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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, 2017**

**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, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting 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)

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

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. Yes  No

The number of the registrant's shares of common stock outstanding was 224,954,941 as of August 9, 2017.

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, 2016 filed on March 1, 2017 and other periodic reports filed with the Securities and Exchange Commission.

These risk factors include the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate safety and efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, 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)

|   | <u>June 30, 2017</u> | <u>December 31, 2016</u> |
|---|----------------------|--------------------------|
| <b>ASSETS</b>   |                      |                          |
| Current Assets:   |                      |                          |
| Cash and cash equivalents   | \$ 81,960            | \$ 82,387                |
| Accounts receivable   | 1,782                | —                        |
| Inventories   | 11,853               | 5,640                    |
| Prepaid expenses and other current assets   | 8,368                | 889                      |
| Total Current Assets  | <u>103,963</u>       | <u>88,916</u>            |
| Property and equipment, net   | 529                  | 593                      |
| Security deposits   | 407                  | 343                      |
| Total Assets  | <u>\$ 104,899</u>    | <u>\$ 89,852</u>         |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                      |                          |
| Current Liabilities:  |                      |                          |
| Accounts payable  | \$ 30,460            | \$ 15,584                |
| Accrued expenses  | 12,390               | 13,552                   |
| Interest payable on senior convertible notes  | 233                  | 294                      |
| Deferred revenues, net  | 1,498                | —                        |
| Total Current Liabilities   | <u>44,581</u>        | <u>29,430</u>            |
| Senior convertible notes, net   | 16,948               | 22,665                   |
| Derivative financial instruments, at estimated fair value-warrants  | 55                   | 216                      |
| Total Liabilities   | <u>61,584</u>        | <u>52,311</u>            |
| Commitments and contingencies   |                      |                          |
| Stockholders' Equity  |                      |                          |
| Preferred stock, authorized 20,000,000 shares and none outstanding, at June 30, 2017 and December 31, 2016  | —                    | —                        |
| Common stock, par value of \$.0001, 400,000,000 shares authorized at June 30, 2017 and 350,000,000 shares authorized at December 31, 2016. Issued and outstanding 224,954,941 shares and 202,737,860 shares at June 30, 2017 and December 31, 2016, respectively. | 23                   | 20                       |
| Additional paid-in capital  | 764,777              | 620,513                  |
| Accumulated deficit   | (721,485)            | (582,992)                |
| Total Stockholders' Equity  | <u>43,315</u>        | <u>37,541</u>            |
| Total Liabilities and Stockholders' Equity  | <u>\$ 104,899</u>    | <u>\$ 89,852</u>         |

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, |             |
|---|-----------------------------|-------------|---------------------------|-------------|
|   | 2017                        | 2016        | 2017                      | 2016        |
| Net sales   | \$ 2,314                    | \$ —        | \$ 2,412                  | \$ —        |
| Cost of goods sold                                      | 2,890                       | —           | 4,695                     | —           |
| Gross profit  | (576)                       | —           | (2,283)                   | —           |
| <b>Costs and expenses:</b>                              |                             |             |                           |             |
| Research and development                                | 22,314                      | 26,611      | 41,443                    | 47,786      |
| Selling, general and administrative                     | 50,693                      | 10,249      | 92,584                    | 16,624      |
| Loss from operations                                    | (73,583)                    | (36,860)    | (136,310)                 | (64,410)    |
| <b>Other expenses</b>                                   |                             |             |                           |             |
| Interest and investment expense, net                    | (345)                       | (1,673)     | (1,135)                   | (8,709)     |
| Debt conversion expense                                 | —                           | —           | (1,209)                   | (25,615)    |
| Change in fair value of derivative instruments-warrants | 39                          | (23)        | 161                       | 237         |
| Total other expenses                                    | (306)                       | (1,696)     | (2,183)                   | (34,087)    |
| Net loss  | \$ (73,889)                 | \$ (38,556) | \$ (138,493)              | \$ (98,497) |
| <b>Weighted Average Common Shares Outstanding</b>       |                             |             |                           |             |
| Basic and Diluted                                       | 224,948,622                 | 168,127,144 | 220,269,223               | 143,017,970 |
| <b>Net Loss per Common Share, Basic and Diluted</b>     |                             |             |                           |             |
| Net Loss per Common Share, Basic and Diluted            | \$ (0.33)                   | \$ (0.23)   | \$ (0.63)                 | \$ (0.69)   |

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

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

|   | Common<br>Shares | Common<br>Stock,<br>Par Value | Additional<br>Paid in<br>Capital | Deficit<br>Accumulated | Total<br>Stockholders'<br>Equity |
|---|------------------|-------------------------------|----------------------------------|------------------------|----------------------------------|
| Balance, December 31, 2016  | 202,737,860      | \$ 20                         | \$ 620,513                       | \$ (582,992)           | \$ 37,541                        |
| Notes conversions   | 1,579,099        | 1                             | 4,911                            | —                      | 4,912                            |
| Debt conversion expense   | 212,800          | —                             | 1,209                            | —                      | 1,209                            |
| Common stock issued in connection with<br>exercise of stock options | 99,978           | —                             | 347                              | —                      | 347                              |
| Common stock issued in registered direct<br>offering                | 20,325,204       | 2                             | 121,949                          | —                      | 121,951                          |
| Fees and expenses — sale of common stock                            | —                | —                             | (347)                            | —                      | (347)                            |
| Stock based compensation expense                                    | —                | —                             | 16,195                           | —                      | 16,195                           |
| Net loss for the period   | —                | —                             | —                                | (138,493)              | (138,493)                        |
| Balance, June 30, 2017  | 224,954,941      | \$ 23                         | \$ 764,777                       | \$ (721,485)           | \$ 43,315                        |

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<br>June 30, 2017 | Six Months Ended<br>June 30, 2016 |
|--|-----------------------------------|-----------------------------------|
| <b>Cash Flows From Operating Activities:</b>                                       |                                   |                                   |
| Net loss   | \$ (138,493)                      | \$ (98,497)                       |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                                   |                                   |
| Depreciation and amortization  | 80                                | 79                                |
| Amortization of deferred debt costs  | 785                               | 4,406                             |
| Stock-based compensation expense   | 16,195                            | 3,909                             |
| Change in fair value of derivative instruments—warrants                            | (161)                             | (237)                             |
| Common stock issued for interest on Notes  |                                   | 2,445                             |
| Debt conversion expense  | 1,209                             | 25,615                            |
| Transaction fees on Note conversions   | —                                 | (434)                             |
| <b>Changes in operating assets and liabilities:</b>                                |                                   |                                   |
| Accounts receivable  | (1,782)                           | —                                 |
| Inventories  | (6,213)                           | —                                 |
| Security deposit   | (64)                              | —                                 |
| Prepaid expenses and other current assets  | (7,479)                           | (961)                             |
| Accounts payable and accrued expenses  | 13,714                            | 4,546                             |
| Deferred revenues, net   | 1,498                             | —                                 |
| Accrued interest expense on senior convertible notes                               | (61)                              | (998)                             |
| <b>Total Adjustments</b>   | <b>17,721</b>                     | <b>38,370</b>                     |
| <b>Net Cash used in Operating Activities</b>                                       | <b>(120,772)</b>                  | <b>(60,127)</b>                   |
| <b>Cash Flows From Investing Activities:</b>                                       |                                   |                                   |
| Net sales of available-for-sale securities   | —                                 | 50,097                            |
| Additions to property and equipment  | (15)                              | (272)                             |
| <b>Net Cash (used in) provided by Investing Activities</b>                         | <b>(15)</b>                       | <b>49,825</b>                     |
| <b>Cash Flows From Financing Activities:</b>                                       |                                   |                                   |
| Proceeds of sale of common stock   | 121,951                           | 89,845                            |
| Payment for deferred financing costs   | (1,591)                           | —                                 |
| Fees and expenses — sale of common stock   | (347)                             | —                                 |
| Proceeds from exercise of stock options  | 347                               | 23                                |
| <b>Net Cash provided by Financing Activities</b>                                   | <b>120,360</b>                    | <b>89,868</b>                     |
| <b>Net (decrease) increase in cash and cash equivalents</b>                        | <b>(427)</b>                      | <b>79,566</b>                     |
| Cash and cash equivalents at beginning of period                                   | 82,387                            | 61,653                            |
| <b>Cash and cash equivalents at end of period</b>                                  | <b>\$ 81,960</b>                  | <b>\$ 141,219</b>                 |
| <b>Supplementary disclosure of cash flow information:</b>                          |                                   |                                   |
| Cash paid for interest on senior convertible notes                                 | \$ 698                            | \$ 2,969                          |
| Cash paid for taxes  | \$ 44                             | \$ 45                             |
| <b>Supplementary disclosure of non-cash investing and financing activities:</b>    |                                   |                                   |
| Conversion of senior convertible notes to Synergy Common Stock                     | \$ 4,912                          | \$ 82,274                         |

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. The Company pioneered the 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, is developing, and controls 100% worldwide rights to its proprietary uroguanylin based GI platform.

Net cash used in operating activities was approximately \$120.8 million for the six months ended June 30, 2017. As of June 30, 2017, Synergy had approximately \$82.0 million of cash and cash equivalents. During the six months ended June 30, 2017, Synergy incurred losses from operations of approximately \$138.5 million. As of June 30, 2017, Synergy had working capital of approximately \$59.4 million.

*Recent Developments*

On January 31, 2017, Synergy entered into an underwriting agreement with Cantor Fitzgerald & Co., as representative of the 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 supplement 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 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 are 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 our common stock, with approximately 1.6 million shares representing the conversion price of \$3.11 pursuant to the existing terms of the Notes. As of June 30, 2017, approximately \$18.6 million of the Notes remain outstanding. The Company recognized a debt conversion expense of \$1.2 million representing 0.2 million shares during the quarter ended March 31, 2017.

**2. Basis of Presentation, Accounting Policies and Going Concern**

These unaudited condensed consolidated financial statements include Synergy and its wholly-owned subsidiaries: (1) Synergy Advanced Pharmaceuticals, Inc., and (2) IgX, Ltd (Ireland—inactive). 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, 2016 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 1, 2017. All intercompany balances and transactions have been eliminated.

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Notwithstanding the Company's recent equity financing, Synergy will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Synergy cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Synergy raises 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 delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Synergy would otherwise seek to develop or commercialize on unfavorable terms.

Synergy's consolidated financial statements as of December 31, 2016 and its unaudited condensed consolidated financial statements as of June 30, 2017 have been prepared under the assumption that the Company will continue as a going concern for the next twelve months. Synergy's independent registered public accounting firm has issued a report as of December 31, 2016 that includes an explanatory paragraph referring to the Company's recurring and continuing losses from operations and expressing substantial doubt in the Company's ability to continue as a going concern without additional capital becoming available. Synergy's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Synergy's consolidated financial statements as of December 31, 2016 and its unaudited condensed consolidated financial statements as of and for the period ended June 30, 2017 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.

### *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 related 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, 2017.

### *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.

In July 2015, the FASB issued an accounting standard update (ASU No. 2015-11) intended to simplify the measurement of inventory by requiring inventory to be measured at the lower of cost or net realizable value. Net realizable value is defined as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation, etc. The Company adopted this standard as of January 1, 2017, which had no impact on the consolidated financial statements.

### *Revenue recognition*

Synergy recognizes revenue from sales of TRULANCE when the earnings process is complete, which under Accounting Standards Codification ASC 605, Revenue Recognition is when revenue is realized or realizable and earned, there is persuasive evidence a revenue arrangement exists, delivery of goods or services has occurred, the sales price is fixed or determinable, and collectability is reasonably assured. Until Synergy has the ability to reliably estimate returns of TRULANCE from its customers, revenue will be recognized based on patient prescriptions, and not based on sales to distributors. Product sales that are not yet patient prescriptions are classified as Deferred revenues, net. Product sales are recorded net of all sales related deductions 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 Company estimates these sales deductions based on contractual terms, historical payment experience, third party data, estimated utilization or redemption rates, government regulations, and customer inventory levels. Accruals for trade discounts, fee for service agreements and chargebacks are reflected as a direct reduction of accounts receivable and accruals for commercial and government rebates and customer loyalty programs are reflected as accrued expenses.

### *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").

### *Prior Period Adjustments*

The three months ended June 30, 2017, includes an adjustment of \$1.0 million related to the prior period. Had the adjustment been made during the prior period, Research and development expenses would have been \$3.1 million higher and Selling, general and administrative expenses would have been \$4.1 million lower during the three months ended March 31, 2017. The cumulative impact of these adjustments were not considered to be material to the Company's condensed consolidated financial statements for the three months ended March 31 2017 and there is no impact to the Company's condensed consolidated financial statements for the six months ended June 30, 2017.

### **3. Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") and the International Accounting Standards Board ("IASB") issued a comprehensive new revenue recognition standard ASC 606 *Revenue From Contracts With Customers*. The new standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard is designed to create greater comparability for financial statement users across industries, jurisdictions and capital markets and also requires enhanced disclosures. The new standard will be effective for the Company beginning January 1, 2018. The guidance permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the cumulative catch-up transition method)

The Company is in the initial stages of its evaluation as to the impact of the new revenue recognition standard on its accounting policies, processes, and system requirements as Synergy launched its first and only commercial product during the first quarter of 2017. Furthermore, Synergy has made and will continue to make investments in systems to enable timely and accurate reporting under the new standard. While Synergy continues to assess the potential impacts of the new standard, Synergy does not know or cannot reasonably estimate the impact of the new standard on our financial statements at this time.

In March 2016, FASB issued Accounting Standards Update ("ASU") No. 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting" ("ASU 2016-09"). The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact,

classification on the statement of cash flows and forfeitures. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. The Company adopted this ASU during the fourth quarter of 2016 and due to losses, the excess tax benefits will not affect expense since these amounts have not, and will not be applicable. The Company is also continuing its policy to estimate the forfeiture rate after adoption of this ASU.

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 the Company's consolidated financial statements and disclosures except upon initial adoption.

#### **4. Cash, Cash Equivalents and Available-for-sale Securities**

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, 2017 and December 31, 2016, the amount of cash and cash equivalents was \$82.0 million and \$82.4 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. Senior Convertible Notes**

On November 3, 2014, Synergy closed a private offering of \$200 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 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 March 18, 2016 Synergy entered into an agreement (the "Exchange") for the exchange of \$79.8 million in aggregate principal amount of the Notes, representing approximately 50% of the outstanding aggregate principal amount of Notes, for 35.3 million shares of Synergy's common stock, with a total of 25.6 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 \$25.6 million representing 9.6 million shares for the quarter ended March 31, 2016.

In November 2016 Synergy exchanged \$55.7 million in aggregate principal amount of the Notes, representing approximately 70% of the outstanding aggregate principal amount of Notes, for 20.5 million shares of Synergy's common stock, with a total of 17.9 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 \$14.5 million representing 2.6 million shares for the quarter ended December 31, 2016.

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

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pursuant to the existing terms of the Notes. As of June 30, 2017, approximately \$18.6 million of the Notes remain outstanding. The Company recognized a debt conversion expense of approximately \$1.2 million representing 0.2 million shares for the quarter ended March 31, 2017.

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<br>Deferred Debt Costs |
|---|---------------|---------------------|--------------------------------------|
| Balance December 31, 2015   | \$ 159,011    | \$ 7,770            | \$ 151,241                           |
| Less: amortization three months ended March 31, 2016 <sup>(1)</sup>                                   |               | (4,153)             | 4,153                                |
| Conversions   | (79,829)      | —                   | (79,829)                             |
| Balance, March 31, 2016   | 79,182        | 3,617               | 75,565                               |
| Less: amortization three months ended June 30, 2016   |               | (253)               | 253                                  |
| Balance, June 30, 2016  | 79,182        | 3,364               | 75,818                               |
| Less: amortization three months ended September 30, 2016  |               | (252)               | 252                                  |
| Balance, September 30, 2016   | 79,182        | 3,112               | 76,070                               |
| Less: amortization three months ended December 31, 2016 <sup>(1)</sup>                                |               | (2,263)             | 2,263                                |
| Conversions   | (55,668)      | —                   | (55,668)                             |
| Balance, December 31, 2016  | 23,514        | 849                 | 22,665                               |
| Deferred financing cost related to debt modification on February 28, 2017                             |               | 1,591               | (1,591)                              |
| Less: amortization three months ended March 31, 2017 <sup>(1)</sup>                                   |               | (608)               | 608                                  |
| Conversions   | (4,911)       | —                   | (4,911)                              |
| Balance, March 31, 2017   | 18,603        | 1,832               | 16,771                               |
| Less: amortization of deferred financing cost for the three months ended June 30, 2017 <sup>(1)</sup> |               | (59)                | 59                                   |
| Less: amortization of debt modification cost for the three months ended June 30, 2017 <sup>(1)</sup>  |               | (118)               | 118                                  |
| Balance, June 30, 2017  | \$ 18,603     | \$ 1,655            | \$ 16,948                            |

(1) Includes accelerated amortization of deferred debt costs attributable to conversions and exchanges

## 6. 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.

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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 and no grants have been awarded as of June 30, 2017.

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. There are no outstanding change of control options as of June 30, 2017.

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

| (\$ in thousands)                               | Three Months Ended June 30, | Three Months Ended June 30, | Six Months Ended June 30, | Six Months Ended June 30, |
|---|-----------------------------|-----------------------------|---------------------------|---------------------------|
|   | 2017                        | 2016                        | 2017                      | 2016                      |
| Included in research and development            | \$ (80)                     | \$ 784                      | 1,793                     | 1,594                     |
| Included in selling, general and administrative | 13,378                      | 1,923                       | 14,402                    | 2,315                     |
| Total stock-based compensation expense          | \$ 13,298                   | \$ 2,707                    | \$ 16,195                 | \$ 3,909                  |

The unrecognized compensation cost related to non-vested stock options outstanding at June 30, 2017, net of expected forfeitures, was approximately \$17.7 million to be recognized over a weighted-average remaining vesting period of approximately 1.39 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, 2017 | Six Months Ended June 30, 2016 |
|--------------------------|--------------------------------|--------------------------------|
| Risk-free interest rate  | 1.85%-2.24%                    | 1.22%-1.49%                    |
| Dividend yield           | —                              | —                              |
| Expected volatility      | 66%-73%                        | 50%                            |
| Expected term (in years) | 6 years                        | 6 years                        |

A summary of stock option activity and of changes in stock options outstanding under the Plan 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, 2016       | 27,867,171        | \$0.44-9.12              | \$ 3.78                                   | \$ 65,618                      | 7.1 years                                   |
| Granted                                      | 2,055,500         | \$3.63-6.77              | 4.98                                      | —                              |   |
| Exercised <sup>(1)</sup>                     | (99,978)          | \$0.50-5.34              | 3.47                                      | 226,757                        |   |
| Forfeited                                    | (940,625)         | \$2.83-7.91              | 4.52                                      | —                              |   |
| Balance outstanding, June 30, 2017           | 28,882,068        | \$0.44-9.12              | \$ 3.90                                   | \$ 27,677                      | 6.8 years                                   |
| Exercisable, at June 30, 2017 <sup>(2)</sup> | 19,238,509        | \$0.44-9.12              | \$ 3.49                                   | \$ 23,650                      | 5.7 years                                   |

(1) The Company received proceeds of approximately \$0.3 million from the exercise of stock options during the three months ended June 30, 2017.

(2) Includes 2,159,500 change of control stock options that were immediately vested during June 2017.

## 7. Stockholders' Equity

On May 5, 2016, Synergy announced that it had entered into definitive agreements with certain institutional investors to sell 29,948,334 shares of common stock at a price of \$3.00 per share. The shares were offered and sold directly to institutional

investors by the Company in a registered direct offering conducted without an underwriter or placement agent. The gross proceeds from the offering were approximately \$89.8 million. The offering closed on May 6, 2016.

From January 1, 2016 through December 31, 2016 warrants to purchase 2,430,657 shares of common stock were exercised, yielding proceeds to the Company of \$11.3 million.

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.

## **8. 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 no prepaid research and development costs as of June 30, 2017 and approximately \$0.5 million as of December 31, 2016, 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.

## **9. Derivative Financial Instruments**

### *Synergy Derivative Financial Instruments*

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, "Derivatives and Hedging: Contracts in Entity's Own Equity" ("ASC Topic 815-40"). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815-10.

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

|                                    | June 30, 2017 | June 30, 2016 |
|------------------------------------|---------------|---------------|
| Fair value of Synergy common stock | \$ 4.45       | \$ 3.80       |
| Expected warrant term              | 0.7 years     | 1.7 years     |
| Risk-free interest rate            | 1.14 %        | 0.52 %        |
| Expected volatility                | 50 %          | 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 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) |
|------------|---|----------|--|
| 12/31/2016 | Balance of derivative financial instruments liability                         | 210,000  | \$ 216   |
| 3/31/2017  | Change in fair value of warrants during the three months ended March 31, 2017 |          | (122)  |
| 6/30/2017  | Change in fair value of warrants during the three months ended June 30, 2016  |          | (39)   |
| 6/30/2017  | Balance of derivative financial instruments liability                         | 210,000  | \$ 55  |

#### 10. Fair Value Measurements

Financial instruments consist of cash and cash equivalents, 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 is stated at its carrying value at June 30, 2017. The Company believes it could obtain borrowings at June 30, 2017 with comparable terms as the November 2014 Notes, 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, 2016 and June 30, 2017:

(\$ in thousands)

| Description                                | Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1) |   |   | Balance as of December 31, 2016 | Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1) |      |       | Balance as of June 30, 2017 |
|--|--|---|---|---------------------------------|--|------|-------|-----------------------------|
|  | Significant Other Observable Inputs (Level 2)                                  | Significant Unobservable Inputs (Level 3) | Significant Other Observable Inputs (Level 2) |                                 | Significant Unobservable Inputs (Level 3)                                      |      |       |                             |
| Derivative liabilities related to Warrants | \$ —   | \$ —                                      | \$ 216  | \$ 216                          | \$ —   | \$ — | \$ 55 | \$ 55                       |

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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, 2017:

(\$ in thousands)

| Description                                | Balance as of<br>December 31, 2016 | (Gain) or loss<br>recognized in<br>earnings from<br>Change in Fair<br>Value | Expiration of<br>warrants | Balance as of<br>June 30, 2017 |
|--|------------------------------------|---|---------------------------|--------------------------------|
| Derivative liabilities related to Warrants | \$ 216                             | \$ (161)  | \$ —                      | \$ 55                          |

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.

## 11. 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:

|   | <b>Six Months Ended<br/>June 30, 2017</b> | <b>Six Months Ended<br/>June 30, 2016</b> |
|---|---|---|
| Stock Options                                     | 28,882,068                                | 26,355,948                                |
| Warrants  | 869,688                                   | 4,726,823                                 |
| Senior Convertible Notes                          | 5,981,672                                 | 25,460,450                                |
| Total shares issuable upon exercise or conversion | <u>35,733,428</u>                         | <u>56,543,221</u>                         |

## **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, 2016 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, are developing and control 100% worldwide rights to our proprietary uroguanylin based GI platform, which includes one commercial product, TRULANCE (plecanatide), and a second product candidate, dolcanatide.

### **TRULANCE (plecanatide)**

Our first and only commercial product, TRULANCE™, is approved and marketed in the United States (U.S.), under the trademark name TRULANCE™, as a once-daily treatment for adults with chronic idiopathic constipation, or CIC. In clinical trials, TRULANCE helped improve stool consistency and provide more regular bowel movements. TRULANCE is the only prescription medication for CIC that can be taken once-daily, with or without food, at any time of the day. In addition, TRULANCE is the only prescription medication for CIC available in a unique calendar pack that is patient preferred versus a traditional pill bottle. We are also developing TRULANCE for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). The FDA has accepted for review our supplemental new drug application (sNDA) for IBS-C and the Prescription Drug User Fee Act (PDUFA) date is January 24, 2018.

TRULANCE is the first drug designed to replicate the function of uroguanylin. Uroguanylin, a guanylate cyclase-C (GC-C) receptor agonist, is thought to work in a pH-sensitive manner primarily in the small intestine to stimulate fluid secretion. Uroguanylin stimulates fluid secretion into the lumen of the intestinal tract and maintains stool consistency that is necessary for normal bowel function. With the exception of a single amino acid, TRULANCE is structurally identical to uroguanylin and is the only treatment that is thought to replicate the pH-sensitive activity of human uroguanylin. The single amino acid substitution results in improved (8x) binding affinity and therefore increases the potency of TRULANCE over uroguanylin.

### ***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.

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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 plan to meet with regulatory agencies to discuss next steps in development for dolcanatide in mild-to-moderate ulcerative colitis.

In November 2014, we reported successful proof-of-concept with dolcanatide in a double-blind, placebo-controlled phase 2 trial in 289 patients with opioid induced constipation ("OIC"), demonstrating the utility of our uroguanylin based GI platform in OIC. We are considering OIC as a potential life cycle growth opportunity for TRULANCE.

### **Recent Developments**

#### **TRULANCE (plecanatide) Commercial Launch Update**

##### ***Driving Awareness of TRULANCE and Stimulating Trial and Adoption***

- Since our launch of TRULANCE on March 20, 2017, our commercial team continues to introduce TRULANCE to more than 27,000 gastroenterologists, primary care physicians, nurse practitioners and physician assistants that represent approximately 70% of the branded prescription business. As of June 30, 2017, we had reached 66% of our targeted prescriber base and over 90% of the high volume prescribers (deciles 8-10). According to QuintilesIMS data as of June 30, 2017:
  - More than 12,600 TRULANCE prescriptions have been filled and total monthly prescription volume has increased on average more than 182% month-over-month during that period.
  - More than 32% of all high prescribers had written a TRULANCE prescription during that period with an average increase for all prescribers of approximately 140% month-over-month.
  - TRULANCE achieved 6.8% new-to-brand prescription (NBRx) total market share and 12% NBRx market share among gastroenterologists.
  - As of June 30, 2017, more than half of new TRULANCE prescriptions filled since launch were coming from new patients not previously on a branded prescription treatment and 45% were patients that converted from other branded prescription treatments.

***Ensuring Market Access***

- As of June 30, 2017, over 61% of adult CIC patients with commercial insurance will have unrestricted access to TRULANCE for 2017 based on the top 20 pharmacy benefit managers (PBMs) and payers. Additionally, approximately 95% of people with commercial insurance had access to TRULANCE for a co-pay of \$25 or less through the TRULANCE Savings-to-Go-Program.
- We have secured a 2018 managed care contract with CVS Caremark, which manages approximately 50 million commercial lives in the U.S., that will place TRULANCE on formulary without restriction (non-preferred) for its Commercial Template Clients or Employer Groups, representing approximately 24 million lives. We are in contract discussions with CVS Caremark for the remaining commercial lives.
- TRULANCE is currently available through Express Scripts (ESI), which manages approximately 80 million total lives in the U.S., and this commercial formulary status will continue for the remainder of 2017. ESI recently released its 2018 National Preferred Formulary List and introduced 64 new drug exclusions, including TRULANCE. This change only affects access to the ESI National Formulary for non-custom clients, representing approximately 22 million lives, effective January 1, 2018. TRULANCE will remain available to ESI lives covered under the National Preferred Formulary via the “Non-Formulary Exception Request” prior authorization process, for which we currently have a support program in place to ensure patient access. ESI also manages a larger book of business with its Custom Clients, representing approximately 49 million lives. We are still in active discussions with ESI to determine 2018 formulary status for individual plans under their Custom Clients book of business.
- We are in active contract negotiations with other PBMs and payers for 2018 coverage to ensure our goal of broad access to TRULANCE.
- Med D and Medicaid discussions are ongoing and we expect several major accounts to include TRULANCE on formulary in 2018.

***Sales Force Update***

- As planned and with the continued progress of the launch, we have initiated the process to transition our Publicis Touchpoint contract sales representatives over to Synergy in preparation of our anticipated approval of TRULANCE in the IBS-C indication this coming January.

**TRULANCE IBS-C Development Update**

- The FDA has accepted for review our sNDA for TRULANCE for the treatment of adults with IBS-C. The Prescription Drug User Fee Act (PDUFA) date is January 24, 2018.

**RESULTS OF OPERATIONS**

**THREE MONTHS ENDED JUNE 30, 2017 AND JUNE 30, 2016**

We had net sales of \$2.3 million during the three months ended June 30, 2017 and no revenues during the three months ended June 30, 2016.

Cost of goods sold (“COGS”) for the three months ended June 30, 2017 totaled \$2.9 million, which 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 overhead represents the majority of COGS in our Statement of Operations for the three months ended June 30, 2017. Technical operations are 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 expenses 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.

Research and development expenses for the three months ended June 30, 2017 decreased approximately \$4.3 million or 16.2%, to approximately \$22.3 million from approximately \$26.6 million for the three months ended June 30, 2016. This decrease in research and development expenses was primarily due to the cost of validation batches as well as pre-commercial inventory build being classified as research and development in 2016.

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The following table sets forth our research and development expenses directly related to our product candidates, as well as indirect costs, for the three months ended June 30, 2017 and 2016. Direct expenses include external costs associated with chemistry, manufacturing and controls including costs of drug substance and product formulation, as well as filing fees for regulatory approval, preclinical studies and clinical trial costs.

|                                       | (\$ in thousands)           |                  |
|---------------------------------------|-----------------------------|------------------|
|                                       | Three Months Ended June 30, |                  |
|                                       | 2017                        | 2016             |
| TRULANCE                              | \$ 18,892                   | \$ 22,511        |
| Dolcanatide                           | 280                         | 449              |
| Total direct costs                    | 19,172                      | 22,960           |
| Total indirect costs                  | 3,142                       | 3,651            |
| <b>Total Research and Development</b> | <b>\$ 22,314</b>            | <b>\$ 26,611</b> |

Indirect research and development costs which are comprised of in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services, are not directly allocated to specific drug candidates. Indirect costs were approximately \$3.1 million in the three months ended June 30, 2017, as compared to approximately \$3.7 million during the three months ended June 30, 2016 representing a decrease of approximately \$0.6 million or 16.2% which was primarily due to reduced consulting spend and lower stock based compensation expense.

Selling, general and administrative expenses increased approximately \$40.4 million or 392.2%, to \$50.7 million for the three months ended June 30, 2017 from approximately \$10.3 million for the three months ended June 30, 2016. These increased expenses reflect primarily marketing and promotional activities as part of our product launch of TRULANCE in the first quarter of 2017. These costs include commercial preparedness and planning expenses including an approximately \$23.1 million increase in marketing and sales expenses, a \$4.7 million increase in employee compensation and benefits costs, and a \$11.5 million increase in stock compensation expense. The increase in stock compensation expense was primarily driven by a \$6.6 million charge related to the immediate vesting due to a modification of previously granted Change of Control options, and a \$2.8 million charge related to stock option modifications for terminated employees. There are no remaining Change of Control options outstanding as of June 30, 2017.

Net loss for the three months ended June 30, 2017 was \$73.9 million as compared to a net loss of a \$38.6 million for the three months ended June 30, 2016. This increase in our net loss of \$35.3 million or 91.5% was a result of the operating items discussed above.

#### SIX MONTHS ENDED JUNE 30, 2017 AND JUNE 30, 2016

We had net sales of \$2.4 million during the six months ended June 30, 2017 and no revenues during the six months ended June 30, 2016.

COGS for the six months ended June 30, 2017 totaled \$4.7 million, which 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 overhead represents the majority of COGS in our Statement of Operations for the six months ended June 30, 2017. Technical operations are 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.

Certain direct costs associated with pre-commercial inventory, other than packaging, were expensed prior to receiving FDA approval.

Research and development expenses for the six months ended June 30, 2017 decreased approximately \$6.4 million or 13.4%, to approximately \$41.4 million from approximately \$47.8 million for the six months ended June 30, 2016. This decrease in research and development expenses was primarily due to a decrease in spending on CIC clinical studies and the cost of validation batches as well as pre-commercial inventory build being classified as research and development in 2016.

## [Table of Contents](#)

The following table sets forth our research and development expenses directly related to our product candidates, as well as indirect costs, for the six months ended June 30, 2017 and 2016. Direct expenses include external costs associated with chemistry, manufacturing and controls including costs of drug substance and product formulation, as well as filing fees for regulatory approval, preclinical studies and clinical trial costs.

|                                       | (\$ in thousands)         |                  |
|---------------------------------------|---------------------------|------------------|
|                                       | Six Months Ended June 30, |                  |
|                                       | 2017                      | 2016             |
| TRULANCE                              | \$ 33,801                 | \$ 39,687        |
| Dolcanatide                           | 527                       | 916              |
| Total direct costs                    | 34,328                    | 40,603           |
| Total indirect costs                  | 7,115                     | 7,183            |
| <b>Total Research and Development</b> | <b>\$ 41,443</b>          | <b>\$ 47,786</b> |

Indirect research and development costs which are comprised of in-house staff compensation, facilities, depreciation, stock-based compensation and research and development support services, are not directly allocated to specific drug candidates. Indirect costs were approximately \$7.1 million in the six months ended June 30, 2017 in line with costs of approximately \$7.2 million during the six months ended June 30, 2016.

Selling, general and administrative expenses increased approximately \$76.0 million or 457.8%, to \$92.6 million for the six months ended June 30, 2017 from approximately \$16.6 million for the six months ended June 30, 2016. These increased expenses primarily reflect the cost of building a Commercial Organization as well as marketing and promotional activities as part of our product launch of TRULANCE in the first quarter of 2017. These costs include commercial preparedness and planning expenses including an approximately \$49.8 million increase in marketing and sales expenses, an \$8.7 million increase in employee compensation and benefits costs, and a \$12.1 million increase in stock compensation expense. The increase in stock compensation expense was primarily driven by a \$6.6 million charge related to the immediate vesting due to a modification of previously granted Change of Control options, and a \$3.4 million charge related to stock option modifications for terminated employees. There are no remaining Change of Control options outstanding as of June 30, 2017.

Net loss for the six months ended June 30, 2017 was \$138.5 million as compared to a net loss of a \$98.5 million for the six months ended June 30, 2016. This increase in our net loss of \$40 million or 40.6% was a result of the operating items discussed above partially offset by approximately a \$24.4 million decrease in debt conversion expense and approximately a \$3.6 million decrease in amortization of deferred financing costs, both related to the conversion of \$25.6 million of our convertible debt in the six months ended June 30, 2016.

## LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities was approximately \$57.3 million for the three months ended June 30, 2017, and \$120.8 million and \$60.1 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had approximately \$82 million of cash and cash equivalents. During the six months ended June 30, 2017 and 2016, we incurred losses from operations of \$73.6 million and \$136.3 million, respectively. As of June 30, 2017, we had working capital of approximately \$59.4 million, as compared to approximately \$59.5 million at December 31, 2016.

Notwithstanding the Company's recent equity financing, we will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that 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 delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our consolidated financial statements as of December 31, 2016 and our unaudited condensed consolidated financial statements as of June 30, 2017 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report as of December 31, 2016 that includes an

explanatory paragraph referring to our recurring and continuing losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate profits. Our consolidated financial statements as of December 31, 2016 and our unaudited condensed consolidated financial statements as of June 30, 2017 do not include any adjustments that might result from the resolution of this uncertainty.

## **CRITICAL ACCOUNTING POLICIES**

### *Revenue recognition*

Synergy recognizes revenue from sales of TRULANCE when the earnings process is complete, which under Accounting Standards Codification ASC 605, Revenue Recognition is when revenue is realized or realizable and earned, there is persuasive evidence a revenue arrangement exists, delivery of goods or services has occurred, the sales price is fixed or determinable, and collectability is reasonably assured. Until we have the ability to reliably estimate returns of TRULANCE from our customers, revenue will be recognized based on patient prescriptions, and not based on sales to distributors. Product sales that are not yet patient prescriptions are classified as Deferred revenues, net. Product sales are recorded net of all sales related deductions 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 Company estimates these sales deductions based on contractual terms, historical payment experience, third party data, estimated utilization or redemption rates, government regulations, and customer inventory levels.

### *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 our inventory production plan and insuring 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.

### *Prior Period Adjustments*

The three months ended June 30, 2017, includes an adjustment of \$1.0 million related to the prior period. Had the adjustment been made during the prior period, Research and development expenses would have been \$3.1 million higher and Selling, general and administrative expenses would have been \$4.1 million lower during the three months ended March 31, 2017. The cumulative impact of these adjustments were not considered to be material to the Company's condensed consolidated financial statements for the three months ended March 31 2017 and there is no impact to the Company's condensed consolidated financial statements for the six months ended June 30, 2017.

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, 2016, filed with the SEC on March 1, 2017. There have been no other changes to our critical accounting policies since December 31, 2016.

## **OFF-BALANCE SHEET ARRANGEMENTS**

We had no off-balance sheet arrangements as of June 30, 2017.

## **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, 2017, we held \$82.0 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.

#### **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, 2017, our disclosure controls and procedures were not 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, due to material weaknesses identified for (1) the calculation of stock compensation expense for 'marked to market' consultant options and (2) account reconciliation controls related to accruals (See 'Prior Period Adjustments' section in Item 1: Notes to the Condensed Consolidated Financial Statements "Note 2 Basis of Presentation, Accounting Policies and Going Concern"). These control deficiencies did not result in a material misstatement to our previously issued condensed consolidated financial statements for the three months ended March 31, 2017 or our condensed consolidated financial statements for the three and six months ended June 30, 2017. However, these control deficiencies constitute a material weakness in our internal control over financial reporting due to the potential for the control deficiency to result in a material misstatement in our annual or interim consolidated financial statements that may not be prevented or detected.

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.

#### **Remediation Plan**

Since April 2017, we have been in the process of implementing a software system to house all issued stock options and to calculate stock based compensation expense, including 'marked to market' consultant options and expect the implementation to be completed for the quarter ending September 30, 2017.

In addition, during the quarter ended June 30, 2017, we implemented an automated reconciliation tool to ensure the completeness of account reconciliations. The material weaknesses cannot be considered remediated until the control has operated for a sufficient period of time and until management has concluded, through testing, that the control is operating effectively. Our goal is to remediate these material weaknesses by the end of 2017.

#### **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, 2017, except for changes to controls to remediate material weaknesses related to account reconciliations for accruals for which we implemented certain automated controls to ensure that certain invoices were entered in a timely basis.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

There have been no material changes from the legal proceedings disclosed in our Form 10-K for the year ended December 31, 2016, filed on March 1, 2017.

**ITEM 1a. RISK FACTORS**

There have been no material changes in our risk factors since the filing on March 1, 2017 of our Form 10-K for the year ended December 31, 2016.

**ITEM 2. PROPERTIES**

There have been no material changes in our properties since the filing on March 1, 2017 of our Form 10-K for the year ended December 31, 2016.

**ITEM 6. EXHIBITS**

- (a) Exhibits
- 3.1 Amendment to the Second Amended and Restated Certificate of Incorporation, as amended, filed with the Delaware Secretary of State on July 5, 2017 (incorporated by reference to Exhibit 3.1 to Form 8-K filed July 7, 2017)
- 10.1 Executive Employment Agreement dated April 17, 2017 by and between Synergy Pharmaceuticals Inc. and Gary Gemignani (incorporated by reference to Exhibit 10.1 to Form 8-K filed April 17, 2017).
- 10.2 Separation and Release Agreement between Synergy Pharmaceuticals Inc. and Kunwar Shailubhai dated May 24, 2017 (incorporated by reference to Exhibit 10.1 to Form 8-K filed May 26, 2017).
- 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, 2017, filed on August 9, 2017, 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.



**CERTIFICATIONS**

I, Gary S. Jacob, 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 9, 2017

/s/ GARY S. JACOB

Gary S. Jacob

*President, Chairman of Board, and Chief Executive Officer*

**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 9, 2017

/s/ GARY G. GEMIGNANI

Gary G. Gemignani

*Executive Vice President, Chief Financial Officer*

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
SYNERGY PHARMACEUTICALS INC.  
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2017  
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, 2017 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 9, 2017

/s/ GARY S. JACOB

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Gary S. Jacob

*President, Chairman of Board, and Chief Executive Officer*

**CERTIFICATION OF SENIOR VICE PRESIDENT, FINANCE  
SYNERGY PHARMACEUTICALS INC.  
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2017  
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, Finance 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, 2017 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 9, 2017

/s/ GARY G. GEMIGNANI

Gary G. Gemignani

*Executive Vice President, Chief Financial Officer*

## CERTIFICATIONS

I, Gary S. Jacob, 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 9, 2017

| /s/ GARY S. JACOB

Gary S. Jacob

*President, Chairman of Board, and Chief Executive Officer*

## 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 9, 2017

| /s/ GARY G. GEMIGNANI

Gary G. Gemignani

*Executive Vice President, Chief Financial Officer*

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**  
**SYNERGY PHARMACEUTICALS INC.**  
**FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2017**  
**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, 2017 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 9, 2017

/s/ GARY S. JACOB

Gary S. Jacob

*President, Chairman of Board, and Chief Executive Officer*

**CERTIFICATION OF EXECUTIVE VICE PRESIDENT, CHIEF FINANCIAL OFFICER**

**SYNERGY PHARMACEUTICALS INC.**

**FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2017**

**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, 2017 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 9, 2017

| /s/ GARY G. GEMIGNANI

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Gary G. Gemignani

*Executive Vice President, Chief Financial Officer*