### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 10-Q

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

For the quarterly period ended March 31, 2014

or

# □ 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: 000 -35005

VENTRUS BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

**20-8729264** (I.R.S. Employer Identification No.)

**99 Hudson Street, 5th Floor, New York, New York 10013** (Address of principal executive offices, including zip code)

(646) 706-5208

(Registrant's telephone number, including area code)

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

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 definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer Non-accelerated Filer Accelerated Filer  $\Box$  (Do not check if smaller reporting company)

Smaller Reporting Company x

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

As of May 12, 2014 there were 23,396,259 shares of registrant's common stock outstanding.

celerated Filer

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# Item 1. Financial Statements

# **VENTRUS BIOSCIENCES, INC.** A Development Stage Company

# CONDENSED BALANCE SHEETS

|  | March 31,<br>2014<br>(Unaudited) |               | D  | ecember 31,<br>2013 |
|--|----------------------------------|---------------|----|---------------------|
| ASSETS   |                                  | ()            |    |                     |
| Current assets:  |                                  |               |    |                     |
| Cash and cash equivalents  | \$                               | 23,636,722    | \$ | 27,061,268          |
| Other current assets   |                                  | 259,194       |    | 63,672              |
| Total current assets   |                                  | 23,895,916    |    | 27,124,940          |
| Computer equipment, net  |                                  | 8,425         |    | 7,102               |
| Total assets   | \$                               | 23,904,341    | \$ | 27,132,042          |
| LIABILITIES AND STOCKHOLDERS' EQUITY   |                                  |               |    |                     |
| Current liabilities:   |                                  |               |    |                     |
| Accounts payable   | \$                               | 1,435,200     | \$ | 2,614,619           |
| Accrued expenses   |                                  | 27,249        |    | 23,435              |
| Total current liabilities  |                                  | 1,462,449     |    | 2,638,054           |
| Commitments  |                                  |               |    |                     |
| Stockholders' equity:  |                                  |               |    |                     |
| Preferred stock, \$.001 par value; 5,000,000 shares authorized; 0 and 220,000 issued and outstanding at March 31, 2014 and December 31, 2013, respectively |                                  | _             |    | 220                 |
| Common stock, \$.001 par value; 50,000,000 shares authorized; 23,396,259 and 20,733,895 issued and   |                                  |               |    | 220                 |
| outstanding at March 31, 2014 and December 31, 2013, respectively  |                                  | 23,396        |    | 20,734              |
| Additional paid-in capital   |                                  | 137,842,936   |    | 135,827,557         |
| Common stock issuable, 125,000 shares at March 31, 2014 and December 31, 2013  |                                  | 368,750       |    | 368,750             |
| Deficit accumulated during the development stage   |                                  | (115,793,190) |    | (111,723,273)       |
| Total stockholders' equity   |                                  | 22,441,892    |    | 24,493,988          |
| Total liabilities and stockholders' equity   | \$                               | 23,904,341    | \$ | 27,132,042          |

See Notes to Condensed Financial Statements

# CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)

|  |    | Three Months<br>Ended<br>March 31,<br>2014 |    | Three Months<br>Ended<br>March 31,<br>2013 |    | Period from<br>ctober 7, 2005<br>Inception) to<br>farch 31, 2014 |
|--|----|--|----|--|----|--|
| Operating expenses:  |    |  |    |  |    |  |
| Research and development                                       | \$ | 2,973,690                                  | \$ | 2,609,103                                  | \$ | 77,046,174   |
| General and administrative                                     |    | 1,136,461                                  |    | 1,159,865                                  |    | 25,298,563   |
|  |    |  |    |  |    |  |
| Loss from operations   |    | (4,110,151)                                |    | (3,768,968)                                |    | (102,344,737)  |
| Other income (expense)   |    |  |    |  |    |  |
| Interest income  |    | 40,234                                     |    | 45,873                                     |    | 402,373  |
| Interest expense:  |    |  |    |  |    |  |
| Beneficial conversion feature                                  |    | -  |    | -  |    | (6,001,496)  |
| Amortization of debt discount and warrants                     |    | -  |    | -  |    | (2,865,758)  |
| Interest expense   |    | -  |    | -  |    | (4,983,572)  |
|  |    |  |    |  |    | (13,850,826)   |
| Net loss   | \$ | (4,069,917)                                | \$ | (3,723,095)                                | \$ | (115,793,190)  |
|  |    |  | -  |  |    |  |
| Basic and diluted net loss per common share                    | \$ | (0.18)                                     | \$ | (0.22)                                     |    |  |
|  | _  |  | -  |  |    |  |
| Weighted average common shares outstanding - basic and diluted |    | 22,094,700                                 |    | 17,055,572                                 |    |  |

See Notes to Condensed Financial Statements

# CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (UNAUDITED) For the Three Months Ended March 31, 2014

|   | Common<br>Shares | Stock<br>Preferred<br>Shares | Amount           | Additional Paid-<br>in<br>Capital | Common Stock<br>Issuable | Deficit<br>Accumulated<br>During the<br>Development<br>Stage | Total         |
|---|------------------|------------------------------|------------------|-----------------------------------|--------------------------|--|---------------|
| Balance at January 1, 2014  | 20,733,895       | 220,000                      | \$ 20,954        | \$ 135,827,557                    | 368,750                  | (\$ 111,723,273)   | \$ 24,493,988 |
| Proceeds from the sale of common stock at<br>average price of \$3.81 per share, net of<br>offering costs        | 462,364          | -                            | 462              | 1,762,642                         | -                        | _  | 1,763,104     |
| Stock-based compensation to employees<br>and directors for the period from January 1, 2014<br>to March 31, 2014 | -<br>-           | -                            | -                | 253,813                           | -                        | -  | 253,813       |
| Stock-based payments to consultants for<br>the period from January 1, 2014 to<br>March 31, 2014                 | -                | -                            | -                | 904                               | -                        | _  | 904           |
| Preferred stock 220,000 shares converted<br>to 2,200,000 Common stock shares                                    | 2,200,000        | (220,000)                    | 1,980            | (1,980)                           | -                        | -  | -             |
| Net loss for the period   | <u> </u>         | <u> </u>                     | <u> </u>         | <u> </u>                          | <u> </u>                 | (4,069,917)  | (4,069,917)   |
| Balance at March 31, 2014   | 23,396,259       | <u> </u>                     | <u>\$ 23,396</u> | \$ 137,842,936                    | \$ 368,750               | <u>\$ (115,793,190</u> )                                     | \$ 22,441,892 |

For changes in the Statement of Stockholders' Equity from October 7, 2005 (inception) to December 31, 2013, refer to the Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 31, 2014.

See Notes to Condensed Financial Statements

# CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)

|  | Ended Ended |             | Ended Ended<br>March 31, March 3 |             | EndedEndedMarch 31,March 31, |  | Ended Ended<br>March 31, March 31, |  | Ended<br>March 31, |  | Ended<br>March 31, |  | Ended Ended<br>March 31, March 31, |  | Ended Ended<br>March 31, March 31 |  | Ended Ended<br>March 31, March 31, |  | EndedEndedMarch 31,March 31 |  | Ended Ended<br>March 31, March 31, |  | Ended Ended<br>March 31, March 31, |  | EndedEndedMarch 31,March 31, |  | Period from<br>October 7, 2005<br>(Inception) to<br>March 31, 2014 |
|--|-------------|-------------|----------------------------------|-------------|------------------------------|--|------------------------------------|--|--------------------|--|--------------------|--|------------------------------------|--|-----------------------------------|--|------------------------------------|--|-----------------------------|--|------------------------------------|--|------------------------------------|--|------------------------------|--|--|
| Cash flows from operating activities:  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Net loss   | \$          | (4,069,917) | \$                               | (3,723,095) | \$ (115,793,190)             |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
|  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Adjustments to reconcile net loss to net cash used in operating activities:    |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Stock-based compensation   |             | 253,813     |                                  | 268,016     | 10,702,524                   |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Stock-based payments to consultants  |             | 904         |                                  | 16,574      | 4,367,321                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Depreciation   |             | 1,266       |                                  | 1,267       | 43,106                       |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Stock issued in connection with license agreement                              |             | -           |                                  | -           | 414,825                      |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Charge resulting from beneficial note conversion                               |             | -           |                                  | -           | 6,001,496                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Stock issued to vendor   |             | -           |                                  | -           | 5,000                        |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Warrants issued in connection with related party note conversion               |             | -           |                                  | -           | 1,255,978                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Amortization of deferred financing costs and debt discount                     |             | -           |                                  | -           | 3,466,010                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Non-cash research and development  |             | -           |                                  | -           | 1,087,876                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Interest payable - notes   |             | -           |                                  | -           | 2,139,909                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
|  |             | -           |                                  | -           |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Expenses paid on behalf of the Company satisfied through the issuance of notes |             | -           |                                  | -           | 227,910                      |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Interest payable - related parties   |             | -           |                                  | -           | 266,279                      |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
|  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Changes in operating assets and liabilities:                                   |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Other current assets   |             | (195,522)   |                                  | (164,066)   | (259,194)                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Accounts payable and accrued expenses  |             | (1,175,605) |                                  | (768,815)   | 1,274,912                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
|  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Net cash used in operating activities  |             | (5,185,061) |                                  | (4,370,119) | (84,799,238)                 |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
|  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Cash flows from investing activities:  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Purchase of office and computer equipment                                      |             | (2,589)     |                                  | -           | (51,530)                     |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Net cash used in investing activities  |             | (2,589)     |                                  | -           | (51,530)                     |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Cash flows from financing activities:  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Net proceeds from sale of common and preferred stock                           |             | 1,763,104   |                                  | 20,754,418  | 95,477,378                   |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Proceeds from notes payable  |             | -           |                                  | -           | 11,522,380                   |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Proceeds from notes payable to related parties                                 |             | -           |                                  | -           | 5,041,953                    |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
| Payment for deferred financing costs   |             | -           |                                  | -           | (1,431,603)                  |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |
|  |             |             |                                  |             |                              |  |                                    |  |                    |  |                    |  |                                    |  |                                   |  |                                    |  |                             |  |                                    |  |                                    |  |                              |  |  |

# **CONDENSED STATEMENTS OF CASH FLOWS (continued)**

|   | Three M<br>End<br>March 3 | ed       | E  | Months<br>nded<br>31, 2013 | Oct<br>(Ir | eriod from<br>ober 7, 2005<br>nception) to<br>rch 31, 2014 |
|---|---------------------------|----------|----|----------------------------|------------|--|
| Repayment of notes  |                           | -        |    | -                          |            | (2,719,380)  |
| Repayment of notes payable - related party  |                           | -        |    | -                          |            | (1,573,000)  |
| Proceeds from the exercise of warrants and options                                  |                           | -        |    | -                          |            | 2,169,762  |
| Net cash provided by financing activities   | 1,                        | 763,104  | 2  | 0,754,418                  |            | 108,487,490  |
| Net increase (decrease) in cash and cash equivalents                                | (3,                       | 424,546) | 1  | 6,384,299                  |            | 23,636,722   |
| Beginning of period   | 27,                       | 061,268  | 2  | 0,489,219                  |            | -  |
| End of period   | 23,                       | 636,722  | 3  | 6,873,518                  |            | 23,636,722   |
| Supplemental schedule of non-cash financing activities:                             |                           |          |    |                            |            |  |
| Warrants issued to placement agent  | \$                        | -        | \$ | -                          | \$         | 341,334  |
| Warrants issued to investors in connection with convertible notes                   | \$                        | _        | \$ | _                          | \$         | 1,166,989  |
| Debt discount on Paramount Credit Partners, LLC notes                               | \$                        | -        | \$ | -                          | \$         | 782,376  |
| Related party notes and accrued interest converted to 2010 Senior convertible notes | \$                        | -        | \$ | -                          | \$         | 3,995,667  |
| Debt discount on 2010 senior convertible notes                                      | \$                        | -        | \$ | _                          | \$         | 1,468,254  |
| Notes and accrued interest converted to common stock                                | \$                        | -        | \$ | -                          | \$         | 14,003,158   |
| Supplemental disclosure - cash paid for interest                                    | \$                        | -        | \$ | -                          | \$         | 685,397  |

See Notes to Condensed Financial Statements

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#### Notes to Condensed Financial Statements (March 31, 2014)

#### Note 1 - Organization, Business and Basis of Presentation:

#### **Organization and business:**

Ventrus BioSciences Inc. ("Ventrus" or the "Company") is a development-stage specialty pharmaceutical company currently focused on the development of gastrointestinal products, including infections of the gastrointestinal system. Ventrus was incorporated in the State of Delaware on October 7, 2005 (date of inception) and commenced operations in April 2007.

The Company has in-licensed four product candidates, two of which it has been actively developing. The Company is developing VEN 307 for the relief of pain associated with anal fissures. The Company plans to develop VEN 310 as a colonic delivery mechanism for bacteria, complex proteins, viral antigens and small molecules. The Company also intends to in-license or acquire other development stage as well as pre-clinical compounds and biologics. The Company is not actively pursuing the development of VEN 308 at this time. In June 2012, the Company ceased all activity related to a former product candidate, VEN 309.

In February 2014 the Company announced the results of the clinical trial for VEN 307 (diltiazem 2% cream) demonstrated no significant improvement compared to a placebo.

#### **Basis of presentation:**

The accompanying condensed balance sheet as of December 31, 2013, which has been derived from the Company's audited financial statements, and the unaudited interim condensed financial statements, have been prepared in accordance with U.S. generally accepted accounting principles and the rules and regulations of the Securities and Exchange Commission ("SEC") related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information presented not misleading. The unaudited interim condensed financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the results for the periods presented. All such adjustments are of a normal and recurring nature. These unaudited condensed financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 31, 2014. The operating results presented in these unaudited condensed financial statements are not necessarily indicative of the results that may be expected for any future periods.

#### **Capital Resources:**

The Company has not derived any revenue from product sales to date as our products have not been approved for sale by the FDA or any foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, the proceeds from the exercise of warrants and stock options and issuance of debt. The Company has incurred losses from operations and negative cash flows since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. Management believes the Company currently has sufficient funds to meet its operating requirements for the next twelve months. If the Company cannot generate significant cash from its operations, it intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, or other arrangements and it cannot assure such funding will be available on reasonable terms, or at all.

### Note 2 - Summary of Significant Accounting Policies:

#### **Cash and Cash Equivalents:**

All highly liquid investments with maturities of three months or less at the time of purchase are considered to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings. The Company maintains its cash in bank deposit and other accounts, the balances of which, at times and at March 31, 2014, exceed federally insured limits.



# Notes to Condensed Financial Statements (continued) (March 31, 2014)

# Use of estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying financial statements include the fair value of stock options and warrants granted to employees, consultants, directors, investors, licensors, placement agents and underwriters.

Additionally, the Company provides a valuation allowance for deferred income tax assets when it is considered more likely than not that all or a portion of such deferred income tax assets will not be realized.

# Stock-based compensation:

The Company's share-based compensation cost is measured at grant date, using the Black-Scholes option pricing model to estimate the fair value of the award, and is recognized as expense over the employee's or director's requisite service period on a straight-line basis. The Company accounts for stock options and warrants granted to non-employees on a fair value basis which is estimated using the Black-Scholes option pricing model. The initial non-cash charge to operations for non-employee options and warrants with vesting are revalued at the end of each reporting period until vested and recognized as consulting expense over the related vesting period.

#### **Research and development:**

Research and development expenses include personnel and facility-related expenses, third party contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where the Company enters into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, costs are expensed as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

The Company's accruals for clinical trials are based on estimates of the services received and pursuant to contracts with the respective clinical trial centers and clinical research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received. As such, expense accruals related to clinical trials are recognized based on an estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

#### **Income taxes:**

The Company's income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.



# Notes to Condensed Financial Statements (continued) (March 31, 2014)

#### Loss per common share:

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. Since the Company has only incurred losses, basic and diluted net loss per share is the same. The number of potentially dilutive securities (options, warrants, restricted stock units and preferred stock) excluded from the diluted loss per share calculation for the three-month periods ended March 31, 2014 and 2013 was 3,814,170 and 4,983,126, respectively.

### Note 3 - Commitments:

#### **Employment agreements:**

On January 15, 2014, the Company entered into an employment agreement with its Chief Executive Officer and its Chief Financial Officer, with an effective date of December 22, 2013. Each agreement has a term of two years and will be automatically extended for additional one-year periods unless the Company notifies the officer at least 180 days prior to the then current expiration date that it intends to not extend the employment agreement. The employment agreements provide for a base salary of \$475,000 per year for the Chief Executive Officer and \$300,000 for the Chief Financial Officer, and an annual discretionary bonus of up to 50% of the officer's base salary based on financial, clinical development and business milestones established by the Board of Directors.

#### Note 4 - Stockholders' Equity:

#### **Common Stock Transactions:**

The Company filed a shelf registration statement with the Securities and Exchange Commission, which became effective on February 10, 2012, under which it may offer shares of its common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of \$100,000,000. As part of the shelf registration statement, the Company included a prospectus for an at-the-market common equity sales program for the sale of up to \$20,000,000 of common stock. From May 2012 through December 2013, the Company sold an aggregate of 8,154,245 shares of common stock and 220,000 shares of Series A Non-Voting Preferred Stock, convertible into 2,200,000 shares of common stock, under the shelf, resulting in net proceeds of approximately \$28,566,000. In January 2014, the Company sold an aggregate of 462,364 shares of common stock under the amended at-the-market common equity sales program, resulting in net proceeds of approximately \$1,763,000. As of March 31, 2014, an aggregate of approximately \$75,000,000 worth of securities was available under the shelf registration statement out of which approximately \$15,000,000 of common stock was available for the at-the-market common equity sales program. However, pursuant to SEC rules, because the Company's publicly held shares had a market value of less than \$75,000,000 as of March 31, 2014, the Company is limited to selling under the shelf in any 12-month period an amount of securities equal to one-third of the market value of its publicly held shares, which, as of March 31, 2014, was approximately \$9,900,000.

# Notes to Condensed Financial Statements (continued) (March 31, 2014)

## **Preferred Stock Transactions:**

The Series A non-voting convertible preferred shares have a liquidation preference of \$0.001 per share and each share of Series A preferred stock is convertible into 10 common shares of the Company's common stock at any time at the holder's option. During February 2014, all 220,000 outstanding shares of Series A preferred stock converted into an aggregate of 2,200,000 shares of the Company's common stock.

#### **Common Stock Options and Warrants:**

#### Warrants

In connection with the Company's financings from 2007 to 2010, the Company issued warrants to investors and/or placement agents to purchase shares of common stock as well as certain consultants.

A summary of the Company's warrant activity and related information is as follows:

|                                       | Three Months Ended March 31, 2014 |         |           |  |  |
|---------------------------------------|-----------------------------------|---------|-----------|--|--|
|                                       |                                   | Weighte | d Average |  |  |
|                                       | Shares                            | Exerci  | se Price  |  |  |
| Outstanding at beginning of period    | 861,046                           | \$      | 7.77      |  |  |
| Granted                               | -                                 | \$      | -         |  |  |
| Exercised                             | -                                 | \$      | -         |  |  |
| Expired                               | (104,867)                         | \$      | 6.60      |  |  |
|                                       |                                   |         |           |  |  |
| Outstanding at end of period          | 756,179                           | \$      | 7.93      |  |  |
| Warrants exercisable at end of period | 756,179                           | \$      | 7.93      |  |  |

#### Common Stock

On April 5, 2013, the Company granted restricted stock units to four employees under the 2010 Plan for an aggregate of 500,000 shares of common stock. Of these units, 25% vested immediately at the grant date. The remaining 75% of the units will vest in equal 25% tranches if the 20 trading day volume-weighted average price of our common stock as reported on the NASDAQ Capital Market is at least \$4.15, \$5.15 and \$6.15, respectively. The performance period for the unvested restricted stock units ends on June 30, 2016; if one or more of the stock price thresholds are not met by that date the unvested units will expire. Each employee elected to defer receipt of all shares issuable under the units, including the immediately vested shares, (these shares are shown as issuable at March 31, 2014) until the earliest of termination of employment, a change in control of Ventrus, or April 1, 2015. The restricted stock units were issued to employees and officers at a price equal to the market price of the Company's stock at the date of grant. The Company estimated the fair value of the restricted stock units using the Monte Carlo valuation model with the following assumptions; volatility of 56.10%, risk free interest rate of 1.934%, and dividend rate of 0%. The total estimated fair value of the restricted stock units is approximately \$1,135,000. Compensation costs for restricted stock award are being recognized on a straight-line basis over the performance period. The first 25% of restricted stock grant was immediately expensed.



## Notes to Condensed Financial Statements (continued) (March 31, 2014)

A summary of the status of our unvested restricted stock units as of March 31, 2014 is as follows:

|   | Three Months I | Three Months Ended March 31, 201 |   |  |  |  |
|---|----------------|----------------------------------|---|--|--|--|
|   | Shares         | Grant Da                         | ed Average<br>ate Fair Value<br>r Share |  |  |  |
| Restricted stock units unvested as of January 1, 2014 | 375,000        | \$                               | 2.04                                    |  |  |  |
| Granted   | -              | \$                               | -                                       |  |  |  |
| Shares vested and issuable                            | -              | \$                               | -                                       |  |  |  |
|   |                |                                  |   |  |  |  |
| Restricted stock units unvested as of March 31, 2014  | 375,000        | \$                               | 2.04                                    |  |  |  |
|   |                |                                  |   |  |  |  |
| Stock Options   |                |                                  |   |  |  |  |

In January 2014, the Company granted options to purchase an aggregate of 608,500 shares under the 2010 Plan to the Chief Executive Officer and the Chief Financial Officer at an exercise price of \$3.81 per share. The Company also granted options to purchase 5,000 shares to a consultant at a price of \$3.76.

A summary of the Company's option activity and related information is as follows:

|                                      |           | Three Months Ended<br>March 31, 2014 |                   |                              |  |
|--------------------------------------|-----------|--------------------------------------|-------------------|------------------------------|--|
|                                      |           | Weighted<br>Average                  |                   |                              |  |
|                                      | Shares    | ]                                    | Exercise<br>Price | Aggregate<br>Intrinsic Value |  |
| Outstanding at beginning of period   | 2,338,491 | \$                                   | 5.87              | \$                           |  |
| Granted                              | 613,500   | \$                                   | 3.81              | \$                           |  |
| Exercised                            | -         | \$                                   | -                 | \$                           |  |
| Forfeited                            | (269,000) |                                      | 7.22              |                              |  |
| Outstanding at end of period         | 2,682,991 | \$                                   | 5.26              | \$                           |  |
| Options exercisable at end of period | 2,069,491 | \$                                   | 5.69              |                              |  |

The fair value of the options granted for the three-month period ended March 31, 2014, was based on the following assumptions:

|                          | 2014    |
|--------------------------|---------|
| Risk-free interest rate  | 2.30%   |
| Expected volatility      | 51.29%  |
| Expected life of options | 5 years |
| Expected dividend yield  | 0%      |

### Notes to Condensed Financial Statements (continued) (March 31, 2014)

Estimated future stock-based compensation expense relating to unvested stock options is as follows:

|   | Ft | iture Stock |
|---|----|-------------|
|   |    | Option      |
|   | Co | mpensation  |
| Calendar Years Ending December 31,                                      |    | Expense     |
| 2014 (April through December))  | \$ | 706,326     |
| 2015  |    | 619,440     |
| 2016  |    | 542,500     |
| 2017  |    | 63,500      |
|   |    |             |
| Total estimated future stock-based compensation expense – stock options | \$ | 1,931,766   |

The weighted average remaining contractual life of options outstanding at March 31, 2014 is approximately 7 years.

Stock-based compensation expensed to research and development expense for the three months ended March 31, 2014 and 2013 was \$ (4,335) (including reversal of charges related to unvested options which were forfeited) and \$143,919, respectively. Stock-based compensation expensed to general and administrative expense for the three months ended March 31, 2014 and 2013 was \$259,052 and \$140,671 respectively.

#### Note 5 - License Agreements:

### Diltiazem (VEN 307) and Phenylepherine (VEN 308)

The Company has an exclusive royalty-bearing license agreement with S.L.A. Pharma, AG ("S.L.A. Pharma") to sell, make and use diltiazem (VEN 307) for treatment, through topical administration, of anal fissures and phenylepherine (VEN 308) for treatment, through topical administration, of fecal incontinence (referred to collectively as the "Compound Technologies") in the United States, Canada and Mexico. In the event that the Compound Technologies are commercialized, Ventrus is obligated to pay to S.L.A. Pharma annual royalties, based upon net sales of the products. In addition, Ventrus is required to make payments to S.L.A. Pharma up to an aggregate amount of \$20 million upon the achievement of various milestones related to regulatory events. On October 9, 2012, Ventrus made a milestone payment of \$125,000 to S.L.A. Pharma which was due upon Investigational Review Board approval of a Phase III study of a licensed product incorporating VEN 307.

Should Ventrus make any improvements regarding the Compound Technologies, Ventrus is required to grant S.L.A. Pharma licenses to use such improvements.

As compensation for S.L.A. Pharma's participation in the management and the development of the Compound Technologies, Ventrus is required to make separate payments to S.L.A. Pharma equal to \$41,500 per month for each of diltiazem and phenylephrine. Per the agreement, Ventrus' obligation to make these monthly payments was to terminate upon a new drug application ("NDA") filing. Pursuant to amendments to the license agreement, the Company, as of September 30, 2010, was no longer required to make the \$41,500 monthly payments for phenylephrine. Management anticipates the \$41,500 per month management fee for diltiazem will cease before the end of 2014.



# Notes to Condensed Financial Statements (continued) (March 31, 2014)

Ventrus is also required to reimburse S.L.A. Pharma for clinical development costs associated with the technology development of both diltiazem and phenylephrine. Ventrus' total payment obligation for the diltiazem project was limited to \$4,200,000, and these payments were made from August 2007 through December 31, 2011. On June 6, 2011, Ventrus further amended the Exclusive License Agreement with S.L.A. Pharma. The amendment added additional services outside the scope of the agreement for which Ventrus was required to pay S.L.A. Pharma \$400,000. The report generated by these services was provided by S.L.A. Pharma during the first quarter of 2013 and Ventrus made the payment in February 2013. S.L.A. Pharma has been paid an additional \$600,000 in 2009 for services and there have been no other payments for the phenylephrine project. Management does not expect any services from S.L.A. Pharma for the phenylephrine project in the foreseeable future.

As of March 31, 2014, Ventrus' does not expect to pay S.L.A. Pharma additional development costs.

#### New Product Candidates

On November 8, 2013, Ventrus entered into a License and Collaboration Agreement with Therabiome, LLC, for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release platform technology. Under the agreement, Therabiome granted to Ventrus the exclusive worldwide license, with rights to sublicense, to develop the intellectual property for commercialization (a) in the use of bacteria, viruses, proteins and small molecules by oral delivery in (i) gastro-intestinal dysbiosis, including but not limited to C. difficile, irritable bowel syndrome-constipation and inflammatory bowel disease, (ii) auto-immune disorders and autism, including but not limited to as controlled by bacteria or virus, and (iii) orally delivered vaccines, including viral and bacterial, and (b) any oral delivery of small molecules using the licensed intellectual property. Ventrus will be solely responsible for all research and development activities with respect to any product it develops under the license.

For the license, Ventrus paid Therabiome an upfront non-refundable license fee of \$300,000. Ventrus must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones. Ventrus also must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region. Ventrus also must pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed two certain thresholds, a one-time cash payment upon reaching each threshold.

Therabiome must pay Ventrus royalties on annual net sales of any product it develops, using the intellectual property, in the low double to middouble percentages, depending on the level of development or involvement Ventrus had in the product.

# Notes to Condensed Financial Statements (continued) (March 31, 2014)

#### Note 6 - Legal Proceedings:

In June 2012, the Company announced that is product iferanserin (VEN 309), failed to meet its end point at the completion of its Phase III clinical trial. In May 2013 two purported class action lawsuits alleging violations of the federal securities laws were filed in New York against the Company, two of its executive officers and the lead underwriter of its initial public offering. The lawsuits include allegations that, during the class period between December 17, 2010 and June 25, 2012, the Company and its executive officers and underwriter made various statements related to the Company's product, iferanserin (VEN 309), including but not limited to, the market for the product, the potential competitors, and the results of clinical trials, thereby inflating the price of our common stock. The complaints seek unspecified damages, interest, attorneys' fees, and other costs. On July 23, 2013, the Court consolidated the actions and appointed lead plaintiffs and lead counsel. On September 16, 2013, lead plaintiffs filed a consolidated amended complaint. On November 22, 2013, the Company filed a motion to dismiss the consolidated amended complaint (the "Motion to Dismiss").

On May 5, 2014, the Court entered an order granting the Motion to Dismiss and dismissed the class action with prejudice. Lead plaintiffs have until June 4, 2014 to file notice of an appeal.

### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2013, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 31, 2014. In addition to historical information, this discussion and analysis contains 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. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1. Business - Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

#### Overview

We are a development-stage specialty pharmaceutical company currently focused on the development of gastrointestinal products, including infections of the gastrointestinal system.

We have in-licensed all of our product candidates, two of which we have been developing. We believe we have completed development of VEN 307 and have scheduled a meeting with the U.S. Food and Drug Administration, or FDA, on June 19, 2014 to discuss the filing of a new drug application, or NDA, for VEN 307 for the relief of pain associated with anal fissures. We plan to develop VEN 310 as a colonic delivery mechanism for bacteria, complex proteins, viral antigens and small molecules. We also intend to in-license or acquire other development stage as well as pre-clinical compounds and biologics. We are not actively pursuing the development of VEN 308 at this time.

In February 2014 we announced that the results of the clinical trial for VEN 307 (diltiazem 2% cream) demonstrated no significant improvement compared to placebo.

Since our inception, we have had no revenue from product sales, and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings since then. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates, maintaining and improving our patent portfolio and raising capital. We have generated significant losses to date, and we expect to continue to generate losses as we continue to develop VEN 307 and VEN 310, and any other product candidate we may acquire. As of March 31, 2014, we had a deficit accumulated during the development stage of \$115,793,190. Because we do not generate revenue from any of our product candidates, our losses will continue as we seek regulatory approval and commercialization of our product candidates. We do not anticipate FDA approval and launch of VEN 307 until at least the second half of 2015. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none is approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

We believe that our existing cash will be sufficient to fund our projected operating requirements through FDA approval of VEN 307 and into the second quarter of 2016. Thereafter, we will need revenue from commercial sales of VEN 307, if any, or additional capital to continue operations.

Our operations are subject to other certain risks and uncertainties, including but not limited to: uncertainty of product candidate development; uncertainty of regulatory approval; unpredictability of the size of the markets for, and market acceptance of, any of our products; our anticipated capital expenditures, our estimates regarding our capital requirements; our ability to retain and hire necessary employees and to staff our operations appropriately; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. Any significant delays in the development or marketing of products could have material adverse effect on our business and financial results.

#### **Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. Our significant accounting policies are more fully described in Note 2 to the December 31, 2013 audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013. The following accounting policies are critical to fully understanding and evaluating our financial results.

## Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements as well as the reported revenue, if any, and expenses during the reporting periods. On an ongoing basis, management evaluates their estimates and judgments. Management bases estimates on historical experience and on various other factors that they believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results might differ from these estimates under different assumptions or conditions.

#### Stock-Based Compensation

We account for stock options granted to employees and directors, measured at grant date, based on the estimated fair value of the award, which is recognized as expense over the employee's or director's requisite service period on a straight-line basis. We account for stock options and warrants granted to non-employees on a fair value basis. The initial non-cash charge to operations for nonemployee options and warrants with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and recognized as consulting expense over the related service period. For the purpose of valuing options and warrants granted to employees and directors and to non-employees, we use the Black-Scholes option pricing model. To determine the risk-free interest rate, we utilize the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the awards. We estimate the expected life of the options granted based on anticipated exercises in the future periods assuming the success of our business model as currently forecasted. For warrants and non-employee options, we use the contractual term of the warrant, the length of the note or option as the expected term. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options will be calculated by examining historical volatilities for publicly traded industry peers as we do not now and for the near future will not have any significant trading history for our common stock. Forfeiture rates will be calculated based on the expected service period for our employees.

#### Research and Development Expense

Research and development expenses consist primarily of costs associated with: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, and consultants; (iii) technology and intellectual property license costs; and (iv) patent reimbursements. All research and development is expensed as incurred. License fees and pre-approved milestone payments due under each research and development arrangement that are paid prior to regulatory approval are expensed when the license is entered into or the milestone is achieved.

Conducting a significant amount of research and development is central to our business model. Since our inception on October 7, 2005 to March 31, 2014, we have incurred \$77,046,174 in research and development expenses. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials.

We plan to continue our research and development expenses for at least the next 18 to 24 months in order to complete development of our most advanced product candidate, VEN 307.



The following table summarizes the research and development expenses related to our product candidates and other projects. The table reflects expenses directly attributable to each development candidate, which are tracked on a project basis.

|         |                 |                 |    | Period from    |
|---------|-----------------|-----------------|----|----------------|
|         | 3 Months        | 3 Months        | Oc | tober 7, 2005  |
|         | ended           | ended           |    | (inception) to |
|         | 3/31/2014       | 3/31/2013       | Μ  | arch 31, 2014  |
| VEN 307 | \$<br>2,699,691 | \$<br>2,465,184 | \$ | 28,549,433     |
| VEN 309 | \$<br>-         | \$<br>-         | \$ | 43,187,867     |
| VEN 310 | \$<br>278,334   | \$<br>-         | \$ | 636,584        |
| Other   | \$<br>(4,335)   | \$<br>143,919   | \$ | 4,672,290      |

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's clinical data, regulatory conversations with FDA, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments and the risks inherent in the development and regulatory process, we are unable to determine with certainty the duration and completion costs of current or future clinical stages of our product candidate or when, or to what extent, we will generate revenues from the commercialization and sale of our product candidate. Any estimate could change significantly depending on the progress, timing and results of non-clinical and clinical trials associated with any product candidate. We believe we currently have sufficient funds to meet our operating requirements and scheduled regulatory and development activities through FDA approval of VEN 307 and into the second quarter of 2016. Assuming such approval and launch, thereafter, if we cannot generate significant cash from our operations, we intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, or other arrangements, but we cannot assure such funding will be available on reasonable terms, or at all.

#### **Off-Balance Sheet Arrangements**

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

## **Results of Operations**

#### Comparison of the Three Months Ended March 31, 2014 and March 31, 2013

# Research and Development Expense

Research and development expense was \$2,973,690 for the three months ended March 31, 2014, an increase of \$364,587 or 0.14%, from \$2,609,103 for the same period in 2013. The reason for the increase was a combination of items: an increase of chemistry, manufacturing and controls, or CMC, of \$195,000, monitors for clinical sites of \$141,871, clinical research organization cost of \$725,728, clinical consulting cost of \$64,914, and salaries for research and development of \$133,733, all for VEN 307; and CMC for VEN 310 of \$278,334. These increased expenses were offset by a decrease in option expense of \$148,000, a decrease of \$413,902 in milestone payments made to S.L.A. Pharma in 2013, of which there were none in 2014, and a decrease in clinical site cost of \$609,000.

#### General and Administrative Expense

General and administrative, or G&A, expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services and accounting services, insurance and travel expenses, as well as the option expense associated with the grants of options to our employees, consultants and directors.



G&A expense was \$1,136,461 for the three months ended March 31, 2014, a decrease of \$23,404 or 0.02% from \$1,159,865 for the three months ended March 31, 2013.

#### Interest Income and Expense

Interest income was \$40,234 for the three months ended March 31, 2014 compared to \$45,873 for the same period in 2013 due to lower cash balances..

## Liquidity and Capital Resources

#### Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through December 31, 2013 principally with debt (which in connection with the initial public offering, all of the convertible notes, and accrued interest thereon, were converted into common stock) and equity financing, raising an aggregate of approximately \$ 108.4 million in net proceeds from public offerings and private placements from inception to March 31, 2014.

Further, under a shelf registration statement filed with the Securities and Exchange Commission, or SEC, we raised approximately \$1.8 million in net proceeds under our at-the-market equity sales program in January 2014. As of March 31, 2014, an aggregate of approximately \$75,000,000 worth of securities was available under the shelf registration statement out of which approximately \$15,000,000 of common stock was available for the at-the-market common equity sales program. However, pursuant to SEC rules, because our publicly held shares had a market value of less than \$75,000,000 as of March 31, 2014, we are limited to selling under the shelf in any 12-month period an amount of securities equal to one-third of the market value of our publicly held shares, which, as of March 31, 2014, was approximately \$9,900,000.

## Net Cash Used in Operating Activities

Net cash used in operating activities was \$5,185,061 for the three months ended March 31, 2014 and funded our research and development program and our general and administrative expenses.

#### Net Cash Used in Investing Activities

Net cash used in investing activities was \$2,589 for the three months ended March 31, 2014.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$1,763,104 for the three months ended March 31, 2014, and was from the sale of shares of our common stock pursuant to the at-the-market common equity sales program.

#### **Funding Requirements**

We expect to incur losses for at least the next several years as we develop VEN 307 and thereafter if the FDA does not approve VEN 307 or we do not launch it successfully. We expect to incur increasing research and development expenses for VEN 307 and to begin incurring the same for VEN 310. We expect that our general and administrative expenses will also increase as we add infrastructure for the planned commercialization of VEN 307, and continue to incur costs related to being a public company, including increased professional fees. Our future capital requirements will depend on a number of factors, including the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates.

Based on our cash position at March 31, 2014, and our analysis of our future development costs, we believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the FDA approval of VEN 307 and into the second quarter of 2016. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, which would cause us to require additional capital earlier. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. We may need to raise additional funds to in-license or acquire any other product candidate.

We may need to finance our future cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements, or a bank credit facility or other financing vehicle if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable. We do not currently have any commitments for future external funding. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we need additional capital and adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

## Item 4. Controls and Procedures

#### **Evaluation of Disclosure Controls and Procedures**

We maintain a system of disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e), which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting in the first quarter of 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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# PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

On May 9 and May 21, 2013, respectively, two purported class action lawsuits were filed in the U.S. District Court for the Southern District of New York against us, two of our executive officers and the lead underwriter of our initial public offering: <u>Ted Davison, William Gould and Ray Lenci, Individually</u> and on Behalf of All Others Similarly Situated , Plaintiffs v. Ventrus Biosciences, Inc., et al, 13CIV 3119; and <u>Michael Bartley, Individually</u> and on Behalf of All Others Similarly Situated , Plaintiffs v. Ventrus Biosciences, Inc., et al, 13CIV 3429.

The complaints have been brought as purported stockholder class actions, and, in general, include allegations that, during the class period between December 17, 2010 and June 25, 2012, we and our two executive officers violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder, and our two executive officers and the lead underwriter of our initial public offering violated Section 20(a) of the Exchange Act in making various statements related to our product, iferanserin (VEN 309), a topical treatment for symptomatic hemorrhoids, including but not limited to, the market for the product, the potential competitors, and the results of clinical trials, thereby inflating the price of our common stock. The complaints seek unspecified damages, interest, attorneys' fees, and other costs.

On July 8, 2013, three prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel (the "Motions to Consolidate"). The Court took the Motions to Consolidate under submission on July 17, 2013. On July 23, 2013, the Court consolidated the actions and appointed lead plaintiffs and lead counsel. On September 16, 2013, lead plaintiffs filed a consolidated amended complaint. On November 22, 2013, we filed a motion to dismiss the consolidated amended complaint (the "Motion to Dismiss").

On May 5, 2014, the Court entered an order granting the Motion to Dismiss and dismissed the class action with prejudice. Lead plaintiffs have until June 4, 2014 to file notice of an appeal.

### Item 5. Other Information

We intend to hold our 2014 Annual Meeting of Stockholders on July 9, 2014.

#### Item 6. Exhibits

| Exhibit<br>Number | Description of Document   | Registrant's<br>Form | Dated | Exhibit<br>Number | Filed<br>Herewith |
|-------------------|---|----------------------|-------|-------------------|-------------------|
| 31.1              | Certification of Chief Executive Officer Pursuant to Section 302 of the     |                      |       |                   | Х                 |
|                   | Sarbanes-Oxley Act of 2002.   |                      |       |                   |                   |
| 31.2              | 1.2 Certification of Chief Financial Officer Pursuant to Section 302 of the |                      |       | Х                 |                   |
|                   | Sarbanes-Oxley Act of 2002.   |                      |       |                   |                   |
| 32.1              | 2.1 Certification of Chief Executive Officer Pursuant to Section 906 of the |                      |       | Х                 |                   |
|                   | Sarbanes-Oxley Act of 2002.   |                      |       |                   |                   |
| 32.2              | 2 Certification of Chief Financial Officer Pursuant to Section 906 of the   |                      |       | Х                 |                   |
|                   | Sarbanes-Oxley Act of 2002.   |                      |       |                   |                   |
| 101               | Financials in XBRL format.  |                      |       |                   | Х                 |
|                   |   |                      |       |                   |                   |

# SIGNATURES

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 14, 2014

Date: May 14, 2014

Ventrus Biosciences, Inc.

By: /s/ Russell H. Ellison Russell H. Ellison

Chief Executive Officer

By: /s/ David J. Barrett

David J. Barrett Chief Financial Officer

## I, Russell H. Ellison, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ventrus Biosciences, 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 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: May 14, 2014

By: /s/ Russell H. Ellison

Russell H. Ellison Chief Executive Officer

## I, David J. Barrett, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ventrus Biosciences, 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 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: May 14, 2014

By: /s/ David J. Barrett

David J. Barrett Chief Financial Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Ventrus Biosciences, Inc. (the "Company") for the period ended March 31, 2014 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Russell H. Ellison, Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Russell H. Ellison Russell H. Ellison Chief Executive Officer

May 14, 2014

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Ventrus Biosciences, Inc. (the "Company") for the period ended March 31, 2014 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, David J. Barrett, Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ David J. Barrett David J. Barrett Chief Financial Officer

May 14, 2014