# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 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**

**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 0-22245**

# APRICUS BIOSCIENCES, INC.

**(Exact Name of Registrant as Specified in Its Charter)**

| **Nevada** | **87-0449967** |
|---|---|
| **(State or Other Jurisdiction of Incorporation or Organization)** | **(I.R.S. Employer Identification No.)** |

**11975 El Camino Real, Suite 300, San Diego, CA 92130**
**(Address of Principal Executive Offices) (Zip Code)**

**(858) 222-8041**
**(Registrant's telephone number, including area code)**

**Securities registered pursuant to Section 12(b) of the Act:**

| **Title of Each Class** | **Name of Exchange on Which Registered** |
|---|---|
| Common Stock, par value $.001 | The NASDAQ Capital Market |

**Securities registered pursuant to Section 12(g) of the Act:**

**None**

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

| | | | | |
|---|---|---|---|---|
| Large accelerated filer | ☐ | | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | (do not check if a smaller reporting company) | Smaller reporting company | ☒ |
| Emerging growth company | ☐ | | | |

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

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

As of July 28, 2017, 12,783,761 shares of the common stock, par value $.001, of the registrant were outstanding.

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**PART I.**

**ITEM 1. FINANCIAL STATEMENTS**

**Apricus Biosciences, Inc. and Subsidiaries**
**Condensed Consolidated Balance Sheets**
**(In thousands, except share and par value data)**

| | June 30, 2017 | December 31, 2016 |
|---|---|---|
| | (Unaudited) | |
| **Assets** | | |
| Current assets | | |
| Cash | $ 7,821 | $ 2,087 |
| Prepaid expenses and other current assets | 322 | 177 |
| Current assets of discontinued operations | 506 | 1,370 |
| Total current assets | 8,649 | 3,634 |
| Property and equipment, net | 121 | 164 |
| Other long term assets | 45 | 60 |
| Noncurrent assets of discontinued operations | — | 842 |
| Total assets | $ 8,815 | $ 4,700 |
| | | |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities | | |
| Note payable, net | $ — | $ 6,650 |
| Accounts payable | 140 | 686 |
| Accrued expenses | 716 | 1,236 |
| Accrued compensation | 657 | 614 |
| Current liabilities of discontinued operations | 331 | 2,108 |
| Total current liabilities | 1,844 | 11,294 |
| Warrant liabilities | 339 | 846 |
| Deferred rent | 60 | 76 |
| Total liabilities | 2,243 | 12,216 |
| | | |
| Commitments and contingencies | | |
| Stockholders' equity (deficit) | | |
| Preferred stock, $.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2017 and December 31, 2016 | $ — | $ — |
| Common stock, $.001 par value, 30,000,000 shares authorized, 12,783,761 and 7,733,205 issued and outstanding as of June 30, 2017 and December 31, 2016, respectively | 13 | 8 |
| Additional paid-in-capital | 316,268 | 308,784 |
| Accumulated deficit | (309,709) | (316,308) |
| Total stockholders' equity (deficit) | 6,572 | (7,516) |
| **Total liabilities and stockholders' equity (deficit)** | $ 8,815 | $ 4,700 |

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

**Apricus Biosciences, Inc. and Subsidiaries**
**Condensed Consolidated Statements of Operations (Unaudited)**
**(In thousands, except per share data)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Operating expense | | | | |
| Research and development | $ 839 | $ 2,503 | $ 1,266 | $ 5,104 |
| General and administrative | 1,602 | 2,122 | 3,043 | 4,328 |
| Total operating expense | 2,441 | 4,625 | 4,309 | 9,432 |
| Loss before other income (expense) | (2,441) | (4,625) | (4,309) | (9,432) |
| Other income (expense) | | | | |
| Interest income (expense), net | 3 | (258) | (92) | (537) |
| Loss on extinguishment of debt | — | — | (422) | — |
| Change in fair value of warrant liability | 716 | 1,637 | (292) | 4,437 |
| Other financing expenses | — | — | — | (205) |
| Other expense, net | — | (7) | (26) | (11) |
| Total other income (expense) | 719 | 1,372 | (832) | 3,684 |
| Loss from continuing operations | (1,722) | (3,253) | (5,141) | (5,748) |
| Income (loss) from discontinued operations | 248 | (85) | 11,740 | (95) |
| Net income (loss) | $ (1,474) | $ (3,338) | $ 6,599 | $ (5,843) |
| | | | | |
| Basic and diluted earnings (loss) per share | | | | |
| Continuing operations | $ (0.15) | $ (0.53) | $ (0.54) | $ (0.98) |
| Discontinued operations | $ 0.02 | $ (0.01) | $ 1.23 | $ (0.02) |
| Total earnings (loss) per share | $ (0.13) | $ (0.54) | $ 0.69 | $ (1.00) |
| | | | | |
| Weighted average common shares outstanding for basic and diluted earnings (loss) per share | 11,335 | 6,182 | 9,547 | 5,843 |

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

**Apricus Biosciences, Inc. and Subsidiaries**
**Condensed Consolidated Statements of Cash Flows (Unaudited)**
**(In thousands)**

| | For the Six Months Ended June 30, | |
|---|---|---|
| | **2017** | **2016** |
| Cash flows from operating activities: | | |
| Net income (loss) | $ 6,599 | $ (5,843) |
| Net income (loss) from discontinued operations | 11,740 | (95) |
| Net loss from continuing operations | (5,141) | (5,748) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities from continuing operations: | | |
| Depreciation and amortization | 77 | 145 |
| Non-cash interest expense | 56 | 194 |
| Stock-based compensation expense | 572 | 1,094 |
| Warrant liabilities revaluation | 292 | (4,437) |
| Loss on debt extinguishment | 422 | — |
| Other financing expenses | — | 205 |
| Changes in operating assets and liabilities from continuing operations: | | |
| Prepaid expenses and other current assets | (145) | 218 |
| Other assets | 14 | 22 |
| Accounts payable | (547) | 401 |
| Accrued expenses | (478) | (513) |
| Accrued compensation | 43 | (383) |
| Deferred compensation | — | (90) |
| Other liabilities | (16) | 20 |
| Net cash used in operating activities from continuing operations | (4,851) | (8,872) |
| Cash flows from investing activities from continuing operations: | | |
| Release of restricted cash | — | 280 |
| Purchase of fixed assets, net | — | (18) |
| Net cash provided by investing activities from continuing operations | — | 262 |
| Cash flows from financing activities from continuing operations: | | |
| Issuance of common stock and warrants, net of offering costs | 6,078 | 9,605 |
| Repayment of capital lease obligations | — | (3) |
| Repayment of notes payable | (7,129) | (1,526) |
| Net cash (used in) provided by financing activities from continuing operations | (1,051) | 8,076 |
| Cash flows from discontinued operations: | | |
| Net cash used in operating activities of discontinued operations | (114) | (630) |
| Net cash provided by investing activities of discontinued operations | 11,750 | — |
| Net cash provided by (used in) discontinued operations | 11,636 | (630) |
| Net increase (decrease) in cash | 5,734 | (1,164) |
| Cash, beginning of period | 2,087 | 3,887 |
| Cash, end of period | $ 7,821 | $ 2,723 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | $ 92 | $ 354 |
| Non-cash investing and financing activities: | | |
| Issuance of restricted stock | $ — | $ 249 |
| Accrued transaction costs for 2017 financing activities | $ (135) | $ — |
| Issuance of placement agent warrants | $ 176 | $ — |
| Reclassification of warrant liabilities to equity | $ 798 | $ — |

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

**Apricus Biosciences, Inc. and Subsidiaries**
**Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)**
**(Unaudited) (In thousands)**

| | Common Stock (Shares) | Common Stock (Amount) | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|
| Balance as of December 31, 2016 | 7,733 | $ 8 | $ 308,784 | $ (316,308) | $ (7,516) |
| Stock-based compensation expense | — | — | 572 | — | 572 |
| Issuance of common stock due to the vesting of restricted stock | 21 | — | — | — | — |
| Issuance of common stock and warrants, net of offering costs | 5,030 | 5 | 6,114 | — | 6,119 |
| Reclassification of warrant liabilities to equity | — | — | 798 | — | 798 |
| Net income | — | — | — | 6,599 | 6,599 |
| Balance as of June 30, 2017 | 12,784 | $ 13 | $ 316,268 | $ (309,709) | $ 6,572 |

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

**Apricus Biosciences, Inc. and Subsidiaries**
**Notes to Condensed Consolidated Financial Statements (Unaudited)**

## 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Financial Statement Presentation

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2016 included in the Apricus Biosciences, Inc. and subsidiaries (the "Company") Annual Report on Form 10-K ("Annual Report") filed with the U.S. Securities and Exchange Commission (the "SEC") on March 13, 2017. The accompanying financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. In the opinion of management, the accompanying condensed consolidated financial statements for the periods presented reflect all adjustments, consisting of only normal, recurring adjustments, necessary to fairly state the Company's financial position, results of operations and cash flows. Certain prior year items have been reclassified to conform to the current year presentation. The December 31, 2016 condensed consolidated balance sheet was derived from audited financial statements, but does not include all GAAP disclosures. The unaudited condensed consolidated financial statements for the interim periods are not necessarily indicative of results for the full year. The preparation of these unaudited condensed consolidated financial statements requires the Company to make estimates and judgments that affect the amounts reported in the financial statements and the accompanying notes. The Company's actual results may differ from these estimates under different assumptions or conditions.

### Liquidity

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes the Company is a going concern and that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company had an accumulated deficit of approximately $309.7 million and working capital of $6.8 million as of June 30, 2017 and reported net income of approximately $6.6 million and negative cash flows from operations for the six months ended June 30, 2017. While the Company believes it has enough cash to fund its current operating plans through the third quarter of 2018, the Company's history and other factors raise substantial doubt about the Company's ability to continue as a going concern. The Company has principally been financed through the sale of its common stock and other equity securities, debt financings, up-front payments received from commercial partners for the Company's products under development, and through the sale of assets. As of June 30, 2017, the Company had cash and cash equivalents of approximately $7.8 million.

On April 26, 2017, the Company completed an underwritten public offering (the "April 2017 Financing") for net proceeds of approximately $5.9 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. Pursuant to the underwriting agreement with H.C. Wainwright & Co., LLC (the "Underwriter"), the Company sold to the Underwriter an aggregate of 5,030,000 units. Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock, sold at a public offering price of $1.40 per unit. At the time of the offering closing, the Company did not have a sufficient number of authorized common stock to cover shares of common stock issuable upon the exercise of the warrants. The sufficient number of authorized common stock became available on May 17, 2017 when the Company received stockholder approval of the proposed amendment to the Company's Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock (the "Charter Amendment") and the Charter Amendment became effective on that date. The warrants will expire five years from May 17, 2017, the date the warrants became exercisable, and the exercise price of the warrants is $1.55 per share of common stock. In connection with this transaction, the Company issued to the underwriters warrants to purchase up to 251,500 shares of common stock (the "Underwriter Warrants"). The Underwriter Warrants have substantially the same terms as the warrants being sold concurrently to the investors in the offering, except that the Underwriter Warrants have a term of five years from the effective date of the related prospectus, or April 20, 2017, and an exercise price of $1.75 per share. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017 (File No. 333-217036), and a related prospectus.

On April 20, 2017, the Company entered into a warrant amendment with the holders of the Company's warrants to purchase common stock of the Company, issued in the September 2016 Financing as described below, pursuant to which, among other things, (i) the exercise price of the warrants was reduced to $1.55 per share (the exercise price of the warrants sold in the April 2017 Financing), and (ii) the date upon which such warrants became exercisable was changed to the effective date of the Charter Amendment, or May 17, 2017.

On March 8, 2017, the Company entered into an asset purchase agreement (the "Ferring Asset Purchase Agreement") with Ferring International Center S.A. ("Ferring'), pursuant to which it sold to Ferring its assets and rights related to Vitaros outside of the United States for up to approximately $12.7 million. In addition to an upfront payment of $11.5 million, Ferring paid the Company approximately $0.7 million for the delivery of certain product-related inventory and $0.25 million related to transition services. The Company is eligible to receive a second quarterly payment of $0.25 million related to transition services, subject to certain limitations, during the third quarter of 2017. The Company has retained the U.S. development and commercialization rights for Vitaros, which the Company has in-licensed from Allergan plc ("Allergan"). The Company used approximately $6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under its Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (Oxford and SVB are referred to together as the "Lenders").

In September 2016, the Company completed a registered direct offering of 1,082,402 shares of common stock for gross proceeds of approximately $3.7 million (the "September 2016 Financing"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase 0.75 of a share of common stock. See note 6 for further description. Under the terms of the securities purchase agreement entered into with such investors, the Company agreed not to sell any shares of common stock or common stock equivalents for a period of 90 days, which expired on December 27, 2016.

In July 2016, the Company and Aspire Capital Fund, LLC ("Aspire Capital") entered into a Common Stock Purchase Agreement (the "Aspire Purchase Agreement"), which provides that Aspire Capital is committed to purchase, if the Company chooses to sell and at the Company's discretion, an aggregate of up to $7.0 million of shares of the Company's common stock over the 24-month term of the Aspire Purchase Agreement. The Aspire Purchase Agreement can be terminated at any time by the Company by delivering notice to Aspire Capital. On July 5, 2016 (the "Aspire Closing Date"), the Company delivered to Aspire Capital a commitment fee of 151,899 shares of the Company's common stock at a value of $0.6 million (the "Commitment Shares") in consideration for Aspire Capital entering into the Aspire Purchase Agreement. Additionally, on the Aspire Closing Date, the Company sold 253,165 shares of the Company's common stock to Aspire Capital for proceeds of $1.0 million. Through June 30, 2017, 455,064 shares of the Company's common stock have been sold for gross proceeds of $1.2 million. However, in connection with the September 2016 and April 2017 Financings, the Company agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of each financing, which prohibition will run through April 20, 2018.

In January 2016, the Company entered into subscription agreements with certain purchasers pursuant to which it agreed to sell an aggregate of 1,136,364 shares of its common stock and warrants to purchase up to an additional 568,184 shares of its common stock to the purchasers for an aggregate offering price of $10.0 million, to take place in separate closings. Each share of common stock was sold at a price of $8.80 and included one half of a warrant to purchase a share of common stock. The warrants have an exercise price of $8.80 per share, became exercisable six months and one day after the date of issuance and will expire on the seventh anniversary of the date of issuance. During the first closing in January 2016, the Company sold an aggregate of 252,842 shares and warrants to purchase up to 126,421 shares of common stock for gross proceeds of $2.2 million. The remaining shares and warrants were sold in a subsequent closing in March 2016 for gross proceeds of $7.8 million following stockholder approval at a special meeting on March 2, 2016.

The Company currently has an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the Securities and Exchange Commission ("SEC") under which it may offer from time to time any combination of debt securities, common and preferred stock and warrants. As of June 30, 2017, the Company had approximately $74.1 million available under its Form S-3 shelf registration statement. Under current SEC regulations, at any time during which the aggregate market value of the Company's common stock held by non-affiliates ("public float"), is less than $75.0 million, the amount it can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Aspire Purchase Agreement, is limited to an aggregate of one-third of the Company's public float. SEC regulations permit the Company to use the highest closing sales price of the Company's common stock (or the average of the last bid and last ask prices of the Company's common stock) on any day within 60 days of sales under the shelf registration statement. As the Company's public float was less than $75.0 million as of June 30, 2017, the Company's usage of its S-3 shelf registration statement is limited. The Company still maintains the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements. The rules and regulations of the SEC or any other regulatory agencies may restrict the Company's ability to conduct certain types of financing activities, or may affect the timing of and amounts it can raise by undertaking such activities.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

The Company's future liquidity and capital funding requirements will depend on numerous factors, including:

- its ability to raise additional funds to finance its operations;
- its ability to maintain compliance with the listing requirements of The NASDAQ Capital Market;
- the timing and outcome of the Company's new drug application ("NDA"), resubmission for Vitaros, and any additional development requirements imposed by the U.S. Food and Drug Administration ("FDA") in connection with such resubmission;
- the outcome, costs and timing of clinical trial results for its product candidates;
- the extent and amount of any indemnification claims made by Ferring under the Ferring Asset Purchase Agreement;
- the emergence and effect of competing or complementary products;
- its ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- its ability to retain its current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that it has or may establish;
- the restrictions from using the Company's committed equity facility with Aspire Capital until April 2018;
- the trading price of the Company's common stock being above the $1.00 closing floor price that is required for the Company to use the committed equity financing facility with Aspire Capital when it becomes available in April 2018;
- the trading price of its common stock; and
- its ability to increase the number of authorized shares outstanding to facilitate future financing events.

In May 2016, the Company received notice from NASDAQ indicating that it was not in compliance with NASDAQ Listing Rule 5550(a)(2) because the closing bid price for its Common Stock had been below $1.00 per share for the previous thirty (30) consecutive business days. In October 2016, the Company regained compliance with NASDAQ Listing Rule 5550(a)(2) by effecting a 1-for-10 reverse stock split of its common stock.

In June 2016, the Company received notice from NASDAQ indicating that it was not in compliance with NASDAQ Listing Rule 5550(b)(2) because the market value of the Company's listed securities ("MVLS") was below $35 million for the previous thirty (30) consecutive business days and in November 2016, the Company received a further notice from NASDAQ that it was subject to delisting for failing to meet the continued listing requirements in Rule 5550(b)(2). Such delisting was stayed when the Company requested a hearing with the NASDAQ hearings panel, after which the Company was granted a grace period to regain compliance. Under Rule 5550(b)(2), compliance can be achieved in several ways, including meeting the $35 million MVLS requirement, maintaining a stockholder's equity value of at least $2.5 million or having net income of at least $500,000 for two of the last three fiscal years. On May 2, 2017, the Company was notified that it had evidenced full compliance with all criteria for continued listing on the NASDAQ Capital Market, including the minimum stockholders' equity requirement.

Notwithstanding the proceeds from the closing of the Ferring Asset Purchase Agreement and the proceeds from the April 2017 Financing, in order to fund its operations during the next twelve months from the issuance date, the Company may need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity, or the completion of a licensing transaction for one or more of the Company's pipeline assets. Specifically, expenses have been significantly reduced as a result of the closing of the Ferring Asset Purchase Agreement. Management has an operating plan in place that focuses almost entirely on the resubmission of the Vitaros NDA during the third quarter of 2017. As part of this plan, there are minimal expenditures for ongoing scientific research, product development or clinical research.

If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development activities, such as the resubmission of the Vitaros NDA, as well as potential future clinical studies for RayVa. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or debt financings may have a dilutive effect on the holdings of the Company's existing stockholders.

**Warrant Liabilities**

The Company's outstanding common stock warrants issued in connection with its February 2015 and January 2016 financings are classified as liabilities in the accompanying condensed consolidated balance sheets as they contain provisions that are considered outside of the Company's control, such as requiring the Company to maintain active registration of the shares underlying such warrants. The warrants were recorded at fair value using the Black-Scholes option pricing model. The fair value of these warrants is re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying condensed consolidated statements of operations.

The warrants issued in connection with the September 2016 financing were reclassified from warrant liabilities to stockholders' equity as a result of an amendment to such warrants executed as part of the April 2017 Financing. The warrants issued in September 2016 were amended so that, under no circumstance or by any event outside of the Company's control, can these awards be cash settled. As a result, such warrants are no longer accounted for as liabilities.

The Company holds other equity-classified warrants in addition to the September 2016 warrants. See note 6 for further details.

**Fair Value Measurements**

The Company determines the fair value measurements of applicable assets and liabilities based on a three-tier fair value hierarchy established by accounting guidance and prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. The Company's common stock warrant liabilities are measured and disclosed at fair value on a recurring basis, and are classified within the Level 3 designation.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

The following table presents the Company's fair value hierarchy for its warrant liabilities measured at fair value on a recurring basis (in thousands) as of June 30, 2017 and December 31, 2016:

| | Quoted Market Prices for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
|---|---|---|---|---|
| **Warrant liabilities** | | | | |
| Balance as of June 30, 2017 | $ — | $ — | $ 339 | $ 339 |
| Balance as of December 31, 2016 | $ — | $ — | $ 846 | $ 846 |

The common stock warrant liabilities are recorded at fair value using the Black-Scholes option pricing model. The following assumptions were used in determining the fair value of the common stock warrant liabilities valued using the Black-Scholes option pricing model as of June 30, 2017 and December 31, 2016:

| | June 30, 2017 | December 31, 2016 |
|---|---|---|
| Risk-free interest rate | 1.91%-1.92% | 1.64%-1.99% |
| Volatility | 86.44%-87.16% | 77.25%-81.03% |
| Dividend yield | —% | —% |
| Expected term | 5.54-5.68 | 4.75-6.17 |
| Weighted average fair value | $ 0.39 | $ 0.49 |

The following table is a reconciliation for all liabilities measured at fair value using Level 3 unobservable inputs (in thousands):

| | Warrant liabilities |
|---|---|
| Balance as of December 31, 2016 | $ 846 |
| Change in fair value measurement of warrant liability | 291 |
| Warrant liability reclassified to stockholders' equity | (798) |
| Balance as of June 30, 2017 | $ 339 |

Of the inputs used to value the outstanding common stock warrant liabilities as of June 30, 2017, the most subjective input is the Company's estimate of expected volatility.

**Revenue Recognition**

Historically, the Company has generated revenues from licensing technology rights and the sale of products. The Company recognizes revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the Company's price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. The Company considers a variety of factors in determining the appropriate method of accounting under its license agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting.

As a result of the Company's sale of its assets and rights related to Vitaros outside of the U.S. to Ferring, pursuant to the Ferring Asset Purchase Agreement, all revenues generated related to Vitaros outside of the United States have been reclassifed as discontinued operations. See note 2 for further details.

*Multiple Element Arrangements*

Deliverables under the arrangement will be separate units of accounting, provided (i) a delivered item has value to the customer on a standalone basis; and (ii) the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company's control.

The Company accounts for revenue arrangements with multiple elements by separating and allocating consideration according to the relative selling price of each deliverable. If an element can be separated, an amount is allocated based upon the relative selling price of each element. The Company determines the relative selling price of a separate deliverable using the price it charges other customers when it sells that product or service separately. If the product or service is not sold separately and third party pricing evidence is not available, the Company will use its best estimate of selling price.

*Milestones*

Revenue is recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the arrangement and the Company's efforts led to the achievement of the milestone (or if the milestone was due upon the occurrence of a specific outcome resulting from the Company's performance). Events for which the occurrence is either contingent solely upon the passage of time or the result of a counterparty's performance are not considered to be milestone events. If both of these criteria are not met, the milestone payment is recognized over the remaining minimum period of the Company's performance obligations under the arrangement, if any. The Company assesses whether a milestone is substantive at the inception of each arrangement.

*License Fee Revenue*

The Company defers recognition of non-refundable upfront license fees if it has continuing performance obligations, without which the licensed data, technology, or product has no utility to the licensee separate and independent of its performance under the other elements of the applicable arrangement. Non-refundable, up-front fees that are not contingent on any future performance by the Company and require no consequential continuing involvement on the Company's part are recognized as revenue when the license term commences and the last element of the licensed data, technology or product is delivered. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement.

*Product Sales Revenue*

Historically, the Company's product sales revenue was comprised of two components: sales of Vitaros to its former commercialization partners and sales of component inventory to its former manufacturing partners. The supply and manufacturing agreements with certain of its former commercialization partners for the manufacture and delivery of Vitaros prior to March 8, 2017, the closing date of the Ferring Asset Purchase Agreement, did not permit the Company's former commercialization partners to return product, unless the product sold to the licensee partner was delivered with a short-dated shelf life as specified in each respective license agreement, if applicable. In those cases, the Company deferred revenue recognition until the right of return no longer existed, which was the earlier of: (i) evidence that the product had been sold to an end customer or (ii) the right of return had expired. As such, the Company did not have a sales and returns allowance recorded during the six months ended June 30, 2017 or 2016.

Historically, sales of component inventory to the former manufacturing partners was accounted for on a net basis since these products were ultimately returned to the Company as finished goods and were then sold onto commercialization partners. Beginning in 2016, the majority of the Company's former commercialization partners bought the finished goods directly from the manufacturers and therefore, the Company's component sales were no longer recognized on a net basis. During the six months ended June 30, 2017, the Company recognized $0.1 million in revenues from component sales to its third party manufacturers, which is presented as discontinued operations in the current period presented. During the three and six months ended June 30,

2016, the Company recognized $0.01 million and $0.3 million, respectively, in revenues from component sales to its third party manufacturers.

*Royalty Revenue*

Historically, the Company relied on its former commercial partners to sell Vitaros in approved markets and received royalty revenue from its former commercial partners based upon the amount of those sales. Royalty revenues are computed and recognized on a quarterly basis, typically one quarter in arrears, and at the contractual royalty rate pursuant to the terms of each respective license agreement. Royalty revenue recognized during the three and six months ended June 30, 2017 was $0.1 million and $0.4 million, respectively. Royalty revenue recognized during the three and six months ended June 30, 2016 was $0.3 million and $0.7 million, respectively. Both are presented as discontinued operations in the current statement of operations.

**Cost of Goods Sold**

Historically, the Company's cost of goods sold included direct material and manufacturing overhead associated with production of Vitaros and component inventory. Cost of goods sold was also affected by manufacturing efficiencies, allowances for scrap or expired material and additional costs related to initial production quantities of new products. Cost of goods sold also included the cost of one-time manufactured samples provided to the Company's former commercialization partners free of charge.

**Income (Loss) Per Common Share**

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the same period. Diluted net income (loss) per share is computed by dividing net loss by the weighted average number of common shares and common equivalent shares outstanding during the same period. Common equivalent shares may be related to stock options, restricted stock, or warrants. The Company excludes common stock equivalents from the calculation of diluted net loss per share when the effect is anti-dilutive.

The following securities that could potentially decrease net income (loss) per share in the future are not included in the determination of diluted income (loss) per share as their effect is anti-dilutive (in thousands):

| | As of June 30, | |
|---|---|---|
| | 2017 | 2016 |
| Outstanding stock options | 400 | 492 |
| Outstanding warrants | 6,095 | 1,452 |
| Restricted stock | 934 | 116 |

**Stock-Based Compensation**

The estimated grant date fair value of stock options granted to employees and directors is calculated based upon the closing stock price of the Company's common stock on the date of the grant and recognized as stock-based compensation expense over the expected service period, which is typically approximated by the vesting period. The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option pricing model.

The table below presents the weighted average assumptions used by the Company to estimate the fair value of stock option grants using the Black-Scholes option-pricing model, as well as the resulting weighted average fair values at their issuance dates during the six months ended June 30, 2016. No stock options were granted during the first six months of 2017.

| | June 30, 2016 |
|---|---|
| Risk-free interest rate | 1.36%-1.78% |
| Volatility | 72.35%-80.02% |
| Dividend yield | —% |
| Expected term | 5.25-6.08 years |
| Forfeiture rate | 11.33% |
| Weighted average grant date fair value | $ 7.20 |

A summary of the Company's stock option activity under its stock option plans during the six months ended June 30, 2017 is as follows (share amounts in thousands):

| | Number of Shares | Weighted Average Exercise Price |
|---|---|---|
| Outstanding as of December 31, 2016 | 415 | $ 17.23 |
| Cancelled | (14) | $ 14.96 |
| Outstanding as of June 30, 2017 | 400 | $ 17.31 |

A summary of the Company's restricted stock unit activity under its stock option plans during the six months ended June 30, 2017 is as follows (share amounts in thousands):

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested as of December 31, 2016 | 115 | $ 5.11 |
| Granted | 873 | $ 1.13 |
| Vested | (35) | $ 5.59 |
| Forfeited | (19) | $ 1.78 |
| Unvested as of June 30, 2017 | 934 | $ 1.44 |

The Company grants restricted stock units ("RSUs") to its employees in order to retain and incentivize its employees to achieve its strategic objectives. During the first quarter of 2017, the Company granted approximately 0.5 million RSUs, one half of which will vest if the Company receives marketing approval of Vitaros in the United States by the FDA and the remaining half will vest on November 2018. During the second quarter of 2017, the Company granted approximately 0.4 million RSUs to its employees, one half of which will vest upon the resubmission of the NDA to the FDA and the remaining half if the Company receives marketing approval of Vitaros in the United States by the FDA. The RSUs are subject to the employee's continued employment with the Company through the applicable date and subject to accelerated vesting upon a change in control of the Company. The RSUs granted to the Company's officers are also subject to accelerated vesting pursuant to the terms of their existing employment agreements.

The Company records expense related to its performance RSUs based on the probability of occurrence, which is reassessed each quarter.

The following table summarizes the total stock-based compensation expense resulting from share-based awards recorded in the Company's condensed consolidated statements of operations (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Research and development | $ 85 | $ 362 | $ 137 | $ 425 |
| General and administrative | 202 | 377 | 435 | 669 |
| Total | $ 287 | $ 739 | $ 572 | $ 1,094 |

**Segment Information**

The Company operates under one segment which develops pharmaceutical products.

**Recent Accounting Pronouncements**

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,* which clarifies the treatment of several cash flow categories. In addition, ASU 2016-15 clarifies that when cash receipts and cash payments have aspects of more than one class of cash flows and cannot be separated, classification will depend on the predominant source or use. This update is effective for annual periods beginning after December 15, 2017, and

interim periods within those fiscal years, with early adoption permitted, including adoption in an interim period. The Company is currently evaluating whether the adoption of the new standard will have a material effect on its condensed consolidated financial statements and related disclosure.

In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers*, the amendment of which addressed narrow-scope improvements to the guidance on collectability, noncash consideration, and completed contracts at transition as well as providing a practical expedient for contract modifications. In April 2016 and March 2016, the FASB issued ASU No. 2016-10 and ASU No. 2016-08, respectively, the amendments of which further clarified aspects of Topic 606: identifying performance obligations and the licensing and implementation guidance and intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. The FASB issued the initial release of Topic 606 in ASU No. 2014-09, which requires entities to 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. Entities may use a full retrospective approach or report the cumulative effect as of the date of adoption. On July 9, 2015, the FASB voted to defer the effective date by one year to December 15, 2017 for interim and annual reporting periods beginning after that date. Early adoption of ASU 2016-10 is permitted but not before the original effective date (annual periods beginning after December 15, 2017). The Company is currently in the initial stages of evaluating its various contracts and revenue streams subject to these updates and plans to retrospectively adopt the standard with the cumulative effect of adopting the standard recognized at the date of initial application. The Company is still in the process of completing its assessment and has not concluded on whether the adoption of this update will have a material effect on its condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-2, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating whether the adoption of the new standard will have a material effect on its condensed consolidated financial statements and related disclosures.

**2. FERRING ASSET PURCHASE AGREEMENT AND DISCONTINUED OPERATIONS**

On March 8, 2017, the Company entered into the Ferring Asset Purchase Agreement, pursuant to which, and on the terms and subject to the conditions thereof, among other things, the Company agreed to sell to Ferring its assets and rights (the "Purchased Assets") related to the business of developing, marketing, distributing, and commercializing, outside the United States, the Company's products currently marketed or in development, intended for the topical treatment of sexual dysfunction (the "Product Business"), including products sold under the name Vitaros (the "Products") for up to approximately $12.7 million. The Purchased Assets include, among other things, certain pending and registered patents and trademarks, contracts, manufacturing equipment and regulatory approvals relating to the Products outside of the United States. The Company retained the U.S. development and commercialization rights for Vitaros and a license from Ferring (the "Ferring License") for intellectual property rights for Vitaros and other products which relate to development both within the United States and internationally.

Pursuant to the terms of the Ferring Asset Purchase Agreement, Ferring paid the Company $11.5 million in cash at closing and paid approximately $0.7 million for the value of inventory related to the Products in April 2017. The Company is eligible to receive two additional quarterly payments totaling $0.5 million for transition services, subject to certain limitations. The first payment of $0.25 million was recognized and earned during the second quarter of 2017 and paid in July 2017. The Company used a portion of the proceeds from the sale of the Purchased Assets to repay all amounts owed, including applicable termination fees, under the Credit Facility, which was approximately $6.6 million. The extinguishment of the Credit Facility was a stipulation of the Ferring Asset Purchase Agreement; however, since it was corporate debt, the loss on extinguishment was not offset against the gain on the sale of the Purchased Assets.

As of the transaction date, Ferring assumed responsibility for future obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Purchased Assets arising after the closing date, including $1.1 million under the termination agreement with Sandoz. The Company will retain all liabilities associated with the Purchased Assets arising prior to the closing date.

Under the Ferring Asset Purchase Agreement, the Company has also agreed to indemnify Ferring for, among other things, breaches of its representations, warranties and covenants, any liability for which it remains responsible and its failure to pay certain taxes or comply with certain laws, subject to a specified deductible in certain cases. The Company's aggregate liability under such indemnification claims is generally limited to $2.0 million.

At the closing of the Ferring Asset Purchase Agreement, the Company entered into the Ferring License with respect to certain intellectual property rights necessary to or useful for its exploitation of the Purchased Assets within the United States and for its exploitation of the Purchased Assets in certain fields outside of sexual dysfunction, including for the treatment of Raynaud's Phenomenon, outside the United States. The parties granted one another a royalty free, perpetual and non-exclusive license to product know-how in their respective fields and territories and Ferring granted the Company a royalty-free, perpetual and exclusive license to certain patents in the field of sexual dysfunction in the United States and in certain fields other than sexual dysfunction outside of the United States.

The total gain on sale of the Purchased Assets to Ferring consisted of the following:

| | | |
|---|---|---|
| Upfront payment received | $ | 11,500 |
| Transition services payment earned in Q2 2017 | | 250 |
| Payment received for inventory | | 709 |
| Total proceeds from sale | $ | 12,459 |
| Carrying value of assets sold in sale | | (1,578) |
| Liabilities transferred upon sale | | 1,186 |
| Total gain on sale of Purchased Assets | $ | 12,067 |

During the first quarter of 2017, the Company recorded a receivable of approximately $0.7 million for the amount to be received related to the inventory sold. The payment was received in April 2017. The Ferring Asset Purchase Agreement was treated as a sale of business and the total proceeds from the sale were allocated to the Purchased Assets.

During the second quarter of 2017, the Company earned $0.25 million in revenue related to the first transition services payment, which is included in the current assets of discontinued operations as of June 30, 2017. The payment was received in July 2017. The $0.25 million related to the future transition services payments will be presented as discontinued operations in the period in which it is recognized.

**Discontinued Operations**

The carrying amounts of the assets and liabilities of the Company's discontinued operations as of June 30, 2017 and December 31, 2016 are as follows (in thousands):

| | | June 30, 2017 | | December 31, 2016 |
|---|---|---|---|---|
| Accounts receivable | $ | 179 | $ | 530 |
| Inventories | | — | | 764 |
| Prepaid expenses and other current assets | | 327 | | 76 |
| Current assets of discontinued operations | | 506 | | 1,370 |
| Property and equipment, net | | — | | 842 |
| Total assets of discontinued operations | $ | 506 | $ | 2,212 |
| | | | | |
| Accounts payable | | 100 | | 274 |
| Accrued expenses | | 231 | | 1,834 |
| Total liabilities of discontinued operations | $ | 331 | $ | 2,108 |

The operating results of the Company's discontinued operations are as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Product sales | $ — | $ 110 | $ 143 | $ 369 |
| Royalty revenue | 147 | 304 | 368 | 671 |
| License fee revenue | — | 50 | — | 50 |
| Cost of goods sold | — | (93) | (74) | (326) |
| Operating expenses | (149) | (456) | (748) | (859) |
| Other expense | — | — | (16) | — |
| Gain on sale | 250 | — | 12,067 | — |
| Income (loss) from discontinued operations | $ 248 | $ (85) | $ 11,740 | $ (95) |

Product sales, royalty revenue and cost of goods sold all relate to the sale of Vitaros product outside of the United States. Pursuant to the Ferring Asset Purchase Agreement, the Company sold all of its rights to these assets and recognized product sales during the first quarter of 2017 related to the sales from January 1, 2017 through the completion of the sale, on March 8, 2017. The Company recorded product sales of $0.1 million and related cost of goods sold of $0.1 million for this time period.

Historically, the Company relied on its former commercial partners to sell Vitaros in approved markets and received royalty revenue from its former commercial partners based upon the amount of those sales. Royalty revenues are computed and recognized on a quarterly basis, typically one quarter in arrears, and at the contractual royalty rate pursuant to the terms of each respective license agreement. The Company recorded $0.1 million and $0.4 million in royalty revenue during the three and six months ended June 30, 2017, respectively, related to sales of Vitaros during the fourth quarter of 2016 and the first quarter of 2017, respectively.

Operating expenses for the current period include primarily patent and legal fees and accounting expenses incurred in connection with the Ferring Asset Purchase Agreement.

**3. ALLERGAN IN-LICENSING AGREEMENT**

In 2009, Warner Chilcott Company, Inc., now a subsidiary of Allergan, acquired the commercial rights to Vitaros in the United States. In September 2015, the Company entered into a license agreement and amendment to the original agreement with Warner Chilcott Company, Inc., granting the Company exclusive rights to develop and commercialize Vitaros in the United States in exchange for a $1.0 million upfront payment and an additional $1.5 million in potential regulatory milestone payments to Allergan.

Upon the FDA's approval of a new drug application for Vitaros in the United States, Allergan has the right to exercise a one-time opt-in right to assume all future commercialization activities in the United States. If Allergan exercises its opt-in right, the Company is eligible to receive up to a total of $25.0 million in upfront and potential launch milestone payments, plus a high double-digit royalty in the ten to twenty percent range on Allergan's net sales of the product. If Allergan does not exercise its opt-in right, the Company may commercialize the product and in return will pay Allergan a high double-digit royalty in the ten to twenty percent range on its net sales of the product.

Since the intangibles acquired in the license agreement do not have alternative future use, all costs incurred including the upfront payment, were treated as research and development expense.

No payments were due or paid to Allergan during the year ended December 31, 2016 or the six months ended June 30, 2017.

**4. OTHER FINANCIAL INFORMATION**

**Accrued Expenses**

Accrued expenses are comprised of the following (in thousands):

| | June 30, 2017 | December 31, 2016 |
|---|---|---|
| Professional fees | $ 395 | $ 783 |
| Deferred compensation | 45 | 134 |
| Outside research and development services | 162 | 142 |
| Other | 114 | 177 |
| | $ 716 | $ 1,236 |

**5. DEBT**

*Credit Facility*

On October 17, 2014 (the "Closing Date"), the Company entered into the Credit Facility with the Lenders, pursuant to which the Lenders agreed, subject to certain conditions, to make term loans totaling up to $10.0 million available to the Company. The first $5.0 million term loan was funded on the Closing Date. A second term loan of $5.0 million was funded at the Company's request on July 23, 2015. The first and second term loans had annual interest rates of 7.95% and 8.01%, respectively. The repayment schedule provided for interest-only payments in arrears until November 2015, followed by consecutive equal monthly payments of principal and interest in arrears through the original maturity date, which was October 1, 2018 (the "Maturity Date").

On the Closing Date, the Company issued warrants to purchase up to an aggregate of 19,380 shares of common stock at an exercise price of $12.90 per share to the Lenders. On July 23, 2015, in connection with the funding of the second term loan, the Company issued additional warrants to purchase up to an aggregate of 15,244 shares of common stock at an exercise price of $16.40 per share to the Lenders. The warrants were exercisable upon issuance and expire ten years from their dates of issuance. The warrants were classified in equity since they do not include provisions that would require the Company to repurchase its shares or cash settle, among other factors that would require liability classification. The fair value of the warrants at issuance of approximately $0.1 million was initially recorded as a discount to the principal balance and was being amortized over the life of the Credit Facility using the effective interest method. As a result of the prepayment of the Credit Facility in March 2017, the remaining discount was also written off.

On March 8, 2017, pursuant to the Ferring Asset Purchase Agreement, the Company repaid to the Lenders all amounts due and owed in full under the Credit Facility. Per the Credit Facility, the Company was subject to a prepayment fee of up to 3% since prepaying the outstanding balance of the term loans in full prior to the Maturity Date. Upon repayment of each term loan, the Company was also required to make a final payment to the Lenders equal to 6% of the original principal amount of each term loan. This final payment had been partially accreted over the life of the Credit Facility using the effective interest method. The final payment included the outstanding balance of the term loans in full as well as (i) a prepayment fee of approximately 2%, or $0.1 million, (ii) a final payment equal to 6% of the original principal amount of each term loan, or $0.6 million, and (iii) per diem interest of approximately $0.05 million, for a total payment of $6.6 million.

The Company's notes payable balance as of June 30, 2017 was zero as the balance had been paid in full. As of December 31, 2016 the notes payable balance consisted of the following (in thousands):

| | December 31, 2016 |
|---|---|
| Notes payable, principal | $ 6,392 |
| Add: accretion of final payment fee | 378 |
| Less: unamortized debt discount | (120) |
| | 6,650 |
| Less: current portion of notes payable, net | (6,650) |
| | $ — |

Pursuant to the terms of the Credit Facility, the Lenders had a senior-secured lien on all of the Company's current and future assets, other than its intellectual property. The Lenders had the right to declare the term loans immediately due and payable in an event of default under the Credit Facility, which included, among other things, a material adverse change in the Company's business, operations, or financial condition or a material impairment in the prospect of repayment of the term loan. As of December 31, 2016, the Company was in compliance with all covenants under the Credit Facility and had not received any notification or indication from the Lenders of an intent to declare the loan due prior to maturity. However, due to the Company's cash flow position and the substantial doubt about its being able to continue as a going concern at the time, the entire principal amount of the Credit Facility was presented in short-term liabilities for the period ended December 31, 2016.

The debt issuance costs, accretion of the final payment and amortization of the warrants were formerly included in interest expense in the Company's condensed consolidated statements of operations prior to the Ferring Asset Purchase Agreement. The Company recognized interest expense related to the Credit Facility of $0.1 million during the six months ended June 30, 2017. The Company recognized interest expense related to the Credit Facility of $0.3 million and $0.5 million during the three and six months ended June 30, 2016, respectively. Although the extinguishment of the debt was a closing condition of the Ferring Asset Purchase Agreement, since the Credit Facility was related to corporate debt, the loss on extinguishment and related interest expense is presented on the condensed consolidated statements of operations as continuing operations.

## 6. STOCKHOLDERS' EQUITY

### Common Stock Offerings

*April 2017 Financing & Warrant Amendment*

On April 26, 2017, the Company completed the April 2017 Financing for net proceeds of approximately $5.9 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. Pursuant to the underwriting agreement with the Underwriter, the Company sold to the Underwriter an aggregate of 5,030,000 units. Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock, sold at a public offering price of $1.40 per unit. The warrants became exercisable only following the Company's announcement that it has received stockholder approval of the effectiveness of the Charter Amendment and the Charter Amendment had become effective. The warrants were exercisable upon the effective date of the Charter Amendment on May 17, 2017, expire five years from such date and have an exercise price $1.55 per share of common stock. In connection with this transaction, the Company issued to the underwriters warrants to purchase up to 251,500 shares of common stock (the "Underwriter Warrants"). The Underwriter Warrants have substantially the same terms as the warrants being sold concurrently to the investors in the offering, except that the Underwriter Warrants have a term of five years from April 20, 2017 and an exercise price of $1.75 per share. The terms of the warrants state that under no circumstance may the shares be settled in cash. Therefore, the warrants have been classified within stockholders' equity. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017 (File No. 333-217036), and a related prospectus.

The total initial $2.9 million fair value of the combined warrants was determined using the Black-Scholes option pricing model and was recorded to equity. The warrants and Underwriter Warrants were valued using assumptions of expected terms of 5.06 and 5.0 years, respectively, volatilities of 88.3% and 88.7%, respectively, annual rate of dividends of 0.0% for each, and risk-free interest rates of 1.8% for each. Transaction costs of approximately $1.1 million were netted against the proceeds allocated to the common stock shares in equity.

Pursuant to the April 2017 Financing, the Company entered into a warrant amendment with the holders of the Company's warrants to purchase common stock of the Company, issued in the September 2016 Financing. See below for details.

*September 2016 Financing*

In September 2016, the Company completed the September 2016 Financing, which was a registered direct offering of 1,082,402 shares of common stock at a purchase price of $3.45 per share with a group of investors. Concurrently in a private placement, for each share of common stock purchased by each investor, such investor received from the Company an unregistered warrant to purchase three quarters of a share of common stock (the "Private Placement Warrants"). Initially, the Private Placement Warrants had an exercise price of $4.50 per share, were exercisable six months from the initial issuance date, and would expire five and a half years from the initial issuance date. The aggregate gross proceeds from the sale of the common stock and warrants was approximately $3.7 million, and the net proceeds after deduction of commissions, fees and expenses was approximately $3.2 million. In connection with this transaction, the Company issued to the placement agent warrants to purchase up to 54,123 shares of common stock sold in this offering (the "Placement Agent Warrants"). The Placement Agent Warrants have substantially the same terms as the Private Placement Warrants, except that initially, the Placement Agent Warrants had an exercise price of $4.3125 per share and would expire five years from the initial issuance date. Initially, the Private Placement Warrants and the Placement Agent Warrants were accounted for as a liability and fair-valued at the issuance date. Out of the total gross proceeds, $1.6 million was allocated to the Private Placement Warrants based on their fair value, and the rest was allocated to the common stock and recorded in equity. Also, in connection with the transaction, the Company incurred cash-based transaction costs of approximately $0.5 million and non-cash transaction costs of $0.1 million related to the fair value of the Placement Agent Warrants. These costs were allocated between the warrant liability and the equity based on their relative values at the issuance date. The transaction costs that were allocated to the warrant liability of approximately $0.3 million were expensed and included in other financing expenses on the condensed consolidated statements of operations and the transaction costs of approximately $0.4 million related to the common stock were netted against the proceeds allocated to the common stock shares in equity.

In connection with the April 2017 Financing, the Private Placement Warrants and the Placement Agent Warrants were amended pursuant to which, among other things, (i) the exercise price of the warrants was reduced to $1.55 per share (the exercise price of the warrants sold in the April 2017 Financing), (ii) the terms of the agreement were amended so that the shares cannot be cash settled under any circumstance, and (iii) the date upon which such warrants became exercisable was changed to the effective date of the Charter Amendment, or May 17, 2017. Based upon the amended terms of the agreement, these warrants were reclassified to stockholders' equity at the time of amendment, or April 20, 2017. The fair value of the warrants on that date was $0.8 million, which resulted in a charge of $0.2 million to change in fair value of warrant liability on the condensed consolidated statements of operations before reclassification to stockholders' equity during the second quarter of 2017.

*July 2016 Aspire Common Stock Purchase Agreement*

In July 2016, the Company and Aspire Capital entered into the Aspire Purchase Agreement, which provides that Aspire Capital is committed to purchase, if the Company chooses to sell and at the Company's discretion, an aggregate of up to $7.0 million of shares of the Company's common stock over the 24-month term of the Aspire Purchase Agreement. The Aspire Purchase Agreement can be terminated at any time by the Company by delivering notice to Aspire Capital. On the Aspire Closing Date, the Company delivered to Aspire Capital a commitment fee of 151,899 shares of the Company's common stock at a value of $0.6 million, in consideration for Aspire Capital entering into the Aspire Purchase Agreement. Additionally, on the Aspire Closing Date, the Company sold 253,165 shares of the Company's common stock to Aspire Capital for proceeds of $1.0 million. In connection with the transaction, the Company incurred cash transaction costs of approximately $0.1 million, which were netted against the proceeds in equity.

On any business day during the 24-month term of the Aspire Purchase Agreement, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice") directing Aspire Capital to purchase up to 10,000 shares of the Company's common stock per business day, subject to certain limitations. The Company and Aspire Capital may mutually agree to increase the number of shares that may be sold pursuant to a Purchase Notice to as much as an additional 200,000 shares of the Company's common stock per business day. The purchase price per share of the Company's common stock sold to Aspire Capital pursuant to a Purchase Notice is equal to the lower of (i) the lowest sales price of the Company's common stock on the purchase date or (ii) the average of the lowest three closing sales prices of the Company's common stock for the twelve business days prior to the purchase date. Under the Aspire Purchase Agreement, the Company and Aspire Capital shall not effect any sales on any purchase date where the closing sale price of the Company's common stock is less than $1.00.

Additionally, on any date on which (i) the Company submits a Purchase Notice to Aspire Capital for at least 10,000 shares of the Company's common stock and (ii) the last closing trade price for the Company's common stock is higher than $3.00, the Company has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of the Company's common stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the next business day (the "VWAP Purchase Date"), subject to certain limitations. The purchase price per share of the Company's common stock sold to Aspire Capital pursuant to a VWAP Purchase

Notice shall be the lesser of (i) the closing sale price of the Company's common stock on the VWAP Purchase Date or (ii) 97% of the volume weighted average price of the Company's common stock traded on the VWAP Purchase Date, subject to certain limitations.

The Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file one or more registration statements, as permissible and necessary to register, under the Securities Act of 1933, as amended, the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. The Company has filed with the SEC a prospectus supplement to the Company's prospectus, dated August 25, 2014, filed as part of the Company's effective $100.0 million shelf registration statement on Form S-3, File No. 333-198066, registering all of the shares of common stock that may be offered and sold to Aspire Capital from time to time.

Pursuant to the Aspire Purchase Agreement, in no case may the Company issue more than 1.2 million shares of the Company's common stock (which is equal to approximately 19.99% of the Company's common stock outstanding on the Aspire Closing Date) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least $3.820 per share (a price equal to the most recent condensed consolidated closing bid price of the Company's common stock prior to the execution of the Aspire Purchase Agreement) or (ii) the Company receives stockholder approval to issue more shares to Aspire Capital. Since the inception of the Aspire Purchase Agreement through June 30, 2017, the Company has issued a total of 0.5 million shares for gross proceeds of $1.2 million. As of July 28, 2017, all of the reserve was available under the committed equity financing facility since the Company's stock price was above $1.00, subject to SEC limitations under the Form S-3 Registration Statement. However, in connection with the September 2016 and April 2017 Financings, the Company agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of each financing.

*January 2016 Financing*

In January 2016, the Company entered into subscription agreements with certain purchasers pursuant to which it agreed to sell an aggregate of 1,136,364 shares of its common stock and warrants to purchase up to an additional 568,184 shares of its common stock to the purchasers for an aggregate offering price of $10.0 million, to take place in separate closings. Each share of common stock was sold at a price of $8.80 and included one half of a warrant to purchase a share of common stock. During the first closing in January 2016, the Company sold an aggregate of 252,842 shares and warrants to purchase up to 126,421 shares of common stock for gross proceeds of $2.2 million. The remaining shares and warrants were sold in a subsequent closing in March 2016 for gross proceeds of $7.8 million following stockholder approval at a special meeting on March 2, 2016. The aggregate net proceeds, after deduction of fees and expenses of approximately $0.4 million, were approximately $9.6 million.

The warrants issued in connection with the January 2016 financing (the "January 2016 Warrants") occurred in separate closings in January 2016 and March 2016 and gave rights to purchase up to 568,184 total shares of the Company's common stock at an exercise price of $8.80 per share. The total initial $4.8 million fair value of the warrants on their respective closing dates was determined using the Black-Scholes option pricing model and was recorded as the initial carrying value of the common stock warrant liabilities. The warrants issued in January 2016 and March 2016 were initially valued using assumptions of expected terms of 7.0 years, volatilities of 101.9% and 99.4%, respectively, annual rate of dividends of 0.0%, and risk-free interest rates of 1.6% and 1.4%, respectively. Fees and expenses of approximately $0.2 million were allocated to the warrant liability and expensed in Other Financing Costs. The remaining expenses were netted against the proceeds allocated to the common stock shares in equity. The fair value of these warrants is remeasured at each financial reporting period with any changes in fair value recognized as a change in fair value of warrant liability in the accompanying condensed consolidated statements of operations. These warrants became exercisable in July 2016 and September 2016 and have expiration dates of January 2023 and March 2023, respectively.

*February 2015 Financing*

In February 2015, the Company entered into subscription agreements with certain purchasers pursuant to which it sold an aggregate of 604,396 shares of its common stock and issued warrants to purchase up to an additional 302,199 shares of its common stock. Each share of common stock was sold at $18.20 and included one half of a warrant to purchase a share of common stock. The total net proceeds from the offering were $10.9 million after deducting expenses of approximately $0.1 million.

The warrants issued in connection with the February 2015 financing (the "February 2015 Warrants") gave rights to purchase up to 302,199 shares of its common stock at an exercise price of $18.20 per share. The initial $5.1 million fair value of the warrants on the transaction date was determined using the Black-Scholes option pricing model and was recorded as the initial carrying value of the common stock warrant liability. The fair value of these warrants is remeasured at each financial reporting period with any changes in fair value recognized as a change in fair value of warrant liability in the accompanying condensed consolidated statements of operations. The February 2015 Warrants became exercisable in July 2016 and have an expiration date of January 2023.

Pursuant to the January 2016 financing, the exercise price of the February 2015 Warrants was reduced from $18.20 per share to $8.80 per share. The modification to the February 2015 warrants resulted in a charge to other financing costs of approximately $0.7 million in 2016.

As of June 30, 2017, the total aggregate fair value of the warrant liability, which includes only the January 2016 Warrants and the February 2015 Warrants, was $0.3 million.

**Warrants**

A summary of warrant activity during the six months ended June 30, 2017 is as follows:

| | Common Shares Issuable upon Exercise | | Weighted Average Exercise Price |
|---|---|---|---|
| Outstanding at December 31, 2016 | 2,317,846 | $ | 15.19 |
| Issued | 4,024,000 | $ | 1.56 |
| Cancelled | (246,914) | | 52.50 |
| Outstanding as of June 30, 2017 | 6,094,932 | $ | 4.26 |
| Exercisable as of June 30, 2017 | 6,094,932 | $ | 4.26 |

In connection with the funding of the first and second term loans under the Credit Facility, the Company issued warrants to purchase up to an aggregate of 19,380 and 15,244 shares of common stock, respectively, at exercise prices of $12.90 and $16.40 per share, respectively, to the Lenders. The warrants were exercisable upon issuance and expire ten years from their dates of issuance. The warrants were classified in equity since they do not include provisions that would require the Company to repurchase its shares or cash settle, among other factors that would require liability classification.

The following table shows the number of outstanding warrants by exercise price and date of expiration as of June 30, 2017:

| Shares Issuable Upon Exercise | Exercise Price | | Expiration Date |
|---|---|---|---|
| 300,000 | $ | 34.00 | May 2018 |
| 251,500 | $ | 1.75 | April 2022 |
| 4,638,425 | $ | 1.55 | May 2022 |
| 428,620 | $ | 8.80 | January 2023 |
| 441,763 | $ | 8.80 | March 2023 |
| 19,380 | $ | 12.90 | October 2024 |
| 15,244 | $ | 16.40 | July 2025 |
| 6,094,932 | | | |

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

**Disclosures Regarding Forward-Looking Statements**

The following should be read in conjunction with the unaudited condensed consolidated financial statements and the related notes that appear elsewhere in this report as well as in conjunction with the Risk Factors section and in our Annual Report on Form 10-K for the year ended December 31, 2016 as filed with the United States Securities and Exchange Commission ("SEC") on March 13, 2017. This report and our Form 10-K include forward-looking statements made based on current management expectations pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended.

Some of the statements contained in this report discuss future expectations, contain projections of results of operations or financial conditions or state other "forward-looking" information, including statements regarding our ability to transition our ex-U.S. assets and rights related to Vitaros to Ferring International Center S.A. ("Ferring"), the timing of regulatory submission and approval of Vitaros in the United Sates, if any, our plans for life-cycle development programs for Vitaros, our development and partnering plans for RayVa, our plans to reduce operating expenses and achieve profitability, including projected 2017 cost savings, our strategic objectives, including efforts to maintain compliance with NASDAQ listing standards, the sufficiency of our current cash holdings and the availability of additional funds, and the development and/or acquisition of additional products. Those statements include statements regarding the intent, belief or current expectations of Apricus Biosciences, Inc. and its subsidiaries ("we," "us," "our" or the "Company") and our management team. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ materially from those projected in the forward-looking statements. In light of the significant risks and uncertainties inherent in the forward-looking statements included in this report, the inclusion of such statements should not be regarded as a representation by us or any other person that our objectives and plans will be achieved. There are many factors that affect our business, condensed consolidated financial position, results of operations and cash flows, including but not limited to, the risk that we fail to provide the transition services as required by the transition services agreement with Ferring, competition in the erectile dysfunction market and other markets in which we operate, our ability to further develop Vitaros, such as delivery device improvements, our ability to carry out further clinical studies for Vitaros, if required, as well as the timing and success of the results of such studies, our ability to maintain compliance with NASDAQ continued listing requirements which could result in our common stock being delisted from the exchange, our ability to retain and attract key personnel, our ability to raise additional funding that we may need to continue to pursue its commercial and development plans, our ability to secure an ex-U.S. strategic partner for RayVa, our ability to enter into partnering agreements or raise financing on acceptable terms, if at all; successful completion of clinical development programs, the timing of resubmission of a revised NDA for Vitaros to the Food and Drug Administration ("FDA"), regulatory review and approval by the FDA and similar regulatory bodies, anticipated revenue growth, manufacturing, competition, and/or other factors, including those set forth under the "Risk Factors" section in Part II, Item 1A and in our Annual Report on Form 10-K for the year ended December 31, 2016, as updated in Part II below, many of which are outside our control.

We operate in a rapidly changing business, and new risk factors emerge from time to time. Management cannot predict every risk factor, nor can it assess the impact, if any, of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those projected in any forward-looking statements. Accordingly, forward-looking statements should not be relied upon as a prediction of actual results and readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Vitaros™ is our trademark in the United States, which is pending registration and subject to our agreement with Warner Chilcott Company, Inc., now a subsidiary of Allergan plc ("Allergan"). Vitaros is a registered trademark of Ferring in certain countries outside of the United States. In addition, we own trademarks for NexACT® and RayVa™. Solely for convenience, trademarks and tradenames referred to in this Quarterly Report on Form 10-Q appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

**Overview**

We are a biopharmaceutical company focused on the development of innovative product candidates in the areas of urology and rheumatology. We have two product candidates currently in development. Vitaros is a product candidate in the United States for the treatment of erectile dysfunction ("ED"), which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan. RayVa is our product candidate in Phase 2 development for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

On March 8, 2017, we entered into an asset purchase agreement with Ferring (the "Ferring Asset Purchase Agreement"), pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for up to approximately $12.7 million. In addition to the upfront payment of $11.5 million, Ferring paid us approximately $0.7 million for the delivery of certain

product-related inventory in April 2017 and $0.25 million related to transition services in July 2017. We are eligible to receive a second quarterly payment of $0.25 million related to transition services, subject to certain limitations, in the third quarter of 2017.

**Our Product Candidates**

**Vitaros**

Vitaros (alprostadil) is a topically-applied cream formulation of alprostadil, which is designed to dilate blood vessels. This combined with NexACT, our proprietary permeation enhancer, increases blood flow to the penis, causing an erection. Vitaros is currently in development in the United States for the treatment of ED and approved and commercialized in certain countries outside of the United States. Allergan owns the rights to Vitaros in the United States and in September 2015, we entered into an agreement with Allergan to license the U.S. development and commercialization rights for Vitaros. Pursuant to the Ferring Asset Purchase Agreement, Ferring now owns the rights to Vitaros outside of the United States.

With our broad Vitaros expertise and internal know-how, coupled with the proven success in obtaining regulatory approvals for Vitaros in other territories, we believe we are well equipped to pursue regulatory approval for Vitaros in the United States. We initiated certain activities in 2015 to address issues previously raised by the U.S. Food and Drug Administration ("FDA") in a 2008 non-approvable letter, including possible safety risks associated with our proprietary permeating enhancer, NexACT, and certain chemistry, manufacturing and control issues. We confirmed the necessary drug-device engineering and compliance requirements, including human factor testing, and those studies are now complete. We plan to re-submit a revised new drug application ("NDA") with the FDA during the third quarter of 2017 with an anticipated FDA approval decision in the first quarter of 2018.

**RayVa**

RayVa is our product candidate for the treatment of Raynaud's Phenomenon associated with scleroderma (systemic sclerosis). RayVa is a topically-applied cream formulation of alprostadil designed to dilate blood vessels, which is combined with our proprietary permeation enhancer NexACT, and applied on-demand to the affected extremities.

RayVa received clearance in May 2014 from the FDA to begin clinical studies. We reported results from our Phase 2a clinical trial of RayVa for the treatment of Raynaud's Phenomenon secondary to scleroderma in September 2015, which we believe supports moving RayVa forward into future clinical trials. We expect to finalize the RayVa Phase 2b delivery device and study protocol and seek an ex-U.S. collaboration partner prior to initiating any future clinical studies.

**Liquidity, Capital Resources and Financial Condition**

We have experienced net losses and negative cash flows from operations each year since our inception. Through June 30, 2017, we had an accumulated deficit of approximately $309.7 million and recorded net income of approximately $6.6 million and negative cash flows from operations for the six months ended June 30, 2017. As of June 30, 2017, we had cash and cash equivalents of approximately $7.8 million. While we believe we have enough cash to fund our operations through the third quarter of 2018, our history and other factors raise substantial doubt about our ability to continue as a going concern. We have principally been financed through the sale of our common stock and other equity securities, debt financings and up-front payments received from commercial partners for our products under development.

On April 26, 2017, we completed an underwritten public offering (the "April 2017 Financing") for net proceeds of approximately $5.9 million, after deducting the underwriting discounts and commissions and our estimated offering expenses. Pursuant to the underwriting agreement with H.C. Wainwright & Co., LLC (the "Underwriter"), we sold to the Underwriter an aggregate of 5,030,000 units. Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock, sold at a public offering price of $1.40 per unit. At the time of the offering closing, we did not currently have a sufficient number of authorized common stock to cover shares of common stock issuable upon the exercise of the warrants. The sufficient number of authorized common stock became available on May 17, 2017 when the Company received stockholder approval of the proposed amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock (the "Charter Amendment") and the Charter Amendment became effective. The warrants will expire five years from the date the warrants were exercisable, or May 17, 2017, and the exercise price of the warrants is $1.55 per share of common stock. In connection with this transaction, we issued to the underwriters warrants to purchase up to 251,500 shares of common stock (the "Underwriter Warrants"). The Underwriter Warrants have substantially the same terms as the warrants being sold concurrently to the investors in the offering, except that the Underwriter Warrants have a term of five years from the effective date of the related prospectus, or April 20, 2017, and an exercise price of $1.75 per share. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017 (File No. 333-217036), and a related prospectus.

On April 20, 2017, we entered into a warrant amendment with the holders of our warrants to purchase common stock, issued in the September 2016 Financing as described below, pursuant to which, among other things, (i) the exercise price of the warrants was reduced to $1.55 per share (the exercise price of the warrants sold in the April 2017 Financing), and (ii) the date upon which such warrants become exercisable was changed to the effective date of the Charter Amendment, or May 17, 2017.

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for up to approximately $12.7 million. We received an upfront payment of $11.5 million and approximately $0.7 million for the delivery of certain product-related inventory and $0.25 million related to transition services. We are eligible to receive a second quarterly payment of $0.25 million related to transition services, subject to certain limitations during the third quarter of 2017. We used approximately $6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under our Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (Oxford and SVB are referred to together as the "Lenders"). See "Ferring Asset Purchase Agreement" below for additional information.

In September 2016, we completed a registered direct offering of 1,082,402 shares of common stock for gross proceeds of approximately $3.7 million (the "September 2016 Financing"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from us an unregistered warrant to purchase three quarters of a share of common stock. See note 6 to our condensed consolidated financial statements for further description.

In July 2016, we and Aspire Capital Fund, LLC ("Aspire Capital") entered into a Common Stock Purchase Agreement (the "Aspire Purchase Agreement"), which provides that Aspire Capital is committed to purchase, if we choose to sell and at our discretion, an aggregate of up to $7.0 million of shares of our common stock over the 24-month term of the Aspire Purchase Agreement. The Aspire Purchase Agreement can be terminated by us at any time by delivering notice to Aspire Capital. On July 5, 2016 (the "Aspire Closing Date"), we delivered to Aspire Capital a commitment fee of 151,899 shares of our common stock at a value of $0.6 million, in consideration for Aspire Capital entering into the Aspire Purchase Agreement. Additionally, on the Aspire Closing Date, we sold 253,165 shares of our common stock to Aspire Capital for proceeds of $1.0 million.

On any business day during the 24-month term of the Aspire Purchase Agreement, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice") directing Aspire Capital to purchase up to 10,000 shares of our common stock per business day, subject to certain limitations. We and Aspire Capital may mutually agree to increase the number of shares that may be sold to as much as an additional 200,000 shares of our common stock per business day. The purchase price per share of our common stock sold to Aspire Capital pursuant to a Purchase Notice shall be the lower of (i) the lowest sales price of our common stock on the purchase date or (ii) the average of the lowest three closing sales prices of our common stock for the twelve business days prior to the purchase date. Under the Aspire Purchase Agreement, we and Aspire Capital shall not effect any sales on any purchase date where the closing sale price of our common stock is less than $1.00.

Additionally, on any date on which (i) we submit a Purchase Notice to Aspire Capital for at least 10,000 shares of our common stock and (ii) the last closing trade price for our common stock is higher than $3.00, we have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of our common stock equal to up to 30% of the aggregate shares of our common stock traded on the next business day (the "VWAP Purchase Date"), subject to certain limitations. The purchase price per share of our common stock sold to Aspire Capital pursuant to a VWAP Purchase Notice shall be the lesser of (i) the closing sale price of our common stock on the VWAP Purchase Date or (ii) 97% of the volume weighted average price of our common stock traded on the VWAP Purchase Date, subject to certain qualifications.

Pursuant to the Aspire Purchase Agreement, in no case may we issue more than 1.2 million shares of our common stock (which is equal to approximately 19.99% of our common stock outstanding on the Aspire Closing Date) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least $3.820 per share (a price equal to the most recent consolidated closing bid price of our common stock prior to the execution of the Aspire Purchase Agreement) or (ii) we receive stockholder approval to issue more shares to Aspire Capital. Through June 30, 2017, we issued a total of 455,064 shares for gross proceeds of $1.2 million. As of July 28, 2017, all of the reserve was available under the committed equity financing facility since our stock price was above $1.00. However, in connection with the September 2016 and April 2017 Financings, we agreed not to make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of each financing, or April 20, 2018.

In January 2016, we entered into subscription agreements with certain purchasers pursuant to which we agreed to sell an aggregate of 1,136,364 shares of our common stock and warrants to purchase up to an additional 568,184 shares of our common stock to the purchasers for an aggregate offering price of $10.0 million, which took place in two separate closings. Each share of common stock was sold at a price of $8.80 and included one half of a warrant to purchase a share of common stock. The warrants have an

exercise price of $8.80 per share, became exercisable six months and one day after the date of issuance and will expire on the seventh anniversary of the date of issuance. During the first closing in January 2016, we sold an aggregate of 252,842 shares and warrants to purchase up to 126,421 shares of common stock for gross proceeds of $2.2 million. The remaining shares and warrants were sold in a subsequent closing in March 2016 for gross proceeds of $7.8 million following stockholder approval at a special meeting on March 2, 2016.

We currently have an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the Securities and Exchange Commission ("SEC") under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. As of July 28, 2017, we had approximately $74.1 million available under our Form S-3 shelf registration statement. However, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates ("public float") is less than $75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Aspire Purchase Agreement, is limited to an aggregate of one-third of our public float. SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the shelf registration statement. As of July 28, 2017, our public float was approximately $14.5 million based on 11.3 million shares of our common stock outstanding at a price of $1.28 per share, which was the closing sale price of our common stock on July 28, 2017. Since our public float is currently less than $75.0 million, as of July 28, 2017, we may only sell an aggregate of approximately $4.8 million of securities under our shelf registration statements on Form S-3. Through July 28, 2017, we have sold $3.7 million in the September 2016 Financing, leaving approximately $1.1 million available for sale under our shelf registration statement. The common shares, warrants and warrant shares in the April 2017 Financing were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017 (File No. 333-217036), and a related prospectus.

We still maintain the ability to raise funds through other means, such as through additional public or private placements. The rules and regulations of the SEC or any other regulatory agencies may restrict our ability to conduct certain types of financing activities, or may affect the timing of and amounts we can raise by undertaking such activities.

The accompanying condensed consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our ability to raise additional funds to finance our operations;
- our ability to maintain compliance with the listing requirements of The NASDAQ Capital Market;
- the timing and outcome of our new drug application ("NDA") resubmission for Vitaros, and any additional development requirements imposed by the U.S. Food and Drug Administration ("FDA") in connection with such resubmission;
- the outcome, costs and timing of clinical trial results for our product candidates;
- the extent and amount of any indemnification claims made by Ferring under the Ferring Asset Purchase Agreement;
- the emergence and effect of competing or complementary products;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- the restrictions from using our committed equity financing facility with Aspire Capital until April 2018;
- the trading price of our common stock being above the $1.00 closing floor price that is required for us to use the committed equity financing facility with Aspire Capital and the restrictions from using such facility when it becomes available in April 2018;
- the trading price of our common stock; and
- our ability to increase the number of authorized shares outstanding to facilitate future financing events.

We may need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity, and/or the completion of a licensing transaction for one or more of our pipeline assets. However, our expenses have been significantly reduced as a result of the Ferring Asset Purchase Agreement. Management's operating plan is now focused almost entirely on the resubmission of the Vitaros NDA during the third quarter of 2017. As part of this plan, there are minimal expenditures for ongoing scientific research, product development or clinical research.

If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. This could affect future development activities, such as the resubmission of a Vitaros NDA as well as future clinical studies for RayVa. There can be no assurance that we will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders.

**Critical Accounting Estimates and Policies**

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, other long-term assets, warrants, stock-based compensation, income taxes, and legal proceedings. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and there have been no material changes during the six months ended June 30, 2017.

**Recent Accounting Pronouncements**

Please refer to the notes to condensed consolidated financial statements (unaudited) for a discussion of recent accounting pronouncements.

**Results of Operations**

***Operating Expense***

Operating expense was as follows (in thousands, except percentages):

| | Three Months Ended June 30, | | 2017 vs 2016 | | Six Months Ended June 30, | | 2017 vs 2016 | |
|---|---|---|---|---|---|---|---|---|
| | 2017 | 2016 | $ Change | % Change | 2017 | 2016 | $ Change | % Change |
| Operating expense | | | | | | | | |
| Research and development | $ 839 | $ 2,503 | $ (1,664) | (66)% | $ 1,266 | $ 5,104 | $ (3,838) | (75)% |
| General and administrative | 1,602 | 2,122 | (520) | (25)% | 3,043 | 4,328 | (1,285) | (30)% |
| Total operating expense | 2,441 | 4,625 | (2,184) | (47)% | 4,309 | 9,432 | (5,123) | (54)% |
| Loss from operations | $ (2,441) | $ (4,625) | $ 2,184 | (47)% | $ (4,309) | $ (9,432) | $ 5,123 | (54)% |

***Research and Development Expenses from Continuing Operations***

Research and development costs are expensed as they are incurred and include the cost of compensation and related expenses, as well as expenses for third parties who conduct research and development on our behalf. The $1.7 million and $3.8 million decreases in research and development expense during the three and six months ended June 30, 2017, respectively, as compared to the same periods in the prior year, resulted primarily from decreases in outside services related to the development of fispemifene and RayVa as well as decreased personnel- related expenses. We expect to continue to incur additional expenses in 2017 related primarily to resubmission of an NDA for Vitaros in the United States, as well as personnel-related expenses.

***General and Administrative Expenses from Continuing Operations***

General and administrative expenses include expenses for personnel, finance, legal, business development and investor relations. General and administrative expenses decreased by $0.5 million and $1.3 million during the three and six months ended June 30, 2017, respectively, as compared to the same periods of the prior year. These decreases were primarily due to lower professional services expenses, such as legal, accounting, and investor relations expenses.

***Other Income and Expense from Continuing Operations***

Other income and expense were as follows (in thousands, except percentages):

| | Three Months Ended June 30, | | 2017 vs 2016 | | Six Months Ended June 30, | | 2017 vs 2016 | |
|---|---|---|---|---|---|---|---|---|
| | 2017 | 2016 | $ Change | % Change | 2017 | 2016 | $ Change | % Change |
| Other (expense) income | | | | | | | | |
| Interest income (expense), net | $ 3 | $ (258) | $ 261 | (101)% | $ (92) | $ (537) | $ 445 | (83)% |
| Loss on extinguishment of debt | — | — | $ — | N/M | (422) | — | (422) | N/M |
| Change in fair value of warrant liability | 716 | 1,637 | (921) | (56)% | (292) | 4,437 | (4,729) | (107)% |
| Other financing expenses | — | — | — | N/M | — | (205) | 205 | (100)% |
| Other expense, net | — | (7) | 7 | (100)% | (26) | (11) | (15) | 136 % |
| Total other income (expense) | $ 719 | $ 1,372 | $ (653) | (48)% | $ (832) | $ 3,684 | $ (4,516) | (123)% |

***Change in Fair Value of Warrant Liability***

In connection with our February 2015 and January 2016 equity financings, we issued warrants to purchase up to 302,199 shares and 568,184 shares, respectively, of our common stock at an exercise price of $18.20 and $8.80 per share, respectively. Pursuant to the January 2016 financing, the February 2015 Warrants were repriced from $18.20 to $8.80 per share.

The initial fair value of the February 2015 Warrants and January 2016 Warrants of $5.1 million and $4.8 million, respectively, were determined using the Black-Scholes option pricing model on each respective transaction date and recorded as the initial carrying values of the common stock warrant liabilities. The fair value of these warrants is remeasured at each financial reporting period with any changes in fair value recognized as a change in fair value of warrant liability in the accompanying condensed consolidated statements of operations (see notes 1 and 6 to our condensed consolidated financial statements for further details). The positive change in fair value of warrant liability is due to the decrease in the Company's stock price for all periods presented.

In connection with our September 2016 equity financing, we issued warrants to the investors and to the placement agent to purchase up to 811,802 shares and 54,123 shares, of our common stock at an exercise price of $4.50 and $4.3125 per share, respectively ("the September 2016 Private Placement Warrants" and the "September 2016 Placement Agent Warrants"). These were initially accounted for as warrant liabilities since they contained settlement requirements that were considered outside of our control. In connection with the April 2017 Financing, the Private Placement Warrants and the Placement Agent Warrants were amended to reduce the exercise price from $4.50 and $4.3125, respectively, to $1.55 for each. In addition, the agreement was amended to remove the settlement requirements and therefore, the Private Placement Warrants and Placement Agent Warrants were no longer required to be accounted for as liabilities as of the amendment date. The fair value of these warrant liabilities when reclassified to equity in April 2017 was $0.8 million.

***Loss on Extinguishment of Debt***

On March 8, 2017, pursuant to the Ferring Asset Purchase Agreement, we repaid to the Lenders all amounts due and owed in full under the Credit Facility. The final payment included the outstanding balance of the term loans in full as well as (i) a prepayment fee contractually owed of approximately 2%, or $0.1 million, (ii) a final payment equal to 6% of the original principal amount of each term loan, or $0.6 million, and (iii) per diem interest of approximately $0.05 million, for a total payment of $6.6 million, which resulted in a loss on extinguishment of debt of $0.4 million.

***Discontinued Operations***

The operating results from our discontinued operations are as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Product sales | $ — | $ 110 | $ 143 | $ 369 |
| Royalty revenue | 147 | 304 | 368 | 671 |
| License fee revenue | — | 50 | — | 50 |
| Cost of goods sold | — | (93) | (74) | (326) |
| Operating expenses | (149) | (456) | (748) | (859) |
| Other expense | — | — | (16) | — |
| Gain on sale | 250 | — | 12,067 | — |
| Income (loss) from discontinued operations | $ 248 | $ (85) | $ 11,740 | $ (95) |

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for up to approximately $12.7 million. In addition to the upfront payment of $11.5 million, Ferring paid us approximately $0.7 million for the delivery of certain product-related inventory in April 2017. We are also eligible to receive two additional quarterly payments totaling $0.50 million related to transition services, subject to certain limitations, of which the first payment of $0.25 million was received in July 2017. We used approximately $6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under the Credit Facility with the Lenders.

As a result of the Ferring Asset Purchase Agreement, all product sales revenue, royalty revenue and cost of goods sold have been reflected as discontinued operations for all periods presented. In addition, operating expenses, such as the transaction costs directly related to the Ferring Asset Purchase Agreement, have been presented as discontinued operations. Transition services payments are presented as discontinued operations in the period in which they are recognized.

**Cash Flow Summary**

The following table summarizes selected items in our condensed consolidated statements of cash flows (in thousands):

| | Six Months Ended June 30, | |
|---|---|---|
| | 2017 | 2016 |
| Net cash used in operating activities from continuing operations | $ (4,851) | $ (8,872) |
| Net cash provided by investing activities from continuing operations | — | 262 |
| Net cash (used in) provided by financing activities from continuing operations | (1,051) | 8,076 |
| Net cash provided by (used in) discontinued operations | 11,636 | (630) |
| Net increase (decrease) in cash | $ 5,734 | $ (1,164) |

*Operating Activities from Continuing Operations*

Cash used in operating activities from continuing operations of $4.9 million during the six months ended June 30, 2017 was primarily due to a net loss from continuing operations of $5.1 million net of adjustments to net loss for non-cash items such as the warrant liability revaluation of $0.3 million, stock-based compensation expense of $0.6 million, and the loss on extinguishment of debt of $0.4 million.

*Financing Activities from Continuing Operations*

Cash used in financing activities from continuing operations of $1.1 million during the six months ended June 30, 2017 was due to the repayment of our Credit Facility of $7.1 million as a closing condition of the Ferring Asset Purchase Agreement, offset by the net proceeds of $6.1 million from issuance of common stock and warrants in our April 2017 Financing.

**Off-Balance Sheet Arrangements**

As of June 30, 2017, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our assessment of our sensitivity to market risk since the presentation set forth in Item 7A, "Quantitative and Qualitative Disclosures about Market Risk," in our Annual Report on Form 10-K for the year ended December 31, 2016.

## ITEM 4. CONTROLS AND PROCEDURES

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

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms.

Under the supervision and with the participation of our management, including the Chief Executive Officer ("CEO"), who serves as the principal executive officer and the principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of June 30, 2017. Based on this evaluation, our CEO concluded that our disclosure controls and procedures were effective as of June 30, 2017.

***Management's Report on Internal Control Over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a15(f). Our internal control over financial reporting is a process designed, under the supervision and, with the participation of our CEO who serves as our principal executive officer and principal financial officer, overseen by our Board of Directors and implemented by our management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Also, 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 performed an assessment of the effectiveness of our internal control over financial reporting as of June 30, 2017 using criteria established in the *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management determined that, as of June 30, 2017, our internal control over financial reporting was effective. Because we are a smaller reporting company, BDO, an independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

***Inherent Limitations on Effectiveness of Controls***

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure system are met. Also, 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.

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

There were no changes in our internal control over financial reporting during the most recent fiscal quarter ended June 30, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II.

### ITEM 1. LEGAL PROCEEDINGS

We are a party to the following litigation and may be a party to certain other litigation that is either judged to be not material or that arises in the ordinary course of business from time to time. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings.

A complaint was filed in the Supreme Court of the State of New York by Laboratoires Majorelle SAS and Majorelle International SARL on July 25, 2017 naming Apricus Biosciences, Inc., NexMed (U.S.A.), Inc. and Ferring International Center S.A. as defendants. The complaint seeks a declaratory judgment that a non-compete provision in a license agreement between us and Majorelle, dated November 12, 2013, is unenforceable and makes other claims relating to invalidity of our assignment of the

license agreement to Ferring. The complaint also alleges breach of contract, fraudulent inducement, misrepresentation and unjust enrichment relating to a separate supply agreement between us and Majorelle. In addition to declaratory relief, Majorelle is seeking damages in excess of $1.0 million, punitive damages, disgorgement of profits and attorney's fees. We believe the allegations are without merit, reject all claims raised by Majorelle and intend to vigorously defend this matter.

## ITEM 1A. RISK FACTORS

*We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.*

The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing material changes from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC on March 13, 2017:

**Risks Related to the Company**

***As a result of our sale of assets to Ferring, we do not expect to generate revenue for the foreseeable future and we may not be successful in executing on our near-term business strategy to solely focus on the U.S. Vitaros NDA resubmission.***

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement with Ferring, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for up to approximately $12.7 million. In addition to the upfront payment of $11.5 million, Ferring paid us approximately $0.7 million for the delivery of certain product-related inventory. We were also eligible to receive two additional quarterly payments totaling $0.5 million related to transition services, subject to certain limitations, of which the first payment of $0.25 million was received in July 2017. Following the Ferring Asset Purchase Agreement, we will no longer have the ability to generate revenues from operations unless and until we file an NDA with the FDA for Vitaros, receive approval of such NDA and successfully commercialize Vitaros in the United States alone or with partners. There can be no assurance that the proceeds from the Ferring Asset Purchase Agreement will be sufficient for us to submit the Vitaros NDA, and we will need to raise additional capital to fund our operations even if we do ultimately receive approval of the NDA. In addition, our future growth will depend on our ability to successfully implement our strategy to focus solely on the Vitaros in the United States, as well as RayVa. If we are unable to successfully execute on this business strategy, our business, financial condition, results of operations and prospects would be materially and adversely affected.

***We expect to continue to require external financing to fund our operations, which may not be available. **

We expect to require external financing to fund our near and long-term operations. Such financing may not be available on terms we deem acceptable or at all.

As of June 30, 2017, we had cash and cash equivalents of approximately $7.8 million. In April 2017, we completed a public offering and raised net proceeds of approximately $5.9 million. On March 8, 2017, we entered into the Ferring Asset Purchase Agreement with Ferring, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for up to approximately $12.7 million. In addition to the upfront payment of $11.5 million, Ferring paid us approximately $0.7 million for the delivery of certain product-related inventory. We were also eligible to receive two additional quarterly payments totaling $0.5 million related to transition services, subject to certain limitations, of which the first payment of $0.25 million was received in July 2017. As part of the Ferring Asset Purchase Agreement, we have agreed to indemnify Ferring against losses suffered as a result of our breach of representations and warranties and our other obligations under our asset purchase agreement, and therefore may be liable for a portion of the consideration we received from Ferring.

We currently have an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. Our ability to sell shares using our Form S-3 shelf registration statement is limited by both the amount remaining "on the shelf" and by our public float. As of July 28, 2017, we had approximately $74.1 million available under our Form S-3 shelf registration statement. However, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates ("public float") is less than $75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Aspire Purchase Agreement, is limited to an aggregate of one-third of our public float. SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the shelf registration statement. As of July 28, 2017, our public float was approximately $14.5 million based on 11.3 million shares of our common stock outstanding at a price of $1.28 per share, which was the closing sale price of our common stock on July 28, 2017. Since our public float is currently less than $75.0 million, as of July 28, 2017, we may only sell an aggregate of approximately $4.8 million of securities under our shelf registration statements on Form S-3. Through July 28, 2017, we have sold $3.7 million in the September 2016 Financing, leaving approximately $1.1 million available for sale under our shelf registration statement. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease.

In addition, our stock price must be $1.00 per share or above in order for us to access the remaining reserve under our committed equity financing facility with Aspire Capital. In no case may we issue more than 1.2 million shares of our common stock (which is equal to approximately 19.99% of our common stock outstanding on the date we entered into Aspire Purchase Agreement) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least $3.820 per share (a price equal to the most recent consolidated closing bid price of our common stock prior to the execution of the Aspire Purchase Agreement) or (ii) we receive stockholder approval to issue more shares to Aspire Capital. As of July 28, 2017, all of the reserve was available under the committed equity financing facility since our stock price was above $1.00. However, in connection with our September 2016 and April 2017 Financings, we agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of each financing, or April 20, 2018.

We still maintain the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements. The rules and regulations of the SEC or any other regulatory agencies may restrict our ability to conduct certain types of financing activities, or may affect the timing of and amounts we can raise by undertaking such activities.

While we have historically generated modest revenues from our operations, following the Ferring Asset Purchase Agreement, we will no longer generate those revenues. Given our current lack of profitability and limited capital resources, we may not be able to fully execute all of the elements of our strategic plan, including resubmitting the NDA for Vitaros in the United States, commercializing Vitaros in the United States if approved, and progressing our development program for RayVa. If we are unable to accomplish these objectives, our business prospects will be diminished, we will likely be unable to achieve profitability, and we may be unable to continue as a going concern.

***We have a history of operating losses and an accumulated deficit, and we may be unable to generate sufficient revenue to achieve profitability in the future.***

We only began generating revenues from the commercialization of Vitaros in the third quarter of 2014, we have never been profitable and we have incurred an accumulated deficit of approximately $309.7 million from our inception through June 30, 2017. We have incurred these losses principally from costs incurred in funding the research, development and clinical testing of our product candidates, from our general and administrative expenses and from our efforts to support commercialization of Vitaros by our partners. As a result of the Ferring Asset Purchase Agreement, we do not expect to generate revenue for the foreseeable future and will continue to incur significant operating losses and capital expenditures for the foreseeable future.

Our ability to generate revenues and become profitable depends, among other things, on (1) the successful development and commercialization of Vitaros in the United States, and (2) the successful development, approval and commercialization of RayVa. If we are unable to accomplish these objectives, we may be unable to achieve profitability and would need to raise additional capital to sustain our operations.

***There is substantial doubt concerning our ability to continue as a going concern.****

Our financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. During the first quarter of 2017, we received an upfront payment of $11.5 million from the Ferring Asset Purchase Agreement but a large portion of that was used to payoff our Credit Facility, and we expect to incur further losses for the foreseeable future. In April 2017, we completed a public offering for net proceeds of approximately $6.2 million. While we believe we have sufficient cash to fund our operations through the third quarter of 2018, our history and other operating circumstances raise substantial doubt about our ability to continue as a going concern. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of June 30, 2017, the Report of Independent Registered Public Accounting Firm included immediately prior to the Consolidated Financial Statements included in our Annual Report on Form 10-K as filed on March 13, 2017, includes a going concern explanatory paragraph. Management plans to raise additional funds with the following activities: future financing events; potential partnering events of our existing technology; and by the reduction of expenditures. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

***Our business is entirely dependent on obtaining FDA approval for Vitaros and our other product candidates, which will require significant additional clinical testing before we can seek regulatory approval and potentially begin commercialization.***

Our future success depends entirely on our ability to obtain regulatory approval for, and then successfully commercialize our product candidates. The success of Vitaros, our leading product candidate, will require resubmission of a NDA to the FDA in order to gain regulatory approval. An NDA was previously submitted for Vitaros, but the FDA issued a non-approvable letter in 2008 identifying certain deficiencies with the application. Based on feedback during our pre-NDA meetings with the FDA, we believe that the resubmission of the Vitaros NDA will not require additional clinical testing and will not resubmit with such data, but there is no assurance that the FDA will accept the NDA for Vitaros or agree that no additional clinical trials will be required. We plan

to resubmit the NDA during the third quarter of 2017. An NDA must include extensive pre-clinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process and may not be obtained on a timely basis, or at all. We have not received marketing approval for any product candidates in the United States, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval for any indication.

Our other product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote our product candidates in the United States before we receive regulatory approval from the FDA and we may not receive such regulatory approvals on a timely basis, or at all.

In addition, approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by foreign regulatory authorities does not ensure approval by FDA or regulatory authorities in other foreign countries. However, the failure to obtain approval in one jurisdiction may have a negative impact on our ability to obtain approval elsewhere.

Our clinical development plan for RayVa includes a Phase 2b take-home clinical trial and up to two Phase 3 clinical trials in patients with Raynaud's Phenomenon secondary to scleroderma. We reported results on the Phase 2a clinical trial in September 2015, which we believe supported moving RayVa forward into future clinical trials. There is no guarantee that we will commence our planned clinical trials or that our ongoing clinical trials will be completed on time or at all, and the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials. Even if such regulatory authorities agree with the design and implementation of our clinical trials, we cannot guarantee that such regulatory authorities will not change their requirements in the future. In addition, even if the clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

If we do not receive regulatory approvals for and successfully commercialize our product candidates on a timely basis or at all, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, on our ability to commercialize our product candidates and on the favorability of the claims in the approved labeling as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for the treatment of Raynaud's Phenomenon secondary to scleroderma are not as significant as we estimate, our business and prospects will be harmed.

***We depend upon third party manufacturers for our product candidates***

We do not manufacture our product candidates, and do not in the future expect to be able to independently conduct our product manufacturing. As such, we are dependent, and expect to continue to rely, on third party manufacturers for the supply of these product candidates and commercial quantities, if approved. The manufacturing process for our product candidates is highly regulated and regulators may refuse to qualify new suppliers and/or terminate manufacturing at existing facilities that they believe do not comply with regulations.

Our third-party manufacturers and suppliers are subject to numerous regulations, including current Good Manufacturing Practices ("cGMP"), regulations governing manufacturing processes and related activities and similar foreign regulations. The facilities used by our third-party manufacturers to manufacture our product candidates must be approved by the applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, our third-party manufacturers and suppliers are independent entities who are subject to their own operational and financial risks that are out of our control, and we have no control over the ability of these third party manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If we or any of these third-party manufacturers or suppliers fail to perform as required or fail to comply with the regulations of the FDA, our ability to deliver our products on a timely basis, receive royalties or continue our clinical trials would be adversely affected. Further, if the FDA does not approve these facilities for the manufacture of our products or if it withdraws such approval in the future, or if our suppliers or third party manufacturers decide they no longer wish to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. Also, the manufacturing processes of our manufacturing partners may be found to violate the proprietary rights of others, which could interfere with their ability to manufacture products on a timely and cost effective basis.

In addition, we are also dependent on third party manufacturers and suppliers of raw materials, components, chemical supplies for the active drugs in our product candidates under development for the formulation and supply of our NexACT enhancers and finished products. We are dependent on these third-party manufacturers for dispensers that are essential in the production of Vitaros and other product candidates. These raw materials, components, chemical supplies, finished products and dispensers must be supplied on a timely basis and at satisfactory quality levels.

If our third party product manufacturers or suppliers of raw materials, components, chemical supplies, finished products and dispensers fail to produce quality products on time and in sufficient quantities, or if we are unable to secure adequate alternative sources of supply for such materials, components, chemicals, finished products and dispensers, our results would suffer, as we or our licensees would encounter costs and delays in re-validating new third party suppliers.

***If we do not secure collaborations with strategic partners to develop and commercialize RayVa we may not be able to successfully develop RayVa and generate meaningful revenues from it.***

A key aspect of our current strategy is to selectively enter into a strategic collaboration with one or more third parties to conduct clinical testing for, seek regulatory approval for and to commercialize RayVa. We may not be successful in securing a strategic partner on favorable terms, or at all. If we are able to identify and reach an agreement with one or more collaborators, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety in required clinical trials and obtaining regulatory approvals. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated.

Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize RayVa. Collaborations involving RayVa pose a number of risks, including the following:

- collaborators may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals;
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing their own or another party's product candidate; or
- collaborators may decide to terminate or not to renew the collaboration for these or other reasons.

As a result, collaboration agreements may not lead to development or commercialization of RayVa in the most efficient manner or at all.

In addition, collaboration agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of RayVa. We also face competition in seeking out collaborators. If we are unable to secure collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance RayVa and may not generate meaningful revenues.

***Pre-clinical and clinical trials are inherently unpredictable and involve a lengthy and expensive process with an uncertain outcome. If we do not successfully conduct the clinical trials or gain regulatory approval, we may be unable to market our product candidates.***

Through pre-clinical studies and clinical trials, our product candidates, Vitaros and RayVa, must be demonstrated to the satisfaction of the FDA to be safe and effective for their indicated uses. Results from pre-clinical studies and early clinical trials may not be indicative of, or allow for, prediction of results in later-stage testing. Many of the pre-clinical studies that we have conducted are in animals with "models" of human disease states. Although these tests are widely used as screening mechanisms for drug candidates before being advanced to human clinical studies, results in animal studies are less reliable predictors of safety and efficacy than results of human clinical studies. Future clinical trials may not demonstrate the safety and effectiveness of our product candidates or may not result in regulatory approval to market our product candidates. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

***If we are unable to adequately establish, maintain and protect our intellectual property rights, we may incur substantial litigation costs and may be unable to generate significant product revenue.***

Protection of the intellectual property for our product candidates is of material importance to our business in the United States and other countries. We have sought and will continue to seek proprietary protection for our product candidates to attempt to prevent others from commercializing equivalent products. Our success may depend on our ability to (1) obtain effective patent protection within the United States and internationally for our proprietary technologies and product candidates, (2) defend patents we own, (3) preserve our trade secrets and (4) operate without infringing upon the proprietary rights of others. In addition, we have agreed to indemnify certain of our former partners for certain liabilities with respect to the defense, protection and/or validity of our patents and would also be required to incur costs or forgo revenue if it is necessary for our former partners to acquire third party patent licenses in order for them to exercise the licenses acquired from us. Upon the closing of the Ferring Asset Purchase Agreement, we transferred the patents related to Vitaros and DDAIP outside the United States to Ferring; however we remain liable for any claims from our former partners prior to the closing of the Ferring Asset Purchase Agreement.

While we have obtained patents and have many patent applications pending, the extent of effective patent protection in the United States and other countries is highly uncertain and involves complex legal and factual questions. No consistent policy addresses the breadth of claims allowed in, or the degree of protection afforded under, patents of medical and pharmaceutical companies. Patents we currently own or may obtain might not be sufficiently broad enough to protect us against competitors with similar technology. Any of our patents could be invalidated or circumvented.

Furthermore, holders of competing patents could allege that our activities infringe on their rights and could potentially prevail in litigation against us. We have also sold certain patents in transactions where we have licensed rights to our drug candidates. In certain of these transactions, we have agreed to indemnify the purchaser from third party patent claims, which could expose us to potentially significant damages for patents that we no longer own. Any litigation could result in substantial cost to us and would divert management's attention, which may harm our business. In addition, our efforts to protect or defend our proprietary rights may not be successful or, even if successful, may result in substantial cost to us.

***The patent protection for NexACT, a key component of Vitaros and RayVa, may expire before we are able to maximize its commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.***

The patents for NexACT alone have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, certain of the U.S. patents directed to NexACT and its use are expected to expire in 2020. Although patents covering the combination of NexACT and alprostadil do not expire until starting in 2032, we may be unable to prevent others from using NexACT following expiration of the patents. In connection with the Ferring Asset Purchase Agreement, we transferred certain non-U.S. patents related to DDAIP and certain U.S. and non-U.S. patents related to DDAIP in combination with alprostodil and received a perpetual, exclusive (even as to Ferring), fully transferable, fully sublicensable, royalty-free, fully paid-up license to such patents.

***We face a high degree of competition.***

We are engaged in a highly competitive industry. If we obtain approval in the United States for Vitaros, we would compete against many companies and research institutions that research, develop and market products in areas similar to those in which we operate. For example, Viagra®(Pfizer), Cialis®(Lilly), Levitra®(Glaxo Smith Kline), Stendra®(Metuchen Pharmaceuticals, LLC), and Spedra®(Menarini Group) are currently approved for treatment of ED.

These and other competitors may have specific expertise and development technologies that are better than ours. Many of these competitors, which include large pharmaceutical companies, have substantially greater financial resources, larger research and development capabilities and substantially greater experience than we do. Accordingly, our competitors may successfully develop competing products. We are also competing with other companies and their products with respect to manufacturing efficiencies and marketing capabilities, areas where we have limited or no direct experience.

***We currently have no sales and marketing resources, and we may not be able to effectively market and sell our products.***

We do not currently have a commercial organization for sales, marketing and distribution of pharmaceutical products, and therefore we must build this organization or make arrangements with third parties to perform these functions in order to commercialize any products that we successfully develop and for which we obtain regulatory approvals. If we develop an internal sales force, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We will also face competition in our search for collaborators and potential co-promoters, if we choose such an option. To the extent we may rely on third parties to co-promote or otherwise commercialize any product candidates in one or more regions that may receive regulatory approval, we are likely to receive less revenue than if we commercialized these products ourselves. Further, by entering into strategic partnerships or similar arrangements, we may rely in part on such third parties for financial and commercialization resources. Even if we are able to identify suitable partners to assist in the commercialization of our product candidates, they may be unable to devote the resources necessary to realize the full commercial potential of our products.

In addition, if the Vitaros NDA is approved by the FDA upon resubmission, Allergan has a one-time opt-in right for a period of sixty days following the later of (i) receipt by Allergan of the option package from the Company following the NDA resubmission or (ii) FDA approval, to assume all future commercialization activities for Vitaros in the United States. If Allergan exercises its opt-in right, we may receive up to a total of $25 million in upfront and potential launch milestone payments, plus a double-digit royalty on net sales of Vitaros. If Allergan elects not to exercise its opt-in right, we expect to commercialize Vitaros, either through an internally built commercial organization, a contract sales force or by partnering with a pharmaceutical company with established sales and marketing capabilities.

Further, we may lack the financial and managerial resources to establish a sales and marketing organization to adequately promote and commercialize any product candidates that may be approved. The establishment of a sales force will result in an increase in our expenses, which could be significant before we generate revenues from any newly approved product candidate. Even though we may be successful in establishing future partnership arrangements, such sales force and marketing teams may not be successful in commercializing our products, which would adversely affect our ability to generate revenue for such products, and could have a material adverse effect on our business, results of operations, financial condition and prospects.

***Our pharmaceutical expenditures may not result in commercially successful products.***

We cannot be sure our business expenditures will result in the successful acquisition, development or launch of products that will prove to be commercially successful or will improve the long-term profitability of our business. If such business expenditures do not result in successful acquisition, development or launch of commercially successful brand products, our results of operations and financial condition could be materially adversely affected.

***Business development activity involves numerous risks, including the risks that we may be unable to integrate an acquired business successfully and that we may assume liabilities that could adversely affect us.***

In order to augment our product pipeline or otherwise strengthen our business, we may decide to acquire or license additional businesses, products and technologies. Acquisitions could require us to raise significant capital and involve many risks, including, but not limited to, the following:

- difficulties in achieving identified financial revenue synergies, growth opportunities, operating synergies and cost savings;
- difficulties in assimilating the personnel, operations and products of an acquired company, and the potential loss of key employees;
- difficulties in consolidating information technology platforms, business applications and corporate infrastructure;
- difficulties in integrating our corporate culture with local customs and cultures;
- possible overlap between our products or customers and those of an acquired entity that may create conflicts in relationships or other commitments detrimental to the integrated businesses;

- our inability to achieve expected revenues and gross margins for any products we may acquire;
- the diversion of management's attention from other business concerns;
- risks and challenges of entering or operating in markets in which we have limited or no prior experience, including the unanticipated effects of export controls, exchange rate fluctuations, foreign legal and regulatory requirements, and foreign political and economic conditions; and
- difficulties in reorganizing, winding-down or liquidating operations if not successful.

In addition, foreign acquisitions involve numerous risks, including those related to changes in local laws and market conditions and due to the absence of policies and procedures sufficient to assure compliance by a foreign entity with United States regulatory and legal requirements. Business development activities require significant transaction costs, including substantial fees for investment bankers, attorneys, and accountants. Any acquisition could result in our assumption of material unknown and/or unexpected liabilities. We also cannot provide assurance that we will achieve any cost savings or synergies relating to recent or future acquisitions. Additionally, in any acquisition agreement, the negotiated representations, warranties and agreements of the selling parties may not entirely protect us, and liabilities resulting from any breaches could exceed negotiated indemnity limitations. These factors could impair our growth and ability to compete, divert resources from other potentially more profitable areas, or otherwise cause a material adverse effect on our business, financial position and results of operations.

The financial statements of acquired companies, or those that may be acquired in the future, are prepared by management of such companies and are not independently verified by our management. In addition, any pro forma financial statements prepared by us to give effect to such acquisitions may not accurately reflect the results of operations of such companies that would have been achieved had the acquisition of such entities been completed at the beginning of the applicable periods.

***We may be subject to product liability and similar claims, which may lead to a significant financial loss if our insurance coverage is inadequate.***

We are exposed to potential product liability risks inherent in the development, testing, manufacturing, marketing and sale of human therapeutic products, including liability resulting from the sale of Vitaros outside of the United States prior to the closing of the Ferring Asset Purchase Agreement. Product liability insurance for the pharmaceutical industry is extremely expensive, difficult to obtain and may not be available on acceptable terms, if at all. Although we maintain various types of insurance, we have no guarantee that the coverage limits of such insurance policies will be adequate. If liability claims were made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. A successful claim against us if we are uninsured, or which is in excess of our insurance coverage, if any, could have a material adverse effect upon us and on our financial condition.

***Our business and operations would be adversely impacted in the event of a failure or security breach of our information technology infrastructure.***

We rely upon the capacity, reliability and security of our information technology hardware and software infrastructure, including internet-based systems, and our ability to expand and update this infrastructure in response to our changing needs. We are constantly updating our information technology infrastructure. Any failure to manage, expand and update our information technology infrastructure or any failure in the operation of this infrastructure could harm our business.

Despite our implementation of security measures, our systems and those of our business partners may be vulnerable to damages from cyber-attacks, computer viruses, natural disasters, unauthorized access, telecommunication and electrical failures, and other similar disruptions. Our business is also potentially vulnerable to break-ins, sabotage and intentional acts of vandalism by third parties as well as employees. Any system failure, accident or security breach could result in disruptions to our operations, could lead to the loss of trade secrets or other intellectual property, could lead to the public exposure of personal information of our employees, clinical trial participants and others, and could result in a material disruption to our clinical and commercialization activities and business operations. To the extent that any disruption or security breach results in a loss or damage to our data, or inappropriate disclosure of confidential information, it could harm our business and cause us to incur liability. In addition, we may be required to incur significant costs to protect against damage caused by these disruptions or security breaches in the future.

***If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully operate our business.***

Our success depends, in part, on our ability to attract, retain and motivate highly qualified management and scientific personnel and on our ability to develop and maintain important relationships with healthcare providers, clinicians and scientists. We are highly dependent upon our senior management and scientific staff. We have incurred attrition at the senior management level in the past, and although we have employment agreements with five of our executives, these agreements are generally terminable at will at any time, and, therefore, we may not be able to retain their services as expected. The loss of services of one or more members of our senior management and scientific staff could delay or prevent us from successfully operating our business. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense, particularly in the San Diego, California area, where our offices are located. We may need to hire additional personnel to support development efforts for U.S. Vitaros and RayVa. We may not be able to attract and retain qualified personnel on acceptable terms.

Our ability to maintain, expand or renew existing business relationships and to establish new business relationships, particularly in the drug development sector, also depends on our ability to subcontract and retain scientific staff with the skills necessary to keep pace with continuing changes in drug development technologies.

***From time to time we are subject to various legal proceedings, which could expose us to significant liabilities.***

We, as well as certain of our officers and distributors, are subject, from time to time, to a number of legal proceedings. Litigation is inherently unpredictable, and any claims and disputes may result in significant legal fees and expenses regardless of merit and could divert management's time and other resources. If we are unable to successfully defend or settle any claims asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted. There is no guarantee of a successful result in any of these lawsuits regardless of merit, either in defending these claims or in pursuing counterclaims.

***We are exposed to potential risks from legislation requiring companies to evaluate internal controls over financial reporting.***

The Sarbanes-Oxley Act requires that we report annually on the effectiveness of our internal controls over financial reporting. Among other things, we must perform systems and processes evaluation testing. This includes an assessment of our internal controls to allow management to report on, and our independent public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In connection with our compliance efforts, we have incurred and expect to continue to incur or expend, substantial accounting and other expenses and significant management time and resources. Further, in connection with our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2014, we determined that, as of December 31, 2014, material weaknesses existed in our internal control over financial reporting over the accounting for and disclosures of technical accounting matters in the consolidated financial statements and effective monitoring and oversight over the controls in the financial reporting process. While our management concluded that we remediated these material weaknesses as of December 31, 2015, there can be no assurances that our future assessments, or the future assessments by our independent registered public accounting firm, will not reveal further material weaknesses in our internal controls. If material weaknesses are identified in the future we would be required to conclude that our internal controls over financial reporting are ineffective, which would likely require additional financial and management resources and could adversely affect the market price of our common stock.

***If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.***

We are party to license agreements with both Allergan and Forendo Pharma Ltd. that impose diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing agreements, we are obligated to pay royalties on net product sales of U.S. Vitaros or fispemifene to the extent they are covered by the agreements. If we fail to comply with our obligations, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements and may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of product candidates being developed using rights licensed to us under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may enter into license agreements in the future that could also impose diligence, development and commercialization timelines, milestone payments, royalty, insurance and other obligations.

**Industry Risks**

***Instability and volatility in the financial markets in the global economy could have a negative impact on our ability to raise necessary funds.***

During the past several years, there has been substantial volatility in financial markets due in part to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to financing is uncertain. If these conditions continue, they are likely to have an adverse effect on our industry and business, including our financial condition, results of operations and cash flows.

We expect to need to raise capital through equity sales and/or incur indebtedness, if available, to finance operations. However, volatility in the capital markets may have an adverse effect on our ability to fund our business strategy through sales of capital stock or through borrowings, in the public or private markets on terms that we believe to be reasonable, if at all.

***Changes in trends in the pharmaceutical and biotechnology industries, including difficult market conditions, could adversely affect our operating results.***

Industry trends and economic and political factors that affect pharmaceutical, biotechnology and medical device companies also affect our business. In the past, mergers, product withdrawals, liability lawsuits and other factors in the pharmaceutical industry have slowed decision-making by pharmaceutical companies and delayed drug development projects. Continuation or increases in these trends could have an adverse effect on our business.

The biotechnology, pharmaceutical and medical device industries generally, and more specifically drug discovery and development, are subject to increasingly rapid technological changes. Our competitors might develop technologies, services or products that are more effective or commercially attractive than our current or future technologies, services or products, or that render our technologies, services or products less competitive or obsolete. If competitors introduce superior technologies, services or products and we cannot make enhancements to our technologies, services or products to remain competitive, our competitive position, and in turn our business, revenue and financial condition, would be materially and adversely affected.

***We are subject to numerous and complex government regulations which could result in delay and expense.***

Governmental authorities in the United States and other countries heavily regulate the testing, manufacture, labeling, distribution, advertising and marketing of our proposed product candidates. None of our proprietary products under development have been approved for marketing in the United States. Before any products we develop are marketed, FDA and comparable foreign agency approval must be obtained through an extensive clinical study and approval process.

The failure to obtain requisite governmental approvals for our product candidates under development in a timely manner, or at all, would delay or preclude us and our licensees from marketing our product candidates or limit the commercial use of our product candidates, which could adversely affect our business, financial condition and results of operations.

Because certain of our product candidates may also be sold and marketed outside the United States, we and/or our licensees may be subject to foreign regulatory requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements. These requirements vary widely from country to country. The failure to meet each foreign country's requirements could delay the introduction of our proposed product candidates in the respective foreign country and limit our revenues from sales of our proposed product candidates in foreign markets.

***We face uncertainty related to healthcare reform, pricing and reimbursement, which could reduce our future revenue.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell Vitaros or any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our potential drug candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump has also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of two percent per fiscal year, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect through 2025, unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. These new laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize our products, if approved.

If reimbursement for our products is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted. Further, numerous foreign governments are also undertaking efforts to control growing healthcare costs through legislation, regulation and voluntary agreements with medical care providers and pharmaceutical companies.

Sales of our product candidates, if approved, will depend in part on the availability of coverage and reimbursement from third-party payors such as United States and foreign government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely that could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in current coverage and reimbursement levels for our products and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

Adoption by the medical community of our product candidates, if approved, may be limited if third-party payors will not offer coverage. Cost control initiatives may decrease coverage and payment levels for drugs, which in turn would negatively affect the price that we will be able to charge. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors to any drug candidate we have in development. Any denial of private or government payor coverage or inadequate reimbursement for our products could harm our business and reduce our revenue.

***Delays in clinical trials are common and have many causes, and if we experience significant delays in the clinical development and regulatory approval of our product candidates, our business may be substantially harmed.***

We may experience delays in commencing and completing clinical trials of our product candidates. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Any of our planned clinical trials may be delayed for a variety of reasons, including delays related to:

- the availability of financial resources for us to commence and complete our planned clinical trials;

- reaching agreement on acceptable terms and pricing with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining independent institutional review board ("IRB") approval at each clinical trial site;
- obtaining regulatory approval to commence clinical trials in each country;
- recruiting a sufficient number of eligible patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of our product candidate for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages or potential side effects of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for such indications.

We could encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs in the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial (if included), or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the CROs' services, we have limited influence over their actual performance. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues from our product candidates. Any of these occurrences may harm our business, prospects, financial condition and results of operations. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize our product candidates and our business will be adversely impacted.***

If we fail to obtain regulatory approval to market our product candidates, we will be unable to sell our product candidates, which will impair our ability to generate additional revenues. To receive approval, we must, among other things, demonstrate with substantial evidence from clinical trials, to the satisfaction of the FDA, that the product candidate is both safe and effective for each indication for which approval is sought. Failure can occur in any stage of development. Satisfaction of the approval requirements is unpredictable but typically takes several years following the commencement of clinical trials, and the time and money needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when our existing and planned clinical trials will generate the data necessary to support an NDA and if, or when, we might receive regulatory approvals for our product candidates. For example, an NDA was previously submitted for Vitaros, but the FDA issued a non-approvable letter in 2008 identifying certain deficiencies with the application. Although we have not conducted additional clinical testing, we have been working to address the issues FDA raised in the non-approvable letter. Based on feedback during our pre-NDA meetings with the FDA, we believe that the resubmission of the Vitaros NDA will not require additional clinical testing, but there is not assurance that the FDA will accept the NDA for Vitaros or agree that no additional clinical trials will be required.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of the proposed indications;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- even after following regulatory guidance or advice, the FDA or comparable foreign regulatory authorities may still reject our ultimate regulatory submissions since their guidance is generally considered non-binding and the regulatory authorities have the authority to revise or adopt new and different guidance at any time.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failure to obtain regulatory approval to market our product candidates, which would significantly harm our business, prospects, financial condition and results of operations. In addition, any approvals that we obtain may not cover all of the clinical indications for which we are seeking approval, or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such event, our ability to generate revenues would be greatly reduced and our business would be harmed.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval.

***If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

We are developing proprietary product candidates for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA

seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

***Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any regulatory approvals that we receive for our product candidates may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require additional risk management activities and labeling which may limit distribution or patient/prescriber uptake. An example would be the requirement of a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record-keeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, and registration. We are also required to maintain continued compliance with cGMP requirements and GCPs requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates or other manufacturers' products in the same class, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements

are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Our relationships with investigators, health care professionals, consultants, third-party payors, and customers are subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and arrangements with investigators, healthcare professionals, consultants, marketing partners, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products and product candidates for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply

with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of undesirable side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors are subject to a number of regulations and standards.***

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, consultant and vendors may engage in fraudulent or other illegal activity for which we may be held responsible. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA and other similar foreign regulatory bodies; including those laws that require the reporting of true, complete and accurate information to the FDA and other similar foreign regulatory bodies, (2) manufacturing standards, (3) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or (4) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We rely on third parties to conduct our preclinical studies and clinical trials. These third parties may not perform as contractually required or expected and issues may arise that could delay the completion of clinical trials and impact regulatory approval of our product candidates.***

We sometimes rely on third parties, such as CROs, medical institutions, academic institutions, clinical investigators and contract laboratories to conduct our preclinical studies and clinical trials. We are responsible for confirming that our preclinical studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA and the European Medicines Agency require us to comply with good laboratory practices for conducting and recording the results of our preclinical studies and GCP, for conducting, monitoring, recording and reporting the results of clinical trials to assure that the data gathered and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with GCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials.

Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

**Risks Related to Owning Our Common Stock**

***If we are not able to comply with the applicable continued listing requirements or standards of the NASDAQ Capital Market, NASDAQ could delist our Common Stock.****

Our common stock is currently listed on the NASDAQ Capital Market ("NASDAQ"). In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

On May 10, 2016, we received a written notification from NASDAQ indicating that we were not in compliance with NASDAQ Listing Rule 5550(a)(2), as the closing bid price for our Common Stock had been below $1.00 per share for 30 consecutive business days. Pursuant to NASDAQ Listing Rule 5810(c)(3)(A), we were granted a 180 calendar day compliance period, or until November 7, 2016, to regain compliance with the minimum bid price requirement. During the compliance period, our shares of common stock continued to be listed and traded on NASDAQ. To regain compliance, the closing bid price of our shares of common stock needed to meet or exceed $1.00 per share for at least 10 consecutive business days during the 180 calendar day compliance period, which was accomplished through a 1-for-10 reverse stock split of our common stock, effected on October 21, 2016. On November 8, 2016, we received a letter from NASDAQ confirming that we are in compliance with NASDAQ Listing Rule 5550(a)(2).

On June 2, 2016, we received a notice from NASDAQ stating that we were not in compliance with NASDAQ Listing Rule 5550(b)(2) because our market value of listed securities ("MVLS") was below $35 million for the previous thirty (30) consecutive business days. In accordance with NASDAQ Marketplace Rule 5810(c)(3), we were granted a 180 calendar day compliance period until November 29, 2016, to regain compliance with the minimum MVLS requirement. Compliance can be achieved by meeting the $35 million MVLS requirement for a minimum of 10 consecutive business days during the 180 calendar day compliance period, maintaining a stockholders' equity value of at least $2.5 million, or meeting the requirement of net income of at least $500,000 for two of the last three fiscal years. On February 8, 2017, we were notified that our request for continued listing on NASDAQ pursuant to an extension through May 30, 2017 to evidence compliance with all applicable criteria for continued listing on NASDAQ was granted. On May 2, 2017, the Company was notified by NASDAQ that it had evidenced full compliance with all criteria for continued listing on the NASDAQ Stock Market and the matter has now been closed.

Despite this, there is no guarantee that we will be able to comply with the applicable continued listing requirements in the future. In the event that our Common Stock is delisted from NASDAQ and is not eligible for quotation or listing on another market or exchange, trading of our Common Stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult

to dispose of, or obtain accurate price quotations for, our Common Stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our Common Stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange. In addition, following delisting, unless our shares of Common Stock were immediately thereafter trading on the OTC Bulletin Board or the OTCQB or OTCQX market places of the OTC Markets, we would no longer be able to sell shares to Aspire Capital under the Purchase Agreement.

***We are vulnerable to volatile stock market conditions.***

The market prices for securities of biopharmaceutical and biotechnology companies, including ours, have been highly volatile. The market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition, future announcements, such as the results of testing and clinical trials, the status of our relationships with third-party collaborators, technological innovations or new therapeutic products, governmental regulation, developments in patent or other proprietary rights, litigation or public concern as to the safety of products developed by us or others and general market conditions concerning us, our competitors or other biopharmaceutical companies, may have a significant effect on the market price of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have been more likely to initiate securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

***We do not expect to pay dividends on our common stock in the foreseeable future.***

Although our stockholders may in the future receive dividends if and when declared by our board of directors, we do not intend to declare dividends on our common stock in the foreseeable future. Therefore, you should not purchase our common stock if you need immediate or future income by way of dividends from your investment.

***We may issue additional shares of our capital stock that could dilute the value of your shares of common stock.***

We are authorized to issue 40,000,000 shares of our capital stock, consisting of 30,000,000 shares of our common stock and 10,000,000 shares of our preferred stock. We currently have an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants.

In light of our future capital needs, we may also issue additional shares of common stock at or below current market prices or issue convertible securities. These issuances would dilute the book value of existing stockholders common stock and could depress the value of our common stock.

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

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

| EXHIBITS NO. | DESCRIPTION |
|---|---|
| 2.1† | Stock Purchase Agreement, dated December 15, 2011, by and among Apricus Biosciences Inc., TopoTarget A/S, and TopoTarget USA, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2012). |
| 2.2 | Stock Contribution Agreement, dated June 19, 2012, by and among Apricus Biosciences, Inc., Finesco SAS, Scomedica SA and the shareholders of Finesco named therein (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report Form 8-K filed with the Securities and Exchange Commission on July 13, 2012). |
| 2.3† | Asset Purchase Agreement by and between Apricus Pharmaceuticals USA, Inc. and Biocodex, Inc., dated March 26, 2013 (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2013). |
| 2.4 | Amendment to Stock Purchase Agreement, dated June 13, 2014, by and between Apricus Biosciences, Inc. and Samm Solutions, Inc. (doing business as BTS Research and formerly doing business as BioTox Sciences) (incorporated herein by reference to Exhibit 2.1 to the Company's Form 10-Q filed with Securities and Exchange Commission on August 11, 2014). |
| 3.1 | Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Registration Statement on Form 10-SB filed with the Securities and Exchange Commission on March 14, 1997). |
| 3.2 | Certificate of Amendment to Articles of Incorporation of Apricus Biosciences, Inc., dated June 22, 2000 (incorporated herein by reference to Exhibit 3.2 to the Company's Form 10-K filed with the Securities and Exchange Commission on March 31, 2003). |
| 3.3 | Certificate of Amendment to Articles of Incorporation of Apricus Biosciences, Inc., dated June 14, 2005 (incorporated herein by reference to Exhibit 3.4 to the Company's Form 10-K filed with the Securities and Exchange Commission on March 16, 2006). |
| 3.4 | Certificate of Amendment to Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc., dated March 3, 2010 (incorporated herein by reference to Exhibit 3.6 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010). |
| 3.5 | Certificate of Correction to Certificate of Amendment to Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc., dated March 3, 2010 (incorporated herein by reference to Exhibit 3.7 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010). |
| 3.6 | Certificate of Designation for Series D Junior-Participating Cumulative Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-A12GK filed with the Securities and Exchange Commission on March 24, 2011). |
| 3.7 | Certificate of Change filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2010). |

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| 3.8 | Certificate of Amendment to Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc., dated September 10, 2010 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 10, 2010). |
| 3.9 | Certificate of Change filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Form 8-K filed with the Securities and Exchange Commission on October 25, 2016). |
| 3.10 | Certificate of Amendment filed with the Nevada Secretary of State. |
| 3.11 | Fourth Amended and Restated Bylaws, dated December 18, 2012 (incorporated herein by reference to Exhibit 3.9 to the Company's Form 10-K filed with the Securities and Exchange Commission on March 18, 2013). |
| 3.12 | Certificate of Withdrawal of Series D Junior Participating Cumulative Preferred Stock, dated May 15, 2013 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2013). |
| 3.13 | Amendment to the Fourth Amended and Restated Bylaws of Apricus Biosciences, Inc., dated January 11, 2016 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016). |
| 3.14 | Second Amendment to the Fourth Amended and Restated Bylaws of Apricus Biosciences, Inc., dated March 3, 2016 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2016). |
| 4.1 | Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2011). |
| 4.2 | Form of Warrant (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on From 8-K filed with the Securities and Exchange Commission on May 24, 2013). |
| 4.3 | Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of October 17, 2014, by and among Apricus Biosciences, Inc., NexMed (U.S.A.), Inc., NexMed Holdings, Inc. and Apricus Pharmaceuticals USA, Inc., as borrowers, Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time including Oxford Finance LLC and Silicon Valley Bank. (incorporated herein by reference to Exhibit 4.2 to the Company's Form 8-K filed with the Securities and Exchange Commission on October 20, 2014). |
| 4.4 | Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 12, 2015). |
| 4.5 | Form of Warrant issued to Sarissa Capital Domestic Fund LP and Sarissa Capital Offshore Master Fund LP (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016). |
| 4.6 | Form of Warrant issued to other purchasers (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016). |
| 4.7 | Form of Warrant Amendment (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016). |

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| 4.8 | Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 28, 2016). |
| 4.9 | Form of Warrant Amendment (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 21, 2017). |
| 4.10 | Form of Warrant (incorporated herein by reference to Exhibit 4.9 of Amendment No. 1 to Company's Registration Statement on Form S-1 (File No. 333-217036) filed with the Securities and Exchange Commission on April 17, 2017). |
| 10.1 | 2012 Stock Long Term Incentive Plan, as amended and restated effective May 17, 2017 (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 13, 2017). |
| 31.1 | Certification of Principal Executive Officer and Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Principal Executive Officer and Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document. (1) |
| 101.SCH | XBRL Taxonomy Extension Schema. (1) |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase. (1) |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase. (1) |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase. (1) |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase. (1) |

(1) Furnished, not filed.

† Confidential treatment has been requested for portions of this exhibit. Those portions have been omitted and filed separately with the Securities and Exchange Commission.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Apricus Biosciences, Inc.

Date: August 2, 2017

/s/ RICHARD W. PASCOE

Richard W. Pascoe

Chief Executive Officer and Secretary

**BARBARA K. CEGAVSKE**
**Secretary of State**
**202 North Carson Street**
**Carson City, Nevada 89701-4201**
**(775) 684-5708**
**Website: www.nvsos.gov**

# Certificate of Amendment (Pursuant to NRS 78.385 AND 78.390)

USE BLACK INK ONLY - DO NOT HIGHLIGHT

ABOVE SPACE IS FOR OFFICE USE ONLY

**Certificate of Amendment to Articles of Incorporation**
**For Nevada Profit Corporation**
**(Pursuant to NRS 78.385 and 78.390 - After Issuance of Stock)**

1. Name of corporation:
Apricus Biosciences, Inc.

2. The articles have been amended as follows: (provide article numbers, if available)
Paragraph A of Article FIFTH of the Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc., as heretofore amended, is hereby amended and restated to read in its entirety as follows:
"FIFTH: A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is forty million (40,000,000), consisting of thirty million (30,000,000) shares of Common Stock, par value one-tenth of one cent ($0.001) per share (the "Common Stock") and ten million (10,000,000) shares of preferred stock, par value one-tenth of one cent ($0.001) per share (the "Preferred Stock")."

3. The vote by which the stockholders holding shares in the corporation entitling them to exercise at least a majority of the voting power, or such greater proportion of the voting power as may be required in the case of a vote by classes or series, or as may be required by the provisions of the articles of incorporation* have voted in favor of the amendment is:
in excess of a majority

4. Effective date and time of filing: (optional) Date: Time:
(must not be later than 90 days after the certificate is filed)

8. Signature: (required)

**X** /s/ Richard W. Pascoe
Signature of Officer

*If any proposed amendment would alter or change any preference or any relative or other right given to any class or series of outstanding shares, then the amendment must be approved by the vote, in addition to the affirmative vote otherwise required, of the holders of shares representing a majority of the voting power of each class or series affected by the amendment regardless to limitations or restrictions on the voting power thereof.

**IMPORTANT:** Failure to include any of the above information and submit with the proper fees may cause this filing to be rejected.

*This form must be accompanied by appropriate fees.*

**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

I, Richard W. Pascoe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Apricus 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: August 2, 2017

/S/ RICHARD W. PASCOE

Richard W. Pascoe

Chief Executive Officer & Secretary

**Exhibit 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**

I, Richard W. Pascoe, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Apricus Biosciences, Inc. on Form 10-Q for the Quarter ended June 30, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Apricus Biosciences, Inc.

Date: August 2, 2017

By: /S/ RICHARD W. PASCOE
Name: Richard W. Pascoe
Title: Chief Executive Officer & Secretary