
**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, 2018

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
(State or Other Jurisdiction of
Incorporation or Organization)

87-0449967
(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 August 6, 2018, 23,441,449 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, 2018	December 31, 2017
	(Unaudited)	
Assets		
Current assets		
Cash	\$ 6,836	\$ 6,331
Prepaid expenses and other current assets	294	261
Total current assets	7,130	6,592
Property and equipment, net	56	79
Other long term assets	36	35
Total assets	\$ 7,222	\$ 6,706
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 1,054	\$ 58
Accrued expenses	454	650
Accrued compensation	374	863
Deferred revenue	—	12
Current liabilities of discontinued operations	21	—
Total current liabilities	1,903	1,583
Warrant liabilities	—	694
Other long term liabilities	35	58
Total liabilities	1,938	2,335
Commitments and contingencies (note 7)		
Stockholders' equity		
Preferred stock, \$.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, \$.001 par value, 60,000,000 and 30,000,000 shares authorized, 23,441,449 and 15,217,231 issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	23	15
Additional paid-in-capital	325,796	320,343
Accumulated deficit	(320,535)	(315,987)
Total stockholders' equity	5,284	4,371
Total liabilities and stockholders' equity	\$ 7,222	\$ 6,706

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

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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,	
	2018	2017	2018	2017
Operating expense				
Research and development	\$ 162	\$ 839	\$ 379	\$ 1,266
General and administrative	2,075	1,602	4,210	3,043
Total operating expense	2,237	2,441	4,589	4,309
Loss before other income (expense)	(2,237)	(2,441)	(4,589)	(4,309)
Other income (expense)				
Interest income (expense), net	—	3	—	(92)
Loss on extinguishment of debt	—	—	—	(422)
Change in fair value of warrant liability	—	716	222	(292)
Amendment of equity classified warrants	(17)	—	(158)	—
Other income (expense), net	1	—	1	(26)
Total other income (expense)	(16)	719	65	(832)
Loss from continuing operations	(2,253)	(1,722)	(4,524)	(5,141)
Income (loss) from discontinued operations	(24)	248	(24)	11,740
Net income (loss)	\$ (2,277)	\$ (1,474)	\$ (4,548)	\$ 6,599
Basic and diluted earnings (loss) per share				
Continuing operations	\$ (0.10)	\$ (0.15)	\$ (0.23)	\$ (0.54)
Discontinued operations	\$ —	\$ 0.02	\$ —	\$ 1.23
Total earnings (loss) per share	\$ (0.10)	\$ (0.13)	\$ (0.23)	\$ 0.69
Weighted average common shares outstanding for basic and diluted earnings (loss) per share	23,362	11,335	19,648	9,547

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

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

	For the Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net income (loss)	\$ (4,548)	\$ 6,599
Net income (loss) from discontinued operations	(24)	11,740
Net loss from continuing operations	(4,524)	(5,141)
Adjustments to reconcile net income (loss) to net cash used in operating activities from continuing operations:		
Depreciation and amortization	23	77
Non-cash interest expense	—	56
Stock-based compensation expense	556	572
Warrant liabilities revaluation	(222)	292
Loss on debt extinguishment	—	422
Amendment of equity classified warrants	158	—
Changes in operating assets and liabilities from continuing operations:		
Prepaid expenses and other current assets	(33)	(145)
Other assets	(1)	14
Accounts payable	996	(547)
Accrued expenses	(294)	(478)
Accrued compensation	(489)	43
Deferred revenue	(12)	—
Other liabilities	(23)	(16)
Net cash used in operating activities from continuing operations	(3,865)	(4,851)
Cash flows from financing activities from continuing operations:		
Proceeds from exercise of warrants	1,275	—
Issuance of common stock and warrants	3,550	6,866
Issuance costs related to common stock and warrants	(452)	(788)
Repayment of notes payable	—	(7,129)
Net cash provided by (used in) financing activities from continuing operations	4,373	(1,051)
Cash flows from discontinued operations:		
Net cash used in operating activities of discontinued operations	(3)	(114)
Net cash provided by investing activities of discontinued operations	—	11,750
Net cash provided by (used in) discontinued operations	(3)	11,636
Net increase in cash	505	5,734
Cash, beginning of period	6,331	2,087
Cash, end of period	\$ 6,836	\$ 7,821
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ —	\$ 92
Non-cash investing and financing activities:		
Accrued transaction costs for financing activities	\$ (98)	\$ (135)
Issuance of placement agent warrants	\$ 105	\$ 176
Reclassification of warrant liabilities to equity	\$ 472	\$ 798

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

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

	Common Stock (Shares)	Common Stock (Amount)	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2017	15,217	\$ 15	\$ 320,343	\$ (315,987)	\$ 4,371
Stock-based compensation expense	—	—	556		556
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	83	—	—	—	—
Proceeds from exercise of warrants	1,041	1	1,274	—	1,275
Issuance of common stock and warrants	7,100	7	3,543	—	3,550
Issuance costs related to common stock and warrants	—	—	(550)	—	(550)
Amendment of equity classified warrants	—	—	158	—	158
Reclassification of warrant liabilities to equity	—	—	472	—	472
Net loss	—	—	—	(4,548)	(4,548)
Balance as of June 30, 2018	<u>23,441</u>	<u>\$ 23</u>	<u>\$ 325,796</u>	<u>\$ (320,535)</u>	<u>\$ 5,284</u>

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, 2017 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 1, 2018. 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. The December 31, 2017 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.

Seelos Merger Agreement

On July 30, 2018, the Company, Arch Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (“Merger Sub”), and Seelos Therapeutics, Inc., a Delaware corporation (“Seelos”), entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Seelos, with Seelos continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the “Merger”). See note 8 below for more information regarding the Merger.

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 \$320.5 million and working capital of \$5.2 million as of June 30, 2018 and reported net loss of approximately \$4.5 million and negative cash flows from operations of \$3.9 million for the six months ended June 30, 2018. The Company also reported negative cash flows from operations of \$10.6 million for the year ended December 31, 2017. 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, 2018, the Company had cash and cash equivalents of approximately \$6.8 million.

On February 15, 2018, the U.S. Food and Drug Administration (“FDA”), issued a complete response letter (a “CRL” and such CRL, the “2018 CRL”) for the new drug application (“NDA”) for Vitaros. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form. In April 2018, the Company met with the FDA and confirmed that two new Phase 3 clinical efficacy trials would be necessary at a lower formulation concentration in order to reach approval. The Company has initiated discussions with parties for the U.S. Vitaros rights to enable Vitaros’ continued development and potential approval in exchange for financial terms commensurate with a development stage asset.

On June 22, 2018, the Company entered into a subscription agreement amendment (the “Subscription Agreement Amendment”) with Sarissa Capital Domestic Fund LP (“Sarissa Domestic”) and Sarissa Capital Offshore Master Fund LP (“Sarissa Offshore” together with Sarissa Domestic, the “Investors”), which, among other things, removed the Investors’ preemptive rights with respect to future issuances of the Company’s equity securities. Concurrently with the Subscription Agreement Amendment, the Company entered into a warrant amendment (the “June 2018 Warrant Amendment”) with Sarissa Offshore regarding the warrants to purchase common stock of the Company, issued in February 2015 (the “February 2015 Warrants”) and January 2016 (together with the February 2015 Warrants, the “2015 and 2016 Warrants”), pursuant to which the exercise price of the warrants was reduced from \$0.71 to \$0.42 per share. Previously, in March 2018, the Company entered into a warrant amendment (the “March 2018 Warrant Amendment”) with the holders of warrants issued pursuant to the Company’s February 2015 and January 2016 financings (the

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“2015 and 2016 Warrants”), which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from \$8.80 to \$0.71 per share, and (ii) amended certain provisions of the 2015 and 2016 Warrants such that they, effective as of the March 2018 Warrant Amendment, can no longer be net-cash settled.

On April 2, 2018, the Company completed a public offering (the “April 2018 Financing”) for net proceeds of approximately \$2.9 million, after deducting placement agent fees and other estimated offering expenses. Pursuant to the agreement, the Company sold 7,100,000 units (the “2018 Units”) at a purchase price of \$0.50 per share, with each unit consisting of one share of the Company’s common stock and one warrant to purchase 0.5 of a share of the Company’s common stock (the “April 2018 Warrants”). 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 April 2018 Warrants. The sufficient number of authorized common stock became available on May 17, 2018 following the Company’s announcement that it had received stockholder approval of an amendment to its Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to a total of 60,000,000 shares (the “2018 Charter Amendment”) and the 2018 Charter Amendment was effective. The April 2018 Warrants have an exercise price equal to \$0.50 per share of common stock and will expire five years from the date they are first exercisable. In addition, the Company issued warrants to purchase up to 355,000 shares of common stock (the “April 2018 Placement Agent Warrants”) to H.C. Wainwright & Co., LLC (“H.C. Wainwright”). The April 2018 Placement Agent Warrants were exercisable upon the announcement of the effectiveness of the 2018 Charter Amendment at an exercise price of \$0.625 per share, and also expire five years from that date.

On September 10, 2017, the Company entered into a Securities Purchase Agreement (the “September 2017 SPA”) with certain investors for net proceeds of approximately \$3.1 million, after deducting commissions and estimated offering expenses payable by the Company. Pursuant to the agreement, the Company sold 2,136,614 shares of the Company’s common stock at a purchase price of \$1.73 per share, and warrants to purchase up to 1,068,307 shares of common stock in a private placement (the “September 2017 Warrants”). The September 2017 Warrants were originally exercisable upon closing, or on September 13, 2017, at an exercise price equal to \$1.67 per share of common stock and are exercisable for two and one half years from that date. In addition, the Company issued warrants to purchase up to 106,831 shares of common stock to H.C. Wainwright (the “September 2017 Placement Agent Warrants”). The September 2017 Placement Agent Warrants were originally exercisable upon closing at an exercise price of \$2.16 per share, and also expire two and one half years from the closing date. In connection with the April 2018 Financing, the September 2017 Warrants and the September 2017 Placement Agent Warrants were amended to, among other things, (i) reduce the exercise price of the warrants to \$0.60 per share (the closing price of the Company’s stock on March 27, 2018, or the date of the amendment), and (ii) change the date upon which such warrants became exercisable to the effective date of the 2018 Charter Amendment (the “April 2018 Warrant Amendment”), or May 17, 2018.

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 offering expenses payable by the Company. Pursuant to the underwriting agreement with H.C. Wainwright, the Company sold to H.C. Wainwright an aggregate of 5,030,000 units (the “2017 Units”). Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock (the “April 2017 Warrants”), 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 April 2017 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 “2017 Charter Amendment”) and the 2017 Charter Amendment became effective on that date. The April 2017 Warrants will expire five years from May 17, 2017, the date they became exercisable, and the exercise price of the April 2017 Warrants is \$1.55 per share of common stock. In connection with this transaction, the Company issued to H.C. Wainwright warrants to purchase up to 251,500 shares of common stock (the “2017 Underwriter Warrants”). The 2017 Underwriter Warrants have substantially the same terms as the April 2017 Warrants sold concurrently to the investors in the offering, except that the 2017 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, and a related prospectus.

On April 20, 2017, the Company entered into a warrant amendment (the “April 2017 Warrant Amendment”) with the holders of the Company’s September 2016 Warrants (as defined below) issued in a financing in September 2016 (the “September 2016 Financing”), which, among other things, (i) reduced the exercise price of the September 2016 Warrants to \$1.55 per share (the exercise price of the April 2017 Warrants), and (ii) changed the date upon which the September 2016 Warrants became exercisable to the effective date of the 2017 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

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United States for approximately \$12.7 million, which consisted of an upfront payment of \$11.5 million, approximately \$0.7 million for the delivery of certain product-related inventory, and an aggregate of \$0.5 million related to transition services. 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”).

The Company currently has an effective shelf registration statement on Form S-3 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, 2018, the Company had approximately \$96.5 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 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, 2018, 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 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 successfully complete the Merger with Seelos or, if the Merger is not completed, another strategic transaction for the Company;
- its ability to raise additional funds to finance its operations;
- its ability to secure a development partner for U.S. Vitaros in order to overcome deficiencies raised in the 2018 CRL;
- its ability to maintain compliance with the listing requirements of The Nasdaq Capital Market (“Nasdaq”);
- the outcome, costs and timing of clinical trial results for the Company’s current or future product candidates;
- the extent and amount of any indemnification claims made by Ferring under the Ferring Asset Purchase Agreement;
- litigation expenses, including the ongoing litigation with Laboratoires Majorelle SAS and Majorelle International SARL;
- 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 trading price of its common stock; and
- its ability to increase the number of authorized shares outstanding to facilitate future financing events.

On April 10, 2018, 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 accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided an initial period of 180 calendar days, or until October 8, 2018, to regain compliance. In order to regain compliance, the bid price of the Company’s common stock must close at \$1.00 per share or more for a minimum of ten consecutive business days.

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. 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 and business activities and potential future clinical studies and/or other future ventures. 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

Prior to 2018, the Company's 2015 and 2016 Warrants were classified as liabilities in the accompanying condensed consolidated 2017 balance sheet as they contained provisions that were considered outside of the Company's control, such as requiring the Company to maintain active registration of the shares underlying such warrants. The 2015 and 2016 Warrants were recorded at fair value using the Black-Scholes option pricing model. The fair value of these warrants was 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 for 2017.

In March 2018, the Company entered into the March 2018 Warrant Amendment with the holders of its 2015 and 2016 Warrants, which amended the terms so that in no circumstances may the 2015 and 2016 Warrants be net-cash settled. As a result, the fair value of the 2015 and 2016 Warrants at the date of the modification were reclassified to equity.

All of the Company's outstanding warrants have similar terms whereas under no circumstance may the warrants be net-cash settled. As such, all warrants are equity-classified. See note 5 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, when applicable, are measured and disclosed at fair value on a recurring basis, and are classified within the Level 3 designation.

In March 2018, the Company entered into the March 2018 Warrant Amendment with the holders of its 2015 and 2016 Warrants, which amended the terms so that in no circumstances may the 2015 and 2016 Warrants be net-cash settled. As a result, the Company's 2015 and 2016 Warrants were reclassified from liabilities to equity during the first quarter of 2018 and will no longer be measured at fair value on a recurring basis.

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

	Warrant liabilities
Balance as of December 31, 2017	\$ 694
Change in fair value measurement of warrant liability	(222)
Warrant liability reclassified to stockholders' equity	(472)
Balance as of June 30, 2018	\$ —

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 dilute 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,	
	2018	2017
Outstanding stock options	1,064	400
Outstanding warrants	9,415	6,095
Restricted stock units	581	934

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

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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, 2018. No stock options were granted during the first six months of 2017.

	June 30, 2018
Risk-free interest rate	2.27%-2.29%
Volatility	98.09%-105.01%
Dividend yield	—%
Expected term	5-6.08 years
Forfeiture rate	—%
Weighted average grant date fair value	\$ 1.66

A summary of the Company's stock option activity under its stock option plans during the six months ended June 30, 2018 is as follows (share amounts in thousands):

	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2017	369	\$ 17.37
Granted	695	\$ 2.11
Outstanding as of June 30, 2018	<u>1,064</u>	<u>\$ 7.40</u>

During the first quarter of 2018, the Company granted approximately 0.7 million options to its employees and Board of Directors which have vesting periods of four years and one year, respectively.

A summary of the Company's restricted stock unit activity under its stock option plans during the six months ended June 30, 2018 is as follows (share amounts in thousands):

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2017	718	\$ 1.57
Vested	(137)	\$ 2.25
Unvested as of June 30, 2018	<u>581</u>	<u>\$ 1.41</u>

The Company grants options and restricted stock units ("RSUs") to its employees annually 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 in November 2018. The Company records expense related to its performance RSUs based on the probability of occurrence, which is reassessed each quarter. Since approval by the FDA is out of the Company's control, the probability of occurrence is zero until met.

The options and 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 options and RSUs granted to the Company's officers are also subject to accelerated vesting pursuant to the terms of their existing employment agreements.

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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,	
	2018	2017	2018	2017
Research and development	\$ 37	\$ 85	\$ 78	\$ 137
General and administrative	219	202	478	435
Total	<u>\$ 256</u>	<u>\$ 287</u>	<u>\$ 556</u>	<u>\$ 572</u>

Segment Information

The Company operates under one segment which develops pharmaceutical products.

Recent Accounting Pronouncements

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. In July 2015, the FASB issued ASU No. 2015-14, which deferred the effective date of ASU 2014-09 by one year to annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, for public entities, though early adoption was permitted. The Company adopted the standard on January 1, 2018 using a modified retrospective approach with the cumulative effect of adopting the standard recognized at the date of initial application. Due to the Company's sale of certain assets and rights to Ferring in March 2017 (see note 2), the Company does not currently have a revenue stream. Accordingly, the adoption of this update on January 1, 2018 did not 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 does not believe the adoption of this 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 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 was also eligible to receive two additional quarterly payments totaling \$0.5 million for transition services, the first of which was received in July 2017 and the second of which was received in September 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

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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, the remainder of the installment payments owed by the Company to Sandoz as a condition under the termination agreement between the two parties. The Company retained 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 Ferring Asset Purchase Agreement was treated as a sale of a business and the total proceeds from the sale were allocated to the Purchased Assets. The total gain on sale of the Purchased Assets to Ferring consisted of the following (in thousands):

Upfront payment received	\$	11,500
Transition services payments		500
Payment received for inventory		709
Total proceeds from sale	\$	12,709
Carrying value of assets sold in sale		(1,578)
Liabilities transferred upon sale		1,186
Total gain on sale of Purchased Assets	\$	12,317

Discontinued Operations

The Company had \$0.02 million in accrued expenses related to discontinued operations as of June 30, 2018. There were no assets and liabilities presented as discontinued operations as of December 31, 2017. The operating results related to discontinued operations during the three and six months ended June 30, 2018 and 2017 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Product sales	\$ —	\$ —	\$ —	\$ 143
Royalty revenue	—	147	—	368
Cost of goods sold	(24)	—	(24)	(74)
Operating expenses	—	(149)	—	(748)
Other expense	—	—	—	(16)
Gain on sale	—	250	—	12,067
Income from discontinued operations	\$ (24)	\$ 248	\$ (24)	\$ 11,740

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Product sales, royalty revenue and cost of goods sold all relate to the sale of Vitaros product outside of the United States. 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 were 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. Operating expenses for the prior 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, paid in September 2015, and a \$1.5 million regulatory milestone payment, paid in September 2017 following the FDA's acknowledgment of receipt of the Company's NDA resubmission. Since the intangibles acquired in the license agreement do not have an alternative future use, all costs incurred including the upfront payment and the regulatory milestone payment, were treated as research and development expense.

As part of the license agreement, Allergan has the right to exercise a one-time opt-in right to assume all future commercialization activities in the United States, assuming FDA approval, in exchange for a total of \$25.0 million in upfront and potential launch milestone payments owed to the Company, plus a high double-digit royalty in the ten to twenty percent range on Allergan's net sales of the product. If Allergan elects not to exercise its opt-in right, the Company expects to commercialize Vitaros by partnering with a pharmaceutical company with established sales and marketing capabilities.

In 2008, the FDA issued a CRL (the "2008 CRL") for the Vitaros NDA, identifying certain deficiencies in the application. Based on the Company's subsequent interactions with the FDA and after completion of further drug-device engineering and other activities intended to address issues previously raised in the 2008 CRL, which included human factor testing and new non-clinical studies, the Company resubmitted the Vitaros NDA in August 2017.

On February 15, 2018, the FDA issued the 2018 CRL, identifying deficiencies related to chemistry, manufacturing and controls ("CMC") and indicating that the modest treatment effect did not outweigh certain safety concerns specific to the 2.5% concentration of its permeation enhancer NexACT (DDAIP.HCl) contained in the current formulation.

In April 2018, the Company met with the FDA and confirmed that two new Phase 3 clinical efficacy trials would be necessary at a lower formulation concentration in order to reach approval. The Company has initiated discussions with interested parties for the U.S. Vitaros rights to enable its continued development and potential approval in exchange for financial terms commensurate with a development stage asset.

4. OTHER FINANCIAL INFORMATION

Accrued Expenses

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

	June 30, 2018	December 31, 2017
Professional fees	\$ 379	\$ 575
Outside research and development services	21	61
Other	54	14
	<u>\$ 454</u>	<u>\$ 650</u>

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Other Long Term Liabilities

Other long term liabilities are comprised of the following (in thousands):

	June 30, 2018	December 31, 2017
Deferred rent	\$ 16	\$ 46
Security deposit	12	12
Other	7	—
	<u>\$ 35</u>	<u>\$ 58</u>

5. STOCKHOLDERS' EQUITY

Common Stock Offerings

June 2018 Warrant Amendment

On June 22, 2018, the Company entered into the Subscription Agreement Amendment with the Investors, which, among other things, removed the Investors' preemptive rights with respect to future issuances of the Company's equity securities. Concurrently with the Subscription Agreement Amendment, the Company entered into the June 2018 Warrant Amendment with Sarissa Offshore regarding the 2015 and 2016 Warrants, pursuant to which the exercise price of the warrants was reduced from \$0.71 to \$0.42 per share. The amendment to the warrants resulted in a charge of approximately \$17,000, which was recorded as amendment of equity classified warrants expense during the three months ended June 30, 2018.

In March 2018, the Company entered into the March 2018 Warrant Amendment with the holders of the 2015 and 2016 Warrants, which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from \$8.80 to \$0.71 per share, and (ii) amended certain provisions of the 2015 and 2016 Warrants such that they can no longer be net-cash settled. The fair value of the 2015 and 2016 Warrants on the date of the modification was \$0.5 million, which resulted in a charge of \$0.1 million to change in fair value of warrant liability on the condensed consolidated statements of operations, resulting in a total charge of \$0.2 million for the three months ended March 31, 2018. Upon modification, the 2015 and 2016 Warrants were reclassified to stockholders' equity.

April 2018 Financing & Warrant Amendment

On April 2, 2018, the Company completed the April 2018 Financing for net proceeds of approximately \$2.9 million, after deducting placement agent fees and other estimated offering expenses for the sale. Pursuant to the agreement, the Company sold 7,100,000 of the Company's 2018 Units. The April 2018 Warrants issued pursuant to the April 2018 Financing have an exercise price equal to \$0.50 per share of common stock, and are only exercisable following the Company's announcement that it has received stockholder approval of the 2018 Charter Amendment and the effective date of the 2018 Charter Amendment. The April 2018 Warrants will expire five years from the date they are first exercisable. In addition, the Company issued the April 2018 Placement Agent Warrants to purchase up to 355,000 shares of common stock to H.C. Wainwright. The April 2018 Placement Agent Warrants are exercisable upon the announcement of the effectiveness of the 2018 Charter Amendment at an exercise price of \$0.625 per share, and also expire five years from that date. It is explicitly stated in the Form of Warrant for both the April 2018 Warrants and the Placement Agent Warrants that under no circumstances may the shares be settled in cash.

The total initial \$1.2 million fair value of the combined warrants was determined using the Black-Scholes option pricing model and was recorded to equity. The April 2018 Warrants and the April 2018 Placement Agent Warrants were classified as equity and valued using assumptions of expected terms of 5.12 years and 5.0 years, volatilities of 104.0% and 105%, respectively, annual rate of dividends of 0%, and risk-free interest rates of 2.55% for each. Transaction costs of approximately \$0.7 million were netted against the proceeds allocated to the common stock shares in equity.

In connection with the April 2018 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 2017 Financing. See below for details.

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September 2017 Financing

On September 10, 2017, the Company entered into the September 2017 SPA with certain accredited investors for net proceeds of approximately \$3.1 million. Pursuant to the agreement, the Company sold 2,136,614 shares of the Company's common stock at a purchase price of \$1.73 per share, and the September 2017 Warrants. The September 2017 Warrants were exercisable upon closing, or on September 13, 2017, at an exercise price equal to \$1.67 per share of common stock and are exercisable for two and one-half years from that date. In addition, the Company issued the September 2017 Placement Agent Warrants to H.C. Wainwright. The September 2017 Placement Agent Warrants were exercisable upon closing at an exercise price of \$2.16 per share, and also expire two and one-half years from the closing date.

The standalone fair value of the combined warrants was determined using the Black-Scholes option pricing model and was recorded to equity. The September 2017 Warrants and the September 2017 Placement Agent Warrants were valued using assumptions of expected terms of 2.5 for each, volatilities of 110.4% for each, annual rate of dividends of 0.0% for each, and risk-free interest rates of 1.38% for each. The terms of the warrants state that under no circumstance may the shares be net-cash settled. Therefore, the September 2017 Warrants and the September 2017 Placement Agent Warrants have been classified within stockholders' equity. The total proceeds from the private placement were allocated to the common stock and warrants on a relative fair values basis, with \$2.8 million attributed to the common stock and \$0.9 million attributed to the warrants. Transaction costs of approximately \$0.6 million were netted against the proceeds and allocated to the common stock shares in equity.

In connection with the April 2018 Financing, the Company entered in the April 2018 Warrant Amendment, which (i) reduced the exercise price of the September 2017 Warrants and the September 2017 Placement Agent Warrants to \$0.60 per share (the closing price of the Company's stock on March 27, 2018, the date of the amendment), and (ii) changed the date upon which such warrants become exercisable to the effective date of the 2018 Charter Amendment. The April 2018 Warrant Amendment resulted in a charge of approximately \$0.1 million, which was recorded as amendment of equity classified warrants in the condensed consolidated statement of operations for the three months ended March 31, 2018.

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 offering expenses payable by the Company. Pursuant to the underwriting agreement with H.C. Wainwright, the Company sold to H.C. Wainwright an aggregate of 5,030,000 of the Company's 2017 Units. The April 2017 Warrants issued pursuant to the April 2017 Financing became exercisable only following the Company's announcement that it has received stockholder approval of the effectiveness of the 2017 Charter Amendment and the 2017 Charter Amendment had become effective. The April 2017 Warrants were exercisable upon the effective date of the 2017 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 also issued to H.C. Wainwright the 2017 Underwriter Warrants, which have substantially the same terms as the April 2017 Warrants, except that the 2017 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 April 2017 Warrants and the 2017 Underwriter Warrants state that under no circumstance may the shares be net-cash settled. Therefore, they 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 the April 2017 Warrant Amendment with the holders of the Company's September 2016 Warrants, issued in the September 2016 Financing. See below for details.

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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 “2016 Private Placement Warrants”). Initially, the 2016 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 “2016 Placement Agent Warrants” and, together with the 2016 Private Placement Warrants, the “September 2016 Warrants”). The 2016 Placement Agent Warrants have substantially the same terms as the 2016 Private Placement Warrants, except that initially, the 2016 Placement Agent Warrants had an exercise price of \$4.3125 per share and would expire five years from the initial issuance date. Initially, the September 2016 Warrants were accounted for as liabilities and fair-valued at the issuance date. Out of the total gross proceeds, \$1.6 million was allocated to the 2016 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 2016 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 Company entered into the April 2017 Warrant Amendment, which, among other things, (i) reduced the exercise price of the September 2016 Warrants to \$1.55 per share (the exercise price of the April 2017 Warrants), (ii) amended the terms of the agreement so that the shares cannot be cash settled under any circumstance, and (iii) changed the date upon which such warrants became exercisable to the effective date of the Charter Amendment, or May 17, 2017. Based upon the amended terms of the agreement, the September 2016 Warrants were reclassified to stockholders’ equity at the time of the April 2017 Warrant Amendment. The fair value of the September 2016 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

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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.

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, 2018, the Company has issued a total of 0.5 million shares for gross proceeds of \$1.2 million. As of August 6, 2018, 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, April 2017 and April 2018 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 (the "January 2016 Financing"). 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.

Pursuant to the January 2016 financing, the exercise price of warrants issued in connection with a financing in February 2015 were reduced from \$18.20 per share to \$8.80 per share. The modification to these warrants resulted in a charge to other financing costs of approximately \$0.7 million in 2016. The exercise price of these warrants was further reduced in March 2018. See above for details.

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Warrants

A summary of warrant activity during the six months ended June 30, 2018 is as follows (in thousands):

	Common Shares Issuable upon Exercise		Weighted Average Exercise Price
Outstanding as of December 31, 2017	7,084	\$	3.91
Issued	3,905	\$	0.51
Exercised	(1,041)	\$	1.48
Cancelled	(533)		19.81
Outstanding as of June 30, 2018	9,415	\$	0.96
Exercisable as of June 30, 2018	9,415	\$	0.96

The following table shows the number of outstanding warrants by exercise price and date of expiration as of June 30, 2018 (in thousands):

Shares Issuable Upon Exercise	Exercise Price	Expiration Date
1,103	\$ 0.60	March 2020
252	\$ 1.75	April 2022
3,251	\$ 1.55	May 2022
89	\$ 0.71	January 2023
340	\$ 0.42	January 2023
109	\$ 0.71	March 2023
332	\$ 0.42	March 2023
355	\$ 0.625	March 2023
3,550	\$ 0.50	May 2023
19	\$ 12.90	October 2024
15	\$ 16.40	July 2025
9,415		

6. RELATED PARTY TRANSACTIONS

The Company had the following related party transaction for the three months ended June 30, 2018:

IRRAS AB

IRRAS AB (“IRRAS”) is a commercial stage medical technology company of which a current director of the Company, Kleanthis G. Xanthopoulos, Ph.D., is currently the President, Chief Executive Officer and director. In January 2018, the Company and IRRAS entered into a sublease, pursuant to which the Company subleased to IRRAS excess capacity in its corporate headquarters (the “IRRAS Sublease”). The IRRAS Sublease has a term of two years and aggregate payments due to the Company of approximately \$0.3 million, which approximate fair value.

7. LITIGATION

The Company is 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. The Company intends to vigorously defend its interests in these matters and does not expect that the resolution of these matters will have a material adverse effect on its 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.

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A complaint was filed in the Supreme Court of the State of New York by Laboratoires Majorelle SAS and Majorelle International SARL (“Majorelle”) 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 the Company and Majorelle, dated November 12, 2013, is unenforceable and makes other claims relating to invalidity of the Company’s assignment of the license agreement to Ferring under the Ferring Asset Purchase Agreement. The complaint also alleges breach of contract, fraudulent inducement, misrepresentation and unjust enrichment relating to a separate supply agreement between the Company and Majorelle. In addition to declaratory relief, Majorelle is seeking damages in excess of \$1.0 million, disgorgement of profits and attorney’s fees. On August 30, 2017, the Company and NexMed removed the case to federal district court in the Southern District of New York. Majorelle filed an amended complaint on October 16, 2017. The Company filed a motion to dismiss all claims in the amended complaint on December 5, 2017, and the motion has been fully briefed since the Company submitted its reply brief on January 9, 2018. Majorelle filed a motion to further amend its complaint on June 6, 2018, which the Company and Ferring opposed, and the motion has been fully briefed since Majorelle submitted its reply brief on June 15, 2018. The Company believes the allegations are without merit, reject all claims raised by Majorelle and intends to vigorously defend this matter.

8. SUBSEQUENT EVENT

Agreement and Plan of Merger

On July 30, 2018, the Company, Merger Sub, and Seelos, entered into the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Seelos, with Seelos continuing as a wholly owned subsidiary of the Company and the surviving corporation of the Merger. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, each outstanding share of Seelos common stock will be converted into the right to receive shares of Company common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to a reverse stock split of Company common stock if determined necessary or appropriate by the Company, Seelos and Merger Sub) such that, immediately following the effective time of the Merger, preexisting Company stockholders are expected to own approximately 14% of the outstanding capital stock of the Company on a fully diluted basis, and preexisting Seelos stockholders are expected to own approximately 86% of the outstanding capital stock of the Company on a fully diluted basis, subject to adjustments for net cash held by the Company and Seelos at the time of closing the Merger.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and Seelos. In accordance with the terms of the Merger Agreement, (i) Raj Mehra, the founder and majority stockholder of Seelos (solely in his capacity as a Seelos stockholder) and (ii) certain executive officers, directors and stockholders of the Company (solely in their respective capacities as Company stockholders) have entered into the Support Agreements. The Support Agreements include covenants with respect to the voting of shares of Seelos or Company capital stock, respectively, in favor of approving the transactions contemplated by the Merger Agreement and against any competing acquisition proposals and place certain restrictions on the transfer of the shares of the Company and Seelos capital stock held by the respective signatories thereto.

The Merger Agreement contains certain termination rights for both the Company and Seelos, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of \$500,000, which may be payable in shares of common stock of the party making such payment in such paying party’s sole discretion, and in some circumstances reimburse the other party’s expenses up to a maximum of \$350,000.

At the effective time of the Merger, the Company’s Board of Directors is expected to consist of five members, four of whom will be designated by Seelos and one of whom will be designated by the Company.

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Contingent Value Rights Agreement

At the closing of the Merger, the Company, Seelos, Richard Pascoe, as representative of the Company's stockholders, and a rights agent will enter into the Contingent Value Rights Agreement (the "CVR Agreement"). Pursuant to the CVR Agreement, Company stockholders will receive one CVR for each share of the Company's common stock held of record immediately prior to the closing of the Merger. Each CVR will represent the right to receive payments based on the Company's Vitaros assets. In particular, CVR holders will be entitled to receive 90% of any cash payments (or the fair market value of any non-cash payments) exceeding \$500,000 received, during a period of ten years from the closing of the Merger, based on the sale or out-licensing of the Vitaros assets, including any Contingent Payments, less reasonable transaction expenses. Seelos will be entitled to retain the first \$500,000 and 10% of any Contingent Payments. In order to be eligible for the CVR, a Company stockholder must be a holder of record at the close of business immediately prior to the closing of the Merger. Seelos has agreed to use commercially reasonable efforts to out-license or sell the Vitaros assets for a period of three years following the closing of the Merger.

The CVR will be not be transferable, except in limited circumstances and will not be registered with the SEC. Richard Pascoe, the Company's current President and CEO, will be appointed to serve as the representative of the CVR holders' /former Company stockholders' interests under the CVR Agreement.

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, 2017 as filed with the United States Securities and Exchange Commission ("SEC") on March 1, 2018. 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 the timing and completion of the proposed merger with Seelos Therapeutics, expectations regarding ownership percentages of the combined company, the timing of regulatory review and approval of Vitaros in the United States, 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 our strategic objectives, including efforts to maintain compliance with The Nasdaq Capital Market ("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 the conditions to the closing of the merger are not satisfied, including the failure to timely or at all obtain shareholder approval for the merger, uncertainties as to the timing of the consummation of the merger and the ability of each of us and Seelos to consummate the merger, risks related to our ability to correctly manage its operating expenses and our expenses associated with the transaction pending closing, potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed merger; certain cash and non-cash adjustments set forth in the merger agreement that may alter the percentage of the combined company held by our shareholders, our ability to retain and attract key personnel, our ability to raise additional funding that we may need to continue to pursue our 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; 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, 2017, 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

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or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Vitaros is a registered trademark of Ferring in certain countries outside of the United States. 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: Vitaros, 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 plc (“Allergan”); and RayVa, a product candidate which has completed a Phase 2a clinical trial for the treatment of Raynaud’s Phenomenon, secondary to scleroderma, for which we own worldwide rights.

On February 15, 2018, the FDA issued a complete response letter (a “CRL” and, such CRL, the “2018 CRL”) for the new drug application (“NDA”) for Vitaros. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form. In April 2018, we met with the FDA and confirmed that two new Phase 3 clinical efficacy trials would be necessary at a lower formulation concentration in order to reach approval. We have initiated discussions with parties for the U.S. Vitaros rights to enable Vitaros’ continued development and potential approval in exchange for financial terms commensurate with a development stage asset.

In parallel, our Board of Directors determined that we should evaluate strategic alternatives, including a sale of the company, a business combination, a merger or reverse merger or a license, with the goal of maximizing shareholder value. On July 30, 2018, we, Arch Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of ours (“Merger Sub”), and Seelos Therapeutics, Inc., a Delaware corporation (“Seelos”), entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Seelos, with Seelos continuing as our wholly owned subsidiary and the surviving corporation of the merger (the “Merger”).

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, each outstanding share of Seelos common stock will be converted into the right to receive shares of our common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to a reverse stock split of our common stock if determined necessary or appropriate by us, Seelos and Merger Sub) such that, immediately following the effective time of the Merger, our preexisting stockholders are expected to own approximately 14% of the outstanding capital stock of the Company on a fully diluted basis, and preexisting Seelos stockholders are expected to own approximately 86% of the outstanding capital stock of the Company on a fully diluted basis, subject to adjustments for net cash held by us and Seelos at the time of closing the Merger.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by ours and Seelos’ stockholders. Should the Merger be terminated prior to consummation, the Merger Agreement contains certain termination rights for both us and Seelos, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of \$500,000, which may be payable in shares of common stock of the party making such payment in such paying party’s sole discretion, and in some circumstances reimburse the other party’s expenses up to a maximum of \$350,000.

At the closing of the Merger, the Company, Seelos, Richard Pascoe, as representative of our stockholders, and a rights agent will enter into a Contingent Value Rights Agreement (the “CVR Agreement”). Pursuant to the CVR Agreement, our stockholders will receive one contingent value right (“CVR”) for each share of our common stock held of record immediately prior to the closing of the Merger. Each CVR will represent the right to receive payments based on Vitaros assets. In particular, CVR holders will be entitled to receive 90% of any cash payments (or the fair market value of any non-cash payments) exceeding \$500,000 received, during a period of ten years from the closing of the Merger, based on the sale or out-licensing of the Vitaros assets, including any milestone payments (“Contingent Payments”), less reasonable transaction expenses. Seelos will be entitled to retain the first \$500,000 and 10% of any Contingent Payments. In order to be eligible for the CVR, a Company stockholder must be a holder of record at the close of business immediately prior to the closing of the Merger. Seelos has agreed to use commercially reasonable efforts to out-license or sell the Vitaros assets for a period of three years following the closing of the Merger.

At the effective time of the Merger, our Board of Directors is expected to consist of five members, four of whom will be designated by Seelos and one of whom will be designated by us.

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Despite devoting significant efforts to identify, evaluate and negotiate the Merger Agreement with Seelos, we may not be successful in completing the Merger. Further, even if the Merger is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value. If the Merger is not completed, we cannot predict whether and to what extent we would be successful in consummating an alternative transaction, the timing of such a transaction or our future cash needs required to complete such a transaction, and we may choose or be forced to dissolve and liquidate our assets.

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. In 2009, Warner Chilcott Company, Inc., now a subsidiary of Allergan, acquired the commercial rights to Vitaros in the United States. In September 2015, we entered into a license agreement and amendment to the original agreement with Warner Chilcott Company, Inc., granting us exclusive rights to develop and commercialize Vitaros in the United States. On March 8, 2017, we entered into an asset purchase agreement (the “Ferring Asset Purchase Agreement”) with Ferring International Center S.A. (“Ferring”), pursuant to which Ferring now owns the rights to Vitaros outside of the United States.

In 2008, the FDA issued a CRL (the “2008 CRL”) for the Vitaros NDA, identifying certain deficiencies in the application. Based on our subsequent interactions with the FDA and after completion of further drug-device engineering and other activities intended to address issues previously raised in the 2008 CRL, which included human factor testing and new non-clinical studies, we resubmitted the Vitaros NDA in August 2017. On February 15, 2018, the FDA issued the 2018 CRL, identifying deficiencies related to chemistry, manufacturing and controls (“CMC”) and indicating that the modest treatment effect did not outweigh certain safety concerns specific to the 2.5% concentration of our permeation enhancer NexACT (DDAIP.HCl) contained in the current formulation. In April 2018, at our end-of-review meeting with the FDA, the FDA confirmed that we should develop a new Vitaros formulation that reduces the concentration of DDAIP.HCl from 2.5% to 0.5% in order to address the tumor promotion and partner transference safety concerns noted in the 2018 CRL. The FDA also confirmed that two new Phase 3 clinical efficacy trials with the reformulated product should be conducted prior to resubmitting the NDA and that the trials should include an assessment of the potential risk of enhanced sexually transmitted infections with the new formulation. In addition, the FDA requested certain pharmacokinetic assessments that we expect can be completed as part of the requested Phase 3 program and any additional clinical or commercial safety data generated prior to a resubmission. Lastly, the FDA stated that the Chemistry, Manufacturing and Control section in the resubmission will need to be updated with data generated during development of the new formulation. We believe the FDA has outlined a path to approval in the United States, but the cost and timeline associated with a reformulation effort and completing additional Phase 3 clinical trials exceeds our current resources and ability to raise additional capital. Therefore, we have initiated discussions with parties for the U.S. Vitaros rights to enable Vitaros’ continued development and potential approval in exchange for financial terms commensurate with a development stage asset.

RayVa

RayVa is our product candidate for the treatment of Raynaud’s Phenomenon associated with scleroderma (systemic sclerosis). It 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 authorization 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. We are still assessing whether the safety concerns specific to the 2.5% concentration of DDAIP.HCl contained in the current formulation of Vitaros that the FDA raised in the 2018 CRL will affect RayVa’s future development path, since the underlying NexACT technology is utilized in both. We are seeking 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. We have recorded a net loss of approximately \$4.5 million for the six months ended June 30, 2018, and had an accumulated deficit of approximately \$320.5 million as of June 30, 2018. Our cash balance was approximately \$6.8 million as of June 30, 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 June 22, 2018, we entered into a subscription agreement amendment (the “Subscription Agreement Amendment”) with Sarissa Capital Domestic Fund LP (“Sarissa Domestic”) and Sarissa Capital Offshore Master Fund LP (“Sarissa Offshore” together with Sarissa Domestic, the “Investors”), which, among other things, removed the Investors’ preemptive rights with respect to future issuances of our equity securities. Concurrently with the Subscription Agreement Amendment, we entered into a warrant

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amendment (the “June 2018 Warrant Amendment”) with Sarissa Offshore regarding warrants to purchase our common stock (the “Common Stock”), issued in February 2015 (the “February 2015 Warrants”) and January 2016 (together with the February 2015 Warrants, the “2015 and 2016 Warrants”), pursuant to which the exercise price of the Warrants was reduced from \$0.71 to \$0.42 per share. In March 2018, we previously entered into a warrant amendment (the “March 2018 Warrant Amendment”) with the holders of warrants issued pursuant to our February 2015 and January 2016 financings (the “2015 and 2016 Warrants”), which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from \$8.80 to \$0.71 per share, and (ii) amended certain provisions of the 2015 and 2016 Warrants such that they can no longer be net-cash settled, effective as of the Warrant Amendment.

On April 2, 2018, we completed a public offering (the “April 2018 Financing”) for net proceeds of approximately \$2.9 million, after deducting placement agent fees and other estimated offering expenses for the sale. Pursuant to the agreement, we sold 7,100,000 units at a purchase price of \$0.50 per share, with each unit consisting of one share and one warrant to purchase 0.5 of a share of our common stock (the “April 2018 Warrants”). The April 2018 Warrants have an exercise price equal to \$0.50 per share of common stock, and were exercisable following our May 17, 2018 announcement that we received stockholder approval of an amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to a total of 60,000,000 shares (the “2018 Charter Amendment”) and the 2018 Charter Amendment became effective. The April 2018 Warrants will expire five years from that date. In addition, we issued warrants to purchase up to 355,000 shares of common stock (the “April 2018 Placement Agent Warrants”) to H.C. Wainwright & Co., LLC (“H.C. Wainwright”). The April 2018 Placement Agent Warrants were exercisable upon the announcement of the effectiveness of the 2018 Charter Amendment at an exercise price of \$0.625 per share, and also expire five years from that date.

On September 10, 2017, we entered into a Securities Purchase Agreement with certain accredited investors for net proceeds of approximately \$3.1 million, after deducting commissions and estimated offering expenses. Pursuant to the agreement, we sold 2,136,614 shares of our common stock at a purchase price of \$1.73 per share, and warrants to purchase up to 1,068,307 shares of common stock in a private placement (the “September 2017 Warrants”). The September 2017 Warrants were originally exercisable upon closing, or on September 13, 2017, at an exercise price equal to \$1.67 per share of common stock and are exercisable for two and one half years from that date. In addition, we issued warrants to purchase up to 106,831 shares of common stock to H.C. Wainwright (the “September 2017 Placement Agent Warrants”). The September 2017 Placement Agent Warrants were originally exercisable upon closing at an exercise price of \$2.16 per share, and also expire two and one half years from the closing date. In connection with the April 2018 Financing, the September 2017 Warrants and the September 2017 Placement Agent Warrants were amended which, among other things, (i) reduced the exercise price of the September 2017 Warrants and the September 2017 Placement Agent Warrants to \$0.60 per share (the closing price of our stock on March 27, 2018, the date of the amendment), and (ii) changed the date upon which such warrants became exercisable to the effective date of the 2018 Charter Amendment (the “April 2018 Warrant Amendment”), or May 17, 2018.

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 offering expenses. Pursuant to the underwriting agreement with H.C. Wainwright, we sold to H.C. Wainwright 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 (the “April 2017 Warrants”), 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 we 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 “2017 Charter Amendment”) and the 2017 Charter Amendment became effective. The April 2017 Warrants will expire five years from the date the warrants were exercisable, or May 17, 2017, and the exercise price of the April 2017 Warrants is \$1.55 per share of common stock. In connection with this transaction, we issued to H.C. Wainwright warrants to purchase up to 251,500 shares of common stock (the “2017 Underwriter Warrants”). The 2017 Underwriter Warrants have substantially the same terms as the April 2017 Warrants, except that the 2017 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 Securities and Exchange Commission (“SEC”) and declared effective on April 20, 2017, 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 a previous financing in September 2016 (the “September 2016 Warrants”), which, among other things, (i) reduced the exercise price of the warrants to \$1.55 per share (the exercise price of the April 2017 Warrants), and (ii) changed the date upon which such warrants become exercisable to the effective date of the 2017 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 approximately \$12.7 million, which consisted of an upfront payment of \$11.5 million, approximately \$0.7 million for the delivery of certain product-related inventory, and an aggregate of \$0.5 million related to transition services. We used approximately \$6.6 million of the proceeds from the sale to repay all outstanding amounts

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due and owed, including applicable termination fees, under the 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”).

We currently have an effective shelf registration statement on Form S-3 filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. As of August 6, 2018, we had approximately \$96.5 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 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 August 6, 2018, our public float was approximately \$8.9 million based on 18.6 million shares of our common stock outstanding at a price of \$0.48 per share, which was the closing sale price of our common stock on June 19, 2018. Since our public float is currently less than \$75.0 million, as of August 6, 2018, we may only sell an aggregate of approximately \$3.0 million of securities under our shelf registration statements on Form S-3, of which none is currently available following our April 2018 Financing. 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.

The accompanying 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 successfully complete the Merger with Seelos or, if the Merger is not completed, another strategic transaction for the Company;
- our ability to raise additional funds to finance our operations;
- our ability to secure a development partner for U.S. Vitaros in order to overcome deficiencies raised in the 2018 CRL;
- our ability to maintain compliance with the listing requirements of Nasdaq;
- the outcome, costs and timing of any clinical trial results for our current or future product candidates;
- the extent and amount of any indemnification claims made by Ferring under the Ferring Asset Purchase Agreement;
- litigation expenses, including the ongoing litigation with Laboratoires Majorelle SAS and Majorelle International SARL;
- 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 trading price of our common stock; and
- our ability to increase the number of authorized shares outstanding to facilitate future financing events.

On April 10, 2018, we received notice from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) because the closing bid price of our common stock had been below \$1.00 per share for the previous thirty (30) consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until October 8, 2018, to regain compliance. In order to regain compliance, the bid price of our common stock must close at \$1.00 per share or more for a minimum of ten consecutive business days.

We will 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 product candidates. 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 and business activities, such as future clinical studies and/or other future ventures. There can be no

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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, 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, 2017 and there have been no material changes during the six months ended June 30, 2018.

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,		2018 vs 2017		Six Months Ended June 30,		2018 vs 2017	
	2018	2017	\$ Change	% Change	2018	2017	\$ Change	% Change
Operating expense								
Research and development	\$ 162	\$ 839	\$ (677)	(81)%	\$ 379	\$ 1,266	\$ (887)	(70)%
General and administrative	2,075	1,602	473	30 %	4,210	3,043	1,167	38 %
Total operating expense	2,237	2,441	(204)	(8)%	4,589	4,309	280	6 %
Loss before other income (expense)	\$ (2,237)	\$ (2,441)	\$ 204	(8)%	\$ (4,589)	\$ (4,309)	\$ (280)	6 %

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 \$0.7 million and \$0.9 million decreases in research and development expense during the three and six months ended June 30, 2018, respectively, as compared to the same periods in the prior year, resulted primarily from decreases in salary-related expenses and decreases in development expenses for U.S. Vitaros upon completion of and resubmission of the NDA during the third quarter of 2017.

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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 increased \$0.5 million and \$1.2 million, during the three and six months ended June 30, 2018, respectively, as compared to the same periods in the prior year, due to increases in legal expenses in connection with the current litigation.

Other Income and Expense from Continuing Operations

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

	Three Months Ended June 30,		2018 vs 2017		Six Months Ended June 30,		2018 vs 2017	
	2018	2017	\$ Change	% Change	2018	2017	\$ Change	% Change
Other income (expense)								
Interest income (expense), net	\$ —	\$ 3	\$ (3)	(100)%	\$ —	\$ (92)	\$ 92	(100)%
Loss on extinguishment of debt	—	—	\$ —	N/M	—	(422)	422	(100)%
Change in fair value of warrant liability	—	716	(716)	(100)%	222	(292)	514	(176)%
Amendment of equity classified warrants	(17)	—	(17)	N/M	(158)	—	(158)	N/M
Other income (expense), net	1	—	1	N/M	1	(26)	27	(104)%
Total other income (expense)	\$ (16)	\$ 719	\$ (735)	(102)%	\$ 65	\$ (832)	\$ 897	(108)%

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.

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 (the “February 2015 Warrants”) 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 2015 and 2016 Warrants was 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 the 2015 and 2016 Warrants was 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 5 to our condensed consolidated financial statements for further details).

In March 2018, we entered into the March 2018 Warrant Amendment with the holders of 2015 and 2016 Warrants which, among other things, (i) reduced the exercise price of the 2015 and 2016 Warrants from \$8.80 to \$0.71 per share, and (ii) changed certain provisions of the 2015 and 2016 Warrants such that the Warrants could no longer be net-cash settled. The fair value of the 2015 and 2016 Warrants on the date of the modification was \$0.5 million, which resulted in a charge of \$0.1 million to change in fair value of warrant liability on the condensed consolidated statements of operations. Upon modification, the 2015 and 2016 Warrants were reclassified to stockholders’ equity.

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Discontinued Operations

We had \$0.02 million in accrued expenses related to discontinued operations as of June 30, 2018. There were no assets and liabilities presented as discontinued operations as of December 31, 2017. The operating results of our discontinued operations for the three and six months ended June 30, 2018 and 2017 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Product sales	\$ —	\$ —	\$ —	\$ 143
Royalty revenue	—	147	—	368
Cost of goods sold	(24)	—	(24)	(74)
Operating expenses	—	(149)	—	(748)
Other expense	—	—	—	(16)
Gain on sale	—	250	—	12,067
Income from discontinued operations	<u>\$ (24)</u>	<u>\$ 248</u>	<u>\$ (24)</u>	<u>\$ 11,740</u>

Product sales, royalty revenue and cost of goods sold all relate to the sale of Vitaros product outside of the United States. Historically, we relied on our former commercial partners to sell Vitaros in approved markets and received royalty revenue from our former commercial partners based upon the amount of those sales. Royalty revenues were 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. Operating expenses for the prior period include primarily patent and legal fees and accounting expenses incurred in connection with the Ferring Asset Purchase Agreement.

Cash Flow Summary

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

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities from continuing operations	\$ (3,865)	\$ (4,851)
Net cash provided by (used in) financing activities from continuing operations	4,373	(1,051)
Net cash provided by (used in) discontinued operations	(3)	11,636
Net increase in cash	<u>\$ 505</u>	<u>\$ 5,734</u>

Operating Activities from Continuing Operations

Cash used in operating activities from continuing operations of \$3.9 million during the six months ended June 30, 2018 was primarily due to a net loss from continuing operations of \$4.5 million, net of adjustments to net loss for non-cash items such as the warrant liability revaluation of \$0.2 million and stock-based compensation expense of \$0.6 million.

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, loss on debt extinguishment of \$0.4 million, and stock-based compensation expense of \$0.6 million.

Financing Activities from Continuing Operations

Cash provided by financing activities from continuing operations of \$4.4 million during the six months ended June 30, 2018 was due to net proceeds of \$3.1 million from the issuance of common stock and warrants in our April 2018 Financing, as well as proceeds of \$1.3 million from the exercise of warrants during the first quarter of 2018.

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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 the issuance of common stock and warrants in our April 2017 Financing.

Discontinued Operations

Cash provided by discontinued operations of \$11.6 million during the six months ended June 30, 2017 was a result of the Ferring Asset Purchase Agreement in March 2017, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for approximately \$12.7 million, which consisted of an upfront payment of \$11.5 million, approximately \$0.7 million for the delivery of certain product-related inventory, and an aggregate of \$0.5 million related to transition services.

Off-Balance Sheet Arrangements

As of June 30, 2018, 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, 2017.

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, 2018. Based on this evaluation, our CEO concluded that our disclosure controls and procedures were effective as of June 30, 2018.

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, 2018 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, 2018, 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, 2018, 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 (“Majorelle”) 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 under the Ferring Asset Purchase Agreement. 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, disgorgement of profits and attorney’s fees. On August 30, 2017, we and NexMed removed the case to federal district court in the Southern District of New York. Majorelle filed an amended complaint on October 16, 2017. We filed a motion to dismiss all claims in the amended complaint on December 5, 2017, and the motion has been fully briefed since we submitted our reply brief on January 9, 2018. Majorelle filed a motion to further amend its complaint on June 6, 2018, which the Company and Ferring opposed, and the motion has been fully briefed since Majorelle submitted its reply brief on June 15, 2018. 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

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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, 2017, as filed with the SEC on March 1, 2018:

Risks Related to the Company

In light of recent setbacks with our Vitaros clinical program, we began evaluating strategic alternatives and other business combinations, and recently entered into the Merger Agreement with Seelos. Our Merger with Seelos may not be consummated and, if consummated, will result in substantial dilution to our stockholders and may not deliver the anticipated benefits we expect.*

In February 2018, after we received a complete response letter with respect to our new drug application for Vitaros, we announced that we would focus our efforts on identifying and evaluating strategic alternatives. In March 2018, we engaged Canaccord Genuity, Inc. to advise us on strategic alternatives including a merger or acquisition of the Company. In July 2018, we entered into the Merger Agreement pursuant to which, among other things, Seelos agreed to sell to us, and we agreed to purchase all of the outstanding shares of capital stock of Seelos. Consummation of the Merger is subject to certain closing conditions, including a majority approval from our stockholders which may take a significant amount of time and will further decrease our cash resources. There can be no assurance that we will be able to successfully complete the Merger and investors may disagree with the new focus of our business. The transaction will result in dilution to our stockholders and could result in other restrictions that may affect our business. Further, if completed, the Merger ultimately may not deliver the anticipated benefits or enhance stockholder value.

If we are unable to complete the transaction, we cannot predict whether and to what extent we would be successful in consummating an alternative transaction, the timing of such a transaction or our future cash needs required to complete such a transaction. Therefore, we may be required to pursue a dissolution and liquidation. In such an event, the amount of cash, if any, available for distribution to our shareholders will depend heavily on the timing of such decision and our other financial obligations. In addition, with the passage of time, the amount of cash, if any, available for distribution will be reduced as we continue to fund our operations. Furthermore, we may be subject to litigation or other claims related to the Merger Agreement.

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 strengthen our business, on July 30, 2018, we entered into the Merger Agreement with Seelos. We cannot be sure this Merger will result in a successful acquisition, development or launch of products that will prove to be commercially successful or will improve the long-term profitability of our business. Acquisitions or licenses could require us to raise significant capital and potentially incur significant dilution through issuance of new shares of capital stock. These strategic transactions 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.

As a result of our sale of non-U.S. Vitaros assets to Ferring and the receipt of the 2018 CRL, we do not expect to generate revenue for the foreseeable future.

In March 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 approximately \$12.7 million, which consisted of an upfront payment of \$11.5 million, approximately \$0.7 million for the delivery of certain product-related inventory, and an aggregate of \$0.5 million related to transition services. Following the Ferring Asset Purchase Agreement, we no longer have the ability to generate revenues from our current operations. Our future growth will depend on our ability to consummate the Seelos Stock Purchase Agreement. 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.

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

Even if we are successful in consummating the Merger, the future success of our product candidates and/or Seelos' product candidates depends on the ability to obtain regulatory approval for, and then successfully commercialize the product candidates. For instance, the success of Vitaros will depend on whether we are able to successfully address, through a partner, the issues identified in the 2018 CRL issued by the FDA in February 2018. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form. The 2018 CRL was the second one received from the FDA with respect to the Vitaros NDA. In 2008, the FDA issued the 2008 CRL, identifying certain deficiencies with the NDA previously submitted. Based on our subsequent interactions with the FDA, we believed that we could address the deficiencies in the 2008 CRL without additional clinical testing and we did not include such data in the NDA submitted in August 2017.

The 2018 CRL identified deficiencies related to CMC and that the modest treatment effect did not outweigh certain safety concerns specific to the 2.5% concentration of our permeation enhancer DDAIP.HCl contained in the current formulation. In April 2018, we met with the FDA and based on the 2018 CRL and guidance we received at this meeting, we determined that will need to complete additional clinical testing. This will require significant expenditures of cash and management resources which we believe exceeds our current resources, and therefore, we are initiating discussions with potential development partners to assist in the Vitaros NDA process. We may be unsuccessful in securing a development partner to complete the trials and ultimately resubmit the Vitaros NDA. 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 candidate, RayVa, 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. The CMC and safety concerns raised in the FDA's 2018 CRL for Vitaros may affect RayVa's future development path since the underlying NexACT technology is utilized in both. Due to our cash constraints, we are seeking to partner RayVa.

Even if we are able to identify and secure a partner for RayVa, there is no guarantee that our partner will be able to commence clinical trials or that future 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 future partner's 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 expect to continue to require external financing to fund our operations, which may not be available. Even if we are successful in consummating the Merger, 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, 2018, we had a cash balance of approximately \$6.8 million. Even if the Merger Agreement with Seelos is successfully consummated, we will need to raise additional funds in order to fund our near and long-term operations.

We currently have an effective shelf registration statement on Form S-3 filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. 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 August 6, 2018, our public float was approximately \$8.9 million based on 18.6 million shares of our common stock outstanding at a price of \$0.48 per share, which was the closing sale price of our common stock on June 19, 2018. Since our public float is currently less than \$75.0 million, as of August 6, 2018, we may only sell an aggregate of approximately \$3.0 million of securities under our shelf registration statements on Form S-3. 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 revenue sources and limited capital resources, we may not be able to execute all of the elements of our strategic plan. 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 have never been profitable and we have incurred an accumulated deficit of approximately \$320.5 million from our inception through June 30, 2018. 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 prior to entering into the Ferring Asset Purchase Agreement. 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. In addition, consummation of the Merger will not provide us with revenue for the foreseeable future.

Our ability to generate revenues and become profitable depends, among other things, on the successful development and commercialization of ours and/or Seelos' product candidates and our ability to identify and execute on other opportunities and business combinations that will enable us to maximize shareholder value. We will need significant additional capital to pursue these objectives and 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 2018, we completed a public offering for net proceeds of approximately \$2.9 million. 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, 2018, the Report of Independent Registered Public Accounting Firm included immediately prior to the Consolidated Financial Statements included in this Quarterly Report, includes a going concern explanatory paragraph. There is no guarantee that the Merger will be successfully completed. In addition, management plans to raise additional funds and preserve existing cash resources 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.

We currently have no long-term agreement with a manufacturer and will be dependent 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. We do not currently have a long-term commitment for the production of finished Vitaros or the raw materials and components thereof. If we are unable to establish any long-term agreements with such third-party manufacturers and suppliers or to do so on acceptable terms, or such parties are unable to produce sufficient quantities of finished Vitaros product or the raw materials and components thereof that we need, we may need to identify and qualify other third-party manufacturers in order to commence or sustain the commercialization of Vitaros.

Even if we establish a long-term manufacturing agreement for finished Vitaros or the raw materials and components thereof, we will continue to be dependent 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 would be 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 in connection with the FDA's review of any resubmission of our NDA. If 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, including our third-party manufacturer for the finished product Vitaros, 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 our product candidates we may not be able to successfully develop our product candidates and generate meaningful revenues from them.

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 our product candidates. 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 our product candidates. Collaborations involving our product candidates 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 our product candidates 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 the product candidate. 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 our product candidates and may not generate meaningful revenues.

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

Our product candidates are in various stages of development. Through clinical trials and life cycle management programs, our current and future product candidates 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. Future clinical trials and studies 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. 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. 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, even if we are successful in securing a development partner for our product candidate(s), the future clinical trials may not be successful.

We do not know whether any future clinical trials conducted will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate is found to be unsafe or lack efficacy during clinical trials, we and our development partner(s) 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. 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. 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 alprostadil 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. Even if we are able to successfully address the issues raised by the FDA in the 2018 CRL and ultimately, 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®(Mist Pharmaceuticals, LLC), Muse® (Meda Pharmaceuticals Inc.), and Caverject® (Pfizer, Inc.) 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, 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 by partnering with a pharmaceutical company with established sales and marketing capabilities.

Further, we 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.

We will need approval from the FDA for our proposed trade names. Any failure or delay associated with such approvals may delay the commercialization of our products.

Any trade name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. Although Ferring currently uses the registered trademark of Vitaros for commercial sales in various countries outside of the United States, the FDA has objected to our commercial use of the name Vitaros in the United States. If we resubmit an NDA for this product candidate, we would need to propose an alternate trade name for review by the FDA. The FDA typically conducts a rigorous review of proposed trade names, including an evaluation of potential for confusion with other trade names and medication error. The FDA also may object to a trade name if it believes the name is inappropriately promotional. Even after the FDA approves a trade name, the FDA may request that we adopt an alternative name for the product if adverse event reports indicate a potential for confusion with other trade names and medication error.

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 current or future product candidates. 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, such as our ongoing litigation with Majorelle. 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, we have previously identified and disclosed 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 previous material weaknesses, 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 a license agreement with Allergan that imposes diligence, development and commercialization timelines, royalty, insurance and other obligations on us. Under our existing licensing agreement, and upon approval, if any, of Vitaros in the United States, we are obligated to pay royalties on net product sales of U.S. Vitaros to the extent they are covered by the agreements. If we fail to comply with our obligations, Allergan may have the right to terminate this agreement, in which event we might not be able to develop, manufacture or market the product covered by this agreement and may face other penalties under the agreement. 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 this agreement or reduction or elimination of our rights under this agreement may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under this agreement, including our rights to important intellectual property or technology.

We may enter into license agreements in the future that could 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. For instance, the FDA issued the 2008 CRL for the Vitaros NDA and we received the 2018 CRL from the FDA in February 2018 following our resubmission of the Vitaros NDA in August 2017. As a result, we currently have no revenue-generating assets and there is doubt as to when, if ever, we will be able to generate revenues in the future.

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, which, through subsequent legislative amendments, was increased to 70%, 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. We expect that the current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. 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, the American Taxpayer Relief Act of 2012 was signed into law, 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. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 coverage for our products is not available, 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 current or any future product candidates, if approved, would 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 our future development partners experience significant delays in the clinical development and regulatory approval of our product candidates, our business may be substantially harmed.

Our future partners 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. Clinical trials may be delayed for a variety of reasons, including delays related to:

- the availability of financial resources for our partners to commence and complete the 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 current or future 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 2018 CRL identified certain deficiencies with the application.

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. It is difficult to predict how these executive actions, including Executive Orders, 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 which 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, which 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, which 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, which 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, which 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 pricing information; 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, 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 will rely on third parties to conduct additional 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.

We do not currently have any long-term agreements with contract manufacturers. If our future 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.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently-enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, adopting elements of a territorial tax system, imposing a one-time transition tax (or “repatriation tax”) on all undistributed earnings and profits of certain U.S.-owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (“IRS”), any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

While our analysis and interpretation of this legislation is ongoing, based on our current evaluation, we have reflected a write-down of our deferred income tax assets (including the value of our net operating loss carryforwards and our tax credit carryforwards) due the reduction of the U.S. corporate income tax rate. We recorded a reduction of \$19.5 million in the fourth quarter of 2017 related to the revaluation of our deferred tax assets, which did not result in additional tax expense in the quarter since we maintain a full valuation allowance on our deferred tax assets. This amount may be subject to further adjustment in subsequent periods throughout 2018 in accordance with subsequent interpretive guidance issued by the SEC or the IRS. Further, there may be other material adverse effects resulting from the legislation that we have not yet identified.

While some of the changes made by the tax legislation may adversely affect the Company in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

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 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, we were notified by Nasdaq that we had evidenced full compliance with all criteria for continued listing on the Nasdaq Stock Market and the matter has now been closed.

On April 10, 2018, 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 October 8, 2018, to regain compliance with the minimum bid price requirement.

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

We are authorized to issue 70,000,000 shares of our capital stock, consisting of 60,000,000 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 filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants.

We may finance our cash needs through a combination of private and public equity financings, debt financings, collaborations, strategic alliances and licensing arrangements. 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. We may also issue shares of common stock or preferred stock in connection with strategic transactions. These issuances would dilute the book value of existing stockholders common stock and could depress the value of our common stock.

*We currently have a limited number of unissued shares of common stock authorized for issuance pursuant to our certificate of incorporation which will limit our ability to issue shares in a financing transaction, as compensation to our officers, directors, employees or consultants or as consideration in a strategic transaction.**

Our certificate of incorporation authorizes our board of directors to issue up to 60.0 million shares of common stock. As of August 6, 2018, there were 23,441,449 shares of common stock issued and outstanding and 36,558,551 shares available for future issuance. We have solicited for, but have not yet received stockholder approval of an amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock to a total of 60,000,000 shares. Unless and until we receive stockholder approval (or take another corporate action to increase the number of shares that may be issued under the certificate of incorporation), we will be limited in our ability to issue shares of common stock in a financing transaction, as compensation to our officers, directors, employees or consultants or as consideration in a strategic transaction. Such limitation will adversely impact our business.

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.

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

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Not applicable.

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ITEM 6. EXHIBITS

<u>EXHIBITS NO.</u>	<u>DESCRIPTION</u>
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).
2.5	Agreement and Plan of Merger, dated July 30, 2018, by and among Apricus Biosciences, Inc., Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Form 8-K filed with Securities and Exchange Commission on July 30, 2018).
2.6	Form of Support Agreement, by and between Apricus Biosciences, Inc., Seelos Therapeutics, Inc. and certain stockholders of Apricus Biosciences, Inc. (incorporated herein by reference to Exhibit 2.2 to the Company's Form 8-K filed with Securities and Exchange Commission on July 30, 2018).
2.7	Support Agreement, dated July 30, 2018, by and between Apricus Biosciences, Inc., Seelos Therapeutics, Inc. and Raj Mehra (incorporated herein by reference to Exhibit 2.3 to the Company's Form 8-K filed with Securities and Exchange Commission on July 30, 2018).
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).

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- [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).
- [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 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).
- [3.10](#) 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).
- [3.11](#) Certificate of Amendment filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.10 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 2, 2017).
- [3.12](#) Certificate of Amendment filed with the Nevada Secretary of State
- [3.13](#) 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).
- [3.14](#) 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).
- [3.15](#) 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).

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- [4.2](#) Form of Warrant (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 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).
- [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).
- [4.11](#) 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 11, 2017).
- [4.12](#) Form of Indenture (incorporated herein by reference to Exhibit 4.13 to the Company's Form S-3 (File No. 333-221285) filed with the Securities and Exchange Commission on November 2, 2017).
- [4.13](#) Amendment to Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.12 of Amendment No. 1 to the Company's Registration Statement on Form S-3 (File No. 333-2223353) filed with the Securities and Exchange Commission on March 22, 2018).
- [4.14](#) Amendment to Warrant to Purchase Common Stock, dated as of March 27, 2018 (incorporated by reference to Exhibit 4.1 to the Company's 8-K filed with the Securities and Exchange Commission on March 29, 2018).

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4.15	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company’s 8-K filed with the Securities and Exchange Commission on March 29, 2018).
4.16	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Company’s 8-K filed with the Securities and Exchange Commission on March 29, 2018).
4.17	Amendment to Warrant to Purchase Common Stock, dated as of June 22, 2018, by and between the Company and Sarissa Offshore (incorporated by reference to Exhibit 4.1 to the Company’s 8-K filed with the Securities and Exchange Commission on June 22, 2018).
10.1	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company’s 8-K filed with the Securities and Exchange Commission on March 29, 2018).
10.2	Engagement Agreement, dated as of March 27, 2018, between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 to the Company’s 8-K filed with the Securities and Exchange Commission on March 29, 2018).
10.3	Amendment No. 1 to Subscription Agreement, dated as of June 22, 2018, by and between the Investors and the Company (incorporated by reference to Exhibit 10.1 to the Company’s 8-K filed with the Securities and Exchange Commission on June 22, 2018).
10.4	Form of CVR Agreement (incorporated by reference to Exhibit 10.1 to the Company’s 8-K filed with the Securities and Exchange Commission on July 30, 2018).
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.

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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.

Date: August 9, 2018

Apricus Biosciences, Inc.

/s/ RICHARD W. PASCOE

Richard W. Pascoe
Chief Executive Officer and Secretary

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 9, 2018

/S/ RICHARD W. PASCOE

Richard W. Pascoe

Chief Executive Officer & Secretary

**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, 2018 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 9, 2018

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