Synthetic Biologics, Inc.
Form 10-Q
August 08, 2018

**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, 2018**

**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*)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ¨ | Accelerated filer | x |
| Non-Accelerated filer | ¨ | Smaller reporting company | ¨ |
| (Do not check if a smaller reporting company) | | Emerging growth company | ¨ |

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

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

As of August 6, 2018, the registrant had 132,969,743 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 "continu 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, 2017 filed with the Securities and Exchange Commission (the "SEC") on February 22, 2018 ("2017 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 Synthet 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, 2018 | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | $ 7,129 | $ 17,116 |
| Prepaid expenses and other current assets | 535 | 827 |
| Total Current Assets | 7,664 | 17,943 |
| Property and equipment, net | 731 | 872 |
| Deposits and other assets | 23 | 23 |
| Total Assets | $ 8,418 | $ 18,838 |
| Liabilities and Stockholders' Deficit | | |
| Current Liabilities: | | |
| Accounts payable | $ 1,217 | $ 2,020 |
| Accrued expenses | 1,000 | 1,526 |
| Warrant liabilities | 645 | 4,083 |
| Accrued employee benefits | 1,362 | 2,074 |
| Deferred rent | 95 | 90 |
| Total Current Liabilities | 4,319 | 9,793 |
| Long term deferred rent | 353 | 402 |
| Total Liabilities | 4,672 | 10,195 |
| Series A convertible preferred stock, $0.001 par value; 10,000,000 and zero shares authorized; 120,000 issued and outstanding | 12,173 | 12,053 |
| Stockholders' Deficit: | | |
| | 130 | 129 |

| | | |
|---|---|---|
| Common stock, $0.001 par value; 350,000,000 shares authorized,130,380,517 issued and 130,299,305 outstanding and 117,254,196 issued and 117,172,714 outstanding | | |
| Additional paid-in capital | 194,186 | 192,545 |
| Accumulated deficit | (200,803) | (194,170) |
| Total Synthetic Biologics, Inc. and Subsidiaries Deficit | (6,487) | (1,496) |
| Non-controlling interest | (1,940) | (1,914) |
| Total Stockholders' Deficit | (8,427) | (3,410) |
| Total Liabilities and Stockholders' Deficit | $ 8,418 | $ 18,838 |

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 30, | | For the six months ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Operating Costs and Expenses: | | | | |
| General and administrative | $ 1,431 | $ 1,644 | $ 3,051 | $ 3,734 |
| Research and development | 3,572 | 4,831 | 6,942 | 10,891 |
| Total Operating Costs and Expenses | 5,003 | 6,475 | 9,993 | 14,625 |
| Loss from Operations | (5,003) | (6,475) | (9,993) | (14,625) |
| Other Income: | | | | |
| Change in fair value of warrant liability | 783 | 2,159 | 3,438 | 7,249 |
| Interest income | 6 | 1 | 15 | 3 |
| Total Other Income | 789 | 2,160 | 3,453 | 7,252 |
| Net Loss | (4,214) | (4,315) | (6,540) | (7,373) |
| Net Loss Attributable to Non-controlling Interest | (17) | (60) | (26) | (272) |
| Net Loss Attributable to Synthetic Biologics, Inc. and Subsidiaries | $ (4,197) | $ (4,255) | (6,514) | (7,101) |
| Series A Preferred Stock Dividends | (61) | | (120) | - |
| Net Loss Attributable to Common Stock Holders | $ (4,258) | $ (4,255) | $ (6,634) | $ (7,101) |
| Net Loss Per Share - Basic and Dilutive | $ (0.03) | $ (0.03) | $ (0.05) | $ (0.06) |
| Weighted average number of shares outstanding during the period - Basic and Dilutive | 128,918,408 | 123,005,220 | 128,743,616 | 120,241,593 |

See accompanying notes to unaudited condensed consolidated financial statements.

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**Synthetic Biologics, Inc. and Subsidiaries**

**Condensed Consolidated Statements of Cash Flows**

**(In thousands)**

**(Unaudited)**

| | For the six months ended June 30, | |
|---|---|---|
| | 2018 | 2017 |
| Cash Flows From Operating Activities: | | |
| Net Loss | $ (6,540) | $ (7,373) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 1,233 | 2,006 |
| Warrant issued to consultant | 9 | - |
| Change in fair value of warrant liabilities | (3,438) | (7,249) |
| Depreciation and amortization | 141 | 116 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 292 | 975 |
| Accounts payable | (803) | (271) |
| Accrued expenses | (526) | (877) |
| Accrued employee benefits | (711) | 896 |
| Deferred rent | (44) | 29 |
| Net Cash Used In Operating Activities | (10,387) | (11,748) |
| | | |
| Cash Flows From Investing Activities: | | |
| Purchases of property and equipment | - | (11) |
| Net Cash Used In Investing Activities | - | (11) |
| | | |
| Cash Flows From Financing Activities: | | |
| Proceeds from issuance of common stock for stock option exercises | - | 166 |
| Proceeds from "at the market" stock issuance | 400 | 5,914 |
| Net Cash Provided By Financing Activities | 400 | 6,080 |
| | | |
| Net decrease in cash | (9,987) | (5,679) |
| | | |
| Cash at beginning of period | 17,116 | 19,055 |
| | | |
| Cash at end of period | $ 7,129 | $ 13,376 |

See accompanying notes to unaudited condensed consolidated financial statements.

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**Synthetic Biologics, Inc. and Subsidiaries**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

## 1. Organization, Nature of Operations and Basis of Presentation

### *Description of Business*

Synthetic Biologics, Inc. (the "Company" or "Synthetic Biologics") is a late-stage clinical company developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. The Company's lead candidates poised for Phase 3 development are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection (CDI), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR), 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). Our preclinical pursuits include an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases as well as monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

### *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 2017 Form 10-K. The interim results for the three and six months ended June 30, 2018 are not necessarily indicative of results for the full year.

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

***Recent Accounting Pronouncements and Developments***

In February 2016, the Financial Accounting Standards Board, ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases (Topic 842*), which establishes a new lease accounting model for lessees. The updated guidance requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In June 2018, FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payments issued to nonemployees, and generally aligns the accounting for nonemployee awards with the accounting for employee awards. The ASU is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

The Tax Cuts and Jobs Act (the Tax Act) was signed into law on December 22, 2017. The Tax Act changed many aspects of U.S. corporate income taxation and included reduction of the corporate income tax rate from 35% to 21%, implementation of a territorial tax system and imposition of a tax on deemed repatriated earnings of foreign subsidiaries. The Company recognized the tax effects of the Tax Act in the year ended December 31, 2017 and recorded $21.6 million in tax expense which relates almost entirely to the remeasurement of deferred tax assets to the 21% tax rate. The Company will continue to assess its provision for income taxes as future guidance is issued but does not currently anticipate significant revisions will be necessary. Accounting Standards Codification ("ASC") No. 740, *Income taxes,* requires the Company to record the effects of a tax law change in the period of enactment. However, shortly after the enactment of the Tax Act, the SEC staff issued Staff Accounting Bulletin ("SAB") 118, which allows the Company to record a provisional amount when it does not have the necessary information available, prepared, or analyzed in reasonable detail to complete its accounting for the change in the tax law. The measurement period ends when the Company has obtained, prepared and analyzed the information necessary to finalize its accounting, but cannot extend beyond one year.

**2. Going Concern**

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has recurring losses and, as of June 30, 2018, the Company has an accumulated deficit of approximately $200.8 million. Since inception, the Company has financed its activities principally with proceeds from the issuance of equity securities.

The Company's ability to continue as a going concern is dependent upon the Company's ability to raise additional debt or equity capital. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

The Company does not have sufficient capital to fund its plan of operations over the next twelve months. In order to address its capital needs, including its planned Phase 2b/3 and phase 3 clinical trials, the Company is actively pursuing additional equity or debt financing, in the form of either a private placement or a public offering. The Company has been in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings. Such additional financing opportunities might not be available to the Company when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms under such circumstances, the Company's operating results and prospects will be adversely affected.

With the exception of the quarter ended June 30, 2010, the Company has incurred negative cash flow from operations since its inception. The Company has spent, and expects to continue to spend, substantial amounts in connection with implementing its business strategy, including its planned product development efforts, clinical trials, and research and discovery efforts.

At June 30, 2018, the Company had cash and cash equivalents of approximately $7.1 million. Based upon the Company's current business plans, management does not believe that the Company's current cash on hand will be sufficient to execute its near term plans. Commencement of planned clinical trials is subject to the Company's successful pursuit of opportunities that will allow it to establish the clinical infrastructure and financial resources necessary to successfully initiate and make significant progress towards completion of its plan. The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the anticipated time periods (including initiation of its planned clinical trials), if at all, and to continue to fund operations at the current cash expenditure levels. Currently, the Company does not have commitments from any third parties to provide it with capital. Potential sources of financing include strategic relationships, public or private sales of equity (including through the "at-the-market" Issuance Sales Agreement (the "B. Riley FBR Sales Agreement") that the

Company entered into with FBR Capital Markets & Co. (now known as B. Riley FBR, Inc.) in August 2016 or debt and other sources. The Company cannot assure that it will meet the requirements for use of the B. Riley FBR Sales Agreement or that additional funding will be available on favorable terms, or at all. Current cash is expected to cover overhead costs, manufacturing costs for clinical supply, clinical start-up costs, business development activities and limited research efforts. If the Company fails to obtain additional funding for its clinical trials in the next few months, whether through the sale of securities or a partner or collaborator, and otherwise when needed, it will not be able to execute its business plan as planned and will be forced to cease certain development activities (including initiation of planned clinical trials) until funding is received and its business will suffer, which would have a material adverse effect on its financial position, results of operations and cash flows. Clinical development will resume once sufficient funding is available.

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

- the progress of research activities;
- the number and scope of research programs;
- the progress of preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements and amount of funding received from partners and collaborators;
- the Company's ability to maintain current research and development licensing arrangements and to establish new research and development, and licensing arrangements;
- the ability to achieve milestones under licensing arrangements;
- the costs associated with manufacturing-related services to produce material for use in its clinical trials;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

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

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

**3. Fair Value of Financial Instruments**

***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, 2018 and December 31, 2017 that are measured using Level 1 inputs.

The Company uses Monte Carlo simulations to estimate the fair value of the 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.

**4. Selected Balance Sheet Information**

*Prepaid expenses and other current assets (in thousands)*

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| Prepaid consulting, subscriptions and other expenses | $ 230 | $ 290 |
| Prepaid insurances | 170 | 351 |
| Prepaid conferences and travel | 130 | 94 |
| At the market subscription receivable | 5 | - |
| Clinical consulting services refund receivable | - | 46 |
| Prepaid clinical research organizations | - | 46 |
| Total | $ 535 | $ 827 |

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

*Property and equipment, net (in thousands)*

| | June 30, 2018 | December 31 2017 |
|---|---|---|
| Computers and office equipment | $ 851 | $ 851 |
| Leasehold improvements | 439 | 439 |
| Software | 11 | 11 |
| | 1,301 | 1,301 |
| Less: accumulated depreciation and amortization | (570 ) | (429 ) |
| Total | $ 731 | $ 872 |

*Accrued expenses (in thousands)*

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| Accrued clinical consulting services | $ 625 | $ 658 |
| Accrued vendor payments | 221 | 193 |
| Accrued manufacturing costs | 143 | 661 |
| Other accrued expenses | 11 | 14 |
| Total | $ 1,000 | $ 1,526 |

*Accrued employee benefits (in thousands)*

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| Accrued bonus expense | $ 672 | $ 1,283 |
| Accrued severance | 395 | 590 |
| Accrued vacation expense | 295 | 201 |
| Total | $ 1,362 | $ 2,074 |

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**5. Stock-Based Compensation**

***Stock Incentive Plans***

On March 20, 2007, the Company's Board of Directors approved the 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. 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 250,000. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of June 30, 2018, there were 712,258 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 3,000,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. On October 22, 2013, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the Plan from 3,000,000 to 6,000,000. On May 15, 2015, the stockholders approved and adopted an amendment to the Company's 2010 Incentive Stock Plan to increase the number of shares of the Company's common stock reserved for issuance under the Plan from 6,000,000 to 8,000,000. 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 8,000,000 to 14,000,000. 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 8,000,000 to 17,500,000. 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, 2018, there were 11,456,257 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 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, 2018. The assumptions used for the six months ended June 30, 2017 are as follows:

| | |
|---|---|
| Exercise price | $0.83-$0.87 |
| Expected dividends | 0% |
| Expected volatility | 90%-92% |
| Risk free interest rate | 1.67%-1.75% |
| Expected life of option | 4.2-4.3 years |

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.

During the six months ended June 30, 2018, the Company did not grant options to employees. During the same period in 2017, the Company granted 543,927 options to employees having an approximate fair value of $308,000 based upon the Black-Scholes option pricing model.

A summary of stock option activities for the six months ended June 30, 2018 is as follows:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Balance - December 31, 2017 | 12,564,098 | $ 1.55 | 4.60 years | $ 1,800 |
| Granted | - | - | | |
| Exercised | - | - | | $ - |
| Expired | (284,119) | 1.52 | | |
| Forfeited | (111,464) | 0.78 | | |
| Balance - June 30, 2018 - outstanding | 12,168,515 | $ 1.55 | 4.15 years | $ - |
| Balance - June 30, 2018 - exercisable | 8,589,284 | $ 1.89 | 3.35 years | $ - |
| Grant date fair value of options granted - June 30, 2018 | | $ - | | |
| Weighted average grant date fair value - June 30, 2018 | | $ - | | |
| Grant date fair value of options granted - December 31, 2017 | | $ 1,164,732 | | |
| Weighted average grant date fair value - December 31, 2017 | | $ 0.37 | | |

Stock-based compensation expense included in operating expenses related to stock options issued to employees and consultants for the three months ended June 30, 2018 and 2017 was $557,000 and $870,000 respectively, and $1.2 million and $2.0 million for the six month ended June 30, 2018 and 2017, respectively.

As of June 30, 2018, total unrecognized stock-based compensation expense related to stock options was $1.6 million, which is expected to be expensed through November 2019.

**6. Stock Purchase Warrants**

On November 18, 2016, the Company completed a public offering of 25 million shares of common stock with accompanying warrants to purchase an aggregate of 50 million shares of common stock. The stock and warrants were sold in combination, with two warrants for each share of common stock sold, a Series A warrant and a Series B warrant, each representing the right to purchase one share of common stock. The purchase price for each share of common stock and accompanying warrants was $1.00. The shares of common stock were immediately separable from the warrants and were issued separately. The initial per share exercise price of the Series A warrants was $1.43 and the per share exercise price of the Series B warrants was $1.72, each subject to adjustment as specified in the warrant agreements. The Series A and Series B warrants may be exercised at any time on or after the date of issuance. The Series A warrants are exercisable until the four year anniversary of the issuance date. The Series B warrants expired on December 31, 2017 and none were exercised prior to expiration. The warrants include a provision that if the Company were to enter into a certain transaction, as defined in the agreement, the warrants would be purchased from the holder for cash. Accordingly, the Company recorded the warrants as a liability at their estimated fair value on the issuance date, which was $15.7 million, and changes in estimated fair value will be recorded as non-cash income or expense in the Company’s condensed consolidated statements of operations at each subsequent period. 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. At June 30, 2017, the fair value of the warrant liability was $6.6 million, which resulted in non-cash income of $2.0 million and $6.1 million for the three and six months ended June 30, 2017, respectively. In accordance with U.S. GAAP, the warrants were valued on the date of grant using a Monte Carlo simulation.

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

| | **Series A** | | |
|---|---|---|---|
| | **June 30, 2018** | **December 31, 2017** | **Issuance Date** |
| Closing stock price | $0.24 | $ 0.51 | $ 0.89 |
| Expected dividends | 0 % | 0 % | 0 % |
| Expected volatility | 80 % | 80 % | 85 % |
| Risk free interest rate | 2.56% | 1.97 % | 1.58 % |
| Expected life of warrant (years) | 2.4 | 2.9 | 4.0 |

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 0.5 shares of common stock. The warrants, exercisable for an aggregate of 7,029,808 shares of common stock, have an exercise price of $1.75 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 condensed consolidated statement of operations at each subsequent period. 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. At June 30, 2017, the fair value of the warrant liability was $1.0 million, which resulted in non-cash income of $0.2 million and $1.1 million for the three and six months ended June 30, 2017, respectively. In accordance with U.S. GAAP, the warrants were valued on the date of grant using the Black-Scholes valuation model which approximates the value derived using a Monte Carlo simulation.

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

| | June 30, 2018 | December 31, 2017 | Issuance Date |
|---|---|---|---|
| Closing stock price | $ 0.24 | $ 0.51 | $ 1.75 |
| Expected dividends | 0 % | 0 % | 0 % |
| Expected volatility | 80 % | 80 % | 95 % |
| Risk free interest rate | 2.39 % | 1.86 % | 1.39 % |
| Expected life of warrant (years) | 1.30 | 1.79 | 5.00 |

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 | (3,438) |
| Balance at June 30, 2018 | $645 |

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 25,000 shares of the Company's common stock on the date of issue. The fair value of the warrant approximated $9,000 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 | $ 0.53 |

| | | |
|---|---|---|
| Expected dividends | 0 | % |
| Expected volatility | 85 | % |
| Risk free interest rate | 2.42 | % |
| Expected life of warrant (years) | 4.92 | |

A summary of warrant activity for the Company for the six months ended June 30, 2018 is as follows:

| | Number of Warrants | Weighted Average Exercise Price |
|---|---|---|
| Balance at December 31, 2017 | 32,029,809 | $ 1.50 |
| Granted | 25,000 | 0.52 |
| Exercised | - | - |
| Forfeited | - | - |
| Balance at June 30, 2018 | 32,054,809 | $ 1.50 |

A summary of all outstanding and exercisable warrants as of June 30, 2018 is as follows:

| **Exercise Price** | **Warrants Outstanding** | **Warrants Exercisable** | **Weighted Average Remaining Contractual Life (years)** |
|---|---|---|---|
| $ 0.52 | 25,000 | 25,000 | 4.49 |
| $ 1.43 | 25,000,000 | 25,000,000 | 2.39 |
| $ 1.75 | 7,029,809 | 7,029,809 | 1.28 |
| $ 1.60 | 32,054,809 | 32,054,809 | 2.15 |

**7. Net Loss per Share**

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Included in net loss is the deemed dividend from preferred shares issuance of $61,000 and $120,000 for the three and six months ended June 30, 2018, respectively. 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 9). 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, 2018 were 12,168,515 and 32,054,809, respectively, and for the three and six months and ended June 30, 2017 were 11,398,111 and 57,341,642, 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, 2018 and 2017 *(in thousands except share and per share amounts)*:

| | 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 | $ (4,214) | 128,918,408 | $ (0.03) | $ (6,540) | 128,743,616 | $ (0.05) |
| Dilutive shares related to warrants | - | - | - | - | - | - |
| Net loss - Dilutive | $ (4,214) | 128,918,408 | $ (0.03) | $ (6,540) | 128,743,616 | $ (0.05) |

| | Three months ended June 30, 2017 | | | Six months ended June 30, 2017 | | |
|---|---|---|---|---|---|---|
| | Net loss (Numerator) | Shares (Denominator) | Per Share Amount | Net Loss (Numerator) | Shares (Denominator) | Per Share Amount |
| Net loss - Basic | $ (4,255) | 123,005,220 | $ (0.03) | $ (7,101) | 120,241,593 | $ (0.06) |
| Dilutive shares related to warrants | - | - | - | - | - | - |
| Net loss - Dilutive | $ (4,255) | 123,005,220 | $ (0.03) | $ (7,101) | 120,241,593 | $ (0.06) |

**8. 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 condensed consolidated balance sheets and reports both net loss attributable to the non-controlling interest and net loss attributable to the Company and its subsidiaries on the face of the condensed consolidated statements of operations. The Company's equity interest in SYN Biomics is 88.5% and the non-controlling stockholder's interest is 11.5%. For the three and six months ended June 30, 2018, the accumulated net loss attributable to the non-controlling interest was $17,000 and $26,000, respectively.

**9. Common and Preferred Stock**

*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 $0.54 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 $2.00, 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 $225.00, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Convertible Preferred Stock, or (ii) the five year anniversary of the issue date, the Company 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 is less than the fair value of the underlying common stock at the date of issuance, there is a beneficial conversion feature ("BCF") at the issuance date. Because the Series A Preferred Stock has no stated maturity or redemption date and is immediately convertible at the option of the holder, the discount created by the BCF is immediately charged to retained earnings as a "deemed dividend" and impacts earnings per share. During the year ended December 31, 2017, the Company recorded a discount of $6.9 million. Because the Series A Preferred Stock is not currently redeemable, the discount arising from issuance costs was allocated to temporary equity and will not be accreted until such time that redemption becomes probable. The stated dividend rate of 2% per annum is cumulative and the Company accrues the dividend on a quarterly basis (in effect accreting the dividend regardless of declaration because the dividend is cumulative). During the year ended December 31, 2017 and the quarters ended March 31, 2018 and June 30, 2018, the Company accrued dividends of $73,000, $59,000 and $61,000, 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 Capital Markets & Co. 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, as amended. B. Riley FBR Capital Markets & Co. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of the Company's common stock sold on the Company's behalf. 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. For the three and six months ending June 30, 2017, the Company sold through the B. Riley FBR Sales Agreement an aggregate of 9.8 million and 10.1 million shares of the Company's common stock, and received net proceeds of approximately $5.6

million and $5.9 million, respectively. Subsequent to June 30, 2018, the Company has sold approximately 2.7 million shares of the Company's common stock, and received net proceeds of approximately $605,000.

**10. Related Party Transactions**

In December 2013, through the Company's subsidiary, Synthetic Biomics, Inc., the Company entered into a worldwide exclusive license agreement with Cedars-Sinai Medical Center ("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 six months ended June 30, 2018 and 2017, the Company did not pay Cedars-Sinai Medical Center for milestone payments related this license agreement.

**11. Subsequent Events**

On July 31, 2018, the Board of Directors approved a 1-for-35 reverse stock split of the Company's issued and outstanding shares of common stock. No other subsequent events occurred through August 8, 2018.

**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, 2017 included in our Annual Report on Form 10-K filed with the SEC on February 22, 2018. 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 Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 22, 2018.*

**Overview**

We are a late-stage clinical company focused on developing therapeutics designed to preserve the microbiome to protect and restore the health of patients. Our lead candidates poised for Phase 3 development are: (1) SYN-004 (ribaxamase) which is designed to protect the gut microbiome from the effects of certain commonly used intravenous (IV) beta-lactam antibiotics for the prevention of *C. difficile* infection (CDI), overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR), 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). Our preclinical pursuits include an oral formulation of the enzyme intestinal alkaline phosphatase (IAP) to treat both local GI and systemic diseases as well as monoclonal antibody therapies for the prevention and treatment of pertussis, and novel discovery stage biotherapeutics for the treatment of phenylketonuria (PKU).

*Product Pipeline:*

C- Cedars-Sinai Medical Center Collaboration

I- Intrexon Collaboration

T- The University of Texas at Austin Collaboration

M- Scientific collaboration with Massachusetts General Hospital

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**Summary of Clinical and Preclinical Programs**

| Therapeutic Area | Product Candidate | Status |
|---|---|---|
| Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV beta-lactam antibiotics) | SYN-004 (ribaxamase) (oral enzyme) | · Reported supportive Phase 1a/1b data (1Q 2015)<br>· Reported supportive topline data from two Phase 2a clinical trials (4Q 2015 & 2Q 2016)<br>· Initiated Phase 2b proof-of-concept clinical trial (3Q 2015)<br>· Received USAN approval of the generic name “ribaxamase” for SYN-004 (July 2016)<br>· Completed Enrollment of Phase 2b proof-of-concept clinical trial (3Q 2016)<br>· Awarded contract by the CDC (4Q 2016)<br>· Announced positive topline data from Phase 2b proof-of-concept clinical trial, including achievement of primary endpoint of significantly reducing CDI (1Q 2017)<br>· Announced additional results from Phase 2b proof-of-concept clinical trial demonstrating SYN-004 (ribaxamase) protected and maintained the naturally occurring composition of gut microbes from antibiotic-mediated dysbiosis in treated patients (2Q 2017) |

- Announced additional results from Phase 2b proof-of-concept clinical trial funded by a contract awarded by the CDC, demonstrating that SYN-004 (ribaxamase) prevented significant change to the presence of certain AMR genes in the gut resistome of patients receiving SYN-004 compared to placebo (3Q 2017)

- Presented additional supportive results regarding several exploratory endpoints from Phase 2b proof-of-concept clinical trial designed to evaluate SYN-004's (ribaxamase) ability to protect the gut microbiome from opportunistic bacterial infections and prevent the emergence of antimicrobial resistance (AMR) in the gut microbiome (4Q 2017)

- Reached preliminary agreement with the U.S. Food and Drug Administrative (FDA) on key elements of a proposed Phase 3 clinical trial program, including de-coupled co-primary endpoints designed to evaluate efficacy separate from safety in a patient population being treated with a representative selection of IV-beta-lactam antibiotics (1H 2018)

- Anticipated End of Phase 2 meeting with FDA to solidify remaining elements of planned Phase 3 clinical trial (3Q 2018)

- Plan to initiate Phase 3 clinical trial(s) (2H 2019)

| | | |
|---|---|---|
| Treatment of IBS-C | SYN-010 (oral modified-release lovastatin lactone) | · Collaboration with Cedars-Sinai Medical Center<br>· Reported supportive topline data from two Phase 2 clinical trials (4Q 2015 & 1Q 2016)<br>· Received Type C meeting responses from FDA regarding late-stage aspects of clinical pathway (2Q 2016)<br>· Presented detailed data supporting previously reported positive topline data from two Phase 2 clinical trials at DDW (May 2016)<br>· Held End of Phase 2 meeting with FDA (July 2016)<br>· Confirmed key elements of Pivotal Phase 2b/3 clinical trial design pursuant to consultations with FDA (1Q 2017)<br>· Announced issuance of key U.S. composition of matter patent providing important intellectual property protection in the U.S until at least 2035 (Q2 2018)<br>· Identified P2A as a potent carbapenemase that is stable in the GI tract |
| Prevention of CDI, overgrowth of pathogenic organisms and AMR (Degrade IV carbapenem antibiotics) | SYN-006 (oral enzyme) | · Manufactured and formulated research lot for oral delivery (2017)<br>· Demonstrated microbiome protection in a pig model if 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 |

| | | |
|---|---|---|
| | | · Presented supportive data from canine animal model at the Microbiome World Congress, America (Q4 2017) |
| | | · 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 (2Q 2018) |
| | | · Generated high expressing manufacturing cell lines for intestinal alkaline phosphatase (IAP) (1H 2017) |
| Preserve gut barrier, treat local GI inflammation, restore gut microbiome | SYN-020 (oral IAP enzyme) | · Identified downstream process and potential tablet formulations (2H 2017) |
| | | · Ongoing preclinical efficacy studies |
| | | · Identified selected target SYN-020 clinical indications in areas of unmet medical need |
| Prevention and treatment of pertussis | SYN-005 (monoclonal antibody therapies) | · Reported supportive preclinical research findings (2014) |
| | | · The University of Texas at Austin (“UT Austin”) received a grant from the Bill and Melinda Gates Foundation to support a preclinical study to evaluate the prophylactic capability of SYN-005 (4Q 2015) |
| | | · Reported supportive preclinical data demonstrating hu1B7, a component of SYN-005, provided protection from pertussis for five weeks in neonatal non-human primate study (Q2 2017) |
| | | · 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 non-human neonatal primate study (Q4 2017) |

- Collaborations with Intrexon and UT Austin

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**Our Microbiome-Focused Pipeline**

Our CDI and IBS-C programs are focused on protecting the healthy function of the gut microbiome, or gut flora, which is composed of billions of microbial organisms including 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 late-stage clinical programs. We continue to actively manage resources in preparation for the late-stage clinical advancement of our two lead microbiome-focused clinical programs, including our pursuit of successful and viable opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete this plan.

**Clinical Update**

***SYN-004 (ribaxamase) — Prevention of C. difficile infections (CDI), overgrowth by pathogenic organisms, and the emergence of antimicrobial resistance (AMR)***

On April 23, 2018, we announced that we had reached preliminary agreement with the FDA on key elements of a proposed clinical trial program for our planned Phase 3 clinical trial for ribaxamase. In accordance with recommendations and guidance received from the FDA, we expect the Phase 3 trial to evaluate the efficacy and safety of ribaxamase as separate, co-primary endpoints in a patient population being treated with a representative selection of intravenous (IV) beta-lactam antibiotics, which will include ceftriaxone and piperacillin/tazabactam. The inclusion of more than one beta-lactam antibiotic in this trial is intended to evaluate the potential utility of ribaxamase for co-administration with a greater number of cephalosporin and penicillin beta-lactam antibiotics. The proposed Phase 3 clinical trial discussed with the FDA will comprise a global, event-driven clinical trial with a fixed maximum number of patients and will seek to evaluate the efficacy and safety of ribaxamase in a broader patient population by enrolling patients with a variety of underlying infections. We expect the primary efficacy endpoint of the proposed Phase 3 trial will be the reduction in the incidence of CDI in the ribaxamase treatment group compared to placebo. We have also reached preliminary agreement with the FDA to evaluate mortality risk as the primary safety endpoint for this trial, which will be separate from the primary efficacy endpoint of reduction of the incidence of CDI. The designation of efficacy and safety as separate and decoupled endpoints is critical for clinical studies of this nature, where the underlying population is projected to have a comparatively high incidence of safety events that may significantly dilute the smaller number of CDI events. During our discussions with the FDA on the development of our proposed Phase 3 clinical trial program, the FDA undertook an additional review of data and analysis submitted by us from the previously completed ribaxamase Phase 2b clinical trial. Following FDA's review of the additional data, it was determined that the requirements for Breakthrough Therapy Designation were no longer met as a result of a disparity in mortality between the treatment groups. This disparity reflected significant differences between the treatment groups in the underlying health and comorbidities of the patients entering the study. The difference could not be fully

evaluated due to the limited safety database, and the study's method of statistical treatment of patients who did not complete the study for any reason. We have reached agreement with the FDA on how each of these factors will be addressed in the Phase 3 trial by evaluating safety and efficacy endpoints separately as described above. As a result, and with the consent of the FDA, we voluntarily withdrew the Breakthrough Therapy Designation for the ribaxamase program. The FDA stated in their official response to us that they remain committed to working with Synthetic Biologics on the development of the ribaxamase program, and the withdrawal of Breakthrough Therapy Designation will not affect interactions between us and them. We plan to continue collaborative discussions with the FDA to solidify the remaining details of the proposed Phase 3 clinical trial program during an anticipated End of Phase 2 meeting with the FDA in the third quarter of 2018, and anticipate initiating a Phase 3 trial(s) in 2H 2019 or later, subject to our successful pursuit of opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and complete this plan. We recently 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 ribaxamase while also providing a framework for potential reimbursement strategies. If approved by the FDA, SYN-004 (ribaxamase) would be the first available drug designed to prevent primary *Clostridium difficile* infection by protecting the gut microbiome from antibiotic-mediated dysbiosis.

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

*Allowance of Key U.S. Patent*

On May 1, 2018, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,956,292 which includes claims related to composition of matter for the use of anti-methanogenic compositions to treat IBS-C. The patent will provide key intellectual property protection in the U.S. for SYN-010 and will expire no later than 2035.

***Research Programs***

Infectious disease outbreaks are increasing while intervention options are declining due to widespread multidrug-resistant bacteria, increasing numbers of immuno-compromised patients (e.g., the elderly and cancer patients) and the isolation of new pathogens.

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

SYN-007 is a specially formulated version of SYN-004 (ribaxamase) designed to degrade orally administered beta-lactam antibiotics to protect the gut microbiome from antibiotic-mediated dysbiosis. SYN-007 is formulated for release in the distal small intestine to allow systemic absorption of the oral antibiotic while still providing protection upstream of the colon and to the gut microbiome. SYN-007 is designed for patients who have been administered SYN-004 (ribaxamase) in combination with intravenous beta-lactam antibiotics and who are then transferred to an oral beta-lactam antibiotic, thereby extending gut microbiome protection from antibiotic-mediated dysbiosis. Data from a recent canine study completed during the second half of 2017 demonstrated that, when co-administered with oral amoxicillin, oral SYN-007 did not interfere with amoxicillin absorption and did demonstrate protection of the gut microbiome. The data from this canine study were presented during recent microbiome conferences in Q4 2017 and Q1 2018. A second canine study was completed during Q2 2018 in which oral SYN-007 was co-administered with oral amoxicillin and oral Augmentin. Again, SYN-007 did not interfere with systemic absorption of the antibiotics but did diminish the microbiome damage associated with these antibiotics.

***SYN-020 — Oral Intestinal Alkaline Phosphatase***

SYN-020 is in the preclinical development stage. SYN-020 is being developed as a modified-release oral dosage form of intestinal alkaline phosphatase (IAP). IAP is an endogenous enzyme expressed in the upper GI tract that functions as a broadly acting phosphatase that generally serves to maintain GI homeostasis and promote commensal microbiota. In animal models, IAP is anti-inflammatory, tightens the gut barrier to diminish “leaky gut,” and accelerates gut microbiome recovery from antibiotic-mediated dysbiosis. Published reports have demonstrated efficacy for several indications with oral IAP in many animal models including colitis, antibiotic-mediated dysbiosis, and metabolic syndrome as well as in a pilot human clinical trial with ulcerative colitis patients.

Despite its therapeutic potential, clinical application of an oral IAP product has been hindered by inefficient manufacturing with a high cost of goods. We have established manufacturing processes with the potential to yield product with a cost of goods which we believe to be suitable for commercialization. Recent advances include cell lines

that express up to 3 grams/L along with a chromatographic downstream process and potential tablet formulations. We are currently optimizing these technologies and pursuing animal efficacy studies. During 2Q 2018, we completed several preclinical animal studies that support the clinical utility of SYN-020 for multiple gastrointestinal disorders. We are currently evaluating and establishing strategies to advance IAP to and through clinical trials for several novel indications, which have unmet medical needs and span a range of market sizes. Importantly, we believe that with a small capital commitment, we can begin moving SYN-020 towards an IND.

**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. 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). Also, 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 for the use of anti-methanogenic compositions to treat IBS-C until 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 2017 Form 10-K.

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**Results of Operations**

***Three Months Ended June 30, 2018 and 2017***

*General and Administrative Expenses*

General and administrative expenses decreased by 13% to $1.4 million for the three months ended June 30, 2018, from $1.6 million for the three months ended June 30, 2017. This decrease is primarily the result of lower salary expense, stock compensation, and related benefits costs incurred during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017 due to the resignation of the Chief Executive Officer, along with the reduction of travel and consulting expense, offset by higher registration, investor relations and legal costs. The charge related to stock-based compensation expense was $264,000 for the three months ended June 30, 2018, compared to $539,000 the three months ended June 30, 2017.

*Research and Development Expenses*

Research and development expenses decreased by 25% to $3.6 million for the three months ended June 30, 2018, from $4.8 million for the three months ended June 30, 2017. This decrease is primarily the result of lower SYN-004 (ribaxamase) and SYN-010 program costs for the three months ended June 30, 2018 since no clinical trials were ongoing during the quarter. The research and development costs incurred during the quarter were primarily related to planning for future Phase 3 (SYN-004) and Phase 2b/3(SYN-010) clinical programs as we seek to secure the financial resources necessary for the completion of these clinical trials. The charge related to stock-based compensation expense was $293,000 for the three months ended June 30, 2018, compared to $331,000 for the three months ended June 30, 2017.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the three months ended June 30, 2018 and 2017. 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, 2018 | June 30, 2017 |
|---|---|---|
| Ribaxamase | $ 130 | $ 500 |

| | | |
|---|---|---|
| SYN-010 | 145 | 520 |
| SYN-005 | 1 | 6 |
| Total direct costs | 276 | 1,026 |
| Total indirect costs | 3,296 | 3,805 |
| Total Research and Development | $ 3,572 | $ 4,831 |

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*Other Income/Expense*

Other income was $789,000 for the three months ended June 30, 2018, compared to other income of $2.2 million for the three months ended June 30, 2017. Other income for the three months ended June 30, 2018 is primarily 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 from the prior quarter.

*Net Loss Attributable to Common Stockholders*

Our net loss attributable to common stockholders was $4.3 million, or $0.03 per basic and dilutive common share for both the three months ended June 30, 2018 and 2017.

***Six Months Ended June 30, 2018 and 2017***

*General and Administrative Expenses*

General and administrative expenses decreased to $3.1 million for the six months ended June 30, 2018, from $3.7 million for the six months ended June 30, 2017. This decrease of 16% is primarily the result of lower salary expense, stock compensation, and related benefits costs incurred during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017 due to the resignation of the Chief Executive Officer, along with the reduction of travel and consulting expense, offset by higher registration, investor relations and legal costs. The charge relating to stock-based compensation expense was $614,000 for the six months ended June 30, 2018, compared to $1.2 million for the six months ended June 30, 2017.

*Research and Development Expenses*

Research and development expenses decreased to $6.9 million for the six months ended June 30, 2018, from $10.9 million for the six months ended June 30, 2017. This decrease of 36% is primarily the result of lower SYN-004 (ribaxamase) and SYN-010 program costs for the six months ended June 30, 2018 since no clinical trials were ongoing during the six months ended June 30, 2018. The research and development costs incurred during the six months ended June 30, 2018 were primarily related to planning for future Phase 3 (SYN-004) and Phase

2b/3(SYN-010) clinical programs as we seek to secure the financial resources necessary for the completion of these clinical trials. Research and development expenses also include a charge relating to stock-based compensation expense of $619,000 for the six months ended June 30, 2018, compared to $769,000 for the six months ended June 30, 2017.

The following table sets forth our research and development expenses directly related to our therapeutic areas for the six months ended June 30, 2018 and 2017. 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, 2018 | June 30, 2017 |
|---|---|---|
| SYN-010 | $ 229 | $ 2,370 |
| SYN-004 (ribaxamase) | 225 | 1,132 |
| SYN-005 | (2) | 21 |
| Other therapeutic areas | - | (1) |
| Total direct costs | 452 | 3,522 |
| Total indirect costs | 6,490 | 7,369 |
| Total Research and Development Expenses | $ 6,942 | $ 10,891 |

*Other Income*

Other income was $3.5 million for the six months ended June 30, 2018, compared to other expense of $7.3 million for the six months ended June 30, 2017. Other income for the six months ended June 30, 2018 is primarily due to non-cash income of $3.4 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 from December 31, 2017.

*Net Loss Attributable to Common Stockholders*

Our net loss attributable to common stockholders was $6.5 million, or $0.05 per basic and dilutive common share for the six months ended June 30, 2018, compared to a net loss of $7.4 million, or $0.06 per basic and dilutive common share for the six months ended June 30, 2017.

**Liquidity and Capital Resources**

With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. To date, we have financed our operations primarily through public and private sales of our common stock and a private placement of our preferred stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of $200.8 million as of June 30, 2018 and expect to continue to incur losses in the future. With the exception of the quarter ended June 30, 2010, we have incurred negative cash flow from operations since our inception. 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, our clinical trials and our research and discovery efforts.

Our cash and cash equivalents totaled $7.1 million as of June 30, 2018, a decrease of $10.0 million from December 31, 2017. During the six months ended June 30, 2018, the primary use of cash was for working capital requirements and operating activities which resulted in a net loss of $6.5 million for the six months ended June 30, 2018.

The B. Riley FBR Sales Agreement enables us to offer and sell shares of our common stock, with aggregate sales of up to $40.0 million (subject to certain SEC offering limitations), from time to time through B. Riley FBR Capital Markets & Co. as our 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 Capital Markets & Co. is entitled to receive a commission rate of up to 3.0% of gross sales in connection with the sale of our common stock sold on our behalf. For the three and six months ending June 30, 2018, the Company sold through the FBR Sales Agreement an aggregate of 1.7 million shares of the Company’s common stock and received net proceeds of approximately $400,000. For the three and six months ending June 30, 2017, the Company sold through the FBR Sales Agreement an aggregate of 9.8 million and 10.1 million shares of the Company’s common stock, and received net proceeds of approximately $5.6 million and $5.9 million, respectively. Subsequent to June 30, 2018, the Company has sold approximately 2.7 million shares of the Company’s common stock, and received net proceeds of approximately $605,000.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 B. Riley 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 when needed, we will be unable to carry out our business plan and we will be forced to delay the initiation of our planned clinical trials until such time as we obtain adequate financing. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

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, our clinical trials and our research and discovery efforts. Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term or long-term expected plans, including initiation or completion of our planned Phase 2b/3 and Phase 3 clinical trials. Our notes to the condensed consolidated financial statements

contain an explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding to achieve our current business plan, obtain the required regulatory approvals for our product candidates or complete additional corporate partnering or acquisition transactions in order to commercialize such product candidates once regulatory approval is received.

Our continued operations as currently planned will primarily depend on our ability to raise additional capital from various sources, including equity (the B. Riley FBR Sales Agreement as well as other equity sources) and debt financings, as well as license fees and other funding received from potential corporate partners, joint ventures and grant funding. Although we have been awarded a contract by the CDC's Broad Agency Announcement (BAA) 2016-N-17812, the amount of the award will not be sufficient to enable us to complete our clinical trials as planned and therefore we will be required to obtain additional capital. Such additional funds may not become available on acceptable terms or at all and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurance that any additional capital that we are able to obtain will be sufficient to meet our needs.

*Current and Future Financing Needs*

Based on our current plans, despite the $12 million of proceeds we received from the sale of the Series A Preferred Stock in September 2017, our cash and cash equivalents will not be sufficient to enable us to meet our financing needs required to commence or complete our anticipated clinical trial and other expected plans. Although we continue to prepare for our clinical trials, our plan to initiate the planned clinical trials is subject to our successful pursuit of opportunities that will allow us to establish the clinical infrastructure and financial resources necessary to successfully initiate and make significant progress towards completion of this plan. Therefore, we do not intend to commence any currently planned trials until we are confident that we have funding necessary to fund a significant portion of the trials. In order to continue the development of our current product candidates as currently planned, including commencing our planned Phase 2b/3 and Phase 3 clinical trials, and to continue to fund operations at the current cash expenditure levels, we are required to obtain additional funding, although we do not currently have commitments from any third parties to provide us with capital. Potential sources of financing that we are pursuing include strategic relationships, public or private sales of our equity (including through the B. Riley FBR Sales Agreement) or debt and other sources. We cannot assure that we will meet the requirements for use of the B. Riley FBR Sales Agreement or our registration statement on Form S-3 (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 B. Riley FBR Sales Agreement due to the market value of our common stock held by non-affiliates) or that additional funding will be available on favorable terms, or at all. If we fail to obtain additional funding in the next few months, we will be forced to delay the initiation of our planned clinical trials until such time as we obtain adequate financing or redesign our currently planned clinical trial and, even after obtaining financing we may have a delay due to long manufacturing lead times. If we fail to obtain additional funding otherwise in the future when needed, we may not be able to execute our business plan as planned and we may be forced to cease certain development activities until funding is received, including manufacturing activities, and our business will suffer, which would have a material adverse effect on our financial position, results of operations and cash flows.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements and amount of funding received from partners and collaborators;

- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;

- our ability to achieve our milestones under licensing arrangements;

- the costs associated with manufacturing-related services to produce material for use in our clinical trials;

- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

- the costs and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares (including through the B. Riley FBR Sales Agreement, if we meet the conditions for sale thereunder) or debt and other sources. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all.

*NYSE American Noncompliance Notice and Compliance Plan*

Our common stock is listed on the NYSE American. The NYSE American's listing standards generally mandate that we meet certain requirements relating to stockholders' equity, market capitalization, aggregate market value of publicly held shares and distribution requirements. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of $6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Exchange Company Guide. The NYSE American Exchange Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer with total value of market capitalization of at least $50.0 million and 1,100,000 shares publicly held, a market value of publicly held shares of at least $15.0 million and 300 round lot shareholders. During the first six months of 2018, our common stock experienced a sustained a period of trading below a price of $0.39, causing our market capitalization to fall below the $50 million requirement needed to maintain compliance with Section 1003(iii) of the NYSE American Company Guide. If our common stock falls below $0.20 per share on a 30-trading-day average it will become subject to the continued listing evaluation and follow-up procedures set forth in Section 1009 of the NYSE American Company Guide which could, among other things, result in initiation of immediate delisting procedures. In the event that we were to fail to meet the requirements of NYSE American per share price requirement or stockholders equity requirement and we could not timely cure such deficiency, our listing could become subject to NYSE American continued listing evaluation and follow-up procedures, which could result in delisting procedures. Based on the recent low stock price on July 28, 2018, our Board of Directors approved a (1) one for 35 (thirty- five) proportionate reverse stock split of our authorized number of shares of common stock and our outstanding number of shares of common stock that we expect to effect on August 10, 2018. However, there can be no assurance that the reverse stock split will result in a sustained higher stock price that will allow us to meet the NYSE American stock price listing requirements or that the reverse stock split will not

inhibit our ability to seek equity financing as a remedy to regain compliance with NYSE American stockholders' equity requirements.

On March 7, 2018, we announced that we received written communication from NYSE American LLC (The "NYSE American") stating the we were no longer in compliance with certain continued listing standards as set forth in the NYSE American Company Guide. Specifically, based on our 2017 Form 10-K, we are below compliance with Part 10, Section 1003(iii) of the NYSE American Company Guide since we reported stockholders' deficit of $1.5 million and net losses in five of our most recent fiscal years as of December 31, 2017. On April 3, 2018, we submitted a plan of compliance to the NYSE American outlining our plan to regain compliance with the continued listing standards as set forth in Part 10, Section 1003(iii) of the NYSE American Company Guide by September 2, 2018, the conclusion of the compliance plan period. Should our common stock incur and maintain a sustained increase in price above $0.39, our market capitalization will surpass the $50 million requirement to regain compliance with Part 10, Section 1003(iii) of the NYSE American Company Guide. The NYSE American notification does not affect our business operations or the listing of our shares on the NYSE American, and does not represent any change or amendment to the our consolidated financial statements or to our 2017 Form 10-K. If our common stock is delisted from the NYSE American due to our failure to regain compliance with the listing standards by the end of the compliance period or for any other reason, and the market value of our shares of common stock held by non-affiliates remain below $15 million, we will likely no longer be eligible to sell common stock pursuant to the B. Riley FBR Sales Agreement or otherwise utilize our shelf registration statement. On May 18, 2018 we received notification from the NYSE American that NYSE Regulation has reviewed our plan of compliance and determined to accept the plan and grant a plan period through September 2, 2019. NYSE Regulation staff will review the company periodically for compliance with the initiatives outlined in the plan. If we are not in compliance with the continued listing standards by September 2, 2019 or if we do not make progress consistent with the plan during the plan period, NYSE Regulation staff will initiate delisting proceedings as appropriate.

**Off-Balance Sheet Arrangements**

During the six months ended June 30, 2018, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

**Contractual Obligations**

There have been no material changes to our contractual obligations during the period covered by this report from those disclosed in our 2017 Form 10-K.

**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, 2018, 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 Interim 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, 2018, the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that based on such evaluation, the Company’s disclosure controls and procedures are effective as of June 30, 2018 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 six months ended June 30, 2018 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 1, Item 1A, “Risk Factors,” contained in our 2017 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2017 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 six months ended June 30, 2018, our operating activities used net cash of approximately $10.4 million and as of June 30, 2018 our cash and cash equivalents were $7.1 million. With the exception of the three months ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. As of June 30, 2018, our accumulated deficit totaled approximately $200.8 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have generated very minimal revenues. We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the

foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any.

We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. Based on our current plans, our cash and cash equivalents will not be sufficient to enable us to meet our near term expected plans. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders. 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. Although we continued preparation for our clinical trials, our planned Phase 2b/3 clinical trials have been delayed until such time as we obtain adequate financing. A failure otherwise to raise additional funds when needed in the future 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 may be 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.

**RISKS RELATING TO OUR STOCK**

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

Our common stock is listed on the NYSE American. The NYSE American's listing standards generally mandate that we meet certain requirements relating to stockholders' equity, stock price, market capitalization, aggregate market value of publicly held shares and distribution requirements. We cannot assure you that we will be able to maintain the continued listing standards of the NYSE American. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of $6.0 million if an issuer has sustained losses from continuing operations and/or net losses in its five most recent years, as outlined in the NYSE American Exchange Company Guide. At June 30, 2018, we had stockholders' deficit of $208.8 million. The NYSE American Exchange Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer with total value of market capitalization of at least $50.0 million and 1,100,000 shares publicly held, a market value of publicly held shares of at least $15.0 million and 400 round lot shareholders. Although we have more than 1,100,000 shares publicly held, a market value of publicly held shares of at least $15.0 million and 400 round lot shareholders, our stock price is volatile and, during the first two quarters of 2018, the price of our common stock experienced a sustained decrease resulting in a period where our market capitalization fell below $50.0 million. Our market capitalization is currently below $50.0 million.

If our common stock falls below $0.20 per share on a 30-trading-day average it will become subject to the continued listing evaluation and follow-up procedures set forth in Section 1009 of the NYSE American Company Guide which could, among other things, result in initiation of immediate delisting procedures. In the event that we were to fail to meet the requirements of NYSE American per share price requirement or stockholders equity requirement and we could not timely cure such deficiency, our listing could become subject to NYSE American continued listing evaluation and follow-up procedures, which could result in delisting procedures. Based on the recent low stock price on July 28, 2018, our Board of Directors approved a (1) one for 35 (thirty- five) proportionate reverse stock split of our authorized number of shares of common stock and our outstanding number of shares of common stock that we expect to effect on August 10, 2018. However, there can be no assurance that the reverse stock split will result in a sustained higher stock price that will allow us to meet the NYSE American stock price listing requirements or that the reverse stock split will not inhibit our ability to seek equity financing as a remedy to regain compliance with NYSE American stockholders' equity requirements.

On March 7, 2018, we announced that we received written communication from the NYSE American stating the we were no longer in compliance with certain continued listing standards as set forth in the NYSE American Company Guide. Specifically, based on our annual report on Form 10-K for the year ended December 31, 2017, and filed with the SEC on February 22, 2018, we are below compliance with Part 10, Section 1003(iii) of the NYSE American Company Guide since we reported a stockholders' deficit equity of $1.5 million and net losses in five of our most

recent fiscal years as of December 31, 2017. On April 3, 2018, we submitted a plan of compliance to the NYSE American outlining our plan to regain compliance with certain continued listing standards as set forth in Part 10, Section 1003(iii) of the NYSE American Company Guide by September 2, 2018, the conclusion of the compliance plan period. There can be no assurance that we can regain compliance with the listing standard of the NYSE American, or that the NYSE American will continue to list our common stock if we regain compliance, or if we continue to fail to maintain the minimum stockholders' equity. In addition, in the future we may not be able to maintain such minimum stockholders' equity and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE American. If we are delisted from the NYSE American then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. If our common stock is delisted from the NYSE American due to our failure to regain compliance with the listing standards by the end of the compliance period or for any other reason, and the market value of our shares of common stock held by non-affiliates remain below $15 million, we will likely no longer be eligible to sell common stock pursuant to the B. Riley FBR Sales Agreement or otherwise utilize our shelf registration statement. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE American could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. On May 18, 2018 we received notification from the NYSE American that NYSE Regulation has reviewed our plan of compliance and determined to accept the plan and grant a plan period through September 2, 2019. NYSE Regulation staff will review our company periodically for compliance with the initiatives outlined in the plan. If we are not in compliance with the continued listing standards by September 2, 2019 or if we do not make progress consistent with the plan during the plan period, NYSE Regulation staff will initiate delisting proceeding as appropriate.

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

We did not sell any equity securities during the quarter ended June 30, 2018 in transactions that were not registered under the Securities Act, other than as previously disclosed in our filings with the SEC and as discussed below:

**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
Interim Chief Executive Officer, Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
Date: August 8, 2018

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EXHIBIT INDEX

| | |
|---|---|
| 1.1 | Amendment No. 1 to At-The-Market Issuance Sales Agreement dated May 7, 2018 between Synthetic Biologics, Inc. and B. Riley FBR, Inc. (Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed May 7, 2018 (File No. 001-12584)). |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) * |
| 32.1 | Certification of Principal Executive 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.