UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2017

OR

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

For the transition period from to

Commission file number 0-22245

APRICUS BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K(§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 February 26, 2018, 16,338,811 shares of the common stock, par value $.001, of the registrant were outstanding.

The aggregate market value of the common stock held by non-affiliates, based upon the last sale price of the registrant's common stock on June 30, 2017, was approximately $14.3 million. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents

PART I.

Cautionary Note Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Those statements include statements regarding the intent, belief or current expectations of Apricus Biosciences, Inc. and its subsidiaries ("we," "us," "our," the "Company" or "Apricus") 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. These risks and uncertainties include but are not limited to those risks and uncertainties set forth in Item 1A of this Report. 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. Further, these forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements and we disclaim any intent to update forward-looking statements after the date of this report to reflect subsequent developments. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission ("SEC").

Vitaros™ is our trademark in the United States, which is pending registration and subject to our agreement with Warner Chilcott Company, Inc., now a subsidiary of Allergan plc ("Allergan"). Vitaros is a registered trademark of Ferring International Center S.A. ("Ferring") in certain countries outside of the United States. In addition, we own trademarks for NexACT® and RayVa™. This Annual Report on Form 10-K also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report on Form 10-K 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.

ITEM 1. BUSINESS

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; 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 U.S. Food and Drug Administration ("FDA"), issued a complete response letter (the "2018 CRL") for the new drug application ("NDA") for Vitaros. In March 2018, we plan to request a meeting with the FDA to further clarify the deficiencies raised in the 2018 CRL and to assess the best path forward for a potential approval of Vitaros. Based on FDA guidelines, we expect this meeting to take place within 30 days of the FDA receiving the request, or April 2018.

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.

On March 8, 2017, we entered into an asset purchase agreement with Ferring (the "Ferring Asset Purchase Agreement"), pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for 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.

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. If the NDA is approved by the FDA, Allergan has a one-time opt-in right to assume all future commercialization activities for Vitaros in the United States. If Allergan exercises its opt-in right, we may receive up to a total of $25 million in upfront and potential launch milestone payments, plus a double-digit royalty on net sales of Vitaros. If Allergan elects not to exercise its opt-in right, we expect to commercialize Vitaros, either through an internally built commercial organization, a contract sales force or by partnering with a pharmaceutical company with established sales and marketing capabilities.

In 2008, the FDA issued a complete response letter (the "2008 CRL") for the Vitaros NDA, identifying certain deficiencies in the application. A complete response letter ("CRL") is a communication from the FDA that informs companies that an application cannot be approved in its present form. 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 as well as new non-clinical studies, we resubmitted the Vitaros NDA in August 2017. The 2018 CRL identified deficiencies related to chemistry, manufacturing and controls ("CMC") and 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.

Alprostadil is one of several treatment options for ED in the United States, and is a widely accepted alternative to the PDE5 inhibitors, such as Viagra®. Following the approval by the European and Canadian Health Authorities, Vitaros has been deemed a safe and effective treatment in those territories, and has the potential to address a meaningful market opportunity due to both its patient-friendly form of administration versus other alprostadil dosage forms and its non-systemic safety profile.

The current leading ED medications are taken in pill form and work by inhibiting an enzyme called PDE5. We believe there is a need for new, safe and effective treatments, especially for those patients who cannot or prefer not to take or do not respond to oral medications. Vitaros is designed as a topically-applied, on-demand, non-PDE5 inhibitor that we believe has the potential to be effective for ED patients who:

1. Want a fast-acting and on-demand treatment;

2. Prefer a locally-acting treatment instead of an oral systemic treatment;

3. Have contraindications to PDE5 inhibitors due to medications or concurrent disease (estimated to be approximately 18% of the ED market);

4. Are healthy enough to take the PDE5 inhibitors but stop taking them because they are non-responders (estimated to be approximately 21% of the ED market); or

5. Drop out because of poor tolerability or side effects from oral PDE5 inhibitors.

Factors such as these lead to an estimated 31% drop out rate after initial prescription for patients taking sildenafil citrate, which increases to an estimated 48% drop-out rate after three years of taking the drug. In clinical studies, Vitaros showed efficacy in patients suffering from ED, including men who did not respond to sildenafil citrate. The side effects reported were localized and transient.

The first-generation version of the Vitaros product, which is currently marketed outside of the United States by Ferring and its commercialization partners, is stored in one chamber. This single-chamber formulation requires that the product be stored by customers in a refrigerator until a short time prior to use. In certain countries in Europe, Vitaros currently has an approved shelf-life of eighteen months and can be left unrefrigerated for up to three days.

It is expected that the product ingredients in the second-generation Vitaros product candidate will be stored in two separate chambers to allow alprostadil to be segregated from ingredients that cause it to become unstable at room temperature. The contents of each of the two chambers would then be mixed in the dispenser immediately prior to use. This mixture is expected to result in the same pharmaceutical formulation as the cold chain Vitaros approved outside of the United States.

We believe Vitaros offers greater market opportunity compared to other alprostadil dosage forms due to its patient-friendly delivery form as well as a competitive alternative to oral ED products. ED affects approximately 150 million men worldwide. In the United States, ED is estimated to affect 20 million men, of which approximately 5 million have been diagnosed and only approximately 1.25 million are being treated. An estimated 600,000 men are newly diagnosed each year in the United States. In the United States, the ED market is approximately $3 billion annually based on data published by the International Journal of Urology in 2007.

Competition for Vitaros

There is significant competition and financial incentive to develop, market and sell drugs for the treatment of ED. Leading drugs approved for ED indications are PDE5 inhibitors that target the vascular system, such as sildenafil citrate (sold by Pfizer under the trade name Viagra®), vardenafil (sold by GlaxoSmith-Kline under the trade name Levitra®), tadalafil (sold by Lilly under the trade name Cialis®) and avanafil (sold in the United States by Metuchen Pharmaceuticals, LLC under the trade name Stendra® and sold in Europe and New Zealand by The Menarini Group under the trade name Spedra®). As patents for the three major PDE5 inhibitors, sildenafil citrate, tadalafil and vardenafil, are expiring over various dates in each country, we anticipate that generic PDE5 inhibitors will impact the overall market for ED products. Generic PDE5 inhibitors are being sold at lower prices than their brand equivalents. Other drugs approved for ED indications include alprostadil for injection directly into the penis (sold by Pfizer under the trade name Caverject Impulse®, and Edex, sold in the United States by Endo Pharmaceuticals, Inc.), and alprostadil in urethral suppository format (sold by Meda under the trade name MUSE®). In addition, a variety of devices, including vacuum devices and surgical penile implants, have been approved for ED indications. We are aware of a number of companies developing

new drugs for ED indications including Futura Medical Inc., which is developing MED 2002, a topical gel applied directly to the penis for the treatment of ED. MED2002 is based on the active compound glyceryl trinitrate within a patented gel delivery system. We are not aware of any company actively developing a topical alprostadil drug for ED.

RayVa

RayVa is our product candidate for the treatment of Raynaud's Phenomenon associated with scleroderma (systemic sclerosis). Raynaud's Phenomenon is characterized by the constriction of the blood vessels in response to cold or stress of the hands and feet, resulting in reduced blood flow and the sensation of pain, which can be severe. Primary Raynaud's Phenomenon, which is not associated with an underlying medical condition, affects an estimated 3-5% of the United States population. Secondary Raynaud's Phenomenon, affecting approximately 500,000 in the United States, is driven by an underlying medical condition, such as scleroderma, lupus or rheumatoid arthritis. Symptoms are severe and patients risk associated fingertip ulcerations. There are an estimated 100,000 adult patients with scleroderma in the United States, of which approximately 90% have secondary Raynaud's Phenomenon. Approximately 80% of scleroderma patients are women. Both primary and secondary Raynaud's Phenomenon disproportionately affect women. We believe that RayVa presents an attractive commercial opportunity as there is currently no approved therapy for Raynaud's Phenomenon in the United States, representing an unmet medical need.

RayVa is a topically-applied cream formulation of alprostadil designed to dilate blood vessels, which is combined with our proprietary permeation enhancer NexACT, and applied on-demand to the affected extremities. RayVa received 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 raised in the FDA's 2018 CRL specific to the 2.5% concentration of DDAIP.HCl contained in the current formulation of Vitaros 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.

NexACT Drug Delivery Technology

The NexACT drug delivery technology is designed to enhance the delivery of an active drug to the patient. We believe the combination of our NexACT technology with active drugs has to the potential to improve therapeutic outcomes and reduce systemic side effects that often accompany existing medications.

The NexACT technology consists of a small molecule permeation enhancer called Dodecyl 2-(N,N dimethylamino)-propionate ("DDAIP") that enables the rapid absorption of high concentrations of an active pharmaceutical ingredient directly at the target site, which is designed to enhance the delivery of an active drug to the patient. NexACT was designed to enable multi-route administration of active drugs across numerous therapeutic classes.

NexACT is based on proprietary permeation enhancers that are biodegradable, biocompatible, and mimic the composition of human skin. NexACT has been tested in clinical trials in over 5,000 patients, including those subjects exposed to Vitaros and RayVa. In these clinical trials, NexACT demonstrated a favorable safety profile, with minimal serious adverse events that were likely attributed to the active ingredients in the drug candidates. We are still assessing how the safety concerns specific to the 2.5% concentration of DDAIP.HCl contained in the current formulation of Vitaros raised in the 2018 CRL may impact future development activities for other product candidates utilizing NexACT technology. The safety concerns raised were specific to Vitaros for the treatment of ED and are not necessarily transferable to other product candidates.

As part of the Ferring Asset Purchase Agreement, we transferred the non-U.S. patents related to DDAIP and 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 in certain fields other than sexual dysfunction.

Ferring Asset Purchase Agreement

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell to Ferring our assets and rights (the "Purchased Assets") related to the business of developing, marketing, distributing, and commercializing, outside the United States, our 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"). 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. We are retaining the U.S. development and commercialization rights for Vitaros and will receive 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, 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.

As of the closing, which occurred on March 8, 2017, Ferring assumed responsibility for our obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Purchased Assets arising after the closing date. We retained all liabilities associated with the Purchased Assets arising prior to the closing date.

Under the Ferring Asset Purchase Agreement, we have also agreed to indemnify Ferring for, among other things, breaches of our representations, warranties and covenants, any liability for which we remain responsible and our failure to pay certain taxes or comply with certain laws, subject to a specified deductible in certain cases. Our aggregate liability under such indemnification claims is generally limited to $2.0 million.

At the closing of the Ferring Asset Purchase Agreement, we entered into the Ferring License with respect to certain intellectual property rights necessary to or useful for our exploitation of the Purchased Assets within the United States and for our 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 territories and Ferring granted us 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.

Patent Portfolio

As of February 26, 2018, we owned or in-licensed approximately 240 issued patents, which will expire from 2017 through 2032, approximately, and approximately 73 patent applications. Should the patent applications issue, they may extend our patent exclusivity on our product candidates and technologies throughout the world until approximately 2032, based upon the potential expiration date of the last to expire of those patent applications. As to the in-licensed patents and patent applications, they include 221 issued patents and 61 patent applications from Ferring pursuant to the Ferring License.

To further strengthen our global patent position on our proprietary products under development and to expand the patent protection to other markets, we have filed foreign patent applications, many of which correspond to our issued United States patents and pending United States patent applications. These foreign filings have resulted in numerous issued patents and currently pending patent applications.

While we have obtained patents and have patent applications pending, the extent of effective patent protection in the United States and other countries is highly uncertain. 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 to protect us against competitors with similar technology. Any of our patents could be invalidated or circumvented.

The holders of competing patents could determine to commence a lawsuit against us and may even prevail in any such lawsuit. Litigation could result in substantial cost to and diversion of effort by us, 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.

Trademark Portfolio

As of February 26, 2018, we owned approximately 15 registered trademarks and 8 pending trademark applications worldwide. Vitaros is our trademark in the United States, which is pending registration and subject to our agreement with Warner Chilcott Company, Inc. Vitaros is a registered trademark of Ferring in certain countries outside of the United States.

While we have obtained registered trademarks, have trademark applications pending and may have common law trademark rights where applicable, the extent of effective trademark protection in the United States and other countries is highly uncertain. Trademarks we currently own or may obtain might not be sufficiently broad to protect us against competitors. Any of our trademarks could be invalidated or circumvented.

Even where we have registered trademarks, competitors could seek to invalidate these registrations. Any such litigation could result in substantial cost to and diversion of effort by us, 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.

Governmental Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as our products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

United States Government Regulation

In the United States, the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act, ("FDCA"), and its implementing regulations. Drugs and devices are also subject to other federal, state and local statutes and regulations. Our product candidates are subject to regulation as combination products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different Centers within the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our product candidates, we believe the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research would have primary jurisdiction over the premarket development, review and approval of our product candidates. Accordingly, we have and plan to continue to investigate our products through the IND framework and seek approval through the NDA pathway. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require a separate medical device authorization for the unit-dose dispenser to be marketed together with our product candidates, though the device component will need to comply with certain requirements applicable to devices. The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an investigational new drug ("IND") which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication in accordance with good clinical practices, or GCPs;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, ("API"), and finished drug product are produced and tested to assess compliance with cGMP regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- Phase 1. Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.

- Phase 2. Phase 2 includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

- Phase 3. Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product, and to provide an adequate basis for product approval. Phase 3 clinical trials usually involve several hundred to several thousand participants.

A pivotal study is a clinical study which adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase 3 studies but may be Phase 2 studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

Once the NDA submission has been accepted for filing, within 60 days following submission, the FDA's goal is to review applications for new molecular entities within ten months of the filing date or, if the application relates to a serious or life-threatening indication and demonstrates the potential to provide a significant improvement in safety or effectiveness over currently marketed therapies, six months from the filing date. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a risk evaluation and mitigation strategy to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

After regulatory approval of a drug product is obtained, manufacturers are required to comply with a number of post-approval requirements. The holder of an approved NDA must report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for the approved product. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long term stability of the drug product and compliance with relevant manufacturing requirements applicable to the device component. The FDA periodically inspects manufacturing facilities to assess compliance

with cGMP, which imposes extensive procedural, substantive and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Act, established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug.

In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant or for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant. We anticipate filing 505(b)(2) NDAs for our lead product candidates, which would rely, in part, on the FDA's previous findings of safety and efficacy of the active ingredient.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented

method-of-use rather than certify to a listed method-of-use patent. If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, ("NCE"), which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification. A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, ("CTA"), must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with cGCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with cGCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Authorization Procedures in the European Union

Medicines can be authorized in the European Union ("EU") by using either the centralized authorization procedure or national authorization procedures.

- Centralized Procedure. Under the Centralized Procedure a so-called Community Marketing Authorization is issued by the European Commission, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency ("EMA"). The Community Marketing Authorization is valid throughout the entire territory of the European Economic Area ("EEA") (which includes the 28 Member States of the EU plus Norway, Liechtenstein and Iceland). The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new

active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

- National Authorization Procedures. There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

    - Decentralized Procedure. Using the Decentralized Procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure. Under the Decentralized Procedure the applicant chooses one country as Reference Member State. The regulatory authority of the Reference Member State will then be in charge of leading the assessment of the marketing authorization application.

    - Mutual Recognition Procedure. In the Mutual Recognition Procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Other Health Care Laws

We may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order 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 federal False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the United States government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the United States, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. 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 in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, "the Affordable Care Act"), among other things, imposed new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information may result in civil monetary penalties of up to an aggregate of approximately $0.2 million per year (or up to an aggregate of $1.1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of marketing expenditures and pricing information as well as gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, ("HITECH"), and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Coverage and Reimbursement

Sales of our product candidates, once approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products and product candidates, if approved, will therefore depend substantially on the extent to which the costs of products and our product candidates will be paid by third-party payors. Additionally, the market for our products and product candidates will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future net revenue and results. Decreases in third-party reimbursement for our products and product candidates or a decision by a third-party payor to not cover our products or product candidates could reduce physician usage of our products and product candidates, if approved, and have a material adverse effect on our sales, results of operations and financial condition.

Health Care Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In particular, in the United States, the Affordable Care Act has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. The Affordable Care Act, among other things, addressed 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, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program

and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and established 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 during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance were also enacted, which may require us to modify our business practices with healthcare providers and entities.

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 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.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 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 and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Segment and Geographic Area Information

We currently operate in a single segment, through which we develop pharmaceutical product candidates. See note 1 to our consolidated financial statements for further details on our segment and geographic area information. For financial information regarding our business, see "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Employees

As of February 26, 2018, we had 11 full time employees in the United States. None of our employees are represented by a collective bargaining agreement. We believe that we have a good relationship with our employees.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the SEC, and we have an Internet website address at http://www.apricusbio.com. We make available free of charge on our Internet website address our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act as well as our proxy statements as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also read and copy any document we file at the SEC's public reference room located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-732-0330 for further information on the operation of such public reference room. You also can request copies of such documents, upon payment of a duplicating fee, by writing to the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549 or obtain copies of such documents from the SEC's website at http://www.sec.gov.

ITEM 1A.RISK FACTORS

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K 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.

Risks Related to the Company

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. As a result of the 2018 CRL, there is doubt as to when, if ever, we will be able to generate revenues in the future. Our future growth will depend on our assessment of the approvability of Vitaros, as well as RayVa, and to identify other business opportunities. 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 Vitaros, for which the FDA issued the 2018 CRL, and our other current and future product candidates, which will require significant additional clinical testing before we can seek regulatory approval and potentially begin commercialization.

Our future success depends on our ability to obtain regulatory approval for, and then successfully commercialize our product candidates. The success of Vitaros, our leading product candidate, will depend on whether we are able to successfully address 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 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 March 2018, we plan to request a meeting with the FDA to further clarify the deficiencies raised in the CRL and to assess the best pathway forward for a potential approval of Vitaros. We may be unsuccessful in identifying a pathway to resubmit the Vitaros NDA, and even if we believe a pathway is available, we may determine it is not commercially reasonable to continue to develop Vitaros. 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. Based on the 2018 CRL and guidance we may receive at our upcoming end-of-review meeting, we may need to complete additional clinical testing, which would likely require significant expenditures of cash and management resources. 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. There is no guarantee that we 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 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.

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 December 31, 2017, we had a cash balance of approximately $6.3 million. In September 2017, we entered into a Securities Purchase Agreement (the "September 2017 SPA") for net proceeds of approximately $3.1 million. In April 2017, we completed a public offering and raised net proceeds of approximately $5.9 million. 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 $0.50 million related to transition services. As part of the Ferring Asset Purchase Agreement, we have agreed to indemnify Ferring against losses suffered as a result of our breach of representations and warranties and our other obligations under our asset purchase agreement, and therefore may be liable for a portion of the consideration we received from Ferring.

We currently have an effective shelf registration statement on Form S-3 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 February 26, 2018, our public float was approximately $46.9 million based on 14.7 million shares of our common stock outstanding at a price of $3.19 per share, which was the closing sale price of our common stock on February 15, 2018. Since our public float is currently less than $75.0 million, as of February 26, 2018, we may only sell an aggregate of approximately $15.6 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 $316.0 million from our inception through December 31, 2017. We have incurred these losses principally from costs incurred in funding the research, development and clinical testing of our product candidates, from our general and administrative expenses and from our efforts to support commercialization of Vitaros by our partners 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.

Our ability to generate revenues and become profitable depends, among other things, on the successful development and commercialization of our 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 2017, we completed a public offering for net

proceeds of approximately $5.9 million and in September 2017, we entered into the September 2017 SPA for net proceeds of approximately $3.1 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 December 31, 2017, the Report of Independent Registered Public Accounting Firm included immediately prior to the Consolidated Financial Statements included in this Annual Report, includes a going concern explanatory paragraph. 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, our future clinical trials may not be successful.

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

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

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

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

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

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

The patents for NexACT alone have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. 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, either through an internally built commercial organization, a contract sales force or by partnering with a pharmaceutical company with established sales and marketing capabilities.

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

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

In order to augment our product pipeline or otherwise strengthen our business, we may decide to acquire or license additional businesses, products and technologies. We cannot be sure our business expenditures will result in the successful acquisition, development or launch of products that will prove to be commercially successful or will improve the long-term profitability of our business. 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.

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. 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 we experience significant delays in the clinical development and regulatory approval of our product candidates, our business may be substantially harmed.

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

- the availability of financial resources for us to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms and pricing with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining independent institutional review board ("IRB") approval at each clinical trial site;
- obtaining regulatory approval to commence clinical trials in each country;
- recruiting a sufficient number of eligible patients to participate in a clinical trial;

- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of our product candidate for use in clinical trials.

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

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

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

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

Despite this, there is no guarantee that we will be able to comply with the applicable continued listing requirements in the future. In the event that our Common Stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our Common Stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our Common Stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our Common Stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange. In addition, following delisting, unless our shares of Common Stock were immediately thereafter trading on the OTC Bulletin Board or the OTCQB or OTCQX market places of the OTC Markets, we would no longer be able to sell shares to Aspire Capital under the Purchase Agreement.

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

We are authorized to issue 40,000,000 shares of our capital stock, consisting of 30,000,000 shares of our common stock and 10,000,000 shares of our preferred stock. We currently have an effective shelf registration statement on Form S-3 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 30.0 million shares of common stock. As of the February 26, 2018, there were 16.3 million shares of common stock issued and outstanding with only 6.0 million shares available for future issuance. Unless and until we receive stockholder approval to increase the number of shares of common stock that are authorized for issuance (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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease one corporate office property in San Diego for approximately 9,000 square feet, a portion of which we sublease to another company. We believe that our leased facility is generally well maintained and in good operating condition and suitable and sufficient for our operational needs.

ITEM 3. 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. 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. We believe the allegations are without merit, reject all claims raised by Majorelle and intend to vigorously defend this matter.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is traded on the Nasdaq Capital Market ("Nasdaq") under the symbol "APRI."

On February 26, 2018, the last reported sales price for our Common Stock on Nasdaq was $0.97 per share, and we had approximately 101 holders of record of our Common Stock. One of our shareholders is Cede & Co., a nominee for Depository Trust Company, ("DTC"). Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

The following table sets forth the range of the high and low sales prices for our Common Stock as reported by Nasdaq for each quarter in 2017 and 2016. These numbers have been adjusted to reflect a 10-for-1 reverse stock split that was effected on October 24, 2016.

	2017		2016	
	High	Low	High	Low
First quarter	$ 4.07	$ 1.19	$ 15.50	$ 5.80
Second quarter	$ 2.45	$ 0.86	$ 6.49	$ 3.21
Third quarter	$ 1.87	$ 1.00	$ 4.94	$ 2.85
Fourth quarter	$ 2.14	$ 1.20	$ 3.70	$ 1.10

Dividends

We have never paid cash dividends on our Common Stock and do not have any plans to pay cash dividends in the foreseeable future. Our Board of Directors anticipates that any earnings that might be available to pay dividends will be retained to finance our business.

Equity Compensation Plan

The following table gives information as of December 31, 2017 about shares of our Common Stock that may be issued upon the exercise of options and restricted stock units under both of our existing equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)(1)	Weighted-average exercise price of outstanding options, warrants and rights (b)(2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)(3)
Equity compensation plans approved by security holders	1,086,509	$ 17.37	225,975

(1) Consists of options and restricted stock units outstanding as of December 31, 2017 under the 2012 Plan, and the 2006 Plan.

(2) Consists of the weighted average exercise price of outstanding options as of December 31, 2017.

(3) Consists entirely of shares of Common Stock that remain available for future issuance under the 2012 Plan as of December 31, 2017.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Disclosures Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 21E of the Exchange Act. Those statements include statements regarding the intent, belief or current expectations of Apricus Biosciences, Inc. and Subsidiaries ("we," "us," "our," the "Company" or "Apricus") 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. These risks and uncertainties include but are not limited to those risks and uncertainties set forth in Item 1A of this Report. 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. Further, these forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements and we disclaim any intent to update forward-looking statements after the date of this report to reflect subsequent developments. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

Vitaros™ is our trademark in the United States, which is pending registration and subject to our agreement with Warner Chilcott Company, Inc., now a subsidiary of Allergan plc ("Allergan"). Vitaros is a registered trademark of Ferring International Center S.A. ("Ferring") in certain countries outside of the United States. In addition, we own trademarks for NexACT® and RayVa™. Solely for convenience, trademarks and tradenames referred to in this Annual Report on Form 10-K 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.

All share data have been adjusted to reflect a 10-for-1 reverse stock split that was effected on October 24, 2016.

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; 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 U.S. Food and Drug Administration ("FDA"), issued a complete response letter (the "2018 CRL") for the new drug application ("NDA") for Vitaros. In March 2018, we plan to request a meeting with the FDA to further clarify the deficiencies raised in the 2018 CRL and to assess the best path forward for a potential approval of Vitaros. Based on FDA guidelines, we expect this meeting to take place within 30 days of the FDA receiving the request, or April 2018.

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. Pursuant to the Ferring Asset Purchase Agreement, Ferring now owns the rights to Vitaros outside of the United States.

In 2008, the FDA issued a complete response letter (the "2008 CRL") for the Vitaros NDA, identifying certain deficiencies in the application. A complete response letter ("CRL") is a communication from the FDA that informs companies that an application cannot be approved in its present form. 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. The 2018 CRL identified deficiencies related to chemistry, manufacturing and controls ("CMC") and 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.

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.

Results of Operations

Operating Expense

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

	Year Ended December 31,		2017 vs 2016	
	2017	2016	$ Change	% Change
Operating expense				
Research and development	$ 3,463	$ 5,880	$ (2,417)	(41)%
General and administrative	7,210	7,778	(568)	(7)%
Loss on disposal of assets	2	14	(12)	(86)%
Total operating expense	10,675	13,672	(2,997)	(22)%
Loss from continuing operations	$ (10,675)	$ (13,672)	$ 2,997	(22)%

Research and Development Expenses

Research and development ("R&D") 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 R&D on our behalf. The $2.4 million decrease in R&D expense during the year ended December 31, 2017 as compared to the prior year, resulted primarily from decreases in outside services related to the development of fispemifene and RayVa as well as decreased personnel-related expenses, partially offset by the $1.5 million payment to Allergan for the NDA resubmission.

General and Administrative Expenses

General and administrative ("G&A") costs include expenses for personnel, finance, legal, business development and investor relations. General and administrative expenses decreased by $0.6 million during the year ended December 31, 2017 as compared to the prior year. These decreases were primarily due to lower professional services expenses, such as decreased accounting expenses, offset, in part, by an increase in legal expense as a result of litigation expenses.

Other Income and Expense

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

	Year Ended December 31,		2017 vs 2016	
	2017	2016	$ Change	% Change
Other (expense) income				
Interest expense, net	$ (83)	$ (983)	$ 900	(92)%
Change in fair value of warrant liabilities	(646)	7,479	(8,125)	(109)%
Loss on extinguishment of debt	(422)	—	(422)	N/M
Other financing expenses	—	(461)	461	(100)%
Other income (expense), net	77	(22)	99	(450)%
Total other income	$ (1,074)	$ 6,013	$ (7,087)	(118)%

Interest Expense, Net

In October 2014, we entered into 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"). On March 8, 2017, we repaid to the Lenders all amounts due and owed under the Credit Facility. The payment included the outstanding balance of the term loans in full, a prepayment fee of approximately 2%, a final payment equal to 6% of the original principal amount of each term loan and per diem interest for a total payment of $6.6 million.

Change in Fair Value of Warrant Liability

The common stock warrants issued in connection with our February 2015 and January 2016 financings are classified as liabilities in the accompanying consolidated balance sheets as they contain provisions that are considered outside of our control, such as requiring us to maintain active registration of the shares underlying such warrants.

The fair value of these warrants is re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying consolidated statements of operations. The change in fair value of warrant liability is primarily driven by the fluctuation in our stock price.

We have issued other warrants that have similar terms whereas under no circumstance or by any event outside of our control may the shares be settled in cash. As such, these warrants are equity-classified and do not affect our consolidated statement of operations. See note 7 for further details.

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.

Other Financing Expenses

Other financing expenses represent the portion of total financing expenses allocated to the warrants issued in our January 2016 and September 2016 financings.

Discontinued Operations

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

	Year Ended December 31,	
	2017	**2016**
Product sales	$ 143	$ 675
Royalty revenue	368	1,088
License fee revenue	—	4,000
Cost of goods sold	(74)	(511)
Cost of Sandoz rights	(10)	(3,380)
Operating expenses	(658)	(1,606)
Other expense	(16)	(40)
Gain on sale	12,317	—
Income from discontinued operations	$ 12,070	$ 226

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, $0.7 million for the delivery of certain product-related inventory (received in April 2017), and an aggregate of $0.5 million related to transition services, the payments of which were received in July 2017 and September 2017. We used approximately $6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under the Credit Facility with the Lenders.

As a result of the Ferring Asset Purchase Agreement, all product sales revenue, royalty revenue, license fee revenue and cost of goods sold have been reflected as discontinued operations in the consolidated statement of operations for both periods presented. Cost of Sandoz rights represents the payments owed by us to Sandoz as a condition under the termination agreement between the two parties related to Vitaros outside of the United States. In addition, operating expenses, such as the transaction costs directly related to the Ferring Asset Purchase Agreement, have been presented as discontinued operations.

Liquidity, Capital Resources and Financial Condition

We have experienced net losses and negative cash flows from operations each year since our inception. Although we recorded net income of approximately $0.3 million for the year ended December 31, 2017, we had an accumulated deficit of approximately $316.0 million as of December 31, 2017. Our cash balance was approximately $6.3 million as of December 31, 2017. 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 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 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, we issued warrants to purchase up to 106,831 shares of common stock to H.C. Wainwright & Co., LLC ("H.C. Wainwright"). These 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.

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, 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 "Charter Amendment") and the Charter Amendment became effective. The warrants will expire five years from the date the warrants were exercisable, or May 17, 2017, and the exercise price of the warrants is $1.55 per share of common stock. In connection with this transaction, we issued to H.C. Wainwright warrants to purchase up to 251,500 shares of common stock (the "Underwriter Warrants"). The Underwriter Warrants have substantially the same terms as the warrants sold concurrently to the investors in the offering, except that the Underwriter Warrants have a term of five years from the effective date of the related prospectus, or April 20, 2017, and an exercise price of $1.75 per share. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the 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, pursuant to which, among other things, (i) the exercise price of the warrants was reduced to $1.55 per share (the exercise price of the warrants sold in the April 2017 Financing), and (ii) the date upon which such warrants become exercisable was changed to the effective date of the Charter Amendment, or May 17, 2017.

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for 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 due and owed, including applicable termination fees, under the Credit Facility with 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 February 26, 2018, we had approximately $100.0 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 February 26, 2018, our public float was approximately $46.9 million based on 14.7 million shares of our common stock outstanding at a price of $3.19 per share, which was the closing sale price of our common stock on February 15, 2018. Since our public float is currently less than $75.0 million, as of February 26, 2018, we may only sell an aggregate of approximately $15.6 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.

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 raise additional funds to finance our operations;
- the outcome of our meeting we plan to request with the FDA regarding the Vitaros NDA resubmission and our ability to overcome deficiencies raised in the 2018 CRL, if we believe it's commercially reasonable to do so;
- 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;
- 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.

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 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.

Cash Flow Summary

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

	2017	2016
Net cash provided by (used in) operations		
Net cash used in operating activities from continuing operations	$ (10,571)	$ (13,780)
Net cash provided by investing activities from continuing operations	—	265
Net cash provided by financing activities from continuing operations	2,501	11,003
Net cash provided by discontinued operations	12,314	712
Net increase (decrease) in cash	$ 4,244	$ (1,800)

Operating Activities from Continuing Operations

Cash used in operating activities from continuing operations of $10.6 million in 2017 was primarily due to a net loss from continuing operations of $11.7 million net of adjustments to net loss for non-cash items such as stock based compensation expense of $1.1 million, the warrant liability revaluation of $0.6 million and the loss on extinguishment of debt of $0.4 million upon repayment of the Credit Facility. Changes in operating assets and liabilities also contributed to the cash used in operating activities, such as decreases in accounts payable and accrued expenses in the current year.

Cash used in operating activities of $13.8 million in 2016 was primarily due to net loss of $7.7 million, adjusted for non-cash items such as the warrant liability revaluation of $7.5 million and stock based compensation expense of $1.7 million. Changes in operating assets and liabilities also contributed to the cash used in operating activities, such as decreases in prepaid expenses and accounts payable due to the decrease in R&D activity in the current year.

Investing Activities from Continuing Operations

There was no cash provided by investing activities during the current year. Cash provided by investing activities of $0.3 million in 2016 was primarily due to the release of restricted cash related to the completion of environmental remediation services on our New Jersey facility. This was offset by lower expenditures for the purchase of fixed assets in the current period.

Financing Activities from Continuing Operations

Cash provided by financing activities of $2.5 million during 2017 was primarily attributable to the $9.3 million in net proceeds that we received from the issuance of common stock and warrants in our April 2017 and September 2017 financings, offset by the repayment of our Credit Facility of $7.1 million as a closing condition of the Ferring Asset Purchase Agreement.

Cash provided by financing activities of $11.0 million during 2016 was primarily attributable to the $14.1 million in net proceeds that we received from the issuance of common stock and warrants in our January 2016, July 2016 and September 2016 financings. This was offset by the repayment of $3.1 million on our Credit Facility.

Discontinued Operations

Cash provided by discontinued operations of $12.3 million during 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 December 31, 2017, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recent Accounting Pronouncements

See note 1 to our consolidated financial statements for a discussion of recent accounting pronouncements and their effect, if any, on us.

Critical Accounting Estimates and Policies

The preparation of financial statements in accordance with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates depend on events over which we may not have control. If market and other conditions change from those that we anticipate, our consolidated financial statements may be materially affected. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect in our consolidated financial statements. We review our estimates, judgments, and assumptions used in our accounting practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, our actual results may differ from these estimates.

We believe that the following critical accounting policies and estimates have a higher degree of inherent uncertainty and require our most significant judgments:

Long-Lived Assets

We review our long-lived assets for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. If such asset is considered impaired, the amount of the impairment loss recognized is measured as the amount by which the carrying value of the asset exceeds the fair value of the asset, the fair value of which is determined based upon discounted cash flows or appraised values, depending on the nature of the asset. There were no impairment charges recorded in 2017 and 2016 related to our long-lived assets.

Stock Based Compensation

Stock based compensation expense includes charges related to options and restricted stock unit awards to employees and directors. The estimated grant date fair value of stock options granted to employees and directors is calculated based upon the closing stock price of our common stock on the date of the grant and recognized as stock-based compensation expense over the expected service period, which is typically approximated by the vesting period.

We estimate the fair value of each option award on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires us to estimate our dividend yield rate, expected volatility and risk free interest rate over the

life of the option. The use of estimates on these factors may cause the fair value of the option to be under or overestimated (see note 8 to our consolidated financial statements for the current estimates used in the Black-Scholes option pricing model).

We also issue performance-based shares which represent a right to receive a certain number of shares of common stock based on the achievement of corporate performance goals and continued employment during the vesting period. At each reporting period, we reassess the probability of the achievement of such corporate performance goals and adjusts expense as necessary.

Valuation of Warrant Liability

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

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

We have issued other warrants that have similar terms whereas under no circumstance may the shares be settled in cash. As such, these warrants are equity-classified. See note 7 for further details.

Income Taxes

We recognize deferred taxes under the asset and liability method of accounting for income taxes by which deferred income taxes are recognized for differences between the financial statement and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In addition, valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

In consideration of our accumulated losses and lack of historical ability to generate taxable income to utilize our deferred tax assets, we have determined it is not more likely than not we will be able to realize any benefit from our temporary differences and have recorded a full valuation allowance. If we become profitable in the future at levels which cause management to conclude that it is more likely than not that we will realize all or a portion of the net operating loss carry-forward, we would record the estimated net realized value of the deferred tax asset at that time and would then provide for income taxes at a rate equal to our combined federal and state effective rates, which would be approximately 26% under current tax laws. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Our policy is to recognize interest and penalties related to income tax matters in income tax expense. As the unrecognized tax benefits relate to un-utilized deferred tax assets and because we have generated net operating losses and capital losses since inception for both federal and state income tax purposes, no tax liabilities, penalties or interest have been recognized for balance sheet or statement of operations purposes as of and for the periods ended December 31, 2017 and 2016.

Tax Cuts and Jobs Act

On December 22, 2017, President Trump signed into law the tax legislation commonly known as the Tax Cuts and Jobs Act, or the Act. The effects of the new federal legislation are recognized upon enactment, which is the date the president signs a bill into law. The Act includes numerous changes in existing tax law, including a permanent reduction in the federal corporate income tax rate from 35% to 21%. The rate reduction takes effect on January 1, 2018. We have concluded that the Act will cause our deferred tax assets to be revalued. Deferred income taxes result from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in years in which those temporary differences are expected to be recovered or settled. As changes in tax laws or rates are enacted, deferred tax assets and liabilities are adjusted through income tax expense. Based on currently available information, we recorded a $19.5 million reduction in the fourth quarter of 2017 related to the revaluation of our deferred tax assets, which will not result in additional tax expense in the quarter as we maintain a full valuation allowance on our deferred tax assets.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Apricus Biosciences, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Apricus Biosciences, Inc. (the "Company") and subsidiaries as of December 31, 2017 and 2016, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2015.

San Diego, California

March 1, 2018

Apricus Biosciences, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2017	December 31, 2016
Assets		
Current assets		
Cash	$ 6,331	$ 2,087
Prepaid expenses and other current assets	261	177
Current assets of discontinued operations	—	1,370
Total current assets	6,592	3,634
Property and equipment, net	79	164
Other long term assets	35	60
Noncurrent assets of discontinued operations	—	842
Total assets	$ 6,706	$ 4,700
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 58	$ 763
Accrued expenses	650	1,333
Accrued compensation	863	614
Deferred revenue	12	—
Note payable, net	—	6,650
Current liabilities of discontinued operations	—	1,934
Total current liabilities	1,583	11,294
Warrant liabilities	694	846
Other long term liabilities	58	76
Total liabilities	2,335	12,216
Commitments and contingencies (note 10)		
Stockholders' equity (deficit)		
Preferred stock, $.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2017 and 2016	—	—
Common stock, $.001 par value, 30,000,000 shares authorized, 15,217,231 and 7,733,205 issued and outstanding as of December 31, 2017 and 2016, respectively	15	8
Additional paid-in-capital	320,343	308,784
Accumulated deficit	(315,987)	(316,308)
Total stockholders' equity (deficit)	4,371	(7,516)
Total liabilities and stockholders' equity (deficit)	$ 6,706	$ 4,700

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

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

	For the Years Ended December 31,	
	2017	2016
Operating expense		
Research and development	$ 3,463	$ 5,880
General and administrative	7,210	7,778
Loss on disposal of assets	2	14
Total operating expense	10,675	13,672
Loss before other income (expense)	(10,675)	(13,672)
Other income (expense)		
Interest expense, net	(83)	(983)
Change in fair value of warrant liabilities	(646)	7,479
Loss on extinguishment of debt	(422)	—
Other financing expenses	—	(461)
Other income (expense), net	77	(22)
Total other income (expense)	(1,074)	6,013
Loss from continuing operations	(11,749)	(7,659)
Income from discontinued operations	12,070	226
Net income (loss)	$ 321	$ (7,433)
Total earnings (loss) per share		
Continuing operations	$ (0.99)	$ (1.18)
Discontinued operations	$ 1.01	$ 0.03
Total earnings (loss) per share	$ 0.02	$ (1.15)
Weighted average common shares outstanding used for basic and diluted earnings (loss) per share	11,892	6,517

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

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

	For the Year Ended December 31,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	$ 321	$ (7,433)
Net income from discontinued operations	12,070	226
Net loss from continuing operations	(11,749)	(7,659)
Adjustments to reconcile net income (loss) to net cash used in operating activities from continuing operations:		
Depreciation and amortization	117	106
Non-cash interest expense	56	362
Stock-based compensation expense	1,138	1,747
Warrant liabilities revaluation	646	(7,479)
Other financing expenses	—	461
Loss on debt extinguishment	422	—
Other	2	10
Changes in operating assets and liabilities from continuing operations:		
Prepaid expenses and other current assets	(84)	408
Other assets	25	40
Accounts payable	(705)	45
Accrued expenses	(681)	(1,340)
Accrued compensation	249	(360)
Other liabilities	(7)	(121)
Net cash used in operating activities from continuing operations	(10,571)	(13,780)
Cash flows from investing activities from continuing operations:		
Purchase of fixed assets, net	—	(18)
Proceeds from the sale of property and equipment	—	3
Release of restricted cash	—	280
Net cash provided by investing activities from continuing operations	—	265
Cash flows from financing activities from continuing operations:		
Issuance of common stock and warrants	10,733	14,762
Issuance costs related to common stock and warrants	(1,392)	(641)
Repayment of notes payable	(7,129)	(3,113)
Proceeds from exercise of warrants	289	—
Repayment of capital lease obligations	—	(5)
Net cash provided by financing activities from continuing operations	2,501	11,003
Cash flows from discontinued operations:		
Net cash (used in) provided by operating activities of discontinued operations	105	712
Net cash provided by investing activities of discontinued operations	12,209	—
Net cash provided by discontinued operations	12,314	712
Net increase (decrease) in cash	4,244	(1,800)
Cash, beginning of period	2,087	3,887
Cash, end of period	$ 6,331	$ 2,087

Supplemental disclosure of cash flow information:				
Cash paid for interest	$	92	$	646
Cash paid for income taxes	$	—	$	6
Non-cash investing and financing activities:				
Reclassification of warrant liabilities to equity	$	798	$	—
Issuance of placement agent warrants	$	287	$	103
Issuance of restricted stock	$	—	$	249
Accrued transaction costs for financing activities	$	—	$	(236)

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

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

	Common Stock (Shares)	Common Stock (Amount)	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance as of December 31, 2015	5,042	$ 5	$ 298,926	$ (308,875)	$ (9,944)
Stock-based compensation expense	—	—	1,747	—	1,747
Issuance of restricted stock units to settle bonus liability	—	—	249	—	249
Issuance of common stock and warrants, net of offering costs	2,691	3	7,862	—	7,865
Net loss	—	—	—	(7,433)	(7,433)
Balance as of December 31, 2016	7,733	8	308,784	(316,308)	(7,516)
Stock-based compensation expense	—	—	1,138	—	1,138
Issuance of common stock due to the vesting of restricted stock units, net of shares withheld to cover taxes	131	—	—	—	—
Issuance of common stock and warrants	7,353	7	10,726	—	10,733
Issuance costs related to common stock and warrants	—	—	(1,392)	—	(1,392)
Proceeds from exercise of warrants	—	—	289	—	289
Reclassification of warrant liabilities to equity	—	—	798	—	798
Net income	—	—	—	321	321
Balance as of December 31, 2017	15,217	$ 15	$ 320,343	$ (315,987)	$ 4,371

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

Apricus Biosciences, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Apricus Biosciences, Inc. and Subsidiaries ("Apricus" or the "Company") is a Nevada corporation that was initially formed in 1987. The Company is a biopharmaceutical company focused on the development of innovative product candidates in the areas of urology and rheumatology. The Company has two product candidates: Vitaros, a product candidate in the United States for the treatment of erectile dysfunction ("ED"), which the Company in-licensed from Warner Chilcott Company, Inc., now a subsidiary of 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 the Company owns worldwide rights.

On February 15, 2018, the U.S. Food and Drug Administration ("FDA"), issued a complete response letter (the "2018 CRL") for the new drug application ("NDA") for Vitaros. In March 2018, the Company plans to request a meeting with the FDA to further clarify the deficiencies raised in the 2018 CRL and to assess the best path forward for a potential approval of Vitaros. Based on FDA guidelines, the Company expects this meeting to take place within 30 days of the FDA receiving the request, or April 2018.

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of these consolidated financial statements in conformity with generally accepted accounting principles ("GAAP") requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. The Company's most significant estimates relate to the valuation of stock based compensation, the valuation of its warrant liabilities, the impairment of long-lived assets and valuation allowances for the Company's deferred tax assets. The Company's actual results may differ from these estimates under different assumptions or conditions.

Liquidity

The accompanying 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. Although the Company reported net income of approximately $0.3 million for the year ended December 31, 2017, the Company had an accumulated deficit of approximately $316.0 million as of December 31, 2017. As of December 31, 2017, the Company had a cash balance of approximately $6.3 million. 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.

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 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 warrants to purchase up to 106,831 shares of common stock (the "September 2017 Placement Agent Warrants") to H.C. Wainwright & Co., LLC ("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.

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. Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock, sold at a public offering price of $1.40 per unit. At the time of the offering closing, the Company did not have a sufficient number of authorized common stock to cover shares of common stock issuable upon the exercise of the warrants. The sufficient number of authorized common stock became available on May 17, 2017 when the Company received stockholder approval of the proposed amendment to the Company's Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock (the "Charter Amendment") and the Charter Amendment became effective on that date. The warrants will expire five years from May 17, 2017, the date the warrants became exercisable, and the exercise price of the warrants is $1.55 per share

of common stock. In connection with this transaction, the Company issued to H.C. Wainwright warrants to purchase up to 251,500 shares of common stock (the "Underwriter Warrants"). The Underwriter Warrants have substantially the same terms as the warrants sold concurrently to the investors in the offering, except that the Underwriter Warrants have a term of five years from the effective date of the related prospectus, or April 20, 2017, and an exercise price of $1.75 per share. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017, and a related prospectus.

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

On March 8, 2017, the Company entered into an asset purchase agreement (the "Ferring Asset Purchase Agreement") with Ferring International Center S.A. ("Ferring'), pursuant to which it sold to Ferring its assets and rights related to Vitaros outside of the United States for 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 December 31, 2017, the Company had approximately $100.0 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 December 31, 2017, the Company's usage of its S-3 shelf registration statement is limited. The Company still maintains the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements. The rules and regulations of the SEC or any other regulatory agencies may restrict the Company's ability to conduct certain types of financing activities, or may affect the timing of and amounts it can raise by undertaking such activities.

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

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

- its ability to raise additional funds to finance its operations;
- the outcome of the Company's meeting with the FDA that it plans to request regarding the Vitaros NDA resubmission and its ability to overcome deficiencies raised in the 2018 CRL, if the Company believes it's commercially reasonable to do so;
- 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;
- 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.

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

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

Notwithstanding the proceeds from the closing of the Ferring Asset Purchase Agreement and the proceeds from the April 2017 and September 2017 financings, in order to fund its operations during the next twelve months from the issuance date of the financial statements contained herein, 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.

Fair Value of Financial Instruments

The Company's financial instruments consist principally of accounts payable, accrued expenses, and historically, its Credit Facility with the Lenders.

The carrying amounts of financial instruments such as accounts receivable, accounts payable and accrued expenses approximate their related fair values due to the short-term nature of these instruments.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. The Company estimates useful lives as follows:

- Machinery and equipment: three to five years
- Furniture and fixtures: ten years
- Computer software: five years

Amortization of leasehold improvements and capital lease equipment is provided on a straight-line basis over the shorter of their estimated useful lives or the lease term. The costs of additions and betterments are capitalized, and repairs and maintenance costs are charged to operations in the periods incurred (see note 5 for further details).

Leases

Leases are reviewed and classified as capital or operating at their inception. Historically, the Company recorded rent expense associated with its operating lease on a straight-line basis over the term of the lease. The difference between rent payments and straight-line rent expense was recorded as deferred rent in accrued liabilities. In January 2018, the Company subleased a portion of its office space. During the first quarter of 2018, the Company will record a liability for the present value of the remaining lease due, offset by the sublease income reasonably expected over the remaining term of the lease.

Fair Value Measurements

The Company determines the fair value measurements of applicable assets and liabilities based on a three-tier fair value hierarchy established by accounting guidance and prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market

data exists, therefore requiring an entity to develop its own assumptions. The Company's common stock warrant liabilities are measured and disclosed at fair value on a recurring basis, and are classified within the Level 3 designation.

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

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

Warrant liabilities	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Balance as of December 31, 2017	$ —	$ —	$ 694	$ 694
Balance as of December 31, 2016	—	$ —	$ 846	$ 846

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

	December 31, 2017	December 31, 2016
Risk-free interest rate	2.2%-2.2%	1.64%-1.99%
Volatility	89%-89.41%	77.25%-81.03%
Dividend yield	—%	—%
Expected term	5.04-5.17	4.75-6.17
Weighted average fair value	$ 0.80	$ 0.49

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

	Warrant liabilities
Balance as of December 31, 2016	$ 846
Change in fair value measurement of warrant liability	646
Warrant liability reclassified to stockholders' equity	(798)
Balance as of December 31, 2017	$ 694

Of the inputs used to value the outstanding common stock warrant liabilities as of December 31, 2017, the most subjective input is the Company's estimate of expected volatility of its common stock.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. If such assets are considered impaired, the amount of the impairment loss recognized is measured as the amount by which the carrying value of the asset exceeds the fair value of the asset, fair value being determined based upon future cash flows or appraised values, depending on the nature of the asset. The Company recognized no impairment losses during either of the periods presented within its financial statements.

Debt Issuance Costs

Historically, amounts paid related to debt financing activities were presented in the balance sheet as a direct deduction from the debt liability.

Warrant Liabilities

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

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

The Company has issued other warrants that have similar terms whereas under no circumstance or by any event outside of the Company's control may the shares be settled in cash. As such, these warrants are equity-classified. See note 7 for further details.

Research and Development

Research and development costs are expensed as incurred and include the cost of compensation and related expenses, as well as expenses for third parties who conduct research and development on the Company's behalf, pursuant to development and consulting agreements in place.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company also follows the provisions of accounting for uncertainty in income taxes which prescribes a model for the recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition.

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 income (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 units, or warrants. The Company excludes common stock equivalents from the calculation of diluted net income (loss) per share when the effect is anti-dilutive.

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

	Year Ended December 31,	
	2017	2016
Outstanding stock options	368	415
Outstanding warrants	7,084	2,318
Restricted stock units	718	115
	8,170	2,848

Stock-Based Compensation

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

Segment Information

The Company operates under one segment which develops pharmaceutical products.

Geographic Information

Revenues by geographic area for the Company's operations are as follows (in thousands):

	Year Ended December 31,	
	2017	2016
Europe [1][2]	$ 364	$ 5,093
Canada[1]	142	570
Asia Pacific [1][2]	—	100
Other[1][2]	5	—
	$ 511	$ 5,763

(1) As a result of the Ferring Asset Purchase Agreement, all revenues have been reflected as discontinued operations in the statement of operations for all periods presented.

(2) Amounts included have not been broken out by country as it is impractical to do so given the nature and structure of the license agreements which cover multiple countries and/or territories. The basis for attributing product sales and royalty revenues from external customers to individual countries was based on the geographic location of the end user customer.

All of the Company's net long-lived assets were located in the United States as of December 31, 2017. As of December 31, 2016, approximately $0.7 million of the Company's net long-lived assets were located in Canada and the remainder were located in the United States.

Recent Accounting Pronouncements

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, which provided clarity on which changes to the terms or conditions of share-based payment awards require an entity to apply the modification accounting provisions required in Topic 718. The standard is effective for all entities for annual periods beginning after December 15, 2017, with early adoption permitted, including adoption in any interim period for which financial statements have not yet been issued. The Company does not expect the adoption of this ASU will have a material impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,* which clarifies the treatment of several cash flow categories. In addition, ASU 2016-15 clarifies that when cash receipts and cash payments have aspects of more than one class of cash flows and cannot be separated, classification will depend on the predominant source or use. This update is effective for annual periods beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted, including adoption in an interim period. The Company does not expect the adoption of the new standard will have a material effect on its consolidated financial statements and related disclosure.

In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers*, the amendment of which addressed narrow-scope improvements to the guidance on collectability, noncash consideration, and completed contracts at transition as well as providing a practical expedient for contract modifications. In April 2016 and March 2016, the FASB issued ASU No. 2016-10 and ASU No. 2016-08, respectively, the amendments of which further clarified aspects of Topic 606: identifying performance obligations and the licensing and implementation guidance and intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations. The FASB issued the initial release of Topic 606 in ASU No. 2014-09, which requires entities to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Entities may use a full retrospective approach or report the cumulative effect as of the date of adoption. 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 does not have a material effect on its consolidated financial statements and related disclosures.

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

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 no assets and liabilities presented as discontinued operations as of December 31, 2017. The carrying amounts of the assets and liabilities of the Company's discontinued operations as of December 31, 2016 are as follows (in thousands):

	December 31, 2016
Accounts receivable	$ 530
Inventories	764
Prepaid expenses and other current assets	76
Current assets of discontinued operations	1,370
Property and equipment, net	842
Total assets of discontinued operations	$ 2,212
Accounts payable	197
Accrued expenses	1,737
Total liabilities of discontinued operations	$ 1,934

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

	Year Ended December 31,	
	2017	2016
Product sales	$ 143	$ 675
Royalty revenue	368	1,088
License fee revenue	—	4,000
Cost of goods sold	(74)	(511)
Cost of Sandoz rights	(10)	(3,380)
Operating expenses	(658)	(1,606)
Other expense	(16)	(40)
Gain on sale	12,317	—
Income from discontinued operations	$ 12,070	$ 226

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. The Company recorded $0.4 million in royalty revenue during the year ended December 31, 2017 related to sales of Vitaros prior to the completion of the Ferring Asset Purchase Agreement, during the fourth quarter of 2016 and the first quarter of 2017. "Cost of Sandoz rights" represents the payments owed by the Company to Sandoz as a condition under the termination agreement between the two parties related to Vitaros outside of the United States. Operating expenses for the current periods 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 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, for a total of $25.0 million in upfront and potential launch milestone payments owed to the Company for that right, plus a high double-digit royalty on Allergan's net sales of the product. If Allergan elects not to exercise its opt-in right, the Company expects to commercialize Vitaros, either through an internally built commercial organization, a contract sales force or by partnering with a pharmaceutical company with established sales and marketing capabilities.

In 2008, the FDA issued a complete response letter (the"2008 CRL") for the Vitaros NDA, identifying certain deficiencies in the application. A complete response letter ("CRL") is a communication from the FDA that informs companies that an application cannot be approved in its present form. 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. The 2018 CRL identified deficiencies related to chemistry, manufacturing and controls ("CMC") and 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 March 2018, the Company plans to request an end-of-review meeting with the FDA to further clarify the deficiencies raised in the CRL and to assess the best pathway forward for a potential approval of Vitaros. Based on FDA guidelines, this meeting is expected to take place within 30 days of the FDA receiving the request, or April 2018.

4. FORENDO IN-LICENSING AGREEMENT

In October 2014, the Company entered into a license agreement (the "Forendo License") and stock issuance agreement with Forendo Pharma Ltd. ("Forendo"), under which the Company was granted the exclusive right in the United States to develop and commercialize fispemifene, a tissue-specific selective estrogen receptor modulator ("SERM") designed to treat symptomatic secondary hypogonadism, as well as chronic prostatitis and lower urinary tract symptoms in men.

In exchange for the license, the Company issued to Forendo approximately 3.6 million shares of common stock with a value of $5.9 million based on the Company's closing stock price on the date of the agreement and made an upfront cash payment of $5.0 million. The Company made an additional payment of $2.5 million to Forendo in April 2015 pursuant to the terms of the agreement. There were additional regulatory milestones for a total of $42.5 million, up to $260.0 million in sales milestones, plus tiered mid-range double-digit royalties in the ten to twenty percent range based on its sales of the product in the United States.

The Company conducted a randomized double-blind Phase 2b clinical trial in symptomatic secondary hypogonadism and released top-line data during the first quarter of 2016 indicating that the study did not achieve statistical significance for either the erectile function primary endpoint or low libido secondary endpoint. Achievement of one or both of these clinical endpoints was essential in order to meet U.S. FDA regulatory requirements.

As a result, the Company discontinued all development of fispemifene in secondary hypogonadism and on August 29, 2017, the Company terminated the Forendo License. Subsequently, in December 2017, the Company and Forendo entered into a mutual termination agreement and release, whereby the parties modified certain terms under the Forendo License and the related stock issuance agreement, primarily related to the Company's recoupment of cost for fispemifene API. Under terms of the mutual termination agreement and release, Forendo paid the Company $0.2 million during the first quarter of 2018 in exchange for the initial transfer of the API and the Company is entitled to future payments up to the remaining cost of acquisition of the API, or $0.6 million, to be paid upon the execution of a future licensing transaction related to the product, which is subject to acceleration in certain circumstances.

5. OTHER FINANCIAL INFORMATION

Property and Equipment

Property and equipment are comprised of the following (in thousands):

	December 31,	
	2017	2016
Leasehold improvements	$ 20	$ 20
Machinery and equipment	270	279
Capital lease equipment	76	76
Computer software	130	130
Furniture and fixtures	25	25
Total property and equipment	521	530
Less: accumulated depreciation and amortization	(442)	(366)
Property and equipment, net	$ 79	$ 164

Depreciation expense totaled $0.1 million for each of the years ended December 31, 2017 and 2016, respectively.

Accrued Expenses

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

	December 31,	
	2017	2016
Professional fees	$ 575	$ 880
Outside research and development services	61	142
Deferred compensation	—	134
Other	14	177
Accrued expenses, net	$ 650	$ 1,333

Other Long Term Liabilities

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

	December 31,	
	2017	2016
Deferred rent	46	76
Security deposit	12	—
Other long term liabilities, net	$ 58	$ 76

6. DEBT

Credit Facility

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

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

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

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

	December 31, 2016
Notes payable, principal	$ 6,392
Add: accretion of final payment fee	378
Less: unamortized debt discount	(120)
Total notes payable	6,650

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

The Company recognized interest expense related to the Credit Facility of $0.1 million and $1.0 million during the years ended December 31, 2017 and 2016, respectively. Although the extinguishment of the debt was a closing condition of the Ferring Asset Purchase Agreement, since the Credit Facility was related to corporate debt, the loss on extinguishment and related interest expense is presented on the consolidated statements of operations as continuing operations.

7. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is authorized to issue 10.0 million shares of preferred stock, par value $0.001, of which 1.0 million shares are designated as Series A Junior Participating Preferred Stock, 800 are designated as Series B 8% Cumulative Convertible Preferred Stock, and 600 are designated as Series C 6% Cumulative Convertible Preferred Stock. No shares of preferred stock were outstanding as of December 31, 2017 or 2016.

Common Stock Offerings

September 2017 Financing

On September 10, 2017, the Company entered into the September 2017 SPA with certain 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 warrants to purchase up to 1,068,307 shares of common stock in a private placement. The 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 warrants to purchase up to 106,831 shares of common stock 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 warrants and 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 settled in cash. Therefore, the 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.

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 units. Each unit consisted of one share of common stock and one warrant to purchase 0.75 of a share of common stock, sold at a public offering price of $1.40 per unit. The warrants became exercisable only following the Company's announcement that it has received stockholder approval of the effectiveness of the Charter Amendment and the Charter Amendment had become effective. The warrants were exercisable upon the effective date of the Charter Amendment on May 17, 2017, expire five years from such date and have an exercise price $1.55 per share of common stock. In connection with this transaction, the Company issued to H.C. Wainwright warrants to purchase up to 251,500 shares of common stock. The Underwriter Warrants have substantially the same terms as the warrants sold concurrently to the investors in the offering, except that the Underwriter

Warrants have a term of five years from April 20, 2017 and an exercise price of $1.75 per share. The terms of the warrants state that under no circumstance may the shares be settled in cash. Therefore, the warrants have been classified within stockholders' equity. The common shares, warrants and warrant shares were issued and sold pursuant to an effective registration statement on Form S-1, which was previously filed with the SEC and declared effective on April 20, 2017, and a related prospectus.

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

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

September 2016 Financing

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

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

July 2016 Aspire Common Stock Purchase Agreement

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

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

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

aggregate shares of the Company's common stock traded on the next business day (the "VWAP Purchase Date"), subject to certain limitations. The purchase price per share of the Company's common stock sold to Aspire Capital pursuant to a VWAP Purchase Notice shall be the lesser of (i) the closing sale price of the Company's common stock on the VWAP Purchase Date or (ii) 97% of the volume weighted average price of the Company's common stock traded on the VWAP Purchase Date, subject to certain limitations.

The Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file one or more registration statements, as permissible and necessary to register, under the Securities Act of 1933, as amended, the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the Purchase Agreement. The Company has filed with the SEC a prospectus supplement to the Company's prospectus, dated August 25, 2014, filed as part of the Company's effective $100.0 million shelf registration statement on Form S-3, registering all of the shares of common stock that may be offered and sold to Aspire Capital from time to time.

Pursuant to the Aspire Purchase Agreement, in no case may the Company issue more than 1.2 million shares of the Company's common stock (which is equal to approximately 19.99% of the Company's common stock outstanding on the Aspire Closing Date) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least $3.820 per share (a price equal to the most recent 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 December 31, 2017, the Company has issued a total of 0.5 million shares for gross proceeds of $1.2 million. As of February 26, 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 and April 2017 Financings, the Company agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of each financing.

January 2016 Financing

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

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

As of December 31, 2017, the total aggregate fair value of the warrant liability, which includes only the January 2016 Warrants and the February 2015 Warrants, was $0.7 million.

Warrants

A summary of warrant activity during the year ended December 31, 2017 is as follows (share amounts in thousands):

	Common Shares Issuable upon Exercise		Weighted Average Exercise Price
Outstanding at December 31, 2016	2,318	$	15.19
Issued	5,199	$	1.60
Exercised	(186)	$	1.55
Cancelled	(247)		52.50
Outstanding as of December 31, 2017	7,084	$	3.91
Exercisable as of December 31, 2017	7,084	$	3.91

The following table shows the number of outstanding warrants by exercise price and date of expiration as of December 31, 2017 (share amounts in thousands):

Shares Issuable Upon Exercise		Exercise Price	Expiration Date
300	$	34.00	May 2018
1,068	$	1.67	March 2020
107	$	2.16	March 2020
252	$	1.75	April 2022
4,452	$	1.55	May 2022
429	$	8.80	January 2023
442	$	8.80	March 2023
19	$	12.90	October 2024
15	$	16.40	July 2025
7,084			

8. EQUITY COMPENSATION PLANS

As of December 31, 2017, the Company has one share-based compensation plan, the 2012 Stock Long Term Incentive Plan (the "2012 Plan"), which provides for the issuance of incentive and non-incentive stock options, restricted and unrestricted stock awards, stock unit awards and stock appreciation rights. Options and restricted stock units granted generally vest over a period of one to four years and have a maximum term of ten years from the date of grant. As of December 31, 2017, an aggregate of 1.4 million shares of common stock were authorized under the 2012 Plan, of which 225,975 common shares were available for future grants.

Stock Options

A summary of stock option activity during the year ended December 31, 2017 is as follows (share amounts in thousands):

	Number of Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)		Total Aggregate Intrinsic Value
Outstanding as of December 31, 2016	415	$	17.23	7.6	$	—
Cancelled	(46)		16.08	—		—
Outstanding as of December 31, 2017	369	$	17.37	6.7	$	—
Vested and expected to vest as of December 31, 2017	356	$	17.61	6.7	$	—
Exercisable as of December 31, 2017	293	$	18.91	6.4	$	—

As of December 31, 2017 and 2016, there were 293,296 and 228,392 options exercisable, respectively. There were no options exercised during either of the years ended December 31, 2017 and 2016. The total fair value of options vested during the years ended December 31, 2017 and 2016 was $0.8 million and $1.3 million, respectively.

Restricted Stock Units

A summary of restricted stock unit activity during the year ended December 31, 2017 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2016	$ 115	$ 5.11
Granted	873	$ 1.13
Vested	(214)	$ 1.70
Forfeited	(56)	$ 1.45
Nonvested as of December 31, 2017	$ 718	$ 1.57

The total fair value of awards vested during the years ended December 31, 2017 and 2016 was $0.4 million and $0.1 million, respectively.

Share-Based Compensation

The value of restricted stock unit grants is calculated based upon the closing stock price of the Company's common stock on the date of the grant. For stock options granted to employees and directors, the Company recognizes compensation expense based on the grant-date fair value over the requisite service period of the awards, which is 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 following table 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 year ended December 31, 2016. No stock options were granted during the year ended December 31, 2017.

	2016
Risk-free interest rate	1.36%-1.78%
Volatility	72.35%-80.02%
Dividend yield	—%
Expected term	5.25-6.08 years
Forfeiture rate	11.33%
Weighted average fair value	$ 7.23

Expected Volatility. The Company uses analysis of historical volatility to determine the expected volatility of its stock options.

Expected Term. The expected life assumptions are based on the simplified method due to the lack of sufficient history as set forth in SEC's Staff Accounting Bulletin Topic 14.

Risk-Free Interest Rate. The interest rate used in valuing awards is based on the yield at the time of grant of a United States Treasury security with an equivalent remaining term.

Dividend Yield. The Company has never paid cash dividends, and does not currently intend to pay cash dividends, and thus has assumed a 0% dividend yield.

Pre-Vesting Forfeitures. Estimates of pre-vesting option forfeitures are based on the Company's experience. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative catch-up adjustment in the period of change and also impact the amount of compensation expense to be recognized in future periods. Adjustments have not been significant to date.

As of December 31, 2017, there was $0.6 million in unrecognized compensation cost related to non-vested stock options expected to be recognized over a weighted average period of 1.7 years. As of December 31, 2017, there was $0.2 million in unrecognized compensation cost related to non-vested restricted stock units expected to be recognized over a weighted average period of 1.0 year. In addition, the Company has $0.6 million in unrecognized compensation cost related to performance restricted stock units.

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

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

	Year Ended December 31,	
	2017	2016
Research and development	$ 227	$ 534
General and administrative	911	1,213
	$ 1,138	$ 1,747

9. RELATED PARTY TRANSACTIONS

The Company had the following related party transaction in January 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 sublease has a term of two years and aggregate payments due to the Company of approximately $0.3 million.

10. INCOME TAXES

The Company has incurred losses since inception, which have generated net operating loss carryforwards and capital loss carryforwards of approximately $108.5 million and $9.8 million for federal and California income tax purposes, respectively. These carryforwards are available to offset future taxable income and expire beginning in 2018 through 2037 for federal income tax purposes and beginning in 2030 through 2033 for California income tax purposes. In addition, the Company has research and development tax credit carryforwards for federal and state income tax purposes as of December 31, 2017 of $1.8 million and $1.0 million, respectively. The federal credits will begin to expire in 2019 unless utilized and the state credits have an indefinite life.

Utilization of the loss carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required under Internal Revenue Code Section 382 ("Section 382"), as well as similar state and foreign provisions. These ownership changes may limit the amount of loss carryforwards that can be utilized annually to offset future taxable income. In general, an "ownership change" as defined by Section 382 results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing stockholders' subsequent disposition of those shares, likely resulted in such an ownership change, or could result in an ownership change in the future upon subsequent disposition.

During the first quarter of 2017, the Company completed a study to assess whether an ownership change occurred and determined that there have been multiple ownership changes since the Company's formation. As a result, utilization of the loss carryforwards are subject to an annual limitation under Section 382, which was determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate. These limitations resulted in the expiration of the majority of the Company's loss carryforwards. These loss carryforwards that have expired due to these limitations have been removed from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate. Despite the assessment completed during the first quarter of 2017, additional ownership changes may have occurred subsequent to the completion of the study, which would continue to limit utilization of any future loss carryforwards.

Deferred tax assets consist of the following (in thousands):

	December 31,	
	2017	2016
Net operating tax loss and capital loss carryforwards	$ 23,463	$ 68,672
Capitalized research and development costs	4,620	5,270
Research and development tax credits	1,923	1,659
Deferred compensation	—	46
Other accruals and reserves	721	1,214
Basis of intangible assets	3,658	3,870
Total deferred tax asset	34,385	80,731
Less valuation allowance	(34,385)	(80,731)
Net deferred tax asset	$ —	$ —

The federal net operating loss carryforwards and tax credit carryforwards resulted in a noncurrent deferred tax asset as of December 31, 2017 and 2016 of approximately $25.4 million and $70.3 million, respectively. In consideration of the Company's accumulated losses and the uncertainty of its ability to utilize this deferred tax asset in the future, the Company has recorded a full valuation allowance as of such dates.

The Company follows the provisions of income tax guidance which provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. The guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities. Tax positions that meet the more likely than not threshold are then measured using a probability weighted approach recognizing the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company's Federal income tax returns for 2014 to 2017 are still open and subject to audit. In addition, net operating losses and capital losses arising from prior years are also subject to examination at the time they are utilized in future years. Unrecognized tax benefits, if recognized, would have no effect on the Company's effective tax rate. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. For the years ended December 31, 2017 and 2016, the Company has not recorded any interest or penalties related to income tax matters. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months.

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2017 and 2016, are as follows (in thousands):

	Year Ended December 31,	
	2017	2016
Beginning balance	$ 3,047	$ 2,882
Change in current period positions	34	68
Change in prior period positions	(2,368)	97
Ending balance	$ 713	$ 3,047

The reconciliation of income taxes computed using the statutory United States income tax rate and the provision (benefit) for income taxes for the years ended December 31, 2017 and 2016, are as follows:

	Year Ended December 31,	
	2017	2016
Federal statutory tax rate	(34)%	(34)%
Change in rate	165 %	— %
Valuation allowance	(360)%	81 %
Deferred tax true-ups	227 %	(5)%
Revaluation of warrants	2 %	(34)%
Permanent differences	1 %	(4)%
Tax credits	(1)%	(4)%
Income tax expense	— %	— %

US Tax Reform

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act ("Tax Act"). The legislation significantly changes U.S. tax law by, among other things, reducing the US federal corporate tax rate from 35% to 21%, implementing a territorial tax system and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries.

Pursuant to the Securities and Exchange Commission Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), given the amount and complexity of the changes in tax law resulting from the Tax Act, the Company has not finalized the accounting for the income tax effects of the Tax Act. This includes the provisional amounts recorded related to the transition tax, re-measurement of the deferred taxes and the change to our valuation allowance. The impact of the Tax Act may differ from this estimate, during the one-year measurement period due to, among other things, further refinement of the Company's calculation, changes in interpretations and assumptions the Company has made, guidance that may be issued and actions the Company may take as a result of the Tax Act.

In connection with our initial analysis of the impact of the Tax Act, the Company has recorded provisional amounts for the revaluation of deferred tax assets and liabilities. We have remeasured our deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21% plus state and local tax. The Company recorded a provisional decrease related to our deferred tax assets and liabilities of $19.5 million as a result of the tax rate decrease, with a corresponding adjustment to our valuation allowance for the year ended December 31, 2017.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

In December 2011, the Company entered into a five year lease agreement for its headquarters location in San Diego, California expiring December 31, 2016. In December 2015, the Company amended the lease agreement to extend the term through December 31, 2020. The Company has an option to extend the lease an additional three years. The original lease term contained a base rent of approximately $24,000 per month with 3% annual escalations, plus a supplemental real estate tax and operating expense charge to be determined annually. The Company received a total of a six month base rent abatement from the lease agreement and amendment. This abatement is recoverable by the landlord on a straight line amortized basis over 60 months should the Company terminate the lease early for any reason.

The Company subleases excess capacity in its headquarters to a subtenant under a non-cancellable lease. The sublease has a term of two years and aggregate payments due to the Company of approximately $0.3 million.

For the years ended December 31, 2017 and 2016, rent expense totaled $0.3 million and $0.5 million, respectively.

Future minimum rental payments under operating leases as of December 31, 2017 are as follows (in thousands):

2018	$	364
2019		374
2020		32
Total	$	770

Certain employees have agreements that provide for severance compensation in the event of termination or a change in control. These agreements can provide for a severance payment of up to 18 months of base salary and bonus in effect at the time of termination and continued health benefits at the Company's cost for up to 18 months.

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.

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 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 att

orney'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. The Company believes the allegations are without merit, reject all claims raised by Majorelle and intends to vigorously defend this matter. No amounts have been accrued as a result of this matter.

12. SUBSEQUENT EVENT

On February 15, 2018, the FDA, issued the 2018 CRL for the NDA for Vitaros. In March 2018, the Company plans to request a meeting with the FDA to further clarify the deficiencies raised in the 2018 CRL and to assess the best path forward for a potential approval of Vitaros. Based on FDA guidelines, the Company expects this meeting to take place within 30 days of the FDA receiving the request.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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 December 31, 2017. Based on this evaluation, our CEO concluded that our disclosure controls and procedures were effective as of December 31, 2017.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a 15(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 December 31, 2017 using criteria established in the *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management determined that, as of December 31, 2017, our internal control over financial reporting was effective. Because we are a smaller reporting company, BDO, an independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure system are met. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter ended December 31, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable

PART III.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Name	Age	Position
Non-Employees Directors		
Kleanthis G. Xanthopoulos, Ph.D.[1][2]	59	Chairman
Paul V. Maier[1][3]	70	Director
Sandford D. Smith[1][2]	70	Director
Russell Ray[1][3]	47	Director
Wendell Wierenga, Ph.D.[2][3]	70	Director
Executive Officers		
Richard W. Pascoe	54	Chief Executive Officer, Secretary and Director
Brian T. Dorsey	49	Senior Vice President, Chief Development Officer
Neil Morton	42	Senior Vice President, Chief Business Officer

[1] Member of the Audit Committee.

[2] Member of the Compensation Committee.

[3] Member of the Corporate Governance/Nominating Committee.

Board of Directors

Kleanthis G. Xanthopoulos, Ph.D. has been a director since November 2011 and became Chairman of the Board in December 2013. He is a member of our Audit Committee and Compensation Committee. Dr. Xanthopoulos is an experienced and visionary leader in the biotechnology and pharmaceutical research industries, with a strong foundation in both operations and corporate development. He is currently President and ECO of IRRAS AB and he has been a Managing General Partner at Cerus DMCC, a life sciences investment company, since August 2015. From 2007 to June 2015, he was the President and Chief Executive Officer and a member of the board of directors of Regulus Therapeutics Inc. (RGLS). Prior to joining Regulus in 2007, Dr. Xanthopoulos was the Managing Director of Enterprise Partners Venture Capital. He co-founded Anadys Pharmaceuticals, Inc., served as their President and Chief Executive Officer from 2000 to 2006, and remained a director until its acquisition by Roche in 2011. Before that, Dr. Xanthopoulos was Vice President at Aurora Biosciences (acquired by Vertex Pharmaceuticals) from 1997 to 2000, and Section Head of the National Human Genome Research Institute from 1995 to 1997. Previously, he was an Associate Professor at the Karolinska Institute, Stockholm, Sweden. Dr. Xanthopoulos is a member of the board of directors of the Biotechnology Industry Organization (BIO), Zosano Pharma Inc. (ZSAN), LDO s.p.a. and he is a co-founder and a member of the board of directors of Sente, Inc. and Aspius Inc. Additionally, Dr. Xanthopoulos received the Ernst & Young Entrepreneur of the Year Award in Health Sciences in 2006 and was named Most Admired CEO by the San Diego Business Journal in 2013. An Onassis Foundation Scholar, Dr. Xanthopoulos received his B.Sc. in Biology with honors from Aristotle University of Thessaloniki, Greece, and his M.Sc. degree in Microbiology and Ph.D. degree in Molecular Biology from the University of Stockholm, Sweden, and a Postdoctoral Research Fellowship at The Rockefeller University, New York.

Paul V. Maier has been a director since June 2012. He is the Chair of our Audit Committee and a member of our Corporate Governance/Nominating Committee. Mr. Maier was most recently the Chief Financial Officer of Sequenom, Inc. from November 2009 until June 2014. Prior to joining Sequenom, Mr. Maier served as Senior Vice President and Chief Financial Officer of Ligand Pharmaceuticals Incorporated from 1992 until 2007, where he helped build Ligand from a venture stage company to a commercial, integrated biopharmaceutical organization. Prior to joining Ligand, he spent six years in various management and finance positions at ICN Pharmaceuticals, Inc. Mr. Maier currently serves on a number of boards, including the following public companies, International Stem Cell Corporation, where he is also a member of the company's audit and compensation committees, MabVax Therapeutics Holdings Inc., where he is also a member of the company's audit and nominating committees, and Ritter Pharmaceuticals, where he is also a member of the company's audit and governance committees. Mr. Maier previously served on the board of directors of the following public companies, Pure Bioscience and Talon Therapeutics, Inc. (previously Hana Bioscience). Mr. Maier has also been an independent financial consultant since February 2007. He received his M.B.A. from Harvard Business School and a B.S. from Pennsylvania State University.

Sandford D. Smith has been a director since August 2014. He is the Chair of our Compensation Committee. Mr. Smith has been actively engaged in the development of international biotech and pharmaceutical companies for almost four decades. Most recently, Mr. Smith served as Interim Chief Executive Officer at Aegerion Pharmaceuticals, Inc. from July 2015 to January 2016. He is chair/founder of Global BioLink LLC, a biotech consultancy formed in 2011. He was President of Genzyme International and Executive Vice President of Genzyme Corporation until the company's acquisition by Sanofi in 2011. He joined Genzyme in 1996, and initially served as Vice President and General Manager of Genzyme International and President of Genzyme Specialty

Therapeutics. Prior to joining Genzyme, Mr. Smith was President and Chief Executive Officer at RepliGen Corporation, a publicly traded biotechnology company, from 1986-1995. Mr. Smith previously held leadership positions at Bristol-Myers Squibb from 1977-1985, including Director of Operations for Bristol-Myers Squibb–Asia Pacific and Vice President of Business Development and Strategic Planning for the Pharmaceutical and Nutritional Division. Mr. Smith currently serves on the board of directors of the following publicly traded companies, Cytokinetics, Inc., Neuralstem, Inc. and Akcea Therapeutics, Inc. He was previously on the board of directors of Novelion Therapeutics, Inc., a public company. He is on the advisory council for Brigham & Women's Hospital, where he created the Smith Scholars Residency in medical education to benefit physicians from resource-poor nations. He is also on the advisory board at Tullis Health Advisors. Mr. Smith holds a bachelor's degree from the University of Denver.

Russell Ray has been a director since December 2009. He is the Chair of our Corporate Governance/Nominating Committee and a member of our Audit Committee. He is currently a partner with 11T Partners, a healthcare-only investment bank. He has worked with a wide variety of clients across the healthcare industry ranging from large pharmaceutical companies to early-stage drug development companies to medical device and service-based companies. Mr. Ray was a partner with Brocair Partners, a healthcare investment banking boutique, beginning in 2004 until he formed 11T Partners in 2012. Mr. Ray served as Deputy Director for eight years with Resources for the Future ("RFF") a non-partisan Washington-based think-tank that conducts independent economic research. During his tenure, RFF conducted a number of studies related to the pharmaceutical and biotechnology industries. Prior to joining RFF, Mr. Ray worked with The Meningitis Research Foundation in London where he worked to support basic research to cure the disease. Beyond life sciences, Mr. Ray has also worked on issues related to emissions credit trading and utility restructuring. Mr. Ray holds an M.B.A. in Finance from the Fordham University School of Business and a B.S. in Biology from Wake Forest University. Mr. Ray resides in New York with his wife and daughter.

Wendell Wierenga, Ph.D. has been a director since March 2014. He is a member of our Compensation Committee and Corporate Governance/Nominating Committee. Dr. Wierenga brings to our Board over four decades of experience in research, drug discovery and drug development, including clinical research, regulatory affairs, manufacturing, safety, and medical affairs. He has an extensive background serving as a public company executive and board member in the pharmaceutical and biotechnology industries. He most recently served as Executive Vice President, Research and Development, at Santarus, Inc., a specialty biopharmaceutical company, from June 2011 until its acquisition by Salix Pharmaceuticals, Inc. in 2014. Prior to Santarus, he was Executive Vice President in Research and Development at Ambit Biosciences Corporation from 2007 until 2011 and Neurocrine Biosciences, Inc. from 2003 until joining Ambit. Additionally, Dr. Wierenga served as Chief Executive Officer of Syrrx, Inc. (now part of Takeda Pharmaceutical Company), Senior Vice President of Worldwide Pharmaceutical Sciences, Technologies and Development at Parke-Davis/Warner Lambert (now Pfizer, Inc.), and he spent 16 years at Upjohn Pharmaceuticals in research and drug discovery roles. Dr. Wierenga serves as a member of the board of directors of the following private companies, Patara Pharma LLC, Dermata Therapeutics, LLC and Crinetics Pharmaceuticals Inc. He also serves on the board of Concert Pharmaceuticals, Inc., a public company, and serves on the board and as a member of the compensation committee at Cytokinetics Inc., a public company. He was previously on the board of directors of Onyx Pharmaceuticals, Inc. (acquired by Amgen), Anacor Pharmaceuticals Inc. (acquired by Pfizer) and Xenoport, Inc. (acquired by Arbor Pharmaceuticals) and Ocera Therapeutics, Inc. (acquired by Mallinckrodt). Additionally, Dr. Wierenga serves on multiple scientific advisory boards, including Concert Pharmaceuticals, Ferring Pharmaceuticals, and aTyr Pharma, Inc. He holds a Ph.D. in Chemistry from Stanford University and a B.A. in Chemistry from Hope College.

Executive Officers

Richard W. Pascoe has been a director and served as our Chief Executive Officer since March 2013, our Secretary since February 2015, and our Principal Financial Officer and Principal Accounting Officer since December 2016. He joined the Company following the merger of Somaxon Pharmaceuticals, Inc. with Pernix Therapeutics Holdings, Inc. Mr. Pascoe was the Chief Executive Officer of Somaxon from August 2008 until joining the Company and was responsible for the FDA approval of Somaxon's lead drug Silenor®. Prior to Somaxon, Mr. Pascoe was with ARIAD Pharmaceuticals, Inc., a specialty pharmaceutical company where he was most recently Senior Vice President and Chief Operating Officer. Prior to joining ARIAD in 2005, Mr. Pascoe held a series of senior management roles at King Pharmaceuticals, Inc. (acquired by Pfizer Inc.), including Senior Vice President positions in both marketing and sales, as well as Vice President positions in both international sales and marketing and hospital sales. Prior to King, Mr. Pascoe was in the commercial groups at Medco Research, Inc. (acquired by King), COR Therapeutics, Inc. (acquired by Millennium Pharmaceuticals Inc., the Takeda Oncology Company), B. Braun Interventional and The BOC Group. Mr. Pascoe is a member of the board of directors of KemPharm, Inc., as well as a member of the company's audit and compensation committees and its lead independent director. He serves as a member of the board of directors of the Johnny Mac Soldiers Fund, a charity for military veterans. Mr. Pascoe is also a member of the board of directors of BIOCOM, as well as its Vice-President of Industry. Mr. Pascoe served as a Commissioned Officer with the U.S. Army 24th Infantry Division. He is a graduate of the United States Military Academy at West Point where he received a B.S. degree in Leadership. Mr. Pascoe was appointed to the Board in connection with his appointment as our Chief Executive Officer.

Brian T. Dorsey has been our Senior Vice President, Chief Development Officer since December 2014. Mr. Dorsey has served in the pharmaceutical and biotechnology industries for over 20 years where he has provided high-level drug development, regulatory

and QC/QA leadership of pharmaceutical candidates from early development to FDA approval. He has held various senior management roles with pharmaceutical companies, most recently at Pernix Therapeutics as Senior Vice President Pharmaceutical Development from April 2013 to September 2014. Mr. Dorsey held managerial positions of increasing responsibility at Somaxon Pharmaceuticals from 2005 to 2013, and before that at Baxter Bioscience and Pfizer Global Research and Development. Mr. Dorsey received his Master of Science in Executive Leadership and his B.A. in Chemistry from the University of San Diego.

Neil Morton has been our Senior Vice President, Chief Business Officer since April 2016. From March 2014 through March 2016, Mr. Morton served as our Vice President, Business Development. Mr. Morton brings to the Company a successful track record in business development in specialty pharmaceuticals, most recently serving as the Executive Director of Business Development at Auxilium Pharmaceuticals Inc. from July 2009 to March 2014, where he successfully led their efforts to build a pipeline of men's health products. Prior to Auxilium Pharmaceuticals, he served in business development and marketing roles at King Pharmaceuticals from July 2002 to April 2009, attaining the position of Senior Director, Commercial Development. Mr. Morton received his M.B.A. degree from the Babcock Graduate School of Management at Wake Forest University and his B.A. degree in biology from Bucknell University.

Section 16(A) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our executive officers, directors and persons who beneficially own greater than 10% of a registered class of its equity securities to file certain reports with the SEC with respect to ownership and changes in ownership of the Common Stock and our other equity securities.

To the Company's knowledge, based solely on our review of the copies of such reports filed with the SEC, our officers, directors and greater than 10% stockholders timely complied with these Section 16(a) filing requirements during the fiscal year ended December 31, 2017.

Code of Ethics

We have adopted a Code of Ethics, as amended, that applies to our Chief Executive Officer and to all of our other officers, directors and employees. The Code of Ethics is available in the Corporate Governance section of the Investors page on our website at www.apricusbio.com. We will disclose future amendments to, or waivers from, certain provisions of our code of ethics, if any, on the above website within four business days following the date of such amendment or waiver.

Audit Committee

Our audit committee currently consists of Dr. Kleanthis Xanthopoulos, Mr. Paul Maier (Chair), and Mr. Russell Ray. All are non-employee directors of the Company and are considered independent under the applicable independence standard promulgated by Nasdaq and the SEC. Our Board of Directors has currently designated Mr. Maier as an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K. We believe that the audit committee members are capable of analyzing and evaluating our financial statements and understanding internal controls over financial reporting.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid by us during the years ended December 31, 2017 and 2016 to (1) our principal executive officer during fiscal year 2017 and (2) the other two most highly paid executive officers who were serving as executive officers as of December 31, 2017 (collectively our "Named Executive Officers"):

Name and Position	Year	Salary	Bonus (4)	Stock Awards (5)	Option Awards (6)	Non-Equity Incentive Plan Compensation (7)	All Other Compensation	Total
Richard W. Pascoe, Chief Executive Officer, Secretary and Director (1)	2017	$ 487,396	$ 97,479	$ 64,000	$ —	$ 176,681	$ 13,036	$ 838,592
	2016	$ 487,396	$ —	$ 179,555	$ 383,891	$ —	$ 12,836	$ 1,063,678
Brian T. Dorsey, Senior Vice President, Chief Development Officer (2)	2017	$ 319,300	$ 63,860	$ 48,000	$ —	$ 92,597	$ 12,788	$ 536,545
	2016	$ 319,300	$ —	$ 95,250	$ 153,559	$ —	$ 12,588	$ 580,697
Neil Morton, Senior Vice President, Chief Business Officer (3)	2017	$ 275,000	$ 55,000	$ 48,000	$ —	$ 79,750	$ 12,006	$ 469,756
	2016	$ 275,000	$ —	$ 46,691	$ 130,180	$ —	$ 11,806	$ 463,677

(1) Mr. Pascoe's all other compensation in 2017 includes $10,800 for the Company's matching and profit sharing contribution to the 401(k) plan and $2,236 in life insurance premiums.

(2) Mr. Dorsey's all other compensation in 2017 includes $10,800 for the Company's matching and profit sharing contribution to the 401(k) plan and $1,988 in life insurance premiums.

(3) Mr. Morton's all other compensation in 2017 includes $10,800 for the Company's matching and profit sharing contribution to the 401(k) plan and $1,206 in life insurance premiums.

(4) Represents the dollar amount of the special one-time bonus approved and ratified by the Compensation Committee on June 1, 2017, which was intended to recognize the efforts of such executives related to the sale of our ex-U.S. Vitaros business.

(5) Represents the grant date fair value of the stock awards granted in the applicable fiscal year, computed in accordance with FASB ASC Topic 718. For information relating to our assumptions made in valuing the stock awards granted to our Named Executive Officers in 2017, see note 8 to our audited consolidated financial statements included in this annual report on Form 10-K for the year ended December 31, 2017.

With respect to the performance-based RSUs granted to Mr. Pascoe, Mr. Dorsey and Mr. Morton in January 2017 and June 2017, the amounts in these columns include the grant-date fair value of such stock awards based upon the probable outcome of such conditions, all of which were not deemed probable of achievement. The full grant date fair value of these stock awards, assuming full achievement of the performance conditions to which such stock awards are subject, is as follows: Mr. Pascoe, $109,000; Mr. Dorsey, $81,750; and Mr. Morton, $81,750. A portion of the stock awards shown in the 2017 column of the table above relates to performance RSUs that were granted in June 2017 and vested upon resubmission of our Vitaros New Drug Application in August 2017.

(6) Represents the grant date fair value of the stock option awards granted in 2016, calculated in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. For a discussion of valuation assumptions for stock-based compensation, see note 8 to our audited consolidated financial statements filed with this annual report on Form 10-K for the year ended December 31, 2017. These figures do not reflect the amortized compensation expense or value received by the officer in the year indicated or that may be received by the officer with respect to such equity awards.

(7) Represents the bonuses paid to the Named Executive Officers in cash in 2018 for 2017 performance pursuant to our annual incentive program. There were no bonuses paid to the Named Executive Officers in 2017 for 2016 performance pursuant to our annual incentive program.

Narrative Disclosure to Summary Compensation Table

Base Salary

In general, base salaries for our Named Executive Officers are approved by the Compensation Committee and are initially established through arm's length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience, prior salary and market pay levels. Base salaries of our Named Executive Officers are approved and reviewed annually by our Compensation Committee and adjustments to base salaries are based on the scope of an executive's responsibilities, individual contribution, prior experience and sustained performance. Decisions regarding salary increases may take into account an executive officer's current salary, equity ownership, and the amounts paid to an executive officer's peers inside our company by conducting an internal analysis, which compares the pay of an executive officer to other members of the management team. Base salaries are also reviewed in the case of promotions or other significant changes in responsibility. Base salaries are not automatically increased if the Compensation Committee believes that other elements of the Named Executive Officer's compensation are more appropriate in light of our stated objectives. This strategy is consistent with our intent of offering compensation that is both cost-effective, competitive and contingent on the achievement of performance objectives.

Our executive officers did not receive base salary increases in 2018 or 2017.

Annual Cash Incentive

The Company also provides executive officers with annual performance-based cash bonuses, which are specifically designed to reward executives for overall Company performance in a given year. Corporate goals are established by the Compensation Committee with input from senior management and approved by the full Board. The target annual cash bonus amounts relative to base salary vary depending on each executive's accountability, scope of responsibilities and potential impact on the Company's performance and for 2017 were as follows: Mr. Pascoe, 50% of base salary; Mr. Dorsey, 40% of base salary; and Mr. Morton, 40% of base salary.

The Compensation Committee considers the Company's overall performance for the preceding fiscal year in deciding whether to award a bonus and, if one is to be awarded, the amount of the bonus. The annual cash bonus for each executive officer is based 100% on overall Company performance. The Compensation Committee retains the ability to apply discretion in making adjustments to the final bonus payouts.

The evaluation of Company performance for 2017 bonus purposes was based on the achievement, or failure to achieve, a set of weighted performance goals. The Company's 2017 performance goals were (1) acceptance of the Vitaros U.S. NDA (weighted at 40%), (2) completion of a RayVa Phase 2b protocol (weighted at 10%), (3) partner RayVa ex U.S. (weighted at 15%), (4) completion of ex-U.S. Vitaros transition to Ferring (weighted at 10%), (5) complete 2017 with one year of operating capital (20% weighting) and (6) increase the number of analyst coverage from two to four (weighed at 5%).

For fiscal year 2017, the Compensation Committee determined that the Company achieved 72.5% of the performance goals and thus the executive officers should be paid their bonuses at 72.5% of the targeted levels.

The following table sets forth the target bonus for each of the Named Executive Officers for 2017 and resulting incentive payout, based on the level of achievement of the 2017 corporate goals:

Name	Title	Fiscal Year 2017 Incentive Bonus Rate at Target	2017 Evaluation of Company Performance	Final Ratio Incentive Bonus as a Percentage of Base Salary	Fiscal 2017 Incentive Bonus Award
Richard W. Pascoe	Chief Executive Officer, Secretary and Director	50%	72.5%	36.25%	$ 176,681
Brian T. Dorsey	Senior Vice President, Chief Development Officer	40%	72.5%	29%	$ 92,597
Neil Morton	Senior Vice President, Chief Business Officer	40%	72.5%	29%	$ 79,750

2017 Special Cash Bonus

In June 2017, the Compensation Committee approved and ratified special one-time bonuses to certain employees, which bonuses were intended to recognize each such employee's efforts related the sale of our ex-U.S. Vitaros business. The 2017 special cash bonuses paid to the Named Executive Officers were as follows: Mr. Pascoe, $97,479; Mr. Dorsey, $63,860; and Mr. Morton, $55,000.

Equity Compensation

The Compensation Committee considers equity incentives to be important in aligning the interests of our executive officers with those of our stockholders. As part of our pay-for-performance philosophy, the Company's compensation program tends to emphasize the long-term equity award component of total compensation packages paid to our executive officers.

Because vesting is based on continued employment, our equity-based incentives also encourage the retention of our Named Executive Officers through the vesting period of the awards. In determining the size of the long-term equity incentives to be awarded to our Named Executive Officers, we take into account a number of internal factors, such as the relative job scope, the value of existing long-term incentive awards, individual performance history, prior contributions to us and the size of prior grants. For 2017, while our Compensation Committee reviewed competitive market data prepared by Radford in connection with its grant of long-term equity incentive awards to the Named Executive Officers, such awards were not determined by reference to any specific target level of compensation or benchmarking. Based upon these factors, the Compensation Committee determines the size of the long-term equity incentives at levels it considers appropriate to create a meaningful opportunity for reward predicated on the creation of long-term stockholder value.

To reward and retain our Named Executive Officers in a manner that best aligns employees' interests with stockholders' interests, we use stock options and restricted stock unit awards as the primary incentive vehicles for long-term compensation. We believe that stock options and restricted stock unit awards are effective tools for meeting our compensation goal of increasing long-term stockholder value by tying the value of the stock to our future performance. Because employees are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, we believe stock options provide meaningful incentives to employees to achieve increases in the value of our stock over time.

We use stock options and restricted stock unit awards to compensate our Named Executive Officers both in the form of initial grants in connection with the commencement of employment and annual refresher grants. Annual grants of equity awards are typically approved by the Compensation Committee during the first quarter of each year. While we intend that the majority of equity awards to our employees be made pursuant to initial grants or our annual grant program, the Compensation Committee retains discretion to grant equity awards to employees at other times, including in connection with the promotion of an employee, to reward an employee, for retention purposes or for other circumstances recommended by management or the Compensation Committee.

The exercise price of each stock option grant is the fair market value of our Common Stock on the grant date. Time-based stock option awards granted to our Named Executive Officers generally vest over a four-year period as follows: 25% of the shares underlying the option vest on the first anniversary of the date of the vesting commencement date and the remainder of the shares underlying the option vest in equal monthly installments over the remaining 36 months thereafter. From time to time, our Compensation Committee may, however, determine that a different vesting schedule is appropriate. We do not have any stock ownership requirements for our Named Executive Officers.

2017 Awards Granted- Restricted Stock Units

In January 2017, the Compensation Committee awarded annual restricted stock units to our Named Executive Officers based on its review of the foregoing factors and comparable company information. 50% of the restricted stock units will vest upon our receipt of marketing approval of Vitaros in the United States by the Food and Drug Administration ("FDA") and 50% will vest on November 30, 2018, in each case subject to the executive's continuous employment or service with us through the vesting date. In addition, all of these restricted stock units will vest in the event of a "covered transaction" (as defined in the Company's Amended and Restated 2012 Stock Long Term Incentive Plan, the "2012 Plan")). Specifically, our Named Executive Officers were granted the following number of restricted stock units in January 2017: Mr. Pascoe, 100,000; Mr. Dorsey, 75,000; and Mr. Morton, 75,000.

Each of our current Named Executive Officers also received an additional award of restricted stock units in June 2017. Each restricted stock unit will vest as follows: 50% of the restricted stock units vested upon the resubmission of our new drug application ("NDA") to the FDA in August 2017 and 50% will vest upon our receipt of marketing approval of Vitaros in the United States by the FDA, in each case subject to the executive's continuous employment or service with us through the vesting date. In addition, all of these restricted stock units will vest in the event of a "covered transaction" (as defined in the 2012 Plan). Specifically, our Named Executive Officers were granted the following number of restricted stock units in June 2017: Mr. Pascoe, 100,000; Mr. Dorsey, 75,000; and Mr. Morton, 75,000.

These awards (other than the awards that vested in August 2017, as described above) are described in detail in the "Outstanding Equity Awards as of December 31, 2017" table below.

Employee Benefit Program

Executive officers, including the Named Executive Officers, are eligible to participate in all of our employee benefit plans, including medical, dental, vision, group life, disability and accidental death and dismemberment insurance, in each case on the same basis as other employees, subject to applicable law. We also provide vacation and other paid holidays to all employees, including

executive officers. These benefit programs are designed to enable us to attract and retain our workforce in a competitive marketplace. Health, welfare and vacation benefits ensure that we have a productive and focused workforce through reliable and competitive health and other benefits.

Our retirement savings plan (401(k) Plan) is a tax-qualified retirement savings plan, pursuant to which eligible employees can begin to participate immediately upon employment. The 401(k) Plan elective deferrals and employer contributions are subject to compensation limitations and annual maximum contribution limits as governed by Internal Revenue Service. Employees are eligible to defer up to 100% of compensation and the Company makes safe harbor matching contributions of 100% match of first 3% of compensation contributed, then 50% match of next 2% of compensation contributed.

Outstanding Equity Awards as of December 31, 2017

The following table shows information regarding our outstanding equity awards as of December 31, 2017 for the Named Executive Officers:

	Option Awards (1)					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Non-Exercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#) (3)	Market Value of Shares or Units of Stock That Have Not Vested ($) (4)	Equity Incentive Plan Awards: Number of Unearned shares, Units or Other Rights That Have Not Vested (#) (5)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) (4)
Richard W. Pascoe	90,000	—	—	$ 25.10	3/18/2023	67,500	$ 124,200	117,500	$ 216,200
	21,875	8,125	—	$ 14.30	1/29/2025				
	21,875	28,125	—	$ 11.10	3/15/2026				
Brian T. Dorsey	22,500	7,500	—	$ 11.30	12/1/2024	50,000	$ 92,000	87,500	$ 161,000
	8,750	11,250	—	$ 11.10	3/15/2026				
Neil Morton	11,250	750	—	$ 23.20	3/20/2024	42,500	$ 78,200	80,000	$ 147,200
	8,000	—	— (2)	$ 23.20	3/20/2024				
	4,375	1,625		$ 14.30	1/29/2025				
	3,721	4,779		$ 11.10	3/15/2026				
	6,875	9,625		$ 5.70	4/1/2026				

(1) Except as otherwise noted, all stock options have a term of ten years from the date of grant and vest over four years, with 25% of the shares subject to the options vesting on the first anniversary of the date of grant and the remainder vesting in 36 monthly tranches thereafter. For a description of the accelerated vesting provisions applicable to the stock options granted to the Named Executive Officer, see "Payments Upon Termination or Change in Control" below.

(2) Represents performance-based stock options that vested based on the Company's initiation of one or more Phase II or later clinical trials of assets approved by the Board (each, a "Qualifying Trial") on or before December 31, 2015, as follows: (1) 25% of the underlying shares vested upon the First Vesting Date (e.g., the enrollment of the first patient in the first Qualifying Trial), which occurred as a result of the randomization and first dosing of the first RayVa Phase 2a patient in December 2014; 1/96th of the total number of shares subject to the option vested monthly thereafter over a 24-month period so that the option was vested and exercisable with respect to 50% of the total number of shares of stock underlying the option on the second anniversary of the First Vesting Date, and (2) 25% of the underlying shares vested upon the Second Vesting Date (e.g., the enrollment of the first patient in the second Qualifying Trial), which occurred as a result of the randomization and first dosing of the first fispemifene patient in May 2015; 1/96th of the total number of shares subject to the option vested monthly thereafter over a 24-month period so that the option was vested and exercisable with respect to 100% of the total number of shares of stock underlying the option on the second anniversary of the Second Vesting Date.

(3) Includes restricted stock units granted in April 2016 (with respect to Mr. Pascoe) and May 2016 (with respect to Messrs. Dorsey and Morton) that vested on January 1, 2018, as follows: Mr. Pascoe, 17,500 restricted stock units; Mr. Dorsey, 12,500 restricted stock units; and Mr. Morton, 5,000 restricted stock units.

Also includes restricted stock units granted in January 2017 that will vest on November 30, 2018, as follows: Mr. Pascoe, 50,000 restricted stock units; Mr. Dorsey, 37,500 restricted stock units; and Mr. Morton, 37,500 restricted stock units. In addition, all of these restricted stock units will vest in the event of a "covered transaction" (as defined in the 2012 Plan).

(4) Computed by multiplying the number of shares underlying each RSU by $1.84, the closing market price of the Company's Common stock on December 29, 2017, the last trading day of 2017.

(5) Includes performance-based restricted stock units granted in April 2016 (with respect to Mr. Pascoe) and May 2016 (with respect to Messrs. Dorsey and Morton) that will vest upon our receipt of marketing approval of Vitaros in the United States by the FDA on or before December 31, 2018, subject to the executive's continuous employment or service with us through the vesting date, as follows: Mr. Pascoe, 17,500 restricted stock units; Mr. Dorsey, 12,500 restricted stock units; and Mr. Morton, 5,000 restricted stock units.

Also includes performance-based restricted stock units granted in January 2017 and June 2017 that will also vest upon our receipt of marketing approval of Vitaros in the United States by the FDA, subject to the executive's continuous employment or service with us through the vesting date, as follows: Mr. Pascoe, 100,000 restricted stock units; Mr. Dorsey, 75,000 restricted stock units; and Mr. Morton, 75,000 restricted stock units.

In addition, all of these restricted stock units will vest in the event of a "covered transaction" (as defined in the 2012 Plan).

Payments Upon Termination or Change In Control

We have entered into employment agreements with each of the Named Executive Officers. These agreements set forth the individual's base salary, annual incentive opportunities, equity compensation and other employee benefits, which are described in this Executive Compensation section. All employment agreements provide for "at-will" employment, meaning that either party can terminate the employment relationship at any time, although our agreements with our Named Executive Officers provide that they would be eligible for severance benefits in certain circumstances following a termination of employment without cause. Our Compensation Committee approved the severance benefits to mitigate certain risks associated with working in a biopharmaceutical company at our current stage of development and to help attract and retain qualified executives.

Richard W. Pascoe

On March 18, 2013, we entered into an employment agreement with Richard W. Pascoe when he became the Chief Executive Officer of the Company. Subsequently, on December 20, 2016, we entered into an amended and restated employment agreement with Mr. Pascoe, which superseded and replaced the initial employment agreement.

The amended and restated agreement provides that if Mr. Pascoe's employment ends due to an involuntary termination, as such term is defined in his agreement, he would receive, in a lump sum payment, 12 months of his annual base salary in effect on the date of termination, any accrued but unpaid bonus for the calendar year preceding his termination (with any bonus for a partial year of employment annualized for such purpose), to the extent that the criteria for the bonus has been met, plus his target bonus for the year in which the date of his involuntary termination occurs, full acceleration and vesting of his unvested equity awards, and reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination (as provided under Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or other applicable law) for 12 months.

If Mr. Pascoe's employment is terminated in connection with his death or a permanent disability, Mr. Pascoe or his estate is entitled to a pro rata bonus for the calendar year in which such termination occurs, equal to the bonus he would have received, to the extent all criteria for such a bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid), for the calendar year of termination multiplied by a fraction, the numerator of which is the number of days in such year preceding and including the date of termination, and the denominator of which is 365. Such pro-rata bonus shall be paid at the same time as the bonus would have been paid had Mr. Pascoe remained employed by the Company through the date of payment, but in any event, not later than March 15 of the calendar year following the calendar year for which the bonus is payable. Mr. Pascoe is also entitled to receive any unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid). Such bonus shall be paid at the same time as the bonus would have been paid had he remained employed by the Company through the date of payment. Additionally, all of his outstanding but unvested equity awards shall vest immediately and the expiration date for all such equity awards shall be extended so that they expire one year after termination due to death or permanent disability.

In the event that Mr. Pascoe suffers an involuntary termination within the 12-month period following the effective date of a change of control, then in addition to all salary and bonuses accrued as of the date of his termination he will also be entitled to severance benefits. These include (i) the Company shall pay to Mr. Pascoe in one lump sum an amount equal to the greater of (A) 18 months of the salary that he was receiving immediately prior to the termination or (B) 18 months of the salary that he was receiving immediately prior to the change of control; (ii) the Company shall pay to Mr. Pascoe in one lump sum (A) any unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the

requirement that he be employed on the date the bonus is to be paid), plus (B) 100% of his target bonus for the year in which the date of his involuntary termination occurs; (iii) full acceleration of the vesting of all equity awards held by Mr. Pascoe at the time of the termination, including any options, restricted stock, RSUs or other awards, and (iv) reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of 18 months following the termination or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law. In addition, Mr. Pascoe's outstanding performance-based stock options as well as the unvested portion of restricted stock units granted in March 2016, April 2016, January 2017, and June 2017 will vest in the event of a "covered transaction" (as defined in the 2012 Plan).

If he is terminated for cause at any time or resigns under circumstances that do not constitute an involuntary termination, then Mr. Pascoe shall not be entitled to receive payment of any severance benefit or any continuation or acceleration of stock option vesting. He will receive payment for all salary accrued as of the date of termination of employment.

Brian T. Dorsey

On December 1, 2014, we entered into an employment agreement with Brian T. Dorsey. Subsequently, on December 20, 2016, we entered into an amended and restated employment agreement with Mr. Dorsey, which superseded and replaced the initial employment agreement.

The amended and restated agreement provides that if Mr. Dorsey's employment ends due to an involuntary termination, as such term is defined in his agreement, he would receive, in a lump sum payment, 12 months of his annual base salary in effect on the date of termination, any accrued but unpaid bonus for the calendar year preceding his termination (with any bonus for a partial year of employment annualized for such purpose), to the extent that the criteria for the bonus has been met, plus his target bonus for the year in which the date of his involuntary termination occurs, full acceleration and vesting of his unvested equity awards, and reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination (as provided under COBRA or other applicable law) for 12 months.

If Mr. Dorsey's employment is terminated in connection with his death or a permanent disability, Mr. Dorsey or his estate is entitled to a pro rata target bonus for the calendar year in which such termination occurs. Mr. Dorsey is also entitled to receive any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid). Such bonus amounts shall be paid in cash in a lump sum following the effectiveness of a general release of claims (or, in the event of his death, within five days following the date of death). Additionally, all of his outstanding but unvested equity awards shall vest immediately and the expiration date for all such equity awards shall be extended so that they expire one year after termination due to death or permanent disability.

In the event that Mr. Dorsey suffers an involuntary termination within the 12-month period following the effective date of a change of control, then in addition to all salary and bonuses accrued as of the date of his termination he will also be entitled to severance benefits. These include (i) the Company shall pay to Mr. Dorsey in one lump sum an amount equal to the greater of (A) 18 months of the salary that he was receiving immediately prior to the termination or (B) 18 months of the salary that he was receiving immediately prior to the change of control; (ii) the Company shall pay to Mr. Dorsey in one lump sum (A) any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid), plus (B) 100% of his target bonus for the year in which the date of his involuntary termination occurs; (iii) full acceleration of the vesting of all equity awards held by Mr. Dorsey at the time of the termination, including any options, restricted stock, RSUs or other awards, and (iv) reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of 18 months following the termination or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law. In addition, Mr. Dorsey's outstanding performance-based stock options as well as the unvested portion of restricted stock units granted in March 2016, May 2016, January 2017, and June 2017 will vest in the event of a "covered transaction" (as defined in the 2012 Plan).

If he is terminated for cause at any time or if he voluntarily resigns under circumstances that do not constitute an involuntary termination, then Mr. Dorsey shall not be entitled to receive payment of any severance benefit or any continuation or acceleration of stock option vesting and all of his restricted stock awards shall remain subject to all applicable forfeiture provisions and transfer restrictions. He will receive payment for all salary accrued as of the date of termination of employment.

Neil Morton

On March 20, 2014, we entered into an employment agreement with Neil Morton, which was later amended and restated on April 25, 2016. Subsequently, on December 20, 2016, we entered into a second amended and restated employment agreement with Mr. Morton, which superseded and replaced the first amended and restated employment agreement.

The second amended and restated agreement provides that if Mr. Morton's employment ends due to an involuntary termination, as such term is defined in his agreement, he would receive, in a lump sum payment, 12 months of his annual base salary in effect on the date of termination, any accrued but unpaid bonus for the calendar year preceding his termination (with any bonus for a

partial year of employment annualized for such purpose), to the extent that the criteria for the bonus has been met, plus his target bonus for the year in which the date of his involuntary termination occurs, full acceleration and vesting of his unvested equity awards, and reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination (as provided under COBRA or other applicable law) for 12 months.

If Mr. Morton's employment is terminated in connection with his death or a permanent disability, Mr. Morton or his estate is entitled to a pro rata target bonus for the calendar year in which such termination occurs. Mr. Morton is also entitled to receive any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid). Such bonus amounts shall be paid in cash in a lump sum following the effectiveness of a general release of claims (or, in the event of his death, within five days following the date of death). Additionally, all of his outstanding but unvested equity awards shall vest immediately and the expiration date for all such equity awards shall be extended so that they expire one year after termination due to death or permanent disability.

In the event that Mr. Morton suffers an involuntary termination within the 12-month period following the effective date of a change of control, then in addition to all salary and bonuses accrued as of the date of his termination he will also be entitled to severance benefits. These include (i) the Company shall pay to Mr. Morton in one lump sum an amount equal to the greater of (A) 18 months of the salary that he was receiving immediately prior to the termination or (B) 18 months of the salary that he was receiving immediately prior to the change of control; (ii) the Company shall pay to Mr. Morton in one lump sum (A) any accrued but unpaid bonus for the calendar year preceding his termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that he be employed on the date the bonus is to be paid), plus (B) 100% of his target bonus for the year in which the date of his involuntary termination occurs; (iii) full acceleration of the vesting of all equity awards held by Mr. Morton at the time of the termination, including any options, restricted stock, RSUs or other awards, and (iv) reimbursement for the cost of continuation of health insurance benefits provided to him immediately prior to the termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of 18 months following the termination or the date upon which he is no longer eligible for such COBRA or other benefits under applicable law. In addition, Mr. Morton's outstanding performance-based stock options as well as the unvested portion of restricted stock units granted in March 2016, May 2016, January 2017, and June 2017 will vest in the event of a "covered transaction" (as defined in the 2012 Plan).

If he is terminated for cause at any time or if he voluntarily resigns under circumstances that do not constitute an involuntary termination, then Mr. Morton shall not be entitled to receive payment of any severance benefit or any continuation or acceleration of stock option vesting and all of his restricted stock awards shall remain subject to all applicable forfeiture provisions and transfer restrictions. He will receive payment for all salary accrued as of the date of termination of employment.

DIRECTOR COMPENSATION

We have adopted a non-employee director compensation policy pursuant to which our non-employee directors are eligible to receive cash and equity compensation.

Each non-employee director is entitled to receive an annual cash retainer of $40,000, with additional annual cash retainers for the chairs of our various Board committees in the following amounts: $15,000 for the chair of the Audit Committee, $12,000 for the chair of the Compensation Committee and $8,000 for the chair of the Corporate Governance/Nominating Committee. Additionally, non-chair members of these committees will receive additional annual cash retainers in the following amounts: $7,000 for members of the Audit Committee, $5,000 for members of the Compensation Committee and $3,000 for members of the Corporate Governance/Nominating Committee. The Chairman of the Board is also entitled to receive an additional annual cash retainer of $40,000 per year.

Each non-employee director is eligible to receive a non-qualified stock option to purchase 60,000 shares of Common Stock upon initial election or appointment to the Board, subject to the terms and provisions of the 2012 Plan. Such initial awards vest over four years, with one-fourth of the shares subject to the initial award vesting on the first anniversary of the date of grant and the remaining shares subject to the initial award vesting in 36 equal monthly installments over the three years thereafter, subject to the director's continuing service on our Board through such dates.

Prior to January 3, 2018, on the third trading day of each calendar year, each non-employee director was eligible to receive an annual grant of 11,250 restricted stock units (or, in the case of our Chairman of the Board, 15,000 restricted stock units), subject to the terms and provisions of the 2012 Plan. Such restricted stock units vested upon the first anniversary of the date of grant, subject to the director's continuing service on our Board on such date.

On January 3, 2018, our Board approved an amendment to the equity component of our non-employee director compensation policy such that the annual grant of equity would be in the form of options rather than restricted stock units. As such, pursuant to the amendment, on the third trading day of each calendar year, each non-employee director is eligible to receive a non-qualified stock option to purchase 35,000 shares of Common Stock (or, in the case of our Chairman of the Board, an option to purchase 50,000 shares of Common Stock), subject to the terms and provisions of the 2012 Plan. Annual awards vest over one year in 12

equal monthly installments, subject to the director's continuing service on our Board through such dates. All initial and annual awards to our non-employee directors will vest in full in the event of a change in control.

Non-Employee Director Compensation for 2017

Below is a summary of the non-employee director compensation paid in fiscal 2017:

Name	Cash Compensation (1)	Option Grants (2)	Stock Awards (3)	Total
Kleanthis G. Xanthopoulos, Ph.D.	$ 92,000	$ —	$ 19,200	$ 111,200
Russell Ray	$ 55,000	$ —	$ 14,400	$ 69,400
Paul V. Maier	$ 58,000	$ —	$ 14,400	$ 72,400
Wendell Wierenga, Ph.D.	$ 48,000	$ —	$ 14,400	$ 62,400
Sandford D. Smith	$ 52,000	$ —	$ 14,400	$ 66,400

(1) Includes the value of the annual retainers payable to our non-employee directors.

(2) No stock options were granted to the directors in 2017. As of December 31, 2017, each of our non-employee directors held stock options to purchase the following number of shares of our Common Stock: Dr. Xanthopoulos, options to purchase 18,200 shares; Mr. Ray, options to purchase 10,700 shares; Mr. Maier, options to purchase 11,600 shares; Dr. Wierenga, options to purchase 15,000 shares; and Mr. Smith, options to purchase 13,500 shares. As of December 31, 2017, each of our non-employee directors held the following amounts of unvested restricted stock units: Dr. Xanthopoulos, 15,000; Mr. Ray, 11,250; Mr. Maier, 11,250; Dr. Wierenga, 11,250; and Mr. Smith, 11,250.

(3) Represents the grant date fair value of the stock awards granted in 2017, computed in accordance with FASB ASC Topic 718. For information relating to our assumptions made in valuing the stock awards granted to our non-employee directors in 2017, see note 8 to our audited consolidated financial statements included in this annual report on Form 10-K for the year ended December 31, 2017.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information with respect to the beneficial ownership, as of February 26, 2018 (the "Reference Date"), of Common Stock by (a) each of our Named Executive Officers and current directors individually, (b) our current directors and executive officers as a group and (c) each holder of more than 5% of the Company's outstanding Common Stock.

Beneficial ownership and percentage ownership are determined in accordance with the Rule 13d-3 of the Exchange Act. Under these rules, shares of Common Stock issuable under stock options or warrants that are exercisable within 60 days of the Reference Date are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrant(s), but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over their shares of Common Stock, except for those jointly owned with that person's spouse.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Class (%) (1)
Armistice Capital Master Fund, Ltd. (2)	2,377,160	13.31%
Sarissa Capital Management LP (3)	2,120,361	12.46%
Iroquois Capital Management, LLC (4)	1,408,455	8.35%
Anson Investments Master Fund, LP (5)	1,016,188	5.86%
Directors and Executive Officers (6)		
Richard W. Pascoe (7)	191,542	1.16%
Brian T. Dorsey (8)	69,537	*
Neil Morton (9)	65,763	*
Kleanthis G. Xanthopoulos, Ph.D. (10)	55,276	*
Wendell Wierenga, Ph.D. (11)	39,124	*
Sandford D. Smith (12)	37,703	*
Russell Ray (13)	36,656	*
Paul V. Maier (14)	34,205	*
All current executive officers and directors as a group (eight persons) (15)	529,806	3.18%

* Less than one percent.

(1) Percentage ownership is calculated based on a total of 16,338,812 shares of Common Stock issued and outstanding as of the Reference Date.

(2) Represents shares of Common Stock beneficially owned by Armistice Capital Master Fund, Ltd. ("Armistice Capital Master Fund") at December 31, 2017, as indicated in the entity's Schedule 13G/A filed with the SEC on February 14, 2018, plus warrants to purchase up to 1,527,160 shares. Armistice Capital, LLC is an investment manager to Armistice Capital Master Fund and Steven J. Boyd, the chief investment officer of Armistice Capital, LLC, may be deemed to have voting and investment power with respect to the securities held by Armistice Capital Master Fund. Armistice Capital Master Fund's beneficial ownership includes warrants to purchase up to 1,527,160 shares. The principal business address of (i) Armistice Capital Master Fund is c/o dms Corporate Services Ltd., 20 Genesis Close, P.O. Box 314, Grand Cayman KY1-1104, Cayman Islands, (ii) Armistice Capital, LLC is 510 Madison Avenue, 22nd Floor, New York, NY 10022 and (iii) Steven Boyd is c/o Armistice Capital, LLC, 510 Madison Avenue, 22nd Floor, New York, NY 10022.

(3) Represents shares of Common Stock beneficially owned by Sarissa Capital Management LP ("Sarissa Management") at January 31, 2018, as indicated in the entity's Schedule 13D/A filed with the SEC on January 31, 2018. The shares of Common Stock are owned by Sarissa Management, Alexander J. Denner, the Chief Investment Officer of Sarissa Management and Sarissa Capital Offshore Master Fund LP ("Sarissa Offshore"). Sarissa Management's beneficial ownership includes warrants to purchase up to 672,455 shares. The principal business address of (i) each of Sarissa Management and Dr. Denner is c/o Sarissa Capital Management LP, 660 Steamboat Road, 3rd Floor, Greenwich, CT 06830 and (ii) Sarissa Offshore is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands.

(4) Represents shares of Common Stock beneficially owned by Iroquois Capital Management, LLC and Iroquois Master Fund, Ltd. (collectively "Iroquois") at December 31, 2017, as indicated in the entity's Schedule 13G/A filed with the SEC on February 14, 2018. Iroquois Capital Management, LLC is the investment manager of Iroquois Master Fund, Ltd. Iroquois Capital Management, LLC has voting control and investment discretion over securities held by Iroquois Master Fund, Ltd. As President of Iroquois Capital Management, LLC, Richard Abbe makes voting and investment decisions on behalf of Iroquois Capital Management, LLC in his capacity as investment manager to Iroquois Master Fund Ltd. As a result of the foregoing, Mr. Abbe may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Iroquois Capital Management, LLC and Iroquois Master Fund Ltd. Iroquois' beneficial ownership includes warrants to purchase up to 521,430 shares. The principal business address of Iroquois is 205 East 42nd Street, 20th Floor, New York, NY 10017.

(5) Represents warrants to purchase shares of Common Stock beneficially owned by Anson Investments Master Fund LP ("Anson") as indicated by information provided by the beneficial owner in connection with the Company's filing of a registration statement on Form S-3 related to the beneficial owner's securities and internal records. Anson Funds Management LP and Anson Advisors Inc. serve as Co-Investment Advisors to Anson and hold voting and dispositive power over the shares held by Anson. Bruce Winson is the managing member of Anson Management GP LLC, which

is the general partner of Anson Funds Management LP. Moez Kassam and Adam Spears are directors of Anson Advisors Inc. Messrs. Winson, Kassam and Spears each disclaim beneficial ownership of the shares offered hereby except to the extent of their pecuniary interest therein. Anson Funds Management LP and Anson Management GP LLC's address is 5950 Berkshire Lane, Suite 210, Dallas, Texas 75225. Anson Advisors Inc.'s address is 155 University Avenue, Suite 207, Toronto, ON M5H 3B7.

(6) Unless otherwise indicated, the address for each of our executive officers and directors is c/o 11975 El Camino Real, Suite 300, San Diego, California, 92130.

(7) Includes 139,796 shares issuable upon exercise of stock options and 1,750 shares issuable upon exercise of warrants exercisable within 60 days of the Reference Date.

(8) Includes 35,421 shares issuable upon exercise of stock options exercisable within 60 days of the Reference Date.

(9) Includes 37,432 shares issuable upon exercise of stock options exercisable within 60 days of the Reference Date.

(10) Includes 30,701 shares issuable upon exercise of stock options exercisable within 60 days of the Reference Date and 24,575 shares of Common Stock held jointly in a trust controlled by Dr. Xanthopoulos.

(11) Includes 23,751 shares issuable upon exercise of stock options exercisable within 60 days of the Reference Date and 15,373 shares of Common Stock held jointly in a trust controlled by Dr. Wierenga.

(12) Includes 21,543 shares issuable upon exercise of stock options exercisable within 60 days of the Reference Date.

(13) Includes 19,451 shares issuable upon exercise of stock options and 250 shares issuable upon exercise of warrants exercisable within 60 days of the Reference Date.

(14) Includes 20,351 shares issuable upon exercise of stock options exercisable within 60 days of the Reference Date.

(15) Includes 328,446 shares issuable upon exercise of stock options and 2,000 shares issuable upon exercise of warrants exercisable within 60 days of the Reference Date.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Review and Approval of Transactions with Related Persons

Our Board has adopted a written policy and procedures for review, approval and monitoring of transactions involving our Company and "related persons" (directors, executive officers and stockholders owning 5% or greater of our outstanding Common Stock and immediate family members of any of the foregoing). The policy covers any related person transaction that meets the minimum threshold for disclosure in our proxy statement under our policy addressing the relevant SEC rules (generally, transactions involving

amounts exceeding the lesser of $120,000 in which a related person has a direct or indirect material interest). Related person transactions must be approved by the Board or by the Audit Committee of the Board consisting solely of independent directors, which will approve the transaction if they determine that it is in our best interests. The Board or Audit Committee will periodically monitor the transaction to ensure that there are no changes that would render it advisable for us to amend or terminate the transaction.

Transactions with Related Persons

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 sublease has a term of two years and aggregate payments due to the Company of approximately $0.3 million.

The severance arrangements we have entered into with each of our executive officers provide for severance benefits in specified circumstances, as well as benefits in connection with a change in control. See "Payments Upon Termination or Change In Control."

Our Bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the laws of the State of Nevada. Further, we have entered into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances.

Director Independence

Our Board has determined that each of Drs. Xanthopoulos and Wierenga, and Messrs. Ray, Maier and Smith met the definitions of independence under the NASDAQ Marketplace Rules and Section 10A-3 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Accordingly, all of our directors, other than our Chief Executive Officer, Mr. Pascoe, are deemed to be independent.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees for Independent Registered Public Accounting Firm

The following is a summary of the fees billed to the Company by BDO for professional services rendered for the fiscal years ended December 31, 2017 and 2016, respectively:

	2017	2016
Audit Fees [1]***:***	$ 349,000	$ 358,000
Other Fees:		
Audit-Related Fees [2]	—	—
Tax Fees [3]	102,000	24,000
All Other Fees [4]	—	—
Total Other Fees	102,000	24,000
Total All Fees	$ 451,000	$ 382,000

[1] *Audit fees consist of fees for professional services performed by BDO USA, LLP for the audit of our annual financial statements included in our Form 10-K filing and review of financial statements included in our quarterly Form 10-Q filings, reviews of registration statements and issuances of consents,*

comfort letters and services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Consists of fees billed for assurance and related services reasonably related to the performance of the annual audit or review of the Financial Statements (defined above)

(3) Consists of fees billed for tax compliance and consulting

(4) Consists of fees billed for other products and services not described above

Pre-Approval Policies and Procedures

All audit and non-audit services provided by BDO must be pre-approved by the Audit Committee. BDO will provide the Audit Committee with an engagement letter during the first half of the fiscal year, outlining the scope of the proposed services and estimated fees for the fiscal year. Pre-approval may be given for a category of services, provided that (i) the category is reasonably narrow and detailed and (ii) the Audit Committee establishes a fee limit for such category. The Audit Committee may delegate to any other member of the Audit Committee the authority to grant pre-approval of permitted non-audit services to be provided by BDO between Audit Committee meetings; provided, however, that any such pre-approval shall be presented to the full Audit

Committee at its next scheduled meeting. The Audit Committee pre-approved all audit and permitted non-audit services provided by BDO in fiscal 2017 and 2016.

PART IV.

ITEM 15. EXHIBITS

(a) 1. Financial Statements:

The information required by this item is included in Item 8 of Part II of this Form 10-K.

2. Financial Statement Schedules

The information required by this item is included in Item 8 of Part II of this Form 10-K.

3. Exhibits

The following exhibits are incorporated by reference or filed as part of this report:

EXHIBITS NO.	DESCRIPTION
2.1†	Stock Purchase Agreement, dated December 15, 2011, by and among Apricus Biosciences Inc., TopoTarget A/S, and TopoTarget USA, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2012).
2.2	Stock Contribution Agreement, dated June 19, 2012, by and among Apricus Biosciences, Inc., Finesco SAS, Scomedica SA and the shareholders of Finesco named therein (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report Form 8-K filed with the Securities and Exchange Commission on July 13, 2012).
2.3†	Asset Purchase Agreement by and between Apricus Pharmaceuticals USA, Inc. and Biocodex, Inc., dated March 26, 2013 (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2013).
2.4	Amendment to Stock Purchase Agreement, dated June 13, 2014, by and between Apricus Biosciences, Inc. and Samm Solutions, Inc. (doing business as BTS Research and formerly doing business as BioTox Sciences) (incorporated herein by reference to Exhibit 2.1 to the Company's Form 10-Q filed with Securities and Exchange Commission on August 11, 2014).
3.1	Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Registration Statement on Form 10-SB filed with the Securities and Exchange Commission on March 14, 1997).
3.2	Certificate of Amendment to Articles of Incorporation of Apricus Biosciences, Inc., dated June 22, 2000 (incorporated herein by reference to Exhibit 3.2 to the Company's Form 10-K filed with the Securities and Exchange Commission on March 31, 2003).

3.3	Certificate of Amendment to Articles of Incorporation of Apricus Biosciences, Inc., dated June 14, 2005 (incorporated herein by reference to Exhibit 3.4 to the Company's Form 10-K filed with the Securities and Exchange Commission on March 16, 2006).
3.4	Certificate of Amendment to Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc., dated March 3, 2010 (incorporated herein by reference to Exhibit 3.6 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010).
3.5	Certificate of Correction to Certificate of Amendment to Amended and Restated Articles of Incorporation of Apricus Biosciences, Inc., dated March 3, 2010 (incorporated herein by reference to Exhibit 3.7 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010).
3.6	Certificate of Designation for Series D Junior-Participating Cumulative Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-A12GK filed with the Securities and Exchange Commission on March 24, 2011).
3.7	Certificate of Change filed with the Nevada Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2010).
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	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).
3.13	Amendment to the Fourth Amended and Restated Bylaws of Apricus Biosciences, Inc., dated January 11, 2016 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016).
3.14	Second Amendment to the Fourth Amended and Restated Bylaws of Apricus Biosciences, Inc., dated March 3, 2016 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2016).
4.1	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2011).
4.2	Form of Warrant (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on From 8-K filed with the Securities and Exchange Commission on May 24, 2013).

4.3	Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of October 17, 2014, by and among Apricus Biosciences, Inc., NexMed (U.S.A.), Inc., NexMed Holdings, Inc. and Apricus Pharmaceuticals USA, Inc., as borrowers, Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time including Oxford Finance LLC and Silicon Valley Bank. (incorporated herein by reference to Exhibit 4.2 to the Company's Form 8-K filed with the Securities and Exchange Commission on October 20, 2014).
4.4	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 12, 2015).
4.5	Form of Warrant issued to Sarissa Capital Domestic Fund LP and Sarissa Capital Offshore Master Fund LP (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016).
4.6	Form of Warrant issued to other purchasers (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016).
4.7	Form of Warrant Amendment (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016).
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).
4.13	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).
10.1*	NexMed, Inc. 2006 Stock Incentive Plan (incorporated herein by reference to Annex A of the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 6, 2006).
10.2*	NexMed, Inc. Amendment to 2006 Stock Incentive Plan (incorporated herein by reference to Appendix A of the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 18, 2008).
10.3	Asset Purchase Agreement, dated February 3, 2009, by and between Warner Chilcott Company, Inc. and NexMed, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2009).

10.4	License Agreement, dated February 3, 2009, by and between NexMed, Inc. and Warner Chilcott Company, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2009).
10.5*	Apricus Biosciences, Inc. 2012 Stock Long Term Incentive Plan (incorporated by reference to Exhibit A of the Registrant's Definitive Proxy Statement filed on April 6, 2012).
10.6	Settlement Agreement and Release, dated as of September 23, 2013, by and between Apricus Biosciences, Inc. and Topotarget A/S (incorporated by reference to Exhibit 10.1 of Amendment No. 1 to the Company's Registration Statement on Form S-3 (File No. 333-191679) filed with the Securities and Exchange Commission on October 31, 2013).
10.7*	Form of Stock Option Grant Notice and Stock Option Agreement under the Apricus Biosciences, Inc. 2012 Stock Long Term Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 11, 2014).
10.8*	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.2 to the Company's Form 10-Q filed with the Securities and Exchange Commission on August 11, 2014).
10.9†	License Agreement by and between NexMed (U.S.A.), Inc. and Forendo Pharma Ltd., dated as of October 17, 2014 (incorporated herein by reference to Exhibit 10.1 to the Company's Form 8-K filed with the Securities and Exchange Commission on October 20, 2014).
10.10	Stock Issuance Agreement, by and among Apricus Biosciences, Inc., Forendo Pharma Ltd. and Birch & Lake Partners, LLC, dated as of October 17, 2014 (incorporated herein by reference to Exhibit 10.2 to the Company's Form 8-K filed with the Securities and Exchange Commission on October 20, 2014).
10.11	Loan and Security Agreement 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, dated as of October 17, 2014 (incorporated herein by reference to Exhibit 10.3 to the Company's Form 8-K filed with the Securities and Exchange Commission on October 20, 2014).
10.12†	License Agreement and Amendment, by and between NexMed (U.S.A.), Inc. and Warner Chilcott Company, LLC, dated September 9, 2015 (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the Securities and Exchange Commission on November 5, 2015).
10.13	Subscription Agreement dated January 12, 2016, among Apricus Biosciences, Inc., Sarissa Capital Domestic Fund LP and Sarissa Capital Offshore Master Fund LP (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2016).
10.14	Employment Transition Agreement, by and between Apricus Biosciences, Inc. and Dr. Barbara Troupin, dated April 13, 2016 (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 2016).
10.15*	Form of Restricted Stock Unit Award Agreement (incorporated herein by reference to Exhibit 10.6 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 9, 2016).

10.16*	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.7 to the Company's Form 10-Q filed with the Securities and Exchange Commission on May 9, 2016).
10.17	Common Stock Purchase Agreement, by and between the Company and Aspire Capital Fund, LLC, dated as of July 5, 2016 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 6, 2016).
10.18	Registration Rights Agreement, by and between the Company and Aspire Capital Fund, LLC, dated as of July 5, 2016 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 6, 2016).
10.19	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 28, 2016).
10.20*	Amended and Restated Employment Agreement by and between Apricus Biosciences, Inc. and Richard W. Pascoe, December 20, 2016 (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2017).
10.21*	Amended and Restated Employment Agreement, by and between Apricus Biosciences, Inc. and Neil Morton, dated December 20, 2016 (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2017).
10.22*	Amended and Restated Employment Agreement by and between Apricus Biosciences, Inc. and Brian Dorsey, dated December 20, 2016 (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2017).
10.23	Asset Purchase Agreement, dated March 8, 2017, by and between Ferring International Center S.A. and Apricus Biosciences, Inc., NexMed (U.S.A.), Inc., NexMed Holdings, Inc. and NexMed International Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 8, 2017).
10.24	License Agreement, dated March 8, 2017, by and between Apricus Biosciences, Inc. and Ferring International Center S.A. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 8, 2017).
10.25	Transition Services Agreement, dated March 8, 2017, by and between Apricus Biosciences, Inc. and Ferring International Center S.A. (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 8, 2017).
10.26	2012 Stock Long Term Incentive Plan, as amended and restated effective May 17, 2017 (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 13, 2017.
10.27	Form of Registration Rights Agreement (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 September 11, 2017).

10.28	Securities Purchase Agreement dated as of September 10, 2017, between Apricus Biosciences, Inc. and each purchaser named in the signature pages thereto (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 11, 2017).
10.29	Engagement Letter between Apricus Biosciences, Inc. and H.C. Wainwright & Co., LLC, dated as of September 10, 2017 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 11, 2017).
10.30	Non-Employee Director Compensation Policy, effective January 3, 2017.
21	Subsidiaries.
23.1	Consent of BDO USA, LLP, independent registered public accounting firm.
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.

* Management compensatory plan or arrangement
† Confidential treatment has been requested for portions of this exhibit. Those portions have been omitted and filed separately with the Securities and Exchange Commission.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

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

Apricus Biosciences, Inc.

Date: March 1, 2018

/s/ RICHARD W. PASCOE
Richard W. Pascoe
Chief Executive Officer and Secretary

Signature	Title	Date
/s/ RICHARD W. PASCOE Richard W. Pascoe	Chief Executive Officer, Secretary and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 1, 2018
/s/ KLEANTHIS G. XANTHOPOULOS, PH.D. Kleanthis G. Xanthopoulos, Ph.D.	Chairman of the Board of Directors	March 1, 2018
/s/ RUSSELL RAY Russell Ray	Director	March 1, 2018
/s/ PAUL V. MAIER Paul V. Maier	Director	March 1, 2018
/s/ WENDELL WIERENGA Wendell Wierenga, Ph.D.	Director	March 1, 2018
/s/ SANDFORD D. SMITH Sandford D. Smith	Director	March 1, 2018

APRICUS BIOSCIENCES, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

(EFFECTIVE JANUARY 3, 2018)

Non-employee members of the board of directors (the "***Board***") of Apricus Biosciences, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Policy. The cash compensation and option grants described in this Non-Employee Director Compensation Policy shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who may be eligible to receive such cash compensation or equity compensation, unless such Non-Employee Director declines the receipt of such cash compensation or equity compensation by written notice to the Company. This Non-Employee Director Compensation Policy shall remain in effect until it is revised or rescinded by further action of the Board. The terms and conditions of this Non-Employee Director Compensation Policy shall supersede any prior cash or equity compensation arrangements between the Company and its directors.

1. Cash Compensation. Each Non-Employee Director shall be eligible to receive an annual retainer of $40,000 for service on the Board. In addition, a Non-Employee Director serving as:

(a) chairman of the Board shall be eligible to receive an additional annual retainer of $40,000 for such service;

(b) chairman of the Audit Committee shall be eligible to receive an additional annual retainer of $15,000 for such service;

(c) a member (other than the chairman) of the Audit Committee shall be eligible to receive an additional annual retainer of $7,000 for such service;

(d) chairman of the Compensation Committee shall be eligible to receive an additional annual retainer of $12,000 for such service;

(e) a member (other than the chairman) of the Compensation Committee shall be eligible to receive an additional annual retainer of $5,000 for such service;

(f) chairman of the Corporate Governance and Nominating Committee shall be eligible to receive an additional annual retainer of $8,000 for such service; and

(g) a member (other than the chairman) of the Corporate Governance and Nominating Committee shall be eligible to receive an additional annual retainer of $3,000 for such service.

The annual retainers shall be paid by the Company in quarterly installments or more frequently as deemed advisable by the officers of the Company for administrative or other reasons.

2. Option Grants. The Non-Employee Directors shall be granted the following option awards. The option awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2012 Stock Long Term Incentive Plan (the "***2012 Plan***") and shall be granted subject to the execution and delivery of option agreements, including attached exhibits, in substantially the same forms previously approved by the Board, setting forth the vesting schedule applicable to such options awards and such other terms as may be required by the 2012 Plan.

(a) Initial Options. Unless otherwise determined by the Board, a person who is initially elected or appointed to the Board, and who is a Non-Employee Director at the time of such initial election or appointment, shall be automatically granted a non-qualified stock option to purchase 60,000 shares of common stock (subject to adjustment as provided in the 2012 Plan) on the date of such initial election or appointment (each, an "***Initial Option***").

(b) Subsequent Options. A person who is a Non-Employee Director as of the third trading day of each calendar year shall be automatically granted a non-qualified stock option to purchase 35,000 shares of common stock (or, in the case of a Non-Employee Director serving as chairman of the Board, a non-qualified stock option to purchase 50,000 shares of common stock) (subject to adjustment as provided in the 2012 Plan) on such date. The option grants described in this clause 2(b) shall be referred to as "***Subsequent Options***."

(c) Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Option grant pursuant to clause 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from employment with the Company and any parent or subsidiary of the Company, Subsequent Options as described in clause 2(b) above.

(d) Terms of Options Granted to Non-Employee Directors

(i) Exercise Price. The per share exercise price of each option granted to a Non-Employee Director shall equal 100% of the fair market value of a share of common stock on the date the option is granted, as determined under the 2012 Plan.

(ii) Vesting. Initial Options granted to Non-Employee Directors shall become exercisable over four years, with one-fourth of the shares subject to such Initial Options vesting on the first anniversary of the date of grant and the remaining shares subject to such Initial Options vesting in thirty- six equal monthly installments over the three years thereafter, such that each Initial Option shall be 100% vested on the fourth anniversary of the date of grant, subject to the director's continuing service on the Board through such dates. Subsequent Options granted to Non-Employee Directors shall become vested in twelve equal monthly installments of one-twelfth of the shares subject to such option on the first day of each calendar month following the date of the Subsequent Option grant, subject to a director's continuing service on the Board through such dates. Unless otherwise determined by the Board, no portion of an option which is unexercisable at the time of a Non-Employee Director's termination of membership on the Board shall thereafter become exercisable. All Initial Options and Subsequent Options granted to the Non- Employee Directors shall vest in full immediately prior to the occurrence of a Covered Transaction (as defined in the 2012 Plan).

(iii) The term of each option granted to a Non-Employee Director shall be ten years from the date the option is granted.

Exhibit 21

SUBSIDIARIES OF APRICUS BIOSCIENCES, INC.

1. NexMed (U.S.A.), Inc., incorporated in Delaware on June 18, 1997.

2. Apricus Pharmaceuticals USA, Inc. (formerly Topotarget USA, Inc.), incorporated in Delaware on July 12, 2006 and acquired by Apricus Biosciences, Inc. on December 29, 2011.

3. NexMed Holdings, Inc., incorporated in Delaware on February 28, 1997.

4. NexMed International Limited, incorporated in the British Virgin Islands on August 2, 1996.

Consent of Independent Registered Public Accounting Firm

Apricus Biosciences, Inc.
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S3 (Nos. 333-221285, 333-220624, 333-220087, 333-200799, 333-198066, 333-191679, 333-182703, 333-178592, 333-165958, 333-152591, 333-148060, 333-140110, 333-132611, 333-125565, 333-122114, 333-117717, 333-111894, 333-107137, 333-105509, 333-96813, 333-46976 and 333-91957) and Form S-8 (Nos. 333-218368, 333-215419, 333-210040, 333-204748, 333-191680, 333-182704, 333-152284, 333-138598, 333-174392, 333-167365 and 333-93435) of Apricus Biosciences, Inc. of our report dated March 1, 2018, relating to the consolidated financial statement, which appear in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

San Diego, California
March 1, 2018

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Richard W. Pascoe, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 1, 2018

/S/ RICHARD W. PASCOE

Richard W. Pascoe

Chief Executive Officer & Secretary

Exhibit 32.1

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

I, Richard W. Pascoe, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Apricus Biosciences, Inc. on Form 10-K for the Year ended December 31, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of Apricus Biosciences, Inc.

Date: March 1, 2018

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