have developed technologies to traverse this hurdle and are currently advancing a SYN-020 product candidate towards an IND which we anticipate filing promptly during the first quarter of 2020. During the second quarter of 2019, we completed a pre-IND meeting with the FDA where we discussed nonclinical and clinical strategies and clarified requirements for IND-enabling toxicology studies to evaluate safety and pharmacokinetics of SYN-020 in healthy volunteers. As part of the SYN-020 nonclinical package, we evaluated SYN-020 in conjunction with radiation and 5-fluorouracil (5-FU) in an exploratory mouse ectopic colon cancer model. 5-FU is a chemotherapy drug commonly used to treat a variety of cancers, including colon, rectal and other GI-related cancers. The purpose was to show that oral administration of SYN-020 does not alter the effectiveness of these cancer therapeutics. As expected, SYN-020 did not diminish anti-cancer efficacy with either radiation or 5-FU. Interestingly, very preliminary data suggest that SYN-020 may have improved the outcomes with 5-FU. A confirmatory study is ongoing with larger cohort sizes and additional mechanistic endpoints which, if repeated, may allow us to further broaden the clinical development strategy for this program.

Intellectual Property

All of our programs are supported by growing patent estates that we either own or exclusively license. Each potential product has issued patents that provide protection. In total, we have over 110 U.S. and foreign patents and over 100 U.S. and foreign patents pending. The SYN-004 (ribaxamase) program is supported by IP that is assigned to Synthetic Biologics, namely U.S. patents and foreign patents (in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others) and U.S. and foreign patents pending in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others). For instance, U.S. Patent Nos. 8,894,994 and 9,587,234, which include claims to compositions of matter and pharmaceutical compositions of beta-lactamases, including SYN-004 (ribaxamase), have patent terms to at least 2031. Further, U.S. Patent 9,301,995 and 9,301,996, both of which will expire in 2031, cover various uses of beta-lactamases, including SYN-004 (ribaxamase), in protecting the microbiome, and U.S. Patent Nos. 9,290,754, 9,376,673, 9,404,103, 9,464,280, and 9,695,409 which will expire in at least 2035, covers further beta-lactamase compositions of matter related to SYN-004 (ribaxamase). The SYN-010 program is supported by IP that is exclusively licensed to (and, in some cases co-owned by) Synthetic Biologics, namely U.S. patents and foreign patents (in most major markets, e.g. Europe (including Germany, Great Britain and France), and Canada, among others) and U.S. and foreign patents pending in most major markets, e.g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others). For instance, U.S. Patent No. 9,192,618, which expires in at least 2023, includes claims that cover use of statins, including SYN-010, for the treatment of IBS-C. U.S. Patent No. 9,289,418, which expires in at least 2033, includes claims that cover the use of a variety of compounds, including the active agent of SYN-010, to treat constipation in certain screened patients. U.S. Patent No. 9,744,208 covers methods of use of the active agent of SYN-010 for the treatment of constipation until at least 2034. U.S. Patent No. 9,956,292 includes claims related to composition of matter of anti-methanogenic compositions that find use in treating IBS-C and will expire in at least 2035.

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

Critical Accounting Policies

The condensed consolidated financial statements are prepared in conformity with U.S. GAAP, which requires the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses in the periods presented. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results may differ from the original estimates, requiring adjustments to these balances in future periods. The critical accounting estimates that affect the condensed consolidated financial statements and the judgments and assumptions used are consistent with those described under Part II, Item 7 of our 2018 Form 10-K.

Results of Operations

Three Months Ended June 30, 2019 and 2018

General and Administrative Expenses

General and administrative expenses decreased by 27% to $1.0 million for the three months ended June 30, 2019 from $1.4 million for the three months ended June 30, 2018. This decrease is primarily due to decreased stock-based compensation expense related to forfeitures and decreased option grants, along with the reduction of investor relations and consulting costs. The charge related to stock-based compensation expense was $59,000 for the three months ended June 30, 2019, compared to $264,000 the three months ended June, 2018.

Research and Development Expenses

Research and development expenses decreased by 27% to $2.6 million for the three months ended June 30, 2019 from $3.6 million for the three months ended June 30, 2018. This decrease is primarily the result of lower SYN-004 (ribaxamase) indirect program costs for the three months ended June 30, 2019, including salary and related expense reductions resulting from the 2018 restructuring and the fact that no clinical trial activity for SYN-004 (ribaxamase) was ongoing during the quarter, offset by an increase in manufacturing costs for SYN-020. The research and development costs incurred during the quarter were primarily related to the investigator-sponsored Phase 2b clinical study of SYN-010 and manufacturing cost for SYN-020. We anticipate research and development expense to increase in association with the ongoing Phase 2b investigator-sponsored clinical study of SYN-010, a potential Phase 1b/2a clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients, and the continued development of SYN-020. Research and development expenses also include a charge relating to stock-based compensation expense of $31,000 for the three months ended June 30, 2019, compared to $293,000 for the three months ended June 30, 2018.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended June 30, 2019 and 2018. 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	**June 30, 2019**	**June 30 31,2018**
SYN-010	$ 159	$ 145
Ribaxamase	46	130
Other therapeutic areas	13	1
Total direct costs	218	276
Total indirect costs	2,376	3,296
Total Research and Development Expenses	$ 2,594	$ 3,572

Other Income

Other income was $80,000 for the three months ended June 30, 2019, compared to other income of $789,000 for the three months ended June 30, 2018. Other income for the three months ended June 30, 2019 is primarily comprised of interest income while the three months ended June 30, 2018 is comprised of non-cash income of $783,000 from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was $3.7 million, or $0.23 per basic and dilutive common share for the three months ended June 30, 2019, compared to a net loss of $4.3 million, or $1.16 per basic common share and dilutive common share for the three months ended June 30, 2018. The net loss was primarily attributed to the net loss from operations described above.

Six Months Ended June 30, 2019 and 2018

General and Administrative Expenses

General and administrative expenses decreased by 27% to $2.2 million for the six months ended June 30, 2019, from $3.1 million for the six months ended June 30, 2018. This decrease is primarily due to decreased stock-based compensation expense related to forfeitures and decreased option grants, along with the reduction of investor relations, consulting, registration, and legal costs. The charge related to stock-based compensation expense was $125,000 for the six months ended June 30, 2019, compared to $614,000 the six months ended June, 2018.

Research and Development Expenses

Research and development expenses decreased by 27% to $5.0 million for the six months ended June 30, 2019, from $6.9 million for the six months ended June 30, 2018. This decrease is primarily the result of lower SYN-004 (ribaxamase) indirect program costs for the three months ended June 30, 2019, including salary and related expense reductions resulting from the 2018 restructuring and the fact that no clinical trial activity for SYN-004 (ribaxamase) was ongoing during the year, offset by an increase in manufacturing costs for SYN-020. The research and development costs incurred during the year were primarily related to the investigator-sponsored Phase 2b clinical study of SYN-010 and manufacturing cost for SYN-020. We anticipate research and development expense to increase in association with the ongoing Phase 2b investigator-sponsored clinical study of SYN-010, a potential Phase 1/2 clinical trial of SYN-004 (ribaxamase) in allogeneic HCT recipients, and the continued development of SYN-020. Research and development expenses also include a charge relating to stock-based compensation expense of $30,000 for the six months ended June 30, 2019, compared to $619,000 for the six months ended June 30, 2018.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the six months ended June 30, 2019 and 2018. 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	**June 30, 2019**	**June 30, 2018**
SYN-010	$ 253	$ 229
SYN-004 (ribaxamase)	112	225
Other therapeutic areas	16	(2)
Total direct costs	381	452
Total indirect costs	4,631	6,490
Total Research and Development Expenses	$ 5,012	$ 6,942

Other Income

Other income was $125,000 for the six months ended June 30, 2019, compared to other income of $3.5 million for the six months ended June 30, 2018. Other income for the six months ended June 30, 2019 is primarily due to interest income while the six months ended June 30, 2018 is comprised of non-cash income of $3.5 million from the change in fair value of warrants. The decrease in the fair value of the warrants was due to the decrease in our stock price.

Net Loss Attributable to Common Stockholders

Our net loss attributable to common stockholders was $7.7 million, or $0.48 per basic and dilutive common share for the six months ended June 30, 2019, compared to a net loss of $6.6 million, or $1.80 per basic common share and dilutive common share for the six months ended June 30, 2018. The net loss was primarily attributed to the net loss from operations described above.

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 $227.1 million as of June 30, 2019 and expect to continue to incur losses in the foreseeable future.

Our cash and cash equivalents totaled $21.7 million as of June 30, 2019, a decrease of $7.2 million from December 31, 2018. During the three and six months ended June 30, 2019, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $3.6 million and $7.1 million for the three and six months ended June 30, 2019, respectively. With the cash available in early August 2019, we believe these resources will be sufficient to fund our operations through at least the end of the third quarter of 2020.

To date, we have financed our operations primarily through public and private sales of our securities, and we expect to continue to seek to obtain our required capital in a similar manner. During the year ended December 31, 2018, our only sources of funding were from our public offering that closed in October 2018 in which we received net proceeds of approximately $16.7 million and sales of 3.5 million shares of our common stock in our at-the-market offering program through the FBR Sales Agreement pursuant to which we received net proceeds of approximately $12.2 million. The FBR Sales Agreement enables us to offer and sell shares of our common stock from time to time through B. Riley FBR, Inc. as our sales agent, with aggregate sales of up to $40.0 million, of which $19.9 million remains available subject to certain conditions and requirements. Sales of common stock under the FBR Sales Agreement are made in sales deemed to be “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act. B. Riley FBR, Inc. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of our common stock sold on our behalf. No shares of our common stock were sold through the FBR Sales Agreement during 2019.

There can be no assurance that we will be able to continue to raise funds through the sale of shares of common stock through the FBR Sales Agreement. 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 spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development efforts, preparation for our planned clinical trials, performance of clinical trials and our research and discovery efforts. With the cash available in early August 2019, we believe these resources will be sufficient to fund our operations through at least the end of the third quarter of 2020, including the anticipated completion of the ongoing Phase 2b investigator-sponsored clinical study of SYN-010, a potential Phase 1/2 clinical study of SYN-004 (ribaxamase) in a specialty population for the prevention of aGVHD in allogeneic HCT recipients, as well as our preclinical activities and planned development of SYN-020.

Although our cash and cash equivalents are expected to be sufficient for us to fund the foregoing, our cash and cash equivalents will not be sufficient to enable us to meet our long-term expected plans, including initiation or completion of future registrational studies for SYN-010, the Phase 3 clinical program of SYN-004 (ribaxamase) for prevention of CDI, or later-stage clinical trials of SYN-020. Therefore, we do not intend to commence future registrational studies of SYN-010, our Phase 3 clinical program of SYN-004 (ribaxamase) for prevention of CDI or later-stage clinical trials of SYN-020 until we are confident that we have funding necessary to complete such trials. In addition, following the completion of our ongoing Phase 2b clinical study of SYN-010, our planned potential Phase 1/2 clinical study of SYN-004 (ribaxamase) and development of SYN-020, we anticipate needing to obtain additional funds for future clinical trials. We do not currently have commitments from any third parties to provide us with capital 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. Potential sources of financing that we are pursuing include strategic relationships, public or private sales of our equity (including through the FBR Sales Agreement) or debt and other sources. We cannot assure that we will meet the requirements for use of the FBR Sales Agreement especially in light of the fact that we are currently limited by rules of the SEC as to the number of shares of common stock that we can sell pursuant to the FBR Sales Agreement due to the market value of our common stock held by non-affiliates. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. If we are unable to obtain additional capital (which is not assured at this time), our long-term business plan may not be accomplished and we may be forced to cease certain development activities. More specifically, the completion of future Phase 3 and/or registrational clinical studies will require significant financing or a significant partnership.

We do not have any committed sources of financing for future clinical trials at this time.

Off-Balance Sheet Arrangements

During the three months ended June 30, 2019, 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. 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 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 June 30, 2019, 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 June 30, 2019, our cash and cash equivalents consisted primarily of money market 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 June 30, 2019, 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 June 30, 2019 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 June 30, 2019 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 2018 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2018 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.

During the three and six months ended June 30, 2019, our operating activities used net cash of approximately $3.0 million and $7.2 million, respectively, and our cash and cash equivalents were $21.7 million as of June 30, 2019. 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 June 30, 2019, our accumulated deficit totaled approximately $227.1 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended September 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Based on our current plans, our cash and cash equivalents, including the proceeds of our recent public offering, will not be sufficient to complete our planned Phase 3 clinical trial for SYN-004 or our planned Phase 3 clinical trial for SYN-010, which are expected to require significant cash expenditures. In addition, based on the anticipated significant cost of a Phase 3 clinical program in a broad indication for SYN-004, we expect it will not be feasible for us to initiate and complete this trial at this time without a partner given the capital constraints tied to our current market cap and share price. In addition, based on the anticipated cost of our planned Phase 3 clinical trial for SYN-010, we expect that we may also reach the same determination regarding the feasibility of initiating and completing the trial without a partner given the capital constraints tied to our current market cap and share price at such time. Following the completion of our ongoing Phase 2b clinical study of SYN-010, our planned potential Phase 1a/2b clinical study of SYN-004 (ribaxamase) and anticipated Phase 1 clinical study of SYN-020, we anticipate needing to obtain additional funds for future clinical trials. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and also have a dilutive effect on our stockholders. A failure otherwise to secure additional funds when needed in the future whether through an equity or debt financing or a sufficient amount of capital without a strategic partnership could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Our ability to raise capital through the sale of securities is currently limited by the rules of the SEC and NYSE American that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on our registration statement on Form S-3 will be limited until such time the market value of our voting securities held by non-affiliates is $75 million or more. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available.

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

We did not sell any equity securities during the quarter ended June 30, 2019 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, Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: August 8, 2019

EXHIBIT INDEX

Exhibit Number	Exhibit Title
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)*
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase*
101.DEF	XBRL Taxonomy Extension Definition Linkbase*
101.LAB	XBRL Taxonomy Extension Label Linkbase*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase*

*Filed herewith.