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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED: June 30, 2018

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

For the transition period from to

Commission File Number: 001-35268

SYNERGY PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**33-0505269**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

420 Lexington Avenue, Suite 2012, New York, New York 10170
(Address of principal executive offices) (Zip Code)

(212) 297-0020
(Registrant's telephone number)

(Former Name, Former Address and Former Fiscal Year, if changed since last report)

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

Indicate by check mark whether the Registrant has submitted electronically 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	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 ☒

The number of the registrant's shares of common stock outstanding was 247,988,996 as of August 8, 2018.

SYNERGY PHARMACEUTICALS INC.

FORM 10-Q

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for Synergy Pharmaceuticals Inc. may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as “may,” “will,” “expect,” “plan,” “intend,” “anticipate,” believe,” “estimate” and “continue” or similar words. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. We do not assume any obligation to update forward-looking statements as circumstances change and thus you should not unduly rely on these statements, which speak only as of the date of this Quarterly Report on Form 10-Q.

We believe that it is important to communicate future expectations to readers. However, there may be events in the future that we are not able to accurately predict or control. Risk factors that may cause such differences between predicted and actual results include, but are not limited to, those discussed in our Form 10-K for the year ended December 31, 2017 filed on March 1, 2018 and other periodic reports filed with the Securities and Exchange Commission.

These risk factors include the uncertainties associated with product development, the risk that we will not obtain approval to market our products in development, fluctuations in our operating results and financial condition, the volatility of the market price of our common stock, our ability to successfully commercialize pharmaceutical products in a timely manner, the impact of competition, the effect of any manufacturing or quality control problems, our ability to manage our growth, the reduction or loss of business with any significant customer, substantial revenues derived from sale of one product, the restrictions imposed by our credit facility, our level of indebtedness and liabilities and the potential impact on cash flow available for operations, the availability of additional funds in the future, the uncertainty of patent litigation and other legal proceedings, the difficulty of predicting FDA filings and approvals, consumer acceptance and demand for our pharmaceutical products, the impact of market perceptions of us and the safety and quality of our products, changes to FDA approval requirements, our ability to successfully conduct clinical trials, our reliance on third parties to conduct clinical trials and testing, impact of illegal distribution and sale by third parties of counterfeits or stolen products, the availability of raw materials and impact of interruptions in our supply chain, our policies regarding returns, rebates, allowances and chargebacks, the effect of current economic conditions on our industry, business, results of operations and financial condition, our ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, our ability to protect our intellectual property, exposure to product liability claims, changes in tax regulations, uncertainties involved in the preparation of our financial statements, our ability to maintain an effective system of internal control over financial reporting, the effect of terrorist attacks on our business, expansion of social media platforms, the risks associated with dependence upon key personnel and the need for additional financing.

PART I—FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share amounts)

	June 30, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 61,233	$ 136,986
Accounts receivable	8,511	6,491
Inventories	17,609	17,214
Prepaid expenses and other current assets	7,772	4,469
Total Current Assets	95,125	165,160
Property and equipment, net	1,168	1,134
Security deposits	312	312
Total Assets	$ 96,605	$ 166,606
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 12,912	$ 23,256
Accrued expenses	15,453	14,658
Interest payable on senior convertible notes	233	233
Deferred revenues	5,000	—
Total Current Liabilities	33,598	38,147
Senior convertible notes, net	17,657	17,302
Long term debt, net	100,327	98,660
Derivative financial instruments, at estimated fair value-warrants	9,334	17,582
Other long-term liabilities	379	433
Total Liabilities	161,295	172,124
Commitments and contingencies		
Stockholders' Deficit		
Preferred stock, authorized 20,000,000 shares and none outstanding, at June 30, 2018 and December 31, 2017	—	—
Common stock, par value of $.0001, 400,000,000 shares authorized at June 30, 2018 and December 31, 2017. Issued and outstanding 247,863,222 shares and 246,660,367 shares at June 30, 2018 and December 31, 2017, respectively.	25	25
Additional paid-in capital	808,410	801,787
Accumulated deficit	(873,125)	(807,330)
Total Stockholders' Deficit	(64,690)	(5,518)
Total Liabilities and Stockholders' Deficit	$ 96,605	$ 166,606

The accompanying notes are an integral part of these condensed consolidated financial statements.

SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net sales	$ 12,254	$ 2,314	$ 20,840	$ 2,412
Cost of goods sold	3,885	1,643	7,589	3,279
Gross profit	8,369	671	13,251	(867)
Costs and expenses:				
Research and development	2,844	22,069	6,236	40,470
Selling, general and administrative	34,615	52,185	74,760	94,973
Total operating expenses	37,459	74,254	80,996	135,443
Loss from operations	(29,090)	(73,583)	(67,745)	(136,310)
Other Income/(Expense)				
Interest expense, net	(3,205)	(345)	(6,328)	(1,135)
Debt conversion expense	—	—	—	(1,209)
State R&D tax credits	—	—	30	—
Change in fair value of derivative instruments-warrants	2,604	39	8,248	161
Total other income (expense)	(601)	(306)	1,950	(2,183)
Net loss	$ (29,691)	$ (73,889)	$ (65,795)	$ (138,493)
Weighted Average Common Shares Outstanding				
Basic and Diluted	246,990,080	224,948,622	246,827,974	220,269,223
Net Loss per Common Share, Basic and Diluted				
Net Loss per Common Share, Basic and Diluted	$ (0.12)	$ (0.33)	$ (0.27)	$ (0.63)

The accompanying notes are an integral part of these condensed consolidated financial statements.

SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share amounts)

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated	Total Stockholders' Deficit
Balance, December 31, 2017	246,660,367	$ 25	$ 801,787	$ (807,330)	$ (5,518)
Common stock issued in connection with exercise of stock options	1,202,855	—	429	—	429
Stock based compensation expense	—	—	6,194	—	6,194
Net loss for the period	—	—	—	(65,795)	(65,795)
Balance, June 30, 2018	247,863,222	$ 25	$ 808,410	$ (873,125)	$ (64,690)

The accompanying notes are an integral part of these condensed consolidated financial statements.

SYNERGY PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Cash Flows From Operating Activities:		
Net loss	$ (65,795)	$ (138,493)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	106	80
Amortization of deferred debt costs and debt discount	805	785
Accretion of back-end facility fee	330	—
Stock-based compensation expense	6,194	16,195
Interest expense — Payment-in-kind (PIK)	3,386	—
Change in fair value of derivative instruments—warrants	(8,248)	(161)
Debt conversion expense	—	1,209
Changes in operating assets and liabilities:		
Accounts receivable	(2,020)	(1,782)
Inventories	(395)	(6,213)
Deferred revenues, net	5,000	1,498
Security deposit	—	(64)
Accounts payable and accrued expenses	(9,549)	13,714
Prepaid expenses and other current assets	(3,303)	(7,479)
Accrued interest expense on senior convertible notes	—	(61)
Total Adjustments	(7,694)	17,721
Net Cash used in Operating Activities	(73,489)	(120,772)
Cash Flows From Investing Activities:		
Additions to property and equipment	(193)	(15)
Net Cash used in Investing Activities	(193)	(15)
Cash Flows From Financing Activities:		
Proceeds of sale of common stock, net of issuance costs	—	121,604
Payment for deferred financing costs	(2,500)	(1,591)
Proceeds from exercise of stock options	429	347
Net Cash (used in) provided by Financing Activities	(2,071)	120,360
Net decrease in cash and cash equivalents	(75,753)	(427)
Cash and cash equivalents at beginning of period	136,986	82,387
Cash and cash equivalents at end of period	$ 61,233	$ 81,960
Supplementary disclosure of cash flow information:		
Cash paid for interest on senior convertible notes	$ 698	$ 698
Cash paid for interest on long term debt	$ 1,603	$ —
Cash paid for taxes	$ —	$ 44
Supplementary disclosure of non-cash investing and financing activities:		
Conversion of senior convertible notes to Synergy Common Stock	$ —	$ 4,912

The accompanying notes are an integral part of these condensed consolidated financial statements.

SYNERGY PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Business Overview

Synergy Pharmaceuticals Inc. ("the Company" or "Synergy") is a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. Synergy has pioneered discovery, research and development efforts around analogs of uroguanylin, a naturally occurring and endogenous human GI peptide, for the treatment of GI diseases and disorders. Synergy discovered and owns 100% worldwide rights to its proprietary uroguanylin based GI platform which includes one commercial product, plecanatide, and one development stage compound, dolcanatide.

The Company's first and only commercial product, plecanatide, is available and being marketed in the United States (U.S.), under the trademark name TRULANCE®, for the treatment of adults with chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). On February 27, 2018 Synergy entered into a definitive licensing agreement with Cipher Pharmaceuticals under which the Company granted Cipher the exclusive right to develop, market, distribute and sell TRULANCE in Canada. Under the terms of the licensing agreement, Synergy received an upfront payment of $5.0 million and is eligible for an additional milestone payment upon regulatory approval in Canada, as well as royalties from product sales in Canada. Cipher expects to file a New Drug Submission with Health Canada in the second half of 2018. Synergy is continuing to evaluate other potential U.S. and ex-U.S. partnership opportunities for TRULANCE.

Dolcanatide is the Company's development stage compound that has demonstrated proof-of-concept in treating patients with opioid induced constipation (OIC) and ulcerative colitis. Synergy is considering OIC as a potential life-cycle growth opportunity for TRULANCE and is currently exploring potential business development opportunities to further advance dolcanatide development in ulcerative colitis. In April 2018, the Company initiated a partnership with the National Cancer Institute (NCI) on a NCI-funded clinical biomarker study designed to evaluate the potential for dolcanatide to prevent colorectal cancer.

Net cash used in operating activities was approximately $73.5 million for the six months ended June 30, 2018. As of June 30, 2018, Synergy had approximately $61.2 million of cash and cash equivalents. During the six months ended June 30, 2018, Synergy incurred losses from operations of approximately $67.7 million. As of June 30, 2018, Synergy had working capital of approximately $61.5 million.

Recent Developments

On September 1, 2017, Synergy entered into a senior secured term loan (the "Term Loan") of up to $300 million with CRG Servicing LLC, as administrative and collateral agent, and the lenders and guarantors party thereto. The Term Loan is available for working capital and general corporate purposes. The Company borrowed $100 million at the time of closing.

The Term Loan has a maturity date of June 30, 2025, unless prepaid earlier. The Term Loan bears interest at a rate equal to 9.5% per annum, with quarterly, interest-only payments until June 30, 2022, subject to extension through the maturity date upon the Company's satisfaction of certain conditions. At the Company's option, until June 30, 2019, a portion of the interest payments may be paid in kind, and thereby added to the principal. Following, the interest-only period, the Term Loans will amortize in equal quarterly installments unless entirely payable at maturity.

On November 13, 2017, Synergy entered into an underwriting agreement with Jefferies LLC, as representative of the several underwriters, to issue and sell 21,705,426 shares of common stock of the Company together with accompanying warrants ("Warrants") to purchase an aggregate of 21,705,426 shares of Common Stock in an underwritten offering pursuant to a Registration Statement on Form S-3ASR and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission (the "Offering"). The offering price was $2.58 per share of Common Stock and accompanying Warrant. The net proceeds from the Offering were approximately $52.2 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

In February 2018, Synergy amended the Term Loan agreement. The amended Term Loan provides for future borrowings of $25 million, $25 million and $50 million on or before June 30, 2018, September 30, 2018 and December 31, 2018, respectively. Additionally, the total amount of the commitment was reduced from $300 million to $200 million (excluding PIK loans) and the Minimum Market Capitalization covenant of $300 million was revised to be 200% of the outstanding principal amount of the Term Loan (excluding PIK loans).

In June 2018, Synergy further amended the Term Loan agreement to extend the draw down date of the second borrowing from June 30, 2018 to prior to August 29, 2018.

2. Basis of Presentation, Accounting Policies and Going Concern

These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiary Synergy Advanced Pharmaceuticals, Inc. These unaudited condensed consolidated financial statements have been prepared following the rules and regulations of the United States Securities and Exchange Commission ("SEC") and accounting principles generally accepted in the United States ("U.S. GAAP") for interim reporting, which permit reduced disclosures for interim reporting. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments necessary to present fairly Synergy's interim financial information. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2017 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 1, 2018. All intercompany balances and transactions have been eliminated.

Synergy's consolidated financial statements as of December 31, 2017 and its unaudited condensed consolidated financial statements as of June 30, 2018 have been prepared under the assumption that the Company will continue as a going concern for the next twelve months. The Company has incurred recurring losses from operations and expects to continue to have losses in the future. In addition, the Company's debt agreement is subject to covenants that could restrict the availability of additional loans and accelerate the repayment of that debt if breached. These factors individually and collectively raise substantial doubt about the Company's ability to continue as a going concern. Synergy's independent registered public accounting firm has issued a report as of December 31, 2017 that includes an explanatory paragraph referring to such conditions and expressing substantial doubt in the Company's ability to continue as a going concern.

Synergy's ability to continue as a going concern is dependent upon its plans to generate significant revenue, attain further operating efficiencies, reduce expenditures, and if deemed necessary obtain additional equity or debt financing, which may not be available on acceptable terms or at all. To the extent that Synergy may need to raise additional funds by issuing equity securities, Synergy's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Synergy's ability to conduct business. If Synergy is unable to raise additional capital when required or on acceptable terms, Synergy may have to (i) significantly scale back our commercialization efforts; (ii) seek commercial partners for our products on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights, on unfavorable terms, to technologies, product candidates or products that Synergy would otherwise seek to develop or commercialize itself. Synergy's consolidated financial statements as of December 31, 2017 and its unaudited condensed consolidated financial statements as of and for the period ended June 30, 2018 do not include any adjustments that might result from the unfavorable outcome of this uncertainty.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP and the rules and regulations of the SEC requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

Reclassifications

Certain prior period amounts were reclassified to conform to the current period presentation and additional information is disclosed in the notes if material.

Accounts Receivable

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not specifically reviewed. The Company's receivables primarily relate to amounts due from 3rd party customers for the sale of TRULANCE. The Company believes that credit risks associated with these customers are not significant. To date, the Company has not had any write-offs of bad debt, and the Company did not have an allowance for doubtful accounts as of June 30, 2018. The adoption of the new revenue standard did not change the Company's historical accounting methods for our accounts receivable.

Inventories

Inventories consist of finished goods, work in process and raw materials and are stated at the lower of cost or net realizable value with cost determined under the first-in, first-out basis. Synergy capitalizes inventories manufactured in preparation for initiating sales of a product candidate when the related product candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales of the inventories. In determining whether or not to capitalize such inventories, Synergy evaluates, among other factors, information regarding the product candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales. In addition, Synergy evaluates risks associated with manufacturing the product candidate and the remaining shelf life of the inventories.

Costs associated with developmental products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred. There is a risk inherent in these judgments and any changes in these judgments may have a material impact on Synergy's financial results in future periods.

Revenue recognition

Adoption

The Company adopted ASC 606 *Revenue From Contracts With Customers* using the modified retrospective method as applied to customer contracts that were not completed as of January 1, 2018. As a result, financial information for reporting periods beginning after January 1, 2018 are reported under the new standard, while comparative financial information has not been adjusted and continues to be reported in accordance with the previous standard. There was no cumulative impact to adopting the new standard on the Company's financial statements.

Product Sales

Revenue from sale of TRULANCE is recognized upon transfer of control of promised goods to customers (typically upon delivery, which is also when transfer of title occurs) in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for those goods. The terms of a contract or historical business practice can give rise to variable consideration, including but not limited to: customer loyalty programs, trade discounts, fee for service agreements, sales returns and allowances, commercial and government rebates, and chargebacks. The transaction price will include estimates of variable consideration to the extent it is probable that a significant reversal of revenue recognized will not occur. Our estimates of variable consideration are probability weighted to derive an estimate of expected value and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of our anticipated performance and all information (historical, current and forecasted) that is reasonably available to us.

Arrangements with multiple-performance obligations

In February 2018, the Company entered into a licensing, development and commercialization agreement to out-license the sale of TRULANCE in Canada ("Cipher Agreement"). This agreement requires the Company to deliver (i) intellectual property rights or licenses and (ii) product supply. The underlying terms of the agreement provides for consideration to Synergy in the form of a non-refundable up-front license payment, milestone payment, and royalty payments. As of June 30, 2018, the Company had not satisfied any performance obligations under this agreement.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on their respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. For future royalties due under the contract the Company will utilize the sales and usage based royalty exception.

The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred for the related goods or services. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur.

Disaggregation of Revenue

As of June 30, 2018, all revenue recognized by the Company is from TRULANCE product sales in the United States. For the six months ended June 30, 2018, our three major customers accounted for an aggregate of 95% of our gross revenue.

Financing and payment

The Company's payment terms vary by the type of customer and the product or service offered. Payment is generally required in a term from 30 to 60 days from date of shipment or satisfaction of the performance obligation. In certain cases, the Company may require payment before the satisfaction of the performance obligation.

Practical expedients

The Company does not disclose the value of unsatisfied performance obligations for contracts with original expected lengths of one year or less.

Cost of Goods Sold

Cost of goods sold ("COGS") includes (i) direct cost of manufacturing and packaging drug product and (ii) technical operations overhead costs which are generally more fixed in nature, including salaries, benefits, consulting, stability testing and other services. Technical operations are responsible for planning, coordinating, and executing the Company's inventory production plan and ensuring that product quality satisfies FDA requirements. Costs incurred by the technical operations organization are recorded as expense in the period in which they are incurred. Certain direct costs associated with pre-commercial inventory, other than packaging, were expensed prior to receiving FDA approval. (See *Inventories* in Footnote 2 "Basis of Presentation, Accounting Policies and Going Concern").

3. Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02 "Leases (Topic 842)" ("ASU 2016-02"). The FASB issued ASU 2016-02 to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under ASU 2016-02, a lessee will recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-to-use asset representing its right to use the underlying asset for the lease term. The amendments of this ASU are effective for reporting periods beginning after December 15, 2018, with early adoption permitted. An entity will be required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The adoption of ASU 2016-02 is not expected to have a material impact on our condensed consolidated financial statements and disclosures except at the time of adoption. At time of adoption the Company will recognize right of use assets and lease liabilities on the condensed consolidated balance sheet.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 was issued to address the complexity associated with applying generally accepted accounting principles (GAAP) for certain financial instruments with characteristics of liabilities and equity. The ASU, among other things, eliminates the need to consider the effects of down round features when analyzing convertible debt, warrants and other financing instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The amendments are effective for fiscal years beginning after December 15, 2018, and should be applied retrospectively. Early adoption is permitted, including adoption in an interim period. The Company does not expect the adoption of this standard to have an impact on its condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for nonemployee share-based payment transactions. The ASU will be effective for the Company for fiscal years beginning after December 15, 2018, and early adoption is permitted. The Company does not expect that the adoption of this ASU will have a significant impact on its condensed consolidated financial statements.

4. Cash and cash equivalents

All highly liquid investments with maturities of three months or less at the date of purchase are classified as cash equivalents. As of June 30, 2018 and December 31, 2017, the amount of cash and cash equivalents was $61.2 million and $137.0 million, respectively and consists of checking accounts and short-term U.S. Treasury money market mutual funds. Checking accounts are held at U.S. commercial banks, and balances were in excess of the FDIC insurance limit.

5. Inventories

Inventories as of June 30, 2018 and December 31, 2017 consisted of the following:

($ in thousands)	June 30, 2018	December 31, 2017
Raw materials	$ 9,127	$ 5,754
Work-in-process	3,740	7,732
Finished goods	4,742	3,728
Inventories	$ 17,609	$ 17,214

6. Debt

Senior Convertible Notes, net

On November 3, 2014, Synergy closed a private offering of $200.0 million aggregate principal amount of 7.50% Convertible Senior Notes due 2019, (the "Notes"), including the full exercise of the over-allotment option granted to the initial purchasers to purchase an additional $25.0 million aggregate principal amount of the Notes, interest payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2015. The net proceeds from the offering were $187.3 million after deducting the initial purchasers' discounts and offering expenses. The Notes will mature on November 1, 2019, unless earlier purchased or converted. The Notes are convertible, at any time, into shares of Synergy's common stock at an initial conversion rate of 321.5434 shares per $1,000 principal amount of notes, which is equivalent to the original conversion price of $3.11 per share.

Initial purchaser's discounts and offering expenses associated with the sale of the Notes of $12.7 million have been deferred and are being recognized as expense over the expected term of the Notes, calculated using the effective interest rate method. The remaining deferred debt costs have been presented as a reduction of the Notes in accordance with the newly adopted ASU No. 2015-3 "*Simplifying the Presentation of Debt Issuance Costs"*.

On February 28, 2017, Synergy received consents from certain holders of its Notes to enter into a Supplemental Indenture which eliminates certain restrictive covenants from the Indenture related to the Notes. The restrictive covenants eliminated from the Indenture are Limitation on Indebtedness, Future Financing Rights for Certain Investors and Licensing Limitations. On February 28, 2017, Synergy entered into the Supplemental Indenture with Wells Fargo, N.A., as trustee and paid an aggregate of approximately $1.6 million to such holders for the consent. These fees associated with the debt modification were accounted for under Accounting Standards Codification ("ASC") 470-50 and amortized using the effective interest method over the remaining term of the debt.

In March 2017, Synergy exchanged approximately $4.9 million aggregate principal amount of the Notes for approximately 1.8 million shares of its common stock, with approximately 1.6 million shares representing the conversion price of $3.11 pursuant to the existing terms of the Notes. The Company recognized a debt conversion expense of approximately $1.2 million representing 0.2 million shares for the quarter ended March 31, 2017. As of June 30, 2018, approximately $18.6 million of the Notes remain outstanding.

A summary of quarterly activity and balances associated with the Notes and related deferred debt costs is presented below:

($ in thousands)	Notes Balance	Deferred Debt Costs	Notes, net of Deferred Debt Costs
Balance, December 31, 2017	$ 18,603	$ 1,301	$ 17,302
Less: amortization for the three months ended March 31, 2018		(178)	178
Balance, March 31, 2018	18,603	1,123	17,480
Less: amortization for the three months ended June 30, 2018		(177)	177
Balance, June 30, 2018	$ 18,603	$ 946	$ 17,657

Long term debt, net

On September 1, 2017, Synergy Pharmaceuticals Inc. entered into a senior secured term loan of up to $300 million with CRG Servicing LLC, as administrative and collateral agent, and the lenders and guarantors party thereto (the "Term Loan"). The Term Loan is available for working capital and general corporate purposes. The Company borrowed $100 million at time of closing. In February 2018, the Company amended the Term Loan agreement. The amended Term Loan provides for future borrowings of $25 million, $25 million and $50 million on or before June 30, 2018, September 30, 2018 and December 31, 2018, respectively. Additionally, the total amount of the commitment was reduced from $300 million to $200 million (excluding PIK loans) and the Minimum Market Capitalization covenant of $300 million was revised to be 200% of the outstanding principal amount of the Term Loan (excluding PIK loans). In June 2018, Synergy further amended the Term Loan agreement to extend the draw down date of the second borrowing from June 30, 2018 to prior to August 29, 2018.

The Term Loan has a maturity date of June 30, 2025, unless earlier prepaid. The Term Loan bears interest at a rate equal to 9.5% per annum, with quarterly, interest-only payments until June 30, 2022, subject to extension through the maturity date upon the Company's satisfaction of certain conditions. At the Company's option, until June 30, 2019, a portion of the interest payments may be paid in kind, and thereby added to the principal. Following, the interest-only period, the Term Loan will amortize in equal quarterly installments unless entirely payable at maturity.

The obligations under the Term Loan are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the Company and the Subsidiary Guarantors, except for certain customary excluded property, and (ii) all of the capital stock owned by the Company and Subsidiary Guarantors (limited, in the case of the stock of certain non-U.S. subsidiaries of the Company and certain U.S. subsidiaries substantially all of whose assets consist of equity interests in non-U.S. subsidiaries, to 65% of the capital stock of such subsidiaries, subject to certain exception). The obligations under the Term Loan are guaranteed by Synergy Advanced Pharmaceuticals, Inc. and each of the Company's future direct and indirect subsidiaries (other than certain subsidiaries whose guarantee would result in material adverse tax consequences, subject to certain exceptions).

The Term Loan contains customary affirmative covenants, including covenants regarding the payment of taxes and other obligations, maintenance of insurance, reporting requirements and compliance with applicable laws and regulations. Further, the Term Loan contains customary negative covenants limiting the ability of the Company and its subsidiaries, among other things, to incur future debt, grant liens, make investments, make acquisitions, make certain restricted payments and sell assets, subject to certain exceptions. In addition, the Term Loan requires the Company to comply with a minimum market capitalization covenant, maintain its status as a national exchange listed company, a daily minimum liquidity covenant and an annual revenue requirement based on the sales of TRULANCE.

The Term Loan may be prepaid by the Company at any time, subject to a prepayment premium of up to 40% of the principal amount, depending on the date of prepayment. Upon the occurrence of certain events relating to asset sales above a specified threshold or in the event of a change of control transaction, the Company may also be required to prepay all or a part of the outstanding principal and interest under the Term Loan in addition to the prepayment premium described above on the principal amount prepaid. Upon payment of the Term Loan at maturity or prepayment on any earlier date, a back-end facility fee will apply to the amounts paid or prepaid.

As of June 30, 2018, the Company was in compliance with all applicable covenants.

As of June 30, 2018, principal and PIK payments under the Term Loan were as follows:

Period Ending December 31,	Principal and PIK Loan Repayments ($ in thousands)
2018	$ —
2019	—
2020	—
2021	—
2022 and thereafter	100,000
	100,000
Add: Accretion of back-end facility fee	436
Add: PIK interest	6,598
	107,034
Less: Debt financing costs, net of amortization	(6,707)
Balance at June 30, 2018	$ 100,327

7. Accounting for Share-based Payments

Stock Options

ASC Topic 718 *"Compensation—Stock Compensation"* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. Synergy accounts for shares of common stock, stock options and warrants issued to employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received.

The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *"Equity -Based Payment to Non-Employees"* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either; a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly, the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the "2008 Plan") during the quarter ended September 30, 2008. Stock options granted under the 2008 Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. On June 8, 2015, Synergy amended its 2008 Plan and increased the number of shares of its common stock reserved for issuance under the Plan from 15,000,000 to 30,000,000.

Synergy adopted the 2017 Equity Incentive Plan (the "2017 Plan") during the quarter ended June 30, 2017. The number of shares of its common stock reserved for issuance under the 2017 Plan is 9,000,000.

In June 2017, the Company modified 2,159,500 stock options, which were previously granted as change of control options, to become immediately vested. The Company recorded a charge of $6.8 million during the three months ended June 30, 2017.

Stock-based compensation has been recognized in operating results as follows:

($ in thousands)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Included in research and development	$ 504	$ (80)	1,175	$ 1,793
Included in selling, general and administrative	2,924	13,378	5,212	14,402
Total stock-based compensation expense [1]	$ 3,428	$ 13,298	$ 6,387	$ 16,195

(1) Stock based compensation expense for the current year periods includes $193,000 recorded as a liability.

The unrecognized compensation cost related to non-vested stock options outstanding at June 30, 2018, net of expected forfeitures, was approximately $15.8 million to be recognized over a weighted-average remaining vesting period of approximately 1.07 years.

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the periods indicated.

	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Risk-free interest rate	2.33-2.85%	1.85%-2.24%
Dividend yield	—	—
Expected volatility	63%-66%	66%-73%
Expected term	6 years	6 years

A summary of stock option activity and of changes in stock options outstanding under the Plans is presented below:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value (in thousands)	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2017	29,868,291	$0.44-9.12	$ 3.83	$ 5,346	6.09 years
Granted	7,694,200	$1.56-2.40	$ 2.13	$ —	
Exercised [1]	(1,485,035)	$ 0.50	$ 0.50	$ 1,846	
Forfeited	(1,168,715)	$1.81-7.91	$ 3.94	$ —	
Balance outstanding, June 30, 2018	34,908,741	$0.44-9.12	$ 3.60	$ 1,229	6.61 years
Exercisable, at June 30, 2018	22,324,074	$0.44-9.12	$ 3.89	$ 1,201	5.24 years

(1) Options exercised includes 282,180 shares withheld for payment of exercise price and related taxes.

8. Commitments and Contingencies

In the normal course of business, Synergy is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, and tax matters. In accordance with FASB ASC Topic 450, Accounting for Contingencies ("ASC Topic 450"), Synergy records accruals for such loss contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Synergy, in accordance with this guidance, does not recognize

gain contingencies until realized. We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote and in Note 7, Commitments and contingencies, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2017.

Certain recent developments concerning our legal proceedings are discussed below:

Litigation

On February 8, 2018, a federal securities action, captioned *David Lee v. Synergy Pharmaceuticals Inc. et al*., was filed in the U.S. District Court for the Eastern District of New York. The complaint names Synergy and certain of its current directors and officers as defendants and seeks to recover on behalf of a putative class of purchasers of Synergy's common stock between September 5, 2017 and November 14, 2017. On February 14, 2018, a substantially identical lawsuit captioned *Eileen Countryman v. Synergy Pharmaceuticals Inc. et al*. was filed in the same court against the same defendants on behalf of an identical putative class. On March 2, 2018, a related federal securities action captioned *Wendell Rose v. Synergy Pharmaceuticals Inc. et al.* was filed in the same court. The *Rose* complaint names the same defendants as well as additional officers of the company and seeks to recover on behalf of a putative class of purchasers of Synergy's common stock between November 10, 2016 and November 12, 2017. Each of the complaints alleges that the defendants made false and misleading statements, including in connection with the Company's senior secured loan from CRG Servicing, LLC. The *Rose* complaint further alleges false and misleading statements in connection with Trulance's side-effect profile. The complaints assert claims under the federal securities laws and seek to recover unspecified damages, as well as interest, costs, and expenses. On June 11, 2018, plaintiffs voluntarily dismissed the Countryman complaint. On June 22, 2018, the court consolidated the remaining *Lee* and *Rose* actions into a single action under the caption *In re Synergy Pharmaceuticals, Inc. Securities Litigation.*

On April 20, 2018, a shareholder derivative action captioned *Solak v. Jacob et al.* was filed in the Supreme Court of the State of New York for New York County. On April 27, 2018 and May 1, 2018, respectively, two substantially identical shareholder derivative actions, captioned *Ecker & Klein v. Jacob et al*. and *Harding v. Jacob et al.*, were filed in the same court. On May 18, 2018, an additional shareholder derivative action captioned *Buker v. Jacob et al*. was filed in the same court. The complaints name Synergy, its directors, and certain of its current or former directors and officers as defendants and seek to recover on behalf of the company. Each of the complaints alleges that the individual defendants breached their fiduciary duties to the company by causing it to issue allegedly false and misleading statements in connection with our senior secured loan from CRG Servicing, LLC and Trulance's side-effect profile. The *Buker* complaint further asserts claims for unjust enrichment and gross mismanagement based on the same allegations. The complaints seek to recover unspecified damages, as well as declaratory relief, equitable remedies, costs, and expenses. On June 19, 2018, the court consolidated these four actions into a single action captioned *Solak v. Jacob et al*. On July 30, 2018, the court granted plaintiffs' unopposed motion seeking the appointment of lead counsel.

On June 8, 2018, a shareholder derivative action captioned *Davydov v. Hamilton et al*. was filed in the U.S. District Court for the Eastern District of New York. The complaint names Synergy, its directors, and certain of its current or former directors and officers as defendants and seeks to recover on behalf of the company. The complaint alleges that the individual defendants violated the federal securities laws and breached their fiduciary duties to the company by causing it to issue allegedly false and misleading statements in connection with the Company's senior secured loan from CRG Servicing, LLC and Trulance's side-effect profile. The complaint also asserts claims for waste of corporate assets and unjust enrichment based on the same allegations. The complaint seeks to recover unspecified damages, as well as equitable remedies, costs, and expenses.

9. Stockholders' Deficit

On January 31, 2017, Synergy entered into an underwriting agreement with Cantor Fitzgerald & Co., as representative of several underwriters, to issue and sell 20,325,204 shares of common stock of the Company in an underwritten public offering pursuant to a Registration Statement on Form S-3 (File No. 333-205484) and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission (the "Offering"). The public offering price was $6.15 per share of Common Stock. The Offering closed on February 6, 2017, yielding net proceeds of approximately $121.6 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

On June 27, 2017, Synergy increased the number of shares of common stock authorized for issuance from 350,000,000 to 400,000,000.

On November 13, 2017, Synergy entered into an underwriting agreement with Jefferies LLC, as representative of the several underwriters, to issue and sell 21,705,426 shares of common stock of the Company together with accompanying warrants ("Warrants") to purchase an aggregate of 21,705,426 shares of Common Stock in an underwritten offering pursuant to

a Registration Statement on Form S-3ASR and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission (the "Offering"). The offering price was $2.58 per share of Common Stock and accompanying Warrant. Net proceeds from the Offering were approximately $52.2 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

10. Research and Development Expense

Research and development costs include expenditures in connection with the Company's research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, and clinical trial insurance.

In accordance with FASB ASC Topic 730-10-55, *Research and Development*, Synergy recorded $0.1 million in prepaid research and development costs as of both June 30, 2018 and December 31, 2017, for nonrefundable advances for production of drug substance and analytical testing services for its drug candidates. In accordance with this guidance, Synergy expenses these costs when drug compound is delivered and services are performed.

The Company recorded inventory, manufactured for sale of a product candidate, when the product candidate was considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales. In determining whether or not to record such inventories, the Company evaluated, among other factors, information regarding the product candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales. Prior to October 1, 2016, all costs associated with batches of inventory, manufactured for sale, were charged to research and development as incurred. Beginning in the fourth quarter of 2016, Synergy began capitalizing inventory costs for TRULANCE in preparation for its planned launch in the U.S. The Company will record inventory, manufactured for sale of a product candidate, when the product candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales. In determining whether or not to record such inventories, the Company evaluates, among other factors, information regarding the product candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales.

11. Derivative Financial Instruments

Synergy Derivative Financial Instruments

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that certain warrants issued in connection with sale of its common stock must be classified as derivative instruments. In accordance with ASC Topic 815-40, these warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value are being recorded in the Company's statement of operations. The Company estimates the fair value of certain warrants using the *Black-Scholes* option pricing model in order to determine the associated derivative instrument liability and change in fair value.

Synergy's warrants issued on November 13, 2017 (See Footnote 9 "Stockholders' Deficit") were recorded as derivative liabilities and the fair value determined using the Monte Carlo simulation. The assumptions to determine fair value at issuance were $2.44 fair value of stock, warrant term of 2 years, 1.62% risk free rate, 66% volatility, and 0% dividend yield.

The assumptions used to determine the fair value of the warrants at each period end was:

	June 30, 2018	June 30, 2017
Fair value of Synergy common stock	$ 1.74	$ 4.45
Expected warrant term	1.4 years	0.7 years
Risk-free interest rate	2.40 %	1.14 %
Expected volatility	65 %	50 %
Dividend yield	—	—

Fair value of stock is the closing market price of the Company's common stock at the end of each reporting period when the derivative instruments are marked to market. Expected volatility is a management estimate of future volatility, over the

expected warrant term, based on historical volatility of Synergy's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 *Share-Based Payment* for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants at the date quarterly revaluation.

The following table sets forth the components of changes in the Synergy's outstanding warrants which were deemed derivative financial instruments and the associated liability balance for the periods indicated:

Date	Description	Warrants	Derivative Instrument Liability (in thousands)
12/31/2017	Balance of derivative financial instruments liability	21,915,426	$ 17,582
3/31/2018	Change in fair value of warrants during the three months ended March 31, 2018		(5,644)
3/31/2018	Expiration of warrants	(210,000)	—
6/30/2018	Change in fair value of warrants during the three months ended June 30, 2018		(2,604)
6/30/2018	Balance of derivative financial instruments liability	21,705,426	$ 9,334

12. Fair Value Measurements

Financial instruments consist of cash and cash equivalents, accounts receivable, security deposits, accounts payable and derivative instruments. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short term nature.

The value of Senior Convertible Notes and the Term Loan is stated at carrying value at June 30, 2018. The Company believes it could obtain borrowings at June 30, 2018 with comparable terms as the November 2014 Notes and the Term Loan, therefore, the carrying value approximates fair value.

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2017 and June 30, 2018:

($ in thousands)

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2017	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2018
Derivative liabilities related to Warrants	$ —	$ —	$ 17,582	$ 17,582	$ —	$ —	$ 9,334	$ 9,334

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the six months ended June 30, 2018:

($ in thousands)

Description	Balance as of December 31, 2017	(Gain) or loss recognized in earnings from Change in Fair Value	Expiration of warrants	Balance as of June 30, 2018
Derivative liabilities related to Warrants	$ 17,582	$ (8,248)	$ —	$ 9,334

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, Synergy reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

13. Loss per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, ("ASC Topic 260") for periods presented. In accordance with ASC Topic 260, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options and warrants would be antidilutive.

The following table sets forth potential common shares issuable upon the exercise of outstanding options, the exercise of warrants, and the conversion of the Senior Convertible Notes, all of which have been excluded from the computation of diluted weighted average shares outstanding as they would be antidilutive, including the impact on dilutive net loss per share of in-the-money warrants as per ASC 260-10-45-35 through ASC 260-10-45-37:

	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Stock Options	34,908,741	28,882,068
Warrants	21,749,134	869,688
Senior Convertible Notes	5,981,672	5,981,672
Total shares issuable upon exercise or conversion	62,639,547	35,733,428

14. Subsequent Events

On August 6, 2018, Synergy announced a license agreement with Luoxin Pharmaceutical Group Co., Ltd., Shandong (Luoxin). Under the terms of the agreement, Synergy will receive an upfront payment of $12.0 million and is eligible for additional regulatory and commercial milestone payments, as well as royalties from product sales in mainland China, Hong Kong and Macau. The agreement provides that Synergy will be responsible for manufacturing and supplying product to Luoxin.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this quarterly report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking statements. You can identify these statements by forward-looking words such as "plan," "may," "will," "expect," "intend," "anticipate," believe," "estimate" and "continue" or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future and thus you should not unduly rely on these statements.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K as of and for the year ended December 31, 2017 and other periodic reports filed with the United States Securities and Exchange Commission ("SEC"). Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of the Company, please be advised that the Company's actual financial condition, operating results and business performance may differ materially from that projected or estimated by the Company in forward-looking statements and thus you should not unduly rely on these statements.

Business Overview

We are a biopharmaceutical company focused on the development and commercialization of novel gastrointestinal (GI) therapies. We have pioneered discovery, research and development efforts around analogs of uroguanylin, a naturally occurring and endogenous human GI peptide, for the treatment of GI diseases and disorders. We discovered and own 100% worldwide rights to our proprietary uroguanylin based GI platform which includes one commercial product, plecanatide, and one development stage compound, dolcanatide.

Our first and only commercial product, plecanatide, is available and being marketed by us in the United States (U.S.), under the trademark name TRULANCE®, for the treatment of adults with chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C). On February 27, 2018 we entered into a definitive licensing agreement with Cipher Pharmaceuticals under which we granted Cipher the exclusive right to develop, market, distribute and sell TRULANCE in Canada. Under the terms of the licensing agreement, we received an upfront payment of $5.0 million and are eligible for an additional milestone payment upon regulatory approval in Canada, as well as royalties from product sales in Canada. Cipher expects to file a New Drug Submission with Health Canada in the second half of 2018. We are continuing to evaluate other potential U.S. and ex-U.S. partnership opportunities for TRULANCE.

Dolcanatide is our development stage compound that has demonstrated proof-of-concept in treating patients with opioid induced constipation (OIC) and ulcerative colitis. We are considering OIC as a potential life-cycle growth opportunity for TRULANCE and are currently exploring potential business development opportunities to further advance dolcanatide development in ulcerative colitis. In April 2018, we initiated a partnership with the National Cancer Institute (NCI) on a NCI-funded clinical biomarker study designed to evaluate the potential for dolcanatide to prevent colorectal cancer.

TRULANCE (plecanatide)

With the exception of a single amino acid substitution for greater binding affinity, TRULANCE is structurally identical to human uroguanylin and is the only treatment thought to replicate the pH-sensitive activity of uroguanylin. Uroguanylin activates GC-C receptors in a pH-sensitive manner primarily in the small intestine, stimulating fluid secretion and maintaining stool consistency necessary for regular bowel function.

In January 2017, the FDA approved TRULANCE 3 mg tablets for the once-daily treatment of adults with CIC. We began commercializing TRULANCE in the U.S. in March 2017. In January 2018, the FDA approved TRULANCE for the treatment of adults with IBS-C. The efficacy and safety of TRULANCE for the treatment of CIC and IBS-C was established in four 12-week, double-blind, placebo-controlled, randomized, multicenter clinical studies involving over 3,100 patients. TRULANCE demonstrated improvement in the abdominal pain, constipation, stool consistency and straining with bowel movements associated with IBS-C, as well as in the constipation, stool consistency and straining with bowel movements associated with CIC. These patient-reported symptoms returned within one week following discontinuation of TRULANCE. The most common adverse event in both CIC and IBS-C studies was diarrhea (≤5.0% vs. 1.0% placebo). TRULANCE is the only prescription medication for adults with CIC and IBS-C that can be taken once-daily, with or without food, at any time of the day. TRULANCE is packaged in a unique, 30-day calendar blister pack.

Ongoing Post Marketing Commitments

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), clinical studies are underway assessing the efficacy and safety of TRULANCE in pediatric patients with CIC and in late planning stages for assessment of the efficacy and safety of TRULANCE in pediatric patients with IBS-C. In addition, development and validation of an anti-drug antibody assay is underway to assess patient clinical trial samples for the potential presence of anti-plecanatide antibodies. As agreed with the FDA following Trulance approval in the CIC indication, we continue with the execution of a milk-only lactation study and the assessment of GC-C receptor density in infants and children (age 0-6 years).

CIC and IBS-C

CIC and IBS-C are chronic, functional GI disorders that afflict millions of people worldwide. An estimated 33 million adults suffer from CIC and 12 million adults suffer from IBS-C in the U.S. alone.

People with CIC have persistent symptoms of difficult-to-pass and infrequent bowel movements. In addition to physical symptoms including abdominal bloating and discomfort, CIC can adversely affect an individual's quality of life, including increasing stress levels and anxiety. Many patients attempt to manage CIC symptoms with improved diet, fiber, and over-the-counter laxatives; however, these options can be ineffective or may not provide long-term relief. For those patients with persistent symptoms, prescription therapy is recommended. Many patients taking prescription medications fail to respond to therapy, or suffer from treatment-related adverse events, such as nausea and diarrhea.

Irritable bowel syndrome (IBS) is characterized by recurrent abdominal pain associated with 2 or more of the following criteria: related to defecation, associated with a change in the frequency of stool, or associated with a change in the form (appearance) of the stool. IBS can be subtyped by the predominant stool form as measured by the Bristol Stool Form Scale (BSFS): constipation (IBS-C), diarrhea (IBS-D), or mixed (IBS-M). Those within the IBS-C subtype experience Bristol types 1 or 2 (hard or lumpy) stools more than 25 percent of the time they have an abnormal bowel movement, and Bristol types 6 or 7 (loose or watery) stools less than 25 percent of the time they have an abnormal bowel movement. Some of the IBS treatment approaches recognized by the American College of Gastroenterology (ACG), including specialized diets, fiber, and psychological interventions, may not always effectively address abdominal pain and discomfort experienced by these patients. While there are prescription drug options, not all patients find complete relief, and many struggle with adverse events.

Dolcanatide (SP-333)

Dolcanatide, our second product candidate, is being evaluated for inflammatory bowel disease (IBD). Dolcanatide is designed to be an analog of uroguanylin with enhanced resistance to standard digestive breakdown by proteases in the intestine. We have demonstrated the potential anti-inflammatory role of uroguanylin and uroguanylin analogs in a number of preclinical colitis models. In these earlier animal studies, oral treatment with dolcanatide was shown to ameliorate DSS- and TNBS-induced acute colitis in murine models and ameliorate spontaneous colitis in T-cell receptor alpha knockout mice.

In January 2016, we announced positive proof-of-concept with dolcanatide in a phase 1b trial evaluating 28 patients with mild-to-moderate ulcerative colitis. We are exploring business development opportunities to further advance dolcanatide development in ulcerative colitis. In April 2018, we entered into a partnership with the National Cancer Institute (NCI) to initiate a NCI-funded and managed clinical biomarker study to evaluate dolcanatide's potential to prevent colorectal cancer. The study will assess the colorectal bioactivity of dolcanatide in healthy volunteers and will inform the feasibility and design of a larger study to evaluate the potential for dolcanatide to prevent colorectal cancer.

Second Quarter 2018 and Recent Developments

We remain focused on executing on our 2018 key business priorities, including Optimizing the Value of TRULANCE, Ensuring a Strong Financial Foundation and Exploring all Strategic and Business Development Opportunities.

Optimizing the Value of TRULANCE

- On August 7, 2018, we announced that Express Scripts, a leading U.S. pharmacy benefit manager, will add TRULANCE to its 2019 National Preferred Formulary List, effective January 1, 2019.
- Total TRULANCE normalized prescription volume in the second quarter of 2018 included approximately 55,000 TRULANCE 30-count packs, up over 24% versus the first quarter, and resulting in over 90% average quarterly growth since the product's launch on March 20, 2017, per IQVIA.
- TRULANCE new prescription volume showed nearly 25% average quarterly growth since launch through June 30, 2018, per IQVIA.
- Total number of unique healthcare practitioners prescribing TRULANCE reached over 14,000 in the second quarter of 2018, increasing more than 20% over the first quarter, and resulting in 60% average quarterly growth since launch, per IQVIA.

Exploring All Strategic and Business Development Opportunities

Collaborations & Partnerships

- On August 3, 2018, we entered into a license agreement with Luoxin Pharmaceutical Group Co., Ltd., Shandong (Luoxin), providing Luoxin exclusive rights to develop and commercialize TRULANCE for the treatment of adults with chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) in mainland China, Hong Kong and Macau. Under the terms of the agreement, we will receive an upfront payment of $12 million. We are also eligible, in the event that certain regulatory and commercial milestones are met, to receive additional payments of up to $56 million in aggregate. In addition, we are eligible to receive tiered royalty payments on aggregate net sales. Pursuant to the license agreement, Luoxin will lead clinical development in China and be responsible for all activities and expenses relating to clinical development, regulatory approval, and commercialization in China. In addition, pursuant to the license agreement, the parties intend to enter into a supply agreement under which we will supply TRULANCE to Luoxin. The foregoing summary is qualified in its entirety by reference to the license agreement, a copy of which will be attached as an exhibit to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018.
- Our Canadian partner, Cipher Pharmaceuticals, remains on-track to file a New Drug Submission for TRULANCE in IBS-C with Health Canada in the second half of 2018. The regulatory review period is approximately one-year from the submission date. Under the terms of the licensing agreement, we are eligible for a milestone payment upon regulatory approval in Canada, as well as royalties from product sales in Canada.
- The National Cancer Institute (NCI) has initiated an NCI-funded and managed clinical biomarker study to evaluate the potential of dolcanatide, our second uroguanylin analog, to prevent colorectal cancer. The study will assess the colorectal bioactivity of dolcanatide in healthy volunteers and will inform the feasibility and design of a potential larger study. This is the first clinical biomarker study evaluating the potential benefit of using a uroguanylin analog in colorectal cancer prevention.

2018 Financial Guidance / Strategic Review Update

- We intend to provide an update to shareholders on our ongoing strategic review, including any anticipated related impact on operating expenses, in the third quarter of 2018.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2018 AND JUNE 30, 2017

We had net sales of $12.3 million during the three months ended June 30, 2018 and $2.3 million revenues during the three months ended June 30, 2017. We launched TRULANCE in mid-March 2017 and expect quarterly net sales to increase as we continue to commercialize the product.

Cost of goods sold (“COGS”) for the three months ended June 30, 2018 totaled $3.9 million compared to $1.6 million for the three months ended June 30, 2017, primarily due to higher net sales during the three months ended June 30, 2018. COGS includes the direct cost of manufacturing and packaging drug product and related technical operations overhead costs which are generally more fixed in nature. Technical Operations is responsible for planning, coordinating, and executing on our inventory

production plan and ensuring that product quality satisfies FDA requirements. Costs incurred by our technical operations organization are recorded as expense in the period in which they are incurred.

Research and development expenses for the three months ended June 30, 2018 decreased approximately $19.3 million or 87%, to approximately $2.8 million from approximately $22.1 million for the three months ended June 30, 2017. This decrease in research and development expenses was due primarily to reduced clinical trial spend associated with the TRULANCE IBS-C indication which was approved in early 2018.

Selling, general and administrative expenses decreased approximately $17.6 million or 33.7%, to $34.6 million for the three months ended June 30, 2018 from approximately $52.2 million for the three months ended June 30, 2017. This decrease in expenses primarily reflect higher marketing and promotional activities for the product launch of TRULANCE in the second quarter of 2017, as well as higher stock compensation expense related to modifications from severance agreements in the prior year quarter.

Net loss for the three months ended June 30, 2018 was $29.7 million as compared to a net loss of a $73.9 million for the three months ended June 30, 2017. This decrease in our net loss of $44.2 million or 59.8% was a result of the operating items discussed above.

RESULTS OF OPERATIONS

SIX MONTHS ENDED JUNE 30, 2018 AND JUNE 30, 2017

We had net sales of $20.8 million during the six months ended June 30, 2018 and $2.4 million during the six months ended June 30, 2017. We launched TRULANCE in mid-March 2017 and expect net sales growth as we continue to commercialize the product.

COGS for the six months ended June 30, 2018 totaled $7.6 million compared to $3.3 million for the six months ended June 30, 2017, primarily due to higher net sales during the six months ended June 30, 2018.

Research and development expenses for the six months ended June 30, 2018 decreased approximately $34.3 million or 84.7% to approximately $6.2 million from approximately $40.5 million for the six months ended June 30, 2017. This decrease in research and development expenses was due primarily to reduced clinical trial spend associated with the TRULANCE IBS-C indication which was approved in early 2018, and related reduction in clinical employees.

Selling, general and administrative expenses decreased approximately $20.2 million or 21.3%, to $74.8 million for the six months ended June 30, 2018 from $95.0 million for the six months ended June 30, 2017. This decrease in expenses primarily reflect higher marketing and promotional activities for the product launch of TRULANCE in the second quarter of 2017, as well as higher stock compensation expense related to modifications from severance agreements in the prior year period.

Net loss for the six months ended June 30, 2018 was $65.8 million as compared to a net loss of $138.5 million for the six months ended June 30, 2017. This decrease in our net loss of $72.7 million or 52.5% was a result of the operating items discussed above.

LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities was approximately $73.5 million and $120.8 million for the six months ended June 30, 2018 and 2017, respectively. Net cash used in financing activities was approximately $2.1 million for the six months ended June 30, 2018 and net cash provided by financing activities was approximately $120.4 million for the six months ended June 30, 2017. As of June 30, 2018, we had approximately $61.2 million of cash and cash equivalents. During the six months ended June 30, 2018 and 2017, we incurred losses from operations of approximately $67.7 million and $136.3 million, respectively. As of June 30, 2018, we had working capital of approximately $61.5 million, as compared to approximately $127.0 million at December 31, 2017.

On September 1, 2017, we entered into a senior secured term loan of up to $300 million with CRG Servicing LLC, as administrative and collateral agent, and the lenders and guarantors party thereto (the "Term Loan"). The Term Loan is available for working capital and general corporate purposes. We borrowed $100 million at time of closing. In February 2018 we amended the Term Loan agreement. The amended Term Loan provides for future borrowings of $25 million, $25 million and $50 million on or before June 30, 2018, September 30, 2018 and December 31, 2018, respectively. Additionally, the total amount of the commitment was reduced from $300 million to $200 million (excluding PIK loans) and the Minimum Market Capitalization covenant of $300 million was revised to be 200% of the outstanding principal amount of the Term Loan (excluding PIK loans). In June 2018, we further amended the Term Loan agreement to extend the draw down date of the second borrowing from June 30, 2018 to prior to August 29, 2018.

On November 13, 2017, we entered into an underwriting agreement with Jefferies LLC, as representative of the several underwriters, to issue and sell 21,705,426 shares of common stock of the Company together with accompanying warrants (“Warrants”) to purchase an aggregate of 21,705,426 shares of Common Stock in an underwritten offering pursuant to a Registration Statement on Form S-3ASR and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission (the “Offering”). The offering price was $2.58 per share of Common Stock and accompanying Warrant. The net proceeds from the Offering were approximately $52.2 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

Our consolidated financial statements as of December 31, 2017 and our unaudited condensed consolidated financial statements as of June 30, 2018 have been prepared under the assumption that we will continue as a going concern for the next twelve months. We have incurred recurring losses from operations and expect to continue to have losses in the future. In addition, our debt agreement is subject to covenants that could restrict the availability of additional loans and accelerate the repayment of that debt if breached. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has issued a report as of December 31, 2017 that includes an explanatory paragraph referring to such conditions and expressing substantial doubt in our ability to continue as a going concern.

Our ability to continue as a going concern is dependent upon our plan to generate significant revenue, attain further operating efficiencies, reduce expenditures, and if deemed necessary obtain additional equity or debt financing, which may not be available on acceptable terms or at all. To the extent that we may need to raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly scale back our commercialization efforts; (ii) seek commercial partners for our products on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights, on unfavorable terms, to technologies, product candidates or products that we would otherwise seek to develop or commercialize itself. Our consolidated financial statements as of December 31, 2017 and our unaudited condensed consolidated financial statements as of and for the period ended June 30, 2018 do not include any adjustments that might result from the unfavorable outcome of this uncertainty.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K as of and for year ended December 31, 2017, filed with the SEC on March 1, 2018. On January 1, 2018, we adopted a new accounting standard on revenue from contracts with customers, using the modified retrospective method applied to contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under that standard, while prior period amounts are not adjusted and continue to be reported in accordance with the previous standard. See *Revenue recognition* below and Note 2 of Notes to Consolidated Financial Statements for further details. There have been no other changes to our critical accounting policies since December 31, 2017.

Revenue recognition

For product sales of TRULANCE, revenue is recognized upon transfer of control of promised goods to customers in an amount that reflects the consideration to which we expect to be entitled to in exchange for those goods. The terms of a contract or historical business practice can give rise to variable consideration, including but not limited to: customer loyalty programs, trade discounts, fee for service agreements, sales returns and allowances, commercial and government rebates, and chargebacks. The transaction price will include estimates of variable consideration to the extent it is probable that a significant reversal of revenue recognized will not occur. Our estimates of variable consideration are probability weighted to derive an estimate of expected value and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of our anticipated performance and all information (historical, current and forecasted) that is reasonably available to us.

For customer contracts with multiple-performance obligations, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on their respective relative stand-alone selling price. The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred for the related goods or services.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of June 30, 2018.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk on the fair values of certain assets is related to credit risk associated with bank checking accounts, securities held in money market mutual funds and accounts receivable. As of June 30, 2018, we held $61.2 million in checking and U.S. Treasury based mutual funds. Our cash and cash equivalents balances are in excess of the Federally insured limit. We believe our cash and cash equivalents do not contain excessive risk, however we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. We limit our credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary. We do not require collateral to secure amounts owed to us by our customers.

Our senior secured term loan (“Term Loan”) of up to $200.0 million, entered into September 2017, as amended, has a fixed annual interest rate of 9.5% and we, therefore, do not have economic interest rate exposure on the Term Loan. However, the Term Loan requires us to comply with a minimum market capitalization covenant, and our shares are subject to market risk.

ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, our Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2018, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms.

Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As required by Rule 13a-15(d) of the Exchange Act, our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded there were no material changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that could significantly affect internal controls over financial reporting during the quarter ended June 30, 2018.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 8, Commitments and contingencies, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended June 30, 2018, for discussions that are limited to certain recent developments concerning our legal proceedings. Those discussions should be read in conjunction with Note 7, Commitments and contingencies, to the consolidated financial statements in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 1, 2018.

ITEM 1a. RISK FACTORS

There have been no material changes in our risk factors since the filing on March 1, 2018 of our Form 10-K for the year ended December 31, 2017.

ITEM 2. PROPERTIES

There have been no material changes in our properties since the filing on March 1, 2018 of our Form 10-K for the year ended December 31, 2017.

ITEM 6. EXHIBITS

(a) Exhibits

31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Chief Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2018, filed on August 8, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statement of Stockholders' Equity (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements tagged as blocks of text.

EXHIBIT 31.1

CERTIFICATIONS

I, Troy Hamilton, certify that:

1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals Inc.

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2018

/s/ TROY HAMILTON

Troy Hamilton

Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, Gary G. Gemignani, certify that:

1) I have reviewed this report on Form 10-Q of Synergy Pharmaceuticals Inc.

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2018

/s/ GARY G. GEMIGNANI

Gary G. Gemignani

Executive Vice President, Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

SYNERGY PHARMACEUTICALS INC.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2018

PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Chief Executive Officer of Synergy Pharmaceuticals Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended June 30, 2018 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2018

/s/ TROY HAMILTON

Troy Hamilton

Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

SYNERGY PHARMACEUTICALS INC.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2018

PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I am the Executive Vice President, Chief Financial Officer of Synergy Pharmaceuticals Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended June 30, 2018 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2018

/s/ GARY G. GEMIGNANI

Gary G. Gemignani

Executive Vice President, Chief Financial Officer