# 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 For the fiscal year ended December 31, 2016 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 (I.R.S. Employer Identification No.) Incorporation or Organization) 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

requirements for the past 90 days. Yes ■ No □

Name of Exchange on Which Registered
The NASDAQ Capital Market

Common Stock, par value \$.001

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

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

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 $\Box$ No $\Box$

	trant has submitted electronically and posted on its corporate W le 405 of Regulation S-T ( $\S$ 232.405 of this chapter) during the post such files). Yes $\blacksquare$ No $\square$		
	delinquent filers pursuant to Item 405 of Regulation S-K(§229.4's knowledge, in definitive proxy or information statements income the statements in the statements in the statement of the statem		
	istrant is a large accelerated filer, an accelerated filer, a non-accelerated filer" and "smaller reporting company" in Rule 12b-2		See
Large accelerated filer		Accelerated filer	
Non-accelerated filer	(do not check if a smaller reporting company)	Smaller Reporting Company	
Indicate by check mark whether the regis	trant is a shell company (as defined in Rule 12b-2 of the Act).	Yes □ No 🗷	
As of March 7, 2017, 7,741,782 shares of	the common stock, par value \$.001, of the registrant were outsta	anding.	
approximately \$23.6 million. Shares of	on stock held by non-affiliates, based upon the last sale price of common stock held by each officer and director and by each acluded in that such persons may be deemed to be affiliates of ton for other purposes.	person who is known to own 10% or more of	the
	DOCUMENTS INCORPORATED BY REFERENCE	E	
	osed in Part III of this report is incorporated by reference from tatement will be filed no later than 120 days after the end of the		ual

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#### 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 ameded, 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 currently in development. Vitaros is a product candidate in the United States under development for the treatment of erectile dysfunction ("ED"), which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan. RayVa is our product candidate in Phase 2 development for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

On March 8, 2017, we entered into an asset purchase agreement (the "Ferring Asset Purchase Agreement") with Ferring International Center S.A. ("Ferring"), pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for approximately \$11.5 million. In addition to the upfront payment received, Ferring will pay us up to \$0.7 million for the delivery of certain product-related inventory. We are also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations. We used approximately \$6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under our Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (Oxford and SVB are referred to together as the "Lenders"). See "Ferring Asset Purchase Agreement" below for additional information.

# **Growth Strategy**

To develop and commercialize our proprietary product candidates, through these primary initiatives:

Resubmit the new drug application ("NDA") for Vitaros, and if approved by the U.S. Food and Drug Administration ("FDA"), commercialize Vitaros in the United States

We are pursuing U.S. regulatory approval for Vitaros. Our plan is to re-submit the NDA for Vitaros in the United States during the third quarter of 2017. If the NDA is approved by the FDA following resubmission, 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.

Develop, seek regulatory approval for and generate revenue through proprietary products developed in-house or acquired from third-parties

Our product candidate for the treatment of Raynaud's Phenomenon secondary to scleroderma, RayVa, is currently in Phase 2 development. We completed and reported top-line data on the Phase 2a clinical trial for RayVa and we believe the data, coupled with previously generated non-clinical data, supports moving RayVa forward into future clinical trials designed to evaluate symptomatic effects in subjects with Raynaud's secondary to scleroderma.

We also continue to explore business development opportunities whereby we may acquire from third parties certain products in development that complement our existing portfolio.

# **Product Candidates**

#### **Vitaros**

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

Alprostadil is one of several treatment options for ED, 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 its patient-friendly form of administration versus both 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.

With our broad Vitaros expertise and internal know-how, coupled with the proven success in obtaining regulatory approvals for Vitaros in other territories, we believe we are well equipped to pursue regulatory approval for Vitaros in the United States. We

initiated certain activities in 2015 to address issues previously raised by the FDA in a 2008 non-approvable letter, including possible safety risks associated with our proprietary permeation enhancer, NexACT, and certain chemistry, manufacturing and control issues. We plan to re-submit an NDA with the FDA during the third quarter of 2017.

# 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.

# Commercialization of Vitaros

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 in exchange for a \$1.0 million upfront payment and an additional \$1.5 million in potential regulatory milestone payments to Allergan.

If the Vitaros NDA is approved by the FDA upon resubmission, Allergan has the right to exercise a one-time opt-in right to assume all future commercialization activities in the United States. If Allergan exercises its opt-in right, we are eligible to receive up to a total of \$25.0 million in upfront and potential launch milestone payments, plus a high double-digit royalty on Allergan's net sales of the product. If Allergan does not exercise its opt-in right, we may commercialize the product, either through an internally built commercial organization, a contract sales force or by partnering with a pharmaceutical company with established sales and marketing capabilities, and in return will pay Allergan a high double-digit royalty on our net sales of the product.

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

# 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.

RayVa is a topically-applied cream formulation of alprostadil designed to dilate blood vessels, which is combined with a proprietary permeation enhancer NexACT, and applied on-demand to the affected extremities. RayVa received clearance in May 2014 from the FDA to begin clinical studies. We reported results from our Phase 2a clinical trial of RayVa for the treatment of Raynaud's Phenomenon secondary to scleroderma in September 2015, which we believe supports moving RayVa forward into future clinical trials. We expect to finalize the RayVa Phase 2b delivery device and study protocol, explore U.S. and European Union Orphan Designation and seek an ex-U.S. collaboration partner prior to initiating any future clinical studies.

We believe that RayVa presents an attractive commercial opportunity. There is currently no approved therapy for Raynaud's Phenomenon in the United States, representing an unmet medical need. Moreover, because there are only approximately 4,500 rheumatologists treating secondary Raynaud's patients in the United States, we believe we can commercialize RayVa efficiently if we receive FDA approval.

#### **Fispemifene**

In October 2014, we licensed from Forendo Pharma Ltd. the exclusive U.S. rights to develop and commercialize fispemifene, a tissue-specific SERM designed to treat secondary hypogonadism, chronic prostatitis and lower urinary tract symptoms in men.

We released top-line data during the first quarter of 2016 indicating that our Phase 2b clinical trial study for the treatment of secondary hypogonadism did not achieve statistical significance to continue our efforts. However, fispemifene has also been shown to provide other benefits in animal models, such as reduction of prostate inflammation, improved urodynamics, and preservation of bone density, among others and we plan to continue to evaluate fispemifene as a product candidate for other urological conditions.

### **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.

As part of the Ferring Asset Purchase Agreement, we transferred the non-U.S. patents related to DDAIP and DDAIP in combination with alprostodil and received a perpetual, exclusive (even as to Ferring), fully transferable, fully sublicensable, royalty-free, fully paid-up license to such patents 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.

Under the terms of the Ferring Asset Purchase Agreement, Ferring paid us \$11.5 million in cash at the closing. In addition to the upfront payment received, Ferring will pay us up to \$0.7 million for the delivery of certain product-related inventory. We are also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations. We used \$6.6 million of the proceeds from the sale of the Purchased Assets to repay all amounts owed, including applicable termination fees, under the Credit Facility.

As of the closing, 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 will retain 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**

We currently own or in-license approximately 269 issued patents which will expire from 2017 through 2032, approximately, and approximately 98 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 217 issued patents and 58 patent applications from Ferring pursuant to the Ferring Asset Purchase Agreement.

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**

We currently own approximately 31 registered trademarks and 7 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 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, generally two months after 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 an unmet medical need in a serious or life-threatening indication, 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 strategies plan 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, we 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 are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

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 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 products and 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 an

In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on 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 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.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included 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 providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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."

#### Concentration of Credit Risk

Laboratories Majorelle ("Majorelle") and Ferring accounted for approximately 11% and 67%, respectively, of our total revenues during the year ended December 31, 2016. One of these companies comprised 26% of our accounts receivable balance as of December 31, 2016. Hexal AG, an affiliate with the Sandoz Division of the Novartis Group of Companies ("Sandoz") and Ferring accounted for approximately 36% and 47%, respectively, of our total revenues during the year ended December 31, 2015. One of these companies comprised 13% of our accounts receivable as of December 31, 2015.

# **Employees**

As of March 7, 2017, we had 15 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 <a href="http://www.apricusbio.com">http://www.apricusbio.com</a>. 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 assets to Ferring, we do not expect to generate revenue for the foreseeable future and we may not be successful in executing on our near-term business strategy to solely focus on the U.S. Vitaros NDA resubmission.

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

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

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

As of December 31, 2016, we had cash and cash equivalents of approximately \$2.1 million. During the first quarter of 2016, we raised \$10.0 million in equity financings. During the third quarter of 2016, we sold an additional \$1.2 million of our common stock pursuant to a Common Stock Purchase Agreement (the "Aspire Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital"). Also during the third quarter of 2016, we raised an additional \$3.7 million through the sale of common stock and warrants (the "September 2016 Financing"). On March 8, 2017, we entered into the Ferring Asset Purchase Agreement with Ferring, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for approximately \$11.5 million. In addition to the upfront payment received, Ferring will pay us up to \$0.7 million for the delivery of certain product-related inventory. We are also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations. As part of the Ferring Asset Purchase Agreement, we have agreed to indemnify Ferring against losses suffered as a result of our breach of representations and warranties and our other obligations under our asset purchase agreement, and therefore may be liable for a portion of the consideration we received from Ferring.

We currently have an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. Our ability to sell shares using our Form S-3 shelf registration statement is limited by both the amount remaining "on the shelf" and by our public float. As of March 7, 2017, we had approximately \$74.1 million available under our Form S-3 shelf registration statement. However, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates ("public float") is less than \$75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Aspire Purchase Agreement, is limited to an aggregate of one-third of our public float. SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the shelf registration statement. As of March 7, 2017, our public float was approximately \$20.1 million based on 6.3 million shares of our common stock outstanding at a price of \$3.21 per share, which was the closing sale price of our common stock on February 17, 2017. Since our public float is currently less than \$75.0 million, as of March 7, 2017, we may only sell an aggregate of approximately \$6.7 million of securities under our shelf registration statements on Form S-3. Through March 7, 2017, we have sold \$1.2 million through the Aspire Purchase Agreement and \$3.7 million in the September 2016 Financing, leaving \$1.8 million available for sale under our shelf registration statement. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease.

In addition, our stock price must be \$1.00 per share or above in order for us to access the remaining reserve under our committed equity financing facility with Aspire Capital. In no case may we issue more than 1.2 million shares of our common stock (which is equal to approximately 19.99% of our common stock outstanding on the date we entered into Aspire Purchase Agreement) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least \$3.820 per share (a price equal to the most recent consolidated closing bid price of our common stock prior to the execution of the Aspire Purchase Agreement) or (ii) we receive stockholder approval to issue more shares to Aspire Capital. As of March 7, 2017, all of the reserve was available under the committed equity financing facility since our stock price was above \$1.00. However, in connection with our September 2016 equity financing, we agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of the financing.

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

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

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

We only began generating revenues from the commercialization of Vitaros in the third quarter of 2014, we have never been profitable and we have incurred an accumulated deficit of approximately \$316.3 million from our inception through December 31, 2016. We have incurred these losses principally from costs incurred in funding the research, development and clinical testing of our product candidates, from our general and administrative expenses and from our efforts to support commercialization of Vitaros by our partners. As a result of the Ferring Asset Purchase Agreement, we do not expect to generate revenue for the foreseeable future and will continue to incur significant operating losses and capital expenditures for the foreseeable future.

Our ability to generate revenues and become profitable depends, among other things, on (1) the successful development and commercialization of Vitaros in the United States, and (2) the successful development, approval and commercialization of RayVa. If

we are unable to accomplish these objectives, we may be unable to achieve profitability and would need to raise additional capital to sustain our operations.

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

Our financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. During the first quarter of 2017, we received an upfront payment of \$11.5 million from the Ferring Asset Purchase Agreement but a large portion of that was used to payoff our Credit Facility, and we expect to incur further losses for the foreseeable future. These 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, 2016, the Report of Independent Registered Public Accounting Firm included immediately prior to the Consolidated Financial Statements included in our Annual Report on Form 10-K as filed March 13, 2017, includes a going concern explanatory paragraph. Management plans to raise additional funds with the following activities: future financing events; potential partnering events of our existing technology; and by the reduction of expenditures. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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

Our future success depends entirely on our ability to obtain regulatory approval for, and then successfully commercialize our product candidates. The success of Vitaros, our leading product candidate, will require resubmission of a NDA to the FDA in order to gain regulatory approval. An NDA was previously submitted for Vitaros, but the FDA issued a non-approvable letter in 2008 identifying certain deficiencies with the application. Based on feedback during our pre-NDA meetings with the FDA, we believe that the resubmission of the Vitaros NDA will not require additional clinical testing and will not resubmit with such data, but there is no assurance that the FDA will accept the NDA for Vitaros or agree that no additional clinical trials will be required. We plan to resubmit the NDA during the third quarter of 2017. An NDA must include extensive pre-clinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process and may not be obtained on a timely basis, or at all. We have not received marketing approval for any product candidates in the United States, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval for any indication.

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

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

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

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

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

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

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

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

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

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

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

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

- collaborators may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;

- collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals;
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing their own or another party's product candidate; or
- · collaborators may decide to terminate or not to renew the collaboration for these or other reasons.

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

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

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

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

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

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

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

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

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

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

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

# We face a high degree of competition.

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

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

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

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

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

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

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

We cannot be sure our business expenditures will result in the successful acquisition, development or launch of products that will prove to be commercially successful or will improve the long-term profitability of our business. If such business expenditures do

not result in successful acquisition, development or launch of commercially successful brand products, our results of operations and financial condition could be materially adversely affected.

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

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

- · difficulties in achieving identified financial revenue synergies, growth opportunities, operating synergies and cost savings;
- difficulties in assimilating the personnel, operations and products of an acquired company, and the potential loss of key employees;
- difficulties in consolidating information technology platforms, business applications and corporate infrastructure;
- difficulties in integrating our corporate culture with local customs and cultures;
- possible overlap between our products or customers and those of an acquired entity that may create conflicts in relationships or other commitments detrimental to the integrated businesses;
- our inability to achieve expected revenues and gross margins for any products we may acquire;
- the diversion of management's attention from other business concerns;
- risks and challenges of entering or operating in markets in which we have limited or no prior experience, including the unanticipated effects of export controls, exchange rate fluctuations, foreign legal and regulatory requirements, and foreign political and economic conditions; and
- · difficulties in reorganizing, winding-down or liquidating operations if not successful.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### **Industry Risks**

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

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

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

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

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

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

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

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

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

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

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

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay

marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell Vitaros or any product candidates for which we obtain marketing approval.

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

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices
  of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be
  covered under Medicare Part D;
- · extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- · expansion of eligibility criteria for Medicaid programs;
- · expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and a new Patient-Centered Outcomes
  Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such
  research.

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

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

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

Sales of our product candidates, if approved, will depend in part on the availability of coverage and reimbursement from third-party payors such as United States and foreign government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement

policies, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely that could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in current coverage and reimbursement levels for our products and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

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

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

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

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

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

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

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

If we fail to obtain regulatory approval to market our product candidates, we will be unable to sell our product candidates, which will impair our ability to generate additional revenues. To receive approval, we must, among other things, demonstrate with substantial evidence from clinical trials, to the satisfaction of the FDA, that the product candidate is both safe and effective for

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

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

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

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

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

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

We are developing proprietary product candidates for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial

resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

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

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

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

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

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

approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes
  obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable
  health information;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value"

made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

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

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

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

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

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

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, consultant and vendors may engage in fraudulent or other illegal activity for which we may be held responsible. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA and other similar foreign regulatory bodies; including those laws that require the reporting of true, complete and accurate information to the FDA and other similar foreign regulatory bodies, (2) manufacturing standards, (3) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or (4) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales

and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

#### Risks Related to Owning Our Common Stock

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

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

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

On June 2, 2016, we received a notice from NASDAQ stating that we were not in compliance with NASDAQ Listing Rule 5550(b)(2) because our market value of listed securities ("MVLS") was below \$35 million for the previous thirty (30) consecutive business days. In accordance with NASDAQ Marketplace Rule 5810(c)(3), we were granted a 180 calendar day compliance period

until November 29, 2016, to regain compliance with the minimum MVLS requirement. Compliance can be achieved by meeting the \$35 million MVLS requirement for a minimum of 10 consecutive business days during the 180 calendar day compliance period, maintaining a stockholders' equity value of at least \$2.5 million, or meeting the requirement of net income of at least \$500,000 for two of the last three fiscal years. On February 8, 2017, we were notified that our request for continued listing on NASDAQ pursuant to an extension through May 30, 2017 to evidence compliance with all applicable criteria for continued listing on NASDAQ was granted. If we do not regain compliance by May 30, 2017, NASDAQ will provide notice that our shares of Common Stock will be subject to delisting. In addition, NASDAQ has the ability to immediately delist our shares of Common Stock prior to May 30, 2017.

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

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

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

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

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

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

We are authorized to issue 25,000,000 shares of our capital stock, consisting of 15,000,000 shares of our common stock and 10,000,000 shares of our preferred stock. We currently have an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the SEC under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants.

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

# ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

### **ITEM 2. PROPERTIES**

We currently lease one corporate office property in San Diego for approximately 9,000 square feet. We believe that our leased facility is generally well maintained and in good operating condition and suitable and sufficient for our operational needs.

# ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to certain litigation that is either judged to be not material or that arises in the ordinary course of business. 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.

# 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 March 7, 2017, the last reported sales price for our Common Stock on NASDAQ was \$2.77 per share, and we had approximately 88 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 2016 and 2015. These numbers have been adjusted to reflect a 10-for-1 reverse stock split that was effected on October 24, 2016.

	2016				2015							
	 High		Low		High		Low					
First quarter	\$ 15.50	\$	5.80	\$	27.50	\$	10.10					
Second quarter	\$ 6.50	\$	3.20	\$	19.00	\$	12.90					
Third quarter	\$ 4.90	\$	2.80	\$	19.90	\$	11.00					
Fourth quarter	\$ 2.98	\$	2.60	\$	16.80	\$	8.20					

#### 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**

Information about our equity compensation plans is incorporated by reference in Item 12 of Part III of this Annual Report on Form 10-K.

# **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<sup>™</sup> 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 ("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 currently in development. Vitaros is a product candidate in the United States for the treatment of erectile dysfunction ("ED"), which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan. RayVa is our product candidate in Phase 2 development for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

On March 8, 2017, we entered into the Ferring Asset Purchase Agreement with Ferring, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for approximately \$11.5 million. In addition to the upfront payment received, Ferring will pay us up to \$0.7 million for the delivery of certain product-related inventory. We are also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations.

#### **Our Product Candidates**

#### Vitaros

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

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

# RayVa

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

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

# **Results of Operations**

Revenues and gross profit were as follows (in thousands, except percentages):

	Year Ended December 31,					2016 vs 2015					
	2016			2015	-	\$ Change	% Change				
License fee revenue	\$	4,000	\$	3,600	\$	400	11 %				
Royalty revenue		1,088		650		438	67 %				
Product sales		675		589		86	15 %				
Total revenue		5,763		4,839		924	19 %				
Cost of goods sold		511		922		(411)	(45)%				
Cost of Sandoz rights		3,380		_		3,380	N/M				
Gross profit	\$	1,872	\$	3,917	\$	(2,045)	(52)%				

#### Revenue

# License Fee Revenue

The increase in license fee revenue from 2015 to 2016 was due to variations in the timing and amount of payments from our commercialization partners. License fee revenue during the year ended December 31, 2016 consisted primarily of \$3.9 million recognized due to the expansion of our license agreement with Ferring to commercialize Vitaros in certain European and Asia-Pacific countries.

License fee revenue during the year ended December 31, 2015 consisted of \$2.25 million in license fee revenue recognized for the upfront payment related to the Ferring license agreement and \$1.35 million from Sandoz, consisting of \$0.35 million for the expansion of its existing territory into certain Asian and Pacific countries during the first quarter of 2015 and \$1.0 million that had been previously deferred awaiting the satisfaction of a contractual condition in the Sandoz license agreement that was met in the third quarter of 2015.

#### Royalty Revenue

Our royalty revenue is computed based on sales reported to us by our licensee partners on a quarterly basis, which are typically one quarter in arrears, and agreed upon royalty rates for the respective license agreement. Royalty revenue during the years ended December 31, 2016 and 2015 of \$1.1 million and \$0.7 million, respectively, was related to sales of Vitaros by Takeda Pharmaceuticals International GmbH ("Takeda"), Hexal AG, an affiliate with the Sandoz Division of the Novartis Group of Companies ("Sandoz"), Recordati Ireland Ltd. ("Recordati"), Laboratories Majorelle ("Majorelle") and Bracco SpA, now a subsidiary of Dompé Primary S.r.l. ("Dompé") in their respective territories.

# **Product Sales**

Our product sales revenue was comprised of two components: sales of Vitaros to our commercialization partners and sales of component inventory to our manufacturing partners. Historically, we accounted for sales of component inventory to our manufacturing partners on a net basis because these products were returned to us as finished goods that we then sold to our commercialization partners. Since the majority of our former commercialization partners are now buying the finished goods directly from the manufacturers, beginning in 2016, we no longer recognized our component sales on a net basis.

Our product sales revenue was comparable in 2016 as compared to the prior year due to sales of component inventory of \$0.6 million to our third party manufacturers, offset by a decline in product sales of Vitaros in 2016 as our former commercialization partners worked directly with our manufacturers.

We do not expect cash inflows from operations beginning during the second half of 2017 as a result of the closing of the Ferring Asset Purchase Agreement. The timing of future revenues is uncertain.

# Cost of Goods Sold

Our cost of goods sold includes direct material costs associated with the production of inventories. Cost of goods sold also includes the cost of manufactured samples provided to our commercialization partners free of charge. The cost of goods sold for the year ended December 31, 2016 decreased by \$0.4 million as compared to the prior year due to the decrease in the amount of Vitaros produced for sale by us since the majority of our former commercialization partners are working directly with our third-party manufacturers.

#### Cost of Sandoz Rights

Cost of Sandoz rights for the year ended December 31, 2016 includes \$3.4 million incurred as a cost of reacquiring and relicensing the rights to certain territories previously licensed to Sandoz. These territories were relicensed to Ferring in the third quarter of 2016.

# **Operating Expense**

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

	Year Ended December 31,					2016 vs 2015			
	2016		2015		\$ Change		% Change		
Operating expense									
Research and development	\$	6,831	\$	14,649	\$	(7,818)	(53)%		
General and administrative		8,434		10,516		(2,082)	(20)%		
Loss on disposal of assets		14		102		(88)	N/M		
Total operating expense		15,279		25,267		(9,988)	(40)%		
Loss from operations	\$	(13,407)	\$	(21,350)	\$	7,943	(37)%		

# 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 \$7.8 million decrease in R&D expense during the year ended December 31, 2016 as compared to the prior year, resulted primarily from decreases in outside services related to the development of fispemifene, Vitaros and RayVa. This was primarily the result of the discontinuation of development of fispemifene in secondary hypogonadism after the release of top-line data during the first quarter of 2016 indicating that the study did not achieve statistical significance to continue our efforts. Following the announcement, during the second quarter of 2016, we announced a cost-reduction plan that included an approximate 30% reduction in our operating expenses and workforce to better align our workforce with the needs of our business. We completed the reduction in workforce and all employee severance and benefit-related payments in the third quarter of 2016.

We expect R&D expenses will decrease in 2017 as we focus our efforts on the resubmission of a new drug application ("NDA") for Vitaros in the United States.

#### 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 \$2.1 million during the year ended December 31, 2016 as compared to the prior year. These decreases were primarily due to lower professional services expenses, such as legal and accounting expenses, in addition to lower personnel-related expenses incurred during the current year.

# Other Income and Expense

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

	Y	ear Ended	Dec	ember 31,	2016 vs 2015			
		2016	16 2015		<b>\$ Change</b>		% Change	
Other income (expense)	-							
Interest expense, net	\$	(1,022)	\$	(895)	\$	(127)	14%	
Change in fair value of warrant liabilities		7,479		3,236		4,243	131%	
Other financing expenses		(461)		_	\$	(461)	N/M	
Other expense, net		(22)		(14)		(8)	57%	
Total other income	\$	5,974	\$	2,327	\$	3,647	157%	

# 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"). Interest expense increased \$0.1

million during the year ended December 31, 2016 as compared to the prior year due to an increase in interest charges in connection with a second term loan funding of \$5.0 million during the third quarter of 2015.

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

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

In connection with our September 2016 equity financing, we issued warrants to the investors and to the placement agent to purchase up to 811,802 shares and 54,123 shares, of our common stock at an exercise price of \$4.50 and \$4.31 per share, respectively ("the September 2016 Private Placement Warrants" and the "September 2016 Placement Agent Warrants").

The initial fair value of the February 2015 Warrants, January 2016 Warrants, the September 2016 Private Placement Warrants and the September 2016 Placement Agent Warrants of \$5.1 million, \$4.8 million, \$1.6 million and \$0.1 million, respectively, were determined using the Black-Scholes option pricing model on each respective transaction date and recorded as the initial carrying values of the common stock warrant liabilities. The fair value of these warrants is remeasured at each financial reporting period with any changes in fair value recognized as a change in fair value of warrant liability in the accompanying consolidated statements of operations (see notes 1 and 7 to our consolidated financial statements for further details). The change in fair value of warrant liability is primarily due to the increase in our stock price.

# Other Financing Expenses

Other financing expenses were \$0.5 million for the year ended December 31, 2016. Other financing expenses represent the portion of total financing expenses allocated to the warrants issued in our January 2016 and September 2016 financings.

# Liquidity, Capital Resources and Financial Condition

We have experienced net losses and negative cash flows from operations each year since our inception. Through December 31, 2016, we had an accumulated deficit of approximately \$316.3 million and recorded a net loss of approximately \$7.4 million and negative cash flows from operations for the year ended December 31, 2016. These 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 March 8, 2017, we entered into the Ferring Asset Purchase Agreement with Ferring, pursuant to which we sold to Ferring our assets and rights related to Vitaros outside of the United States for approximately \$11.5 million. In addition to the upfront payment received, Ferring will pay us up to \$0.7 million for the delivery of certain product-related inventory. We are also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations. We used approximately \$6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under our Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (Oxford and SVB are referred to together as the "Lenders"). See "Ferring Asset Purchase Agreement" below for additional information.

In September 2016, we completed a registered direct offering of 1,082,402 shares of common stock at a purchase price of \$3.45 per share (the "September 2016 Financing"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from us an unregistered warrant to purchase three quarters of a share of common stock. The warrants have an exercise price of \$4.50 per share, are exercisable six months from the date of issuance, and will expire five and a half years from the initial issuance date. The aggregate gross proceeds from the sale of the common stock and warrants were approximately \$3.7 million, and the net proceeds after deduction of commissions, fees and expenses were approximately \$3.2 million. Under the terms of the securities purchase agreement entered into with such investors, we agreed not to sell any shares of common stock or common stock equivalents for a period of 90 days, which expired on December 27, 2016.

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

of \$0.6 million, in consideration for Aspire Capital entering into the Aspire Purchase Agreement. Additionally, on the Aspire Closing Date, we sold 253,165 shares of our common stock to Aspire Capital for proceeds of \$1.0 million.

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

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

Pursuant to the Aspire Purchase Agreement, in no case may we issue more than 1.2 million shares of our common stock (which is equal to approximately 19.99% of our common stock outstanding on the Aspire Closing Date) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least \$3.820 per share (a price equal to the most recent consolidated closing bid price of our common stock prior to the execution of the Aspire Purchase Agreement) or (ii) we receive stockholder approval to issue more shares to Aspire Capital. Through December 31, 2016, we issued a total of 455,064 shares for gross proceeds of \$1.2 million. As of March 7, 2017, all of the reserve was available under the committed equity financing facility since our stock price was above \$1.00. However, in connection with the September 2016 Financing, we agreed not to make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of the September 2016 Financing. Pursuant to the Aspire Purchase Agreement, we and Aspire Capital terminated the prior Common Stock Purchase Agreement, dated August 12, 2014, between the parties.

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

As of December 31, 2016, we had cash and cash equivalents of approximately \$2.1 million. During the first quarter of 2017, we raised additional funds of \$11.5 million upon the closing of the Ferring Asset Purchase Agreement. In addition to the upfront payment received, Ferring will pay us up to \$0.7 million for the delivery of certain product-related inventory. We are also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations.

We currently have an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the Securities and Exchange Commission ("SEC") under which we may offer from time to time any combination of debt securities, common and preferred stock and warrants. As of March 7, 2017, we had approximately \$74.1 million available under our Form S-3 shelf registration statement. However, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates ("public float") is less than \$75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Aspire Purchase Agreement, is limited to an aggregate of one-third of our public float. SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the shelf registration statement. As of March 7, 2017, our public float was approximately \$20.1 million based on 6.3 million shares of our common stock outstanding at a price of \$3.21 per share, which was the closing sale price of our common stock on February 17, 2017. Since our public float is currently less than \$75.0 million, as of March 7, 2017, we may only sell an aggregate of approximately \$6.7 million of securities under our shelf registration statements on Form S-3. Through March 7, 2017, we have sold \$1.2 million through the Aspire Purchase Agreement and \$3.7 million in the September 2016 Financing, leaving \$1.8 million available for sale

under our shelf registration statement. 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;
- our ability to maintain compliance with the listing requirements of The NASDAQ Capital Market;
- the timing and outcome of our NDA resubmission for Vitaros, and any additional development requirements imposed by the FDA in connection with such resubmission;
- the outcome, costs and timing of clinical trial results for our product candidates;
- the extent and amount of any indemnification claims made by Ferring under the Ferring Asset Purchase Agreement;
- the emergence and effect of competing or complementary products;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we
  may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or
  other intellectual property rights;
- · our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- the trading price of our common stock being above the \$1.00 closing floor price that is required for us to use the committed equity financing facility with Aspire Capital and the restrictions from using such facility from our September 2016 Financing;
- · the trading price of our common stock; and
- · our ability to increase the number of authorized shares outstanding to facilitate future financing events.

Notwithstanding the proceeds from the closing of the Ferring Asset Purchase Agreement, in order to fund our operations during the next twelve months, we will need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity, accessing additional capital under our committed equity financing facility with Aspire Capital, as described above or the completion of a licensing transaction for one or more of our pipeline assets. Specifically, expenses will be significantly reduced as a result of the closing of the Ferring Asset Purchase Agreement. Management's operating plan is now focused almost entirely on the resubmission of the Vitaros NDA during the third quarter of 2017. As part of this plan, we expect minimal expenditures for ongoing scientific research, product development and clinical research. While management is pursuing its near term financial and strategic alternatives it is also, in parallel, continuing to evaluate the timing of implementation of an alternative operating plan and the initiation of further cost reductions.

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

### **Cash Flow Summary**

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

	2016	2015
Net cash provided by (used in) operations		
Net cash used in operating activities	\$ (13,068)	\$ (22,642)
Net cash provided by (used in) investing activities	265	(322)
Net cash provided by financing activities	11,003	15,451
Net decrease in cash	\$ (1,800)	\$ (7,513)

Operating Activities

Cash used in operating activities of \$13.1 million in 2016 was primarily due to a net loss of \$7.4 million net of adjustments to net loss 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.

Cash used in operating activities of \$22.6 million in 2015 was primarily due to net loss of \$19.0 million, adjusted for non-cash items such as the warrant liability revaluation of \$3.2 million, stock based compensation expense of \$1.2 million, and a \$1.0 million decrease in deferred revenue primarily due to the recognition of license fee revenue related to Sandoz of \$1.0 million that had been previously deferred awaiting the satisfaction of a contractual condition in the Sandoz license agreement that was met in the third quarter of 2015. Changes in operating assets and liabilities also contributed to the cash used in operating activities, such as a decrease to accrued expenses primarily due to the decrease in accrued outside R&D services.

### Investing Activities

Cash provided by investing activities of \$0.3 million during 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.

Cash used in investing activities of \$0.3 million in 2015 was related to expenditures for the purchase of fixed assets.

#### Financing Activities

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.

Cash provided by financing activities of \$15.5 million during 2015 was primarily attributable to the \$10.9 million in net proceeds that we received from the issuance of common stock and warrants in our February 2015 equity financing as well as \$5.0 million in proceeds from the funding of a second term loan in July 2015. These inflows of cash were offset by the principal payments of \$0.5 million on our Credit Facility.

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

As of December 31, 2016, 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:

## Revenue Recognition

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

Historically, payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. We consider a variety of factors in determining the appropriate method of accounting under our license agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting. Deliverables under the arrangement will be separate units of accounting, provided (i) a delivered item has value to the customer on a standalone basis; and (ii) the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in our control.

### Multiple Element Arrangements

Historically, we have accounted for revenue arrangements with multiple elements by separating and allocating consideration according to the relative selling price of each deliverable. If an element can be separated, an amount is allocated based upon the relative selling price of each element. We determine the relative selling price of a separate deliverable using the price we charge other customers when we sell that product or service separately. If the product or service is not sold separately and third party pricing evidence is not available, we will use our best estimate of selling price.

#### Milestones

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

## License Fee Revenue

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

#### Product Sales Revenue

Historically, our product sales revenue has been comprised of two components: sales of Vitaros to our former commercialization partners and sales of component inventory to our former manufacturing partners. The supply and manufacturing agreements that existed as of December 31, 2016 with certain of our former commercialization partners for the manufacture and delivery of Vitaros did not permit our licensee partners to return product, unless the product sold to the licensee partner was delivered with a short-dated shelf life as specified in each respective license agreement, if applicable. In those cases, we deferred revenue recognition until the right of return no longer existed, which was the earlier of: (i) evidence that the product had been sold to an end customer or (ii) the right of return had expired. As such, we did not have a sales and returns allowance recorded as of December 31, 2016 and December 31, 2015.

## Royalty Revenue

Historically, we relied on our former commercial partners to sell Vitaros in approved markets and we received royalty revenue from our former commercial partners based upon the amount of those sales. Royalty revenues are computed and recognized on a quarterly basis, typically one quarter in arrears, and at the contractual royalty rate pursuant to the terms of each respective license agreement. We do not expect future cash inflows from operations beginning in the second half of 2017 as a result of the closing of the Ferring Asset Purchase Agreement.

## 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 2016 and 2015 related to our long-lived assets.

### Stock Based Compensation

In preparation of our consolidated financial statements, we calculate the value of stock options issued to employees, non-employee contractors and the Board of Directors and warrants issued to investors and debtholders. The fair value of each option and warrant is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model is a generally accepted method of estimating the fair value of stock options and warrants.

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 the February 2015, January 2016 and September 2016 financings are classified as liabilities in the accompanying consolidated balance sheets as they contain provisions that require us to maintain active registration of the shares underlying such warrants, which is considered outside of our control. The warrants were recorded at fair value using the Black-Scholes option pricing model. The fair value of these warrants is re-measured at the end of each financial reporting period with any changes in fair value being recognized as change in fair value of warrant liability in the accompanying consolidated statements of operations.

Of the inputs used to value the outstanding common stock warrant liabilities as of December 31, 2016, the most subjective input is our estimate of expected volatility.

#### Clinical Trial Accruals

In preparation of our consolidated financial statements, we are required to estimate our expenses resulting from our obligations under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract, and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our financial statements by matching those expenses with the period in which the services and efforts are expended. We account for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models, taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period. As of December 31, 2016, there have been no material adjustments to our prior period estimates of expenses for clinical trials.

## 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 40% 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, 2016 and 2015.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

## ITEM 8. FINANCIAL STATEMENTS

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### Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders Apricus Biosciences, Inc.

We have audited the accompanying consolidated balance sheets of Apricus Biosciences, Inc. (the "Company") as of December 31, 2016 and 2015 and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 negative working capital and has suffered recurring losses and negative cash flows 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.

As described in Note 11, subsequent to December 31, 2016, the Company entered into an asset purchase agreement for the sale of its assets and rights to Vitaros outside of the United States.

/s/ BDO USA, LLP San Diego, California

March 13, 2017

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

	December 31, 2016		I	December 31, 2015	
Assets					
Current assets					
Cash	\$	2,087	\$	3,887	
Accounts receivable		530		519	
Restricted cash		_		280	
Inventories		764		469	
Prepaid expenses and other current assets		253		1,062	
Total current assets	'	3,634		6,217	
Property and equipment, net		1,006		1,290	
Other long term assets		60		274	
Total assets	\$	4,700	\$	7,781	
Liabilities and stockholders' deficit					
Current liabilities					
Note payable, net	\$	6,650	\$	9,401	
Accounts payable		960		1,580	
Accrued expenses		3,070		3,343	
Accrued compensation		614		1,223	
Deferred revenue		_		137	
Total current liabilities		11,294		15,684	
Warrant liabilities		846		1,841	
Other long term liabilities		76		200	
Total liabilities		12,216		17,725	
Commitments and contingencies					
Stockholders' deficit					
Preferred stock, \$.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2016 and 2015		_		_	
Common stock, \$.001 par value, 15,000,000 shares authorized, 7,733,205 and 5,041,526 issued and outstanding as of December 31, 2016 and 2015, respectively		8		5	
Additional paid-in-capital		308,784		298,926	
Accumulated deficit		(316,308)		(308,875)	
Total stockholders' deficit		(7,516)		(9,944)	
Total liabilities and stockholders' deficit	\$	4,700	\$	7,781	

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,		
	2016		2015
License fee revenue	\$ 4,000	\$	3,600
Royalty revenue	1,088		650
Product sales	 675		589
Total revenue	5,763		4,839
Cost of goods sold	511		922
Cost of Sandoz rights	 3,380		
Gross profit	1,872		3,917
Operating expense			
Research and development	6,831		14,649
General and administrative	8,434		10,516
Loss on disposal of assets	 14		102
Total operating expense	 15,279		25,267
Loss before other expense	(13,407)		(21,350)
Other income (expense)			
Interest expense, net	(1,022)		(895)
Change in fair value of warrant liabilities	7,479		3,236
Other financing expenses	(461)		_
Other expense, net	(22)		(14)
Total other income	5,974		2,327
Net loss	\$ (7,433)	\$	(19,023)
Basic and diluted loss per common share	\$ (1.14)	\$	(3.83)
Weighted average common shares outstanding used for basic and diluted loss per share	 6,516,662		4,972,858

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

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

		ear Ended nber 31,
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (7,433)	\$ (19,02
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	289	30
Non-cash interest expense	362	26
Stock-based compensation expense	1,747	1,21
Warrant liabilities revaluation	(7,479)	(3,23
Loss on disposal of fixed assets	10	10
Other financing expenses	461	_
Other		5
Changes in operating assets and liabilities:		
Accounts receivable	(11)	15
Inventories	(295)	(19
Prepaid expenses and other current assets	809	(46
Other assets	40	(1
Accounts payable	(509)	60
Accrued expenses	(442)	(1,27
Accrued compensation	(360)	11
Deferred revenue	(137)	(1,08
Other liabilities	(120)	(15
Net cash used in operating activities	(13,068)	(22,64
Cash flows from investing activities:		
Purchase of fixed assets, net	(18)	(33
Proceeds from the sale of property and equipment	3	
Release of restricted cash	280	1
Net cash provided by (used in) investing activities	265	(32
Cash flows from financing activities:		
Issuance of common stock and warrants, net of offering costs	14,121	10,86
Proceeds from issuance of notes payable	_	5,00
Repayment of principal on notes payable	(3,113)	(49
Repayment of capital lease obligations	(5)	(
Proceeds from the exercise of stock options	_	8
Net cash provided by financing activities	11,003	15,45
Net decrease in cash	(1,800)	(7,51
Cash, beginning of period	3,887	11,40
Cash, end of period	\$ 2,087	\$ 3,88
Supplemental disclosure of cash flow information:		<b>A</b> = -
Cash paid for interest	\$ 646	\$ 53
Cash paid for income taxes	\$ 6	\$
Non-cash investing and financing activities:		
Accrued transaction costs for 2016 financing activities	\$ (236)	\$ (17
46		

Issuance of restricted stock to settle bonus liability	\$ 249 \$	_
Issuance of 54,123 Placement Agent warrants	\$ 103 \$	_
Issuance of 15,244 common stock warrants to debtholders	\$ — \$	75

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

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

	Common Stock (Shares)	Common Stock (Amount)		Additional Paid-In Capital		Accumulated Deficit			Total ockholders' eficit) Equity		
Balance as of December 31, 2014	4,434	\$	4	\$	291,767	\$	(289,852)	\$	1,919		
Stock-based compensation expense	_		_		1,210		_		1,210		
Stock options exercises	4		_		83	83 —			83		
Issuance of common stock and warrants, net of offering costs	604		1		5,866		_		5,867		
Net loss	_		_		_		(19,023)		(19,023)		
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 to settle bonus liability	_		_	249 —		_		.9 —			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)		

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 currently in development. Vitaros is a product candidate in the United States for the treatment of erectile dysfunction ("ED"), which the Company in-licensed from Warmer Chilcott Company, Inc., now a subsidiary of Allergan plc ("Allergan"). RayVa is the Company's product candidate in Phase 2 development for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which the Company owns worldwide rights.

### **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.

On October 21, 2016, the Company effected a one-for-ten (1:10) reverse stock split whereby the Company (i) decreased the number of authorized shares of Common Stock by a ratio equal to one-for-ten (1:10) (the "Reverse Split Ratio"), and (ii) correspondingly and proportionately decreased, by a ratio equal to the Reverse Split Ratio, the number of issued and outstanding shares of Common Stock (the "Reverse Stock Split"). Under Nevada law, because the Reverse Stock Split was approved by the Board of Directors in accordance with Nevada Revised Statutes ("NRS") Section 78.207, no stockholder approval was required. NRS Section 78.207 provides that the Company may effect the Reverse Stock Split without stockholder approval if (x) both the number of authorized shares of Common Stock and the number of outstanding shares of Common Stock are proportionally reduced as a result of the Reverse Stock Split, (y) the Reverse Stock Split does not adversely affect any other class of stock of the Company and (z) the Company does not pay money or issue scrip to stockholders who would otherwise be entitled to receive a fractional share as a result of the Reverse Stock Split. As described herein, the Company has complied with these requirements. The Reverse Stock Split was effected by the Company filing a Certificate of Change pursuant to NRS Section 78.209 with the Secretary of State of the State of Nevada on October 21, 2016, which became effective at 5 p.m. PST on October 21, 2016. Upon effectiveness of the Reverse Stock Split, the number of shares of the Company's common stock (x) issued and outstanding decreased from approximately 77.3 million shares (as of October 21, 2016) to approximately 7.7 million shares; (y) reserved for issuance upon exercise of outstanding options, restricted stock units and warrants decreased from approximately 4.9 million, 1.2 million and 23.2 million shares, respectively, to approximately 0.5 million, 0.1 million and 2.3 million shares, respectively, and (z) reserved but unallocated under the Company's current equity incentive plans decreased from approximately 0.1 million common shares to approximately 0.01 million common shares. In connection with the Reverse Stock Split, the Company's total number of authorized shares of common stock decreased from 150.0 million to 15.0 million. The number of authorized shares of preferred stock remained unchanged at 10.0 million shares. Following the Reverse Stock Split, certain reclassifications have been made to prior period financial statements to conform to the current period's presentation. The Reverse Stock Split was applied retroactively to both periods presented to adjust the number and per share amounts of common stock shares, options, restricted stock units and warrants for the Company's common stock. The Company adjusted shareholders' equity to reflect the Reverse Stock Split by reclassifying an amount equal to the par value of the shares eliminated by the split from common stock to additional paid-in capital, resulting in no net impact to shareholders' equity on the Company's consolidated balance sheets for both periods presented. The Company's shares of common stock commenced trading on a split-adjusted basis on October 24, 2016. Proportional adjustments for the reverse stock split were made to the Company's outstanding stock options, warrants and equity incentive plans for both periods presented.

## 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 whether revenue recognition criteria have been met, accounting for clinical trials, 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. The Company had an accumulated deficit of approximately \$316.3 million and negative working capital of \$7.7 million as of December 31, 2016 and reported a net loss of approximately \$7.4 million and negative cash flows from operations for the year ended December 31, 2016. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company has principally been financed through the sale of its common stock and other equity securities, debt financings, up-front payments received from commercial partners for the Company's products under development, and through the sale of assets. As of December 31, 2016, the Company had cash and cash equivalents of approximately \$2.1 million.

On March 8, 2017, the Company entered into the 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 \$11.5 million. In addition to the upfront payment received, Ferring will pay the Company up to \$0.7 million for the delivery of certain product-related inventory. The Company is also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations. The Company has retained the U.S. development and commercialization rights for Vitaros, which the Company has licensed from Allergan. The Company used approximately \$6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed, including applicable termination fees, under its Loan and Security Agreement (the "Credit Facility") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (Oxford and SVB are referred to together as the "Lenders").

In September 2016, the Company completed a registered direct offering of 1,082,402 shares of common stock for gross proceeds of approximately \$3.7 million (the "September 2016 Financing"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase three quarters of a share of common stock. See note 7 for further description. Under the terms of the securities purchase agreement entered into with such investors, the Company agreed not to sell any shares of common stock or common stock equivalents for a period of 90 days, which expired on December 27, 2016.

In July 2016, the Company and Aspire Capital Fund, LLC ("Aspire Capital") entered into a Common Stock Purchase Agreement (the "Aspire Purchase Agreement"), which provides that Aspire Capital is committed to purchase, if the Company chooses to sell and at the Company's discretion, an aggregate of up to \$7.0 million of shares of the Company's common stock over the 24-month term of the Aspire Purchase Agreement. The Aspire Purchase Agreement can be terminated at any time by the Company by delivering notice to Aspire Capital. On July 5, 2016 (the "Aspire Closing Date"), the Company delivered to Aspire Capital a commitment fee of 151,899 shares of the Company's common stock at a value of \$0.6 million (the "Commitment Shares") in consideration for Aspire Capital entering into the Aspire Purchase Agreement. Additionally, on the Aspire Closing Date, the Company sold 253,165 shares of the Company's common stock to Aspire Capital for proceeds of \$1.0 million. Through December 31, 2016, 455,064 shares of the Company's common stock have been sold for gross proceeds of \$1.2 million. However, in connection with the September 2016 Financing, the Company agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of the September 2016 Financing. Pursuant to the Aspire Purchase Agreement, the Company and Aspire Capital terminated the prior Common Stock Purchase Agreement, dated August 12, 2014, between the parties. See note 7 for additional discussion of the Aspire Purchase Agreement.

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

The Company currently has an effective shelf registration statement on Form S-3 (No. 333-198066) filed with the Securities and Exchange Commission ("SEC") under which it may offer from time to time any combination of debt securities, common and preferred stock and warrants. As of December 31, 2016, the Company had approximately \$74.1 million available under its Form S-3 shelf registration statement. Under current SEC regulations, at any time during which the aggregate market value of the Company's common stock held by non-affiliates ("public float"), is less than \$75.0 million, the amount it can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Aspire Purchase Agreement, is limited to an aggregate of one-third of the Company's public float. SEC regulations permit the Company to use the highest closing sales price of the Company's common stock (or the average of the last bid and last ask prices of the Company's common stock) on any day within 60 days of sales under the shelf registration statement. As the Company's public float was less than \$75.0 million as of December 31, 2016, 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;
- its ability to maintain compliance with the listing requirements of The NASDAQ Capital Market;
- the timing and outcome of the Company's NDA resubmission for Vitaros, and any additional development requirements imposed by the FDA in connection with such resubmission;
- the outcome, costs and timing of clinical trial results for its product candidates;
- the extent and amount of any indemnification claims made by Ferring under the Ferring Asset Purchase Agreement;
- · the emergence and effect of competing or complementary products;
- its ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- its ability to retain its current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that it has or may establish;
- the trading price of the Company's common stock being above the \$1.00 closing floor price that is required for the Company to use the committed equity financing facility with Aspire Capital and the restrictions from using such facility from its September 2016 Financing;
- the trading price of its common stock; and
- its ability to increase the number of authorized shares outstanding to facilitate future financing events.

On May 10, 2016, the Company received a written notification from NASDAQ indicating that it was not in compliance with NASDAQ Listing Rule 5550(a) (2), as the closing bid price for its Common Stock had been below \$1.00 per share for 30 consecutive business days. Pursuant to NASDAQ Listing Rule 5810(c)(3)(A), the Company was 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, its shares of common stock continued to be listed and traded on NASDAQ. To regain compliance, the closing bid price of the Company's 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 its common stock, effected on October 21, 2016. On November 8, 2016, the Company received a letter from NASDAQ confirming that it is in compliance with NASDAQ Listing Rule 5550(a)(2).

On June 2, 2016, the Company received a notice from NASDAQ stating that the Company 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. In accordance with NASDAQ Marketplace Rule 5810(c)(3), the Company was 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, the Company was notified that the Company's 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. If the Company is not within compliance by May 30, 2017, NASDAQ will provide notice that shares of the Company's Common Stock will be subject to delisting.

Notwithstanding the proceeds from the closing of the Ferring Asset Purchase Agreement, in order to fund its operations during the next twelve months from the issuance date, the Company will need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity, accessing additional capital under its committed equity financing facility with Aspire Capital, as described above or the completion of a licensing transaction for one or more of the Company's pipeline assets. Specifically, expenses will be significantly reduced as a result of the closing of the Ferring Asset Purchase Agreement. Management has a future operating plan in place that will focus almost entirely on the resubmission of the NDA during the third quarter of 2017. As part of this plan, there would be minimal expenditures for ongoing scientific research, product development or clinical research. While management is actively pursuing it's near term financial and strategic alternatives it is also, in parallel, continuing to evaluate the timing of implementation of the alternative operating plan and the initiation of the identified reductions.

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

#### Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash, accounts receivable, 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. Further, based on the borrowing rates currently available for loans with similar terms, the Company believes the carrying amount of its Credit Facility as of December 31, 2016 approximated its relative fair value.

## **Cash Equivalents**

Cash equivalents represent all highly liquid investments with an original maturity date of three months or less from the purchase date.

### **Restricted Cash**

Short term restricted cash of \$0.3 million as of December 31, 2015 was primarily restricted cash held in escrow for environmental remediation services to be performed and for taxes in connection with the sale of our New Jersey facility, both of which are the obligation of the Company. The Company recorded a liability for the environmental remediation as well as tax liabilities, both of which were included in accrued liabilities as of December 31, 2015. These obligations were classified as current restricted cash and current liabilities as of December 31, 2015, respectively and were satisfied and released from restricted cash and current liabilities during 2016.

## Concentration of Credit Risk

From time to time, the Company maintains cash in bank accounts that exceed the FDIC insured limits. The Company has not experienced any losses on its cash accounts. It performs credit evaluations of its customers, but generally does not require collateral to support accounts receivable. Ferring and Laboratories Majorelle ("Majorelle") accounted for approximately 67% and 11% and of its total revenues, respectively, during the year ended December 31, 2016. Majorelle comprised 26% of the Company's accounts receivable balance as of December 31, 2016. Hexal AG, an affiliate with the Sandoz Division of the Novartis Group of Companies ("Sandoz") and Ferring accounted for approximately 36% and 47% of its total revenues, respectively, during the year ended December 31, 2015. Sandoz comprised 13% of the Company's accounts receivable as of December 31, 2015.

Historically, the Company's revenues have been primarily generated from its foreign commercialization partners and its foreign manufacturers, which subjected it to various risks, including but not limited to currency exchange fluctuations, longer payment cycles, and greater difficulty in accounts receivable collection. The Company is also subject to general geopolitical risks, such as political, social and economic instability, and changes in diplomatic and trade relations.

### **Inventory Valuation**

Inventories are stated at the lower of cost or net realizable value on a first in, first out basis. These inventories consisted of the different component parts for commercialization of Vitaros. Historically, the Company has capitalized inventory costs associated with its products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. If applicable, the Company will periodically analyze its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and will write-down such inventories as appropriate.

## **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. The Company records 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 is recorded as deferred rent in accrued liabilities.

#### 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 assets and liabilities measured at fair value on a recurring basis (in thousands) as of December 31, 2016 and 2015, respectively:

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, 2016	\$	\$	\$ 846	\$ 846
Balance as of December 31, 2015		\$ —	\$ 1,841	\$ 1,841

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 for 2016 and 2015:

	December 31, 2016		December 31, 2015
Risk-free interest rate	1.64%-1.9	9%	1.82%
Volatility	77.25%-81.0	3%	83.00%
Dividend yield		<u>%</u>	%
Expected term	4.75-6	.17	6.13
Weighted average fair value	\$ 0	.49 \$	6.09

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

	Warran	t liabilities
Balance as of December 31, 2015	\$	1,841
Issuance of warrants in connection with January 2016 financing		4,807
Issuance of warrants in connection with September 2016 financing		1,677
Change in fair value measurement of warrant liability		(8,155)
Repricing of February 2015 warrants in connection with January 2016 financing		676
Balance as of December 31, 2016	\$	846

Of the inputs used to value the outstanding common stock warrant liabilities as of December 31, 2016, 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 are presented in the current 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, January 2016 and September 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.

### **Revenue Recognition**

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

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

### Multiple Element Arrangements

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

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

## Milestones

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

## License Fee Revenue

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

for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement.

#### Product Sales Revenue

Historically, the Company's product sales revenue was comprised of two components: sales of Vitaros to its former commercialization partners and sales of component inventory to its former manufacturing partners. The supply and manufacturing agreements that existed as of December 31, 2016 with certain of its former commercialization partners for the manufacture and delivery of Vitaros did not permit the Company's former commercialization partners to return product, unless the product sold to the licensee partner was delivered with a short-dated shelf life as specified in each respective license agreement, if applicable. In those cases, the Company deferred revenue recognition until the right of return no longer existed, which was the earlier of: (i) evidence that the product had been sold to an end customer or (ii) the right of return had expired. As such, the Company did not have a sales and returns allowance recorded as of December 31, 2016 and December 31, 2015.

Historically, sales of component inventory to the former manufacturing partners was accounted for on a net basis since these products were ultimately returned to the Company as finished goods and were then sold onto commercialization partners. Beginning in 2016, the majority of the Company's former commercialization partners bought the finished goods directly from the manufacturers and therefore, the Company's component sales were no longer recognized on a net basis. During the year ended December 31, 2016, the Company recognized \$0.6 million, respectively, in revenues from component sales to its third party manufacturers.

#### Royalty Revenue

Historically, the Company relied on its former commercial partners to sell Vitaros in approved markets and received royalty revenue from its former commercial partners based upon the amount of those sales. Royalty revenues are computed and recognized on a quarterly basis, typically one quarter in arrears, and at the contractual royalty rate pursuant to the terms of each respective license agreement.

#### Cost of Goods Sold

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

## Cost of Sandoz Rights

In July 2016, the Company and Sandoz mutually agreed to terminate the exclusive license agreement, previously entered into by the parties in February 2012, as amended and restated in December 2013 and further amended in February 2015, granting Sandoz exclusive rights to market Vitaros for the treatment of ED in certain European and Asia-Pacific countries, as well as any ancillary agreements related to the manufacture or sale of the product. Sandoz, as a result of the mutual termination, received a one-time payment of \$2.0 million upon transfer of the marketing authorization in Germany to Ferring in August 2016. Sandoz is eligible to receive an additional \$1.5 million to be paid in six equal installments, of which \$0.3 million was paid through December 31, 2016. As the rights acquired from Sandoz were immediately transferred to Ferring, the present value of the payments to Sandoz of \$3.4 million was expensed and included as Cost of Sandoz Rights in the consolidated statements of operations. In connection with the Ferring Asset Purchase Agreement, Ferring has assumed any remaining installment payments owed to Sandoz.

## **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.

## Loss Per Common Share

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

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

	Year Ended D	ecember 31,
	2016	2015
Outstanding stock options	415	405
Outstanding warrants	2,318	884
Restricted stock	115	_
	2,848	1,289

#### **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.

### **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,			
	2016		2015	
Europe (1)	\$ 5,093	\$	2,239	
Canada	570		_	
Asia Pacific (1)	100		350	
Latin America (1)	_		2,250	
	\$ 5,763	\$	4,839	

(1) 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. See note 2 for further details related to these agreements.

All of the Company's net long-lived assets were located in the United States and Canada as of December 31, 2016 and 2015. As of December 31, 2016 and 2015, approximately \$0.7 million and \$0.9 million of the Company's net long-lived assets were located in Canada.

## **Recent Accounting Pronouncements**

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash, which requires entities to include in their cash and cash-equivalent balances in the statement of cash flows those amounts that are deemed to be restricted cash and restricted cash equivalents. The ASU does not define the terms "restricted cash" and "restricted cash equivalents." The amendments are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company does not believe the adoption of this standard will have a material effect 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 is currently evaluating whether 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. On July 9, 2015, the FASB voted to defer the effective date by one year to December 15, 2017 for interim and annual reporting periods beginning after that date. Early adoption of ASU 2016-10 is permitted but not before the original effective date (annual periods beginning after December 15, 2017). The Company is currently in the initial stages of evaluating its various contracts and revenue streams subject to these updates but has not completed its assessment and therefore has not yet concluded on whether the adoption of this update will have a material effect on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard simplifies income tax consequences and the classification of awards as either equity or liabilities and the classification on the statement of cash flows. The Company adopted this ASU for the year ended December 31, 2016 and it had no material impact on the Company's 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.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* ("ASU 2015-11"). ASU 2015-11 affects reporting entities that measure inventory using first-in, first-out or average cost. Specifically, ASU 2015-11 requires that inventory be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The Company adopted this ASU for the year ended December 31, 2016 and it had no material impact on the Company's consolidated financial statements and related disclosures.

In April 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. This ASU requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company adopted this ASU on January 1, 2016 and this ASU had no material impact on the Company's consolidated financial statements and related disclosures. ASU 2015-03 requires a retroactive method of adoption, and therefore, the Company reclassified approximately \$0.07 million from other current assets to the current portion of its note payable as of December 31, 2015. Approximately \$0.05 million was reclassified from other expense to interest expense for the year ended December 31, 2015.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will require management to assess, at each annual and interim reporting period, the entity's ability to continue as a going concern and, if management identifies conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, to disclose in the notes to the entity's financial statements the principal conditions or events that raised substantial doubt about the entity's ability to continue as a going concern, management's evaluation of their significance, and management's plans that alleviated or are intended to alleviate substantial doubt about the entity's ability to continue as a going concern. The Company adopted this guidance to assess going concern as of December 31, 2016 and has updated its liquidity disclosures as necessary.

### 2. VITAROS LICENSING AND DISTRIBUTION AGREEMENTS

The following table summarizes the total revenue by the Company's former commercialization partner recorded in the Company's consolidated statements of operations (in thousands):

	Year Ended December 31,				
	 2016 (1)				
Ferring	\$ 3,850	\$	2,250		
Majorelle	630		245		
Takeda Pharmaceuticals International GmbH ("Takeda") (2)	214		398		
Recordati Ireland Ltd. ("Recordati")	184		194		
Bracco SpA, now a subsidiary of Dompé Primary S.r.l. ("Dompé")	150		16		
Elis Pharmaceuticals Limited ("Elis")	100		_		
Sandoz (3)	16		1,736		
	\$ 5,144	\$	4,839		

- (1) Product sales to the Company's contract manufacturers are not shown in the table above since they were unrelated to any of the Company's commercialization partners. License revenue from parties unrelated to Vitaros are also not shown above.
- (2) Effective April 2016, the Company terminated its license agreement with Takeda, transitioning the commercialization of Vitaros in Takeda's prior territory to Ferring
- (3) Effective July 2016, the Company terminated its license agreement with Sandoz, transitioning the commercialization of Vitaros in Sandoz's prior territory to Ferring

#### Ferring

In October 2015, the Company entered into a distribution agreement with Ferring, granting Ferring the exclusive right to commercialize Vitaros for the treatment of ED in certain countries in Latin America. In April 2016, the Company extended the exclusive license grant to include the United Kingdom. In July 2016, the Company further extended the exclusive license grant to include certain European and Asian-Pacific countries (the "Expanded Territories").

The product has been approved for the treatment of ED in Argentina, Austria, Belgium, Denmark, Finland, Germany, Iceland, Luxemburg, Mexico, the Netherlands, Norway, Sweden, Switzerland and the United Kingdom.

The Company received an upfront payment in April 2016 of \$0.3 million from Ferring for the rights in the United Kingdom. This upfront payment was deemed to be related to the license deliverable and was recognized in its statement of operations upon completion of the transfer of the United Kingdom marketing authorization, which occurred in August 2016. The Company received an upfront payment in July 2016 of \$2.0 million from Ferring for the rights in the Expanded Territories. In August 2016, the Company received a milestone payment of \$1.6 million from Ferring upon the transfer of the Germany marketing authorization from Sandoz to Ferring. The Company concluded that the fair value of the Vitaros license for the United Kingdom and the Expanded Territories was equal to the sum of the upfront payments and the milestone payment upon the transfer of the Germany marketing authorization (a total of \$3.9 million) and recognized this as license fee revenue in its statement of operations during the third quarter of 2016. The rights the Company licensed to Ferring in July 2016 were purchased from Sandoz as discussed below.

On March 8, 2017, the Company entered into the Ferring Asset Purchase Agreement with Ferring, pursuant to which it sold to Ferring its assets and rights related to Vitaros outside of the United States for approximately \$11.5 million. In addition to the upfront payment received, Ferring will pay the Company up to \$0.7 million for the delivery of certain product-related inventory. The Company is also eligible to receive two additional quarterly payments totaling \$0.5 million related to transition services, subject to certain limitations. The Company has retained the U.S. development and commercialization rights for Vitaros, which the Company has licensed from Allergan. In connection with the Ferring Asset Purchase Agreement, the Company and Ferring also entered into a new license agreement with respect to certain intellectual property rights necessary to or useful for Ferring's exploitation of the purchased rights outside of the United States and for the Company's exploitation of certain retained rights with respect to Vitaros in the United States and the Company's proprietary drug delivery technology and other related pipeline assets.

## Majorelle

In November 2013, the Company entered into a license agreement with Majorelle, granting Majorelle the exclusive right to market Vitaros for the treatment of ED in France, Monaco and certain countries in Africa. To date, the product has been approved for the treatment of ED in France, where it was launched in May 2015.

Pursuant to the Ferring Asset Purchase Agreement described above, the Company assigned the license agreement with Majorelle and any related ancillary agreements to Ferring.

#### Dompé

In December 2010, the Company entered into a license agreement with Dompé, granting Dompé the exclusive right to commercialize Vitaros for the treatment of ED in Italy. The product has been approved for the treatment of ED in Italy, where it was launched in September 2015.

Pursuant to the Ferring Asset Purchase Agreement described above, the Company assigned the license agreement with Dompé and any related ancillary agreements to Ferring.

### Sandoz

In July 2016, the Company and Sandoz mutually agreed to terminate the exclusive license agreement, previously entered into by the parties in February 2012, as amended and restated in December 2013 and further amended in February 2015, granting Sandoz exclusive rights to market the Company's Vitaros drug for the treatment of ED in certain European and Asian-Pacific countries, as well as any ancillary agreements related to the manufacture or sale of the product. Sandoz, as a result of the mutual termination, received a one-time payment of \$2.0 million upon transfer of the marketing authorization in Germany to Ferring in August 2016. Sandoz is eligible to receive an additional \$1.5 million to be paid in equal quarterly installments in 2016 and 2017, of which \$0.3 million was been paid through December 31, 2016. This commitment was transferred to Ferring as part of the Ferring Asset Purchase Agreement entered into on March 8, 2017.

#### Recordati

In February 2014, the Company entered into a license agreement with Recordati, granting Recordati the exclusive right to market Vitaros for the treatment of ED in certain European and African countries. Recordati launched the product as Virirec™ in Spain in May 2015, as Vytaros® in Poland in September 2016, and as Vitaros in Portugal, Ireland, the Czech Republic and Slovakia in September 2016.

Pursuant to the Ferring Asset Purchase Agreement described above, the Company assigned the license agreement with Recordati and any related ancillary agreements to Ferring.

#### Mylan

In January 2012, the Company entered into a license agreement with Abbott Laboratories Limited, now a subsidiary of Mylan, granting Mylan the exclusive right to commercialize Vitaros for the treatment of ED in Canada. The product was approved for the treatment of ED by Health Canada in late 2010.

Pursuant to the Ferring Asset Purchase Agreement described above, the Company assigned the license agreement with Mylan and any related ancillary agreements to Ferring.

### Elis

In January 2011, the Company entered into a license agreement with Elis, granting Elis the exclusive rights to market Vitaros for the treatment of ED in the United Arab Emirates, Oman, Bahrain, Qatar, Saudi Arabia, Kuwait, Lebanon, Syria, Jordan, Iraq and Yemen. The product has been approved for the treatment of ED in Lebanon. In July 2016, the Company earned a milestone of \$0.1 million in conjunction with the Lebanon approval, which was recorded as revenues in the statement of operations during the third quarter of 2016.

Pursuant to the Ferring Asset Purchase Agreement described above, the Company assigned the license agreement with Elis and any related ancillary agreements to Ferring.

## Neopharm

In February 2011, the Company entered into a license agreement with Neopharm, granting Neopharm the exclusive rights to market Vitaros for the treatment of ED in Israel and the Palestinian Territories.

Pursuant to the Ferring Asset Purchase Agreement described above, the Company assigned the license agreement with Neopharm and any related ancillary agreements to Ferring.

## Global Harvest

In June 2009, the Company entered into a license agreement with Global Harvest, granting Global Harvest the exclusive rights to market Vitaros for the treatment of ED in Australia and New Zealand.

Pursuant to the Ferring Asset Purchase Agreement described above, the Company assigned the license agreement with Global Harvest to Ferring.

### 3. ALLERGAN IN-LICENSING AGREEMENT

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

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

Since the intangibles acquired in the license agreement do not have alternative future use, all costs incurred including the upfront payment were treated as research and development expense. The Company recorded research and development expense of approximately \$1.05 million during the third quarter of 2015, which represented the upfront payment made as well as transaction costs incurred. No other payments were due to Allergan in 2016 or 2015.

### 4. FORENDO IN-LICENSING AGREEMENT

In October 2014, the Company entered into a license agreement 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. This payment was previously considered deferred consideration and was recorded as a liability as of December 31, 2014 because the agreement was not terminable prior to the payment. The liability was released upon payment in April 2015.

The Company may be obligated to pay Forendo up to an additional \$42.5 million based on completion of certain regulatory milestones in the United States, 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.

### 5. OTHER FINANCIAL INFORMATION

#### Inventory

Inventory is comprised of the following (in thousands):

	 December 31,				
	2016		2015		
Raw materials	\$ 336	\$	145		
Work in process	428		324		
Inventory, net	\$ 764	\$	469		

## **Property and Equipment**

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

	December 31,			
		2016		2015
Leasehold improvements	\$	20	\$	43
Machinery and equipment		1,569		1,591
Capital lease equipment		76		76
Computer software		130		130
Furniture and fixtures		29		35
Total property and equipment		1,824		1,875
Less: accumulated depreciation and amortization		(818)		(585)
Property and equipment, net	\$	1,006	\$	1,290

Depreciation expense totaled \$0.3 million for each of the years ended December 31, 2016 and 2015.

#### **Accrued Expenses**

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

		December 31,			
	·	2016		2015	
Sandoz termination payments	\$	1,170	\$	_	
Professional fees		1,154		466	
Outside research and development services		370		2,228	
Deferred compensation		134		178	
Other		242		471	
Accrued expenses, net	\$	3,070	\$	3,343	

## Other Long Term Liabilities

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

	<u></u>	December 31,			
	2	016		2015	
Deferred compensation	\$		\$	135	
Deferred rent		76		65	
Other long term liabilities, net	\$	76	\$	200	

## 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. Pursuant to the terms of the Credit Facility, the Lenders have a senior-secured lien on all of the Company's current and future assets, other than its intellectual property. The Lenders have the right to declare the term loans immediately due and payable in an event of default under the Credit Facility, which includes, 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 and December 31, 2015, 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, the entire principal amount of the Credit Facility was presented in short-term liabilities for both periods presented.

The first term loan had an annual interest rate of 7.95%. The second term loan had an annual interest rate of 8.01%. 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 maturity date, which was October 1, 2018 (the "Maturity Date"). Per the agreement, the Company had the option to prepay the outstanding balance of the term loans in full prior to the Maturity Date, subject to a prepayment fee of up to 3%. 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.

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 recorded as a discount to the principal balance and is being amortized over the life of the Credit Facility using the effective interest method.

The Company's notes payable balance consisted of the following (in thousands):

	December 31,			
	 2016		2015	
Notes payable, principal	\$ 6,392	\$	9,505	
Add: accretion of final payment fee	378		171	
Less: unamortized debt discount	(120)		(275)	
	 6,650		9,401	
Less: current portion of notes payable, net	(6,650)		(9,401)	
	\$ _	\$	_	

The debt issuance costs, accretion of the final payment and amortization of the warrants were included in interest expense in the Company's consolidated statements of operations as of December 31, 2016 and 2015. The Company recognized interest expense related to the Credit Facility of \$1.0 million and \$0.8 million during the years ended December 31, 2016 and 2015, respectively.

On March 8, 2017, pursuant to the Ferring Asset Purchase Agreement, the Company 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.

## 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, 600 are designated as Series C 6% Cumulative Convertible Preferred Stock and 50,000 have been designated as Series D Junior Participating Cumulative Preferred Stock. No shares of preferred stock were outstanding as of December 31, 2016 or 2015.

### **Common Stock Offerings**

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"). The Private Placement Warrants have an exercise price of \$4.50 per share, are exercisable six months from the initial issuance date, and will expire five and a half years from the initial issuance date. The aggregate gross proceeds from the sale of the common stock and warrants were approximately \$3.7 million, and the net proceeds after deduction of commissions, fees and expenses were 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 the Placement Agent Warrants have substantially the same terms as the Private Placement Warrants, except that the Placement Agent Warrants were accounted for as a

liability and fair-valued at the issuance date. Out of the total gross proceeds, \$1.6 million was allocated to the Private Placement Warrants based on their fair value, and the rest was allocated to the common stock and recorded in equity. Also, in connection with the transaction, the Company incurred cash-based transaction costs of approximately \$0.5 million and non-cash transaction costs of \$0.1 million related to the fair value of the Placement Agent Warrants. These costs were allocated between the warrant liability and the equity based on their relative values at the issuance date. The transaction costs that were allocated to the warrant liability of approximately \$0.3 million were expensed and included in Other Financing Expenses on the 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.

The total initial \$1.7 million fair value of the Private Placement Warrants and the Placement Agent Warrants were determined using the Black-Scholes option pricing model and were recorded as the initial carrying value of the common stock warrant liabilities. The Private Placement Warrants were initially valued using assumptions of a 5.5 year expected term, a 73.7% volatility, a 0.0% annual rate of dividends and a 1.2% risk-free interest rate. The Placement Agent Warrants were initially valued using assumptions of a 5.0 year expected term, a 74.8% volatility, a 0.0% annual rate of dividends and a 1.1% risk-free interest rate. 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 Private Placement Warrants and the Placement Agent Warrants become exercisable in March 2017 and have expiration dates of March 2022 and September 2021, respectively. Under the terms of the securities purchase agreement entered into with such investors, the Company agreed not to sell any shares of common stock or common stock equivalents for a period of 90 days, which expired on December 27, 2016.

## 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. Pursuant to the Aspire Purchase Agreement, the Company and Aspire Capital terminated the prior Common Stock Purchase Agreement, dated August 12, 2014, between the parties.

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

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

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

Pursuant to the Aspire Purchase Agreement, in no case may the Company issue more than 1.2 million shares of the Company's common stock (which is equal to approximately 19.99% of the Company's common stock outstanding on the Aspire Closing Date) to Aspire Capital unless (i) the average price paid for all shares issued under the Aspire Purchase Agreement is at least \$3.820 per share (a price equal to the most recent 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 agreement through December 31, 2016, the Company has issued a total of 0.5 million shares for gross proceeds of \$1.2 million. As of March 7, 2017, all of the reserve was available under the committed equity financing facility since the Company's stock price was above \$1.00, subject to SEC limitations under the Form S-3 Registration Statement. However, in connection with the September 2016 Financing, the Company agreed to not make any further sales under the Aspire Purchase Agreement for a period of twelve months following the date of the September 2016 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.

## February 2015 Financing

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

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

Pursuant to the January 2016 financing, the exercise price of the February 2015 Warrants was reduced from \$18.20 per share to \$8.80 per share. The modification to the February 2015 warrants resulted in a charge to other financing costs of approximately \$0.7 million for the year ended December 31, 2016.

As of December 31, 2016, the total aggregated fair value of the Private Placement Warrants, the Placement Agent Warrants, the January 2016 Warrants and the February 2015 Warrants was \$0.8 million.

### Warrants

A summary of warrant activity during the year ended December 31, 2016 is as follows:

	Common Shares Issuable upon Exercise	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2015	883,737	\$ 29.79	3.6
Issued	1,434,109	\$ 6.20	5.6
Outstanding as of December 31, 2016	2,317,846	\$ 15.19	4.6
Exercisable as of December 31, 2016	1,451,921	\$ 21.57	4.2

In connection with the funding of the second term loan under the Credit Facility during the third quarter of 2015, the Company issued warrants to the Lenders to purchase up to an aggregate of 15,244 shares of common stock at an exercise price of \$16.40 per share.

The following table shows the number of outstanding warrants by exercise price and date of expiration as of December 31, 2016:

Shares Issuable Upon Exercise	Exercise Price	Expiration Date
246,914	\$ 52.50	February 2017
300,000	\$ 34.00	May 2018
428,620	\$ 8.80	January 2023
441,763	\$ 8.80	March 2023
19,380	\$ 12.90	October 2024
15,244	\$ 16.40	July 2025
811,802	\$ 4.50	March 2022
54,123	\$ 4.31	September 2021
2,317,846		

## 8. EQUITY COMPENSATION PLANS

As of December 31, 2016, 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, 2016, an aggregate of 0.9 million shares of common stock were authorized under the 2012 Plan, of which 0.1 million common shares were available for future grants.

## **Stock Options**

A summary of stock option activity during the year ended December 31, 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Aggregate Intrinsic Value
Outstanding as of December 31, 2015	405,348	\$ 19.46	8.2	\$ _
Granted	166,695	10.57	_	_
Cancelled	(157,178)	15.92	_	_
Outstanding as of December 31, 2016	414,865	\$ 17.23	7.6	\$
Vested and expected to vest as of December 31, 2016	391,010	\$ 17.54	7.5	\$ _
Exercisable as of December 31, 2016	228,392	\$ 20.88	6.7	\$ _
	65			

As of December 31, 2016 and 2015, there were 228,392 and 173,133 options exercisable, respectively. There were no options exercised during the year ended December 31, 2016 and the aggregate intrinsic value of options exercised during the year ended December 31, 2015 was approximately \$14,000. The total fair value of awards vested during the years ended December 31, 2016, and 2015 was \$1.3 million in each year.

#### Stock Awards

A summary of restricted stock unit activity during the year ended December 31, 2016 is as follows:

	Number of Shares	eighted Average Grant Date Fair Value
Nonvested as of December 31, 2015	\$ 	\$ _
Granted	143,416	\$ 5.29
Vested	(17,842)	\$ 5.86
Forfeited	(10,459)	\$ 6.28
Nonvested as of December 31, 2016	\$ 115,115	\$ 5.11

#### **Share-Based Compensation**

The value of stock 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 years ended December 31, 2016 and 2015:

	Year Ended	Year Ended December 31,				
	2016		2015			
Risk-free interest rate	1.36%-1.78%	1.36%-1.78%				
Volatility	72.35%-80.02%		66.85%-101.54%			
Dividend yield	<b>—</b> %		<u> </u>			
Expected term	5.25-6.08 years		5.25-6.46 years			
Forfeiture rate	11.33%		11.54%			
Weighted average fair value	\$ 7.23	\$	10.67			

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 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, 2016, there was \$1.4 million in unrecognized compensation cost related to non-vested stock options expected to be recognized over a weighted average period of 2.2 years. As of December 31, 2016, there was \$0.6 million in unrecognized compensation cost related to non-vested stock awards expected to be recognized over a weighted average period of 1.8 years.

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	Deceml	ber 31,
	2016		2015
Research and development	\$ 534	\$	199
General and administrative	1,213		1,011
	\$ 1,747	\$	1,210

#### 9. INCOME TAXES

The Company has incurred losses since inception, which have generated net operating loss carryforwards and capital loss carryforwards of approximately \$200.6 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 2036 for federal income tax purposes and beginning in 2030 through 2034 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, 2016 of \$4.0 million and \$0.9 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.

The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such a study, and the fact that there may be additional such ownership changes in the future. If the Company has experienced an ownership change at any time since its formation, utilization of the loss carryforwards would be subject to an annual limitation under Section 382, which is 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, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the loss carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit under authoritative accounting guidance. Once such a study is completed, any loss carryforwards that will expire prior to utilization as a result of such limitations will be 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.

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

		December 31,		
	·	2016		2015
Net operating tax loss and capital loss carryforwards	\$	68,672	\$	65,783
Capitalized research and development costs		5,270		2,890
Research and development tax credits		1,659		950
Deferred compensation		46		106
Other accruals and reserves		1,214		1,092
Basis of intangible assets		3,870		4,197
Total deferred tax asset		80,731		75,018
Less valuation allowance		(80,731)		(75,018)
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, 2016 and 2015 of approximately \$70.3 million and \$66.7 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 2013 to 2016 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, 2016 and 2015, 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, 2016 and 2015, are as follows (in thousands):

	Year Ended December 31,			
		2016		2015
Beginning balance	\$	2,882	\$	2,822
Change in current period positions		68		56
Change in prior period positions		97		4
Ending balance	\$	3,047	\$	2,882

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, 2016 and 2015, are as follows:

	Year Ended December 31,		
	2016	2015	
Federal statutory tax rate	(34)%	(34)%	
Valuation allowance	81 %	45 %	
Prior year true-ups	(5)%	(1)%	
Revaluation of warrants	(34)%	(6)%	
Permanent differences	(4)%	(2)%	
Tax credits	(4)%	(2)%	
Income tax expense	—%	<u> </u>	

For the years ended December 31, 2016 and 2015, the Company's effective tax rate differs from the federal statutory rate principally due to various permanent tax differences, including the revaluation of warrants, and the impact of the valuation allowance recorded against the Company's deferred tax assets.

#### 10. 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.

For each of the years ended December 31, 2016 and 2015, rent expense totaled \$0.5 million.

Future minimum rental payments under operating leases as of December 31, 2016 are as follows (in thousands):

2017	\$ 32	23
2018	36	64
2019	37	75
2020	3	32
Total	\$ 1,09	94

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.

### 11. SUBSEQUENT EVENT

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"). 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 is 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 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 the closing and will pay the value of inventory related to the Products equal to an amount up to \$0.7 million, subject to certain customary adjustments and limitations. Additionally, the Company is eligible to receive two additional quarterly payments totaling \$0.5 million for transition services, subject to certain limitations. 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.

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. The Company will retain all liabilities associated with the Purchased Assets arising prior to the closing date.

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

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

### 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,

2016. Based on this evaluation, our CEO concluded that our disclosure controls and procedures were effective as of December 31, 2016.

### 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, 2016 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, 2016, 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, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

This Item 9B amends the Current Report on Form 8-K we filed on March 8, 2017 (the "Form 8-K") in order to file the proforma information required by Item 9.01(b)(1) of Form 8-K. The Form 8-K is amended by this filing. The unaudited proforma condensed consolidated information which give effect to the Ferring Asset Purchase Agreement is attached hereto as Exhibit 99.2 and incorporated herein by reference.

## PART III.

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERANCE

### 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. The other information required by this item is incorporated herein by reference to the Proxy Statement under the sections "Executive Compensation," "Directors Compensation," and "Board of Directors and Committees; Corporate Governance" to be filed with the Securities and Exchange Commission in connection with our 2017 Annual Meeting of Stockholders.

## ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to the Proxy Statement under the sections "Executive Compensation," "Directors Compensation," and "Board of Directors and Committees; Corporate Governance."

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

The information required by this item is incorporated herein by reference to the Proxy Statement under the section "Security Ownership of Certain Beneficial Owners and Management."

## ITEM 13, CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated herein by reference to the Proxy Statement under the sections "Certain Relationships and Related Party Transactions" and "Board of Directors and Committees; Corporate Governance."

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated herein by reference to the Proxy Statement under the section "Fees for Independent Registered Public Accounting Firm."

## 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 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 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).
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3.9	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).
3.10	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).
3.11	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).
3.12	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).
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 Warmer 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.
10.21*	Amended and Restated Employment Agreement, by and between Apricus Biosciences, Inc. and Neil Morton, dated December 20, 2016.
10.22*	Amended and Restated Employment Agreement by and between Apricus Biosciences, Inc. and Brian Dorsey, dated December 20, 2016.
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).
21	Subsidiaries.
23.1	Consent of BDO USA, LLP, independent registered public accounting firm.

31.1	Chief Executive Officer's Certificate, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Chief Executive Officer's Certificate, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Pro Forma Financial Information
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)

<sup>(1)</sup> 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 13, 2017	/s/ RICHARD W. PASCOE					
	Richard W. Pascoe Chief Executive Officer and Secretary					
Signature	Title	Date				
/s/ RICHARD W. PASCOE	Chief Executive Officer, Secretary and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 13, 2017				
Richard W. Pascoe	<u> </u>					
/s/ KLEANTHIS G. XANTHOPOULOS, PH.D.	Chairman of the Board of Directors	March 13, 2017				
Kleanthis G. Xanthopoulos, Ph.D.	<del></del>					
/s/ RUSTY RAY	Director	March 13, 2017				
Rusty Ray						
/s/ PAUL V. MAIER	Director	March 13, 2017				
Paul V. Maier						
/s/ WENDELL WIERENGA	Director	March 13, 2017				
Wendell Wierenga, Ph.D.						
/s/ SANDFORD D. SMITH	Director	March 13, 2017				
Sandford D. Smith						

## **APRICUS BIOSCIENCES, INC.**

## AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (the "<u>Agreement</u>") is dated as of December 20, 2016 (the "Effective Date"), by and between Richard W. Pascoe ("<u>Employee</u>") and Apricus Biosciences, Inc., a Nevada corporation ("<u>Apricus</u>," and collectively with its subsidiaries, the "<u>Company</u>").

#### RECITALS

- A. Employee became a full-time employee of the Company on March 18, 2013 and Employee and Apricus entered into an Employment Agreement, dated March 18, 2013 (the "Original Agreement").
- B. The Board of Directors of Apricus (the "Board") believes it is in the best interests of the Company and its shareholders to retain Employee and provide incentives to Employee to serve the Company as set forth herein.
- C. The Board further believes that it is necessary to provide Employee with certain benefits upon certain terminations of Employee's employment, which benefits are intended to provide Employee with financial security and provide sufficient income and encouragement to Employee to remain employed with the Company, notwithstanding the possibility of a Change in Control.
- D. To accomplish the foregoing objectives, the Board has directed the Company, upon execution of this Agreement by Employee, to agree to the terms provided in this Agreement.

It is therefore agreed as follows:

- 1. At-Will Employment. The Company and Employee acknowledge that Employee's employment is and shall continue to be at-will, as defined under applicable law, and that Employee's employment with the Company may be terminated by either party at any time for any or no reason. This "at-will" nature of Employee's employment shall remain unchanged during Employee's tenure as an employee and may not be changed, except in an express writing signed by Employee and a duly authorized director of the Company. If Employee's employment terminates for any reason, Employee shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law.
- <u>Duties.</u> Employee shall be employed by the Company as Chief Executive Officer and Secretary of the Company, and, as such, Employee shall faithfully perform for the Company the duties of said office and shall perform such other duties of an executive, managerial or administrative nature as shall be specified and designated from time to time by the Board. Additionally, the Employee will serve as a Class II director, subject to re-election by the Company's shareholders in accordance with the Company's certificate of incorporation, Bylaws and Corporate Governance Guidelines. While employed by the Company, Employee shall not, without the prior consent of the Board, (i) render to others services of any kind for compensation or engage in any other business activity that would materially interfere with the performance of Employee's duties under this Agreement, or (ii) directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. Employee shall not invest in any company or business that competes in any manner with the Company; *provided that*, Employee may, without violating this section, own as a passive investment, shares of capital stock of a publicly-traded corporation that engages in competition if (i) such

shares are actively traded on an established national securities market in the United States, (ii) the number of shares of such corporation's capital stock that are beneficially owned (directly or indirectly) by Employee represents less than one percent of the total number of shares of such corporation's outstanding capital stock, and (iii) Employee is not otherwise associated directly or indirectly with such corporation or with any affiliated of such corporation. Employee may also participate freely in the affairs of any recognized charitable organizations, non-profit or in any community affairs of Employee's choice. Employee shall be subject to and comply with the policies and procedures generally applicable to employees of the Company to the extent the same are not inconsistent with any term of this Agreement.

- 3. <u>Compensation</u>. As compensation for the services to be rendered by Employee to the Company pursuant to this Agreement, Employee shall be paid the following compensation and other benefits, which compensation and benefits may be paid or provided by Apricus or NexMed (U.S.A.), Inc., Apricus' wholly-owned subsidiary.
- (a) <u>Salary</u>. The Company shall pay Employee a salary at an initial rate of \$487,396.00 per annum, which may be adjusted by the Compensation Committee of the Board from time to time (the "<u>Annual Salary</u>"), and shall be paid in accordance with the customary payroll practices of the Company applicable to employees.
- (b) **Bonus**. For each fiscal year completed during the term hereof, Employee shall be eligible to participate in any annual bonus plan provided by the Company for its employees generally, as in effect from time to time. Employee's annual target bonus shall be 50% of the Annual Salary (the "<u>Target Bonus</u>"), with the actual amount of the bonus, if any, to be determined by the Board or the Compensation Committee in accordance with the terms of the bonus plan. Employee shall be required to be employed with the Company on the date that bonuses are paid in order to be entitled to receive such payment.
- Benefits. During the term hereof, Employee shall be eligible for inclusion, to the extent permitted by law, as a fultime employee of the Company or any of its subsidiaries, in any and all of the following plans, programs, and policies in effect at the time, subject to the terms and conditions of such plans, programs and policies: (i) pension, profit sharing, savings, and other retirement plans and programs, (ii) life and health (medical, dental, hospitalization, short-term and long-term disability) insurance plans and programs, (iii) stock option and stock purchase plans and programs, (iv) accidental death and dismemberment protection plans and programs, (v) travel accident insurance plans and programs, (vi) vacation policy (Employee shall accrue paid vacation per calendar year based on seniority in accordance with Company's policies), and (vii) other plans and programs sponsored by the Company or any subsidiary for employees generally, including any and all plans and programs that supplement any or all of the foregoing types of plans or programs. Nothing in this Agreement shall preclude the Company or any of its subsidiaries or affiliates from terminating or amending any employee benefit plan, program or policy from time to time after the date of this Agreement.
- (d) <u>Expenses</u>. The Company shall pay or reimburse Employee for all ordinary and reasonable out-of-pocket expenses actually incurred (and, in the case of reimbursement, paid) by Employee during the term of employment in the performance of Employee's services under this Agreement; *provided* that Employee submits proof of such expenses, with the properly completed forms as prescribed from time to time by the Company, no later than thirty (30) days after such expenses have been so incurred or as otherwise provided in accordance with the standard practices of the Company.
  - 4. **Benefits Upon Termination of Employment.**
- (a) <u>Severance Upon Involuntary Termination.</u> In the event that Employee suffers an Involuntary Termination, and subject to the limitations set forth in Section 6, then in addition to any accrued

but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination, Employee will be entitled to receive severance benefits as follows: (i) the Company shall pay to Employee in one lump sum an amount equal to (A) twelve (12) months of Employee's Annual Salary that Employee was receiving immediately prior to the Involuntary Termination; plus (B) any accrued but unpaid bonus for the calendar year preceding Employee's termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee be employed on the date the bonus is to be paid) (as determined by the Compensation Committee of the Board in its discretion); plus (C) 100% of the Employee's Target Bonus for the year in which the date of Employee's Involuntary Termination occurs; (ii) full acceleration of the vesting of all equity awards held by Employee at the time of the Involuntary Termination, including any options, restricted stock, restricted stock units or other awards; and (iii) reimbursement for the cost of continuation of health insurance benefits provided to Employee immediately prior to the Involuntary Termination pursuant to the terms of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or other applicable law through the earliest to occur of (A) twelve (12) months following the Involuntary Termination, (B) the date Employee becomes eligible for coverage under health and/or dental plans of another employer, or (C) the date upon which Employee is no longer eligible for such COBRA or other benefits under applicable law through the company cannot provide the foregoing benefits in a manner that is exempt from Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") or that is otherwise compliant with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), instead of providing the reimbursements as set forth in clause (i

(b) <u>Disability or Death.</u> If Employee should suffer a Permanent Disability, the Company may terminate Employee's employment hereunder upon ten (10) or more days' prior written notice to Employee. If Employee should pass away during the term of this Agreement, Employee's employment shall be deemed terminated on Employee's date of death. For purposes of this Agreement, a "<u>Permanent Disability</u>" shall be deemed to have occurred only when Employee has qualified for benefits (including satisfaction of any applicable waiting period) under the Company's or a subsidiary's long-term disability insurance arrangement. In the event of the termination of Employee's employment hereunder by reason of Permanent Disability or death, the Employment Term shall end on the day of such termination and the Company shall pay, no later than the first payroll date following Employee's termination, to Employee or Employee's legal representative (in the event of Permanent Disability), or any beneficiary or beneficiaries designated by Employee's death), a single lump sum payment of: (i) any accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination; and (ii) any amounts owing, but not yet paid, pursuant to Section 3(d) hereof. In addition, upon a termination under this Section 4(b): (1) Employee shall receive a prorata bonus for the calendar year in which such termination occurs, equal to Employee's Target Bonus for the calendar year of said 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 three hundred sixty-five (365); (2) Employee shall receive any accrued but unpaid bonus for the calendar year preceding Employee's termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee's termination, to the extent that all criteria for such bonus

so that they expire one year after the date of Employee's termination under this Section 4(b). Subject to Section 6(c), the amounts payable pursuant to clauses (1) and (2) above shall be paid within five (5) days following the date Employee's Release becomes effective and irrevocable (or, in the event of Employee's death, within five (5) days following the date of Employee's death).

- (c) Severance Upon a Change in Control. In the event that Employee suffers an Involuntary Termination within the 12-month period following the effective date of a Change in Control, then in addition to all accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of Employee's termination of employment, Employee will be entitled to receive severance benefits as follows: (i) the Company shall pay to Employee in one lump sum an amount equal to the greater of (A) eighteen (18) months of Employee's Annual Salary that Employee was receiving immediately prior to the Involuntary Termination or (B) eighteen (18) months of Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control, (ii) the Company shall pay to Employee in one lump sum (A) any accrued but unpaid bonus for the calendar year preceding Employee's termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee be employed on the date the bonus is to be paid) (as determined by the Compensation Committee of the Board in its discretion), plus (B) 100% of the Employee's Target Bonus for the year in which the date of Employee's Involuntary Termination occurs; (iii) full acceleration of the vesting of all equity awards held by Employee at the time of the Involuntary Termination, including any options, restricted stock units or other awards; and (iv) reimbursement for the cost of continuation of health insurance benefits provided to Employee immediately prior to the Involuntary Termination or the date u
- (d) <u>Termination for Cause</u>. Notwithstanding any other provision of this Agreement, if Employee's employment is terminated for Cause at any time, then Employee shall not be entitled to receive payment of any severance benefits or any continuation or acceleration of stock award vesting and all of Employee's stock awards shall remain subject to all applicable forfeiture provisions and transfer restrictions. Employee will receive payment(s) for all accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination.
- (e) <u>Voluntary Resignation</u>. If Employee voluntarily resigns from the Company under circumstances which do not constitute an Involuntary Termination, then Employee shall not be entitled to receive payment of any severance benefits, or option acceleration, or relinquishment of forfeiture and transfer restrictions. Employee will receive payment(s) for all accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination.
  - 5. **Definition of Terms.** The following terms referred to in this Agreement shall have the following meanings:

- "Cause" means any of the following: (i) Employee's theft, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, or falsification of any Company or affiliate documents or records; (ii) Employee's material failure to abide by a Company's or affiliate's code of conduct or other policies (including without limitation, policies relating to confidentiality and reasonable workplace conduct); (iii) Employee's unauthorized use, misappropriation, destruction or diversion of any tangible or intangible asset or corporate opportunity of the Company or an affiliate (including, without limitation, Employee's improper use or disclosure of confidential or proprietary information); (iv) any intentional act by Employee which has a material detrimental effect on the Company or an affiliate's reputation or business; (v) Employee's repeated failure or inability to perform any reasonable assigned duties after written notice from the Company or an affiliate (including, without limitation, habitual absence from work for reasons other than illness), and a reasonable opportunity to cure, such failure or inability; (vi) any material breach by Employee of any employment or service agreement between Employee and the Company or an affiliate, which breach is not cured pursuant to the terms of such agreement; or (vii) Employee's conviction (including any plea of guilty or *nolo contendere*) of any criminal act involving fraud, dishonesty, misappropriation or moral turpitude, or which materially impairs Employee's ability to perform his duties with the Company or an affiliate.
  - (b) "Change in Control" means the occurrence of any of the following:
    - an Ownership Change Event or a series of related Ownership Change Events (collectively, a "<u>Transaction</u>") in which the shareholders of Apricus immediately before the Transaction do not retain immediately after the Transaction, in substantially the same proportions as their ownership of shares of Apricus' voting stock immediately before the Transaction, direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding voting securities of Apricus or such surviving entity immediately outstanding after the Transaction, or, in the case of an Ownership Change Event the entity to which the assets of Apricus were transferred (the "<u>Transferee</u>"), as the case may be; or
    - (ii) the liquidation or dissolution of Apricus.
      - For purposes of Section 5(b)(i), indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own Apricus or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Board shall have the right to determine whether multiple sales or exchanges of the voting securities in Apricus or multiple Ownership Change Events are related, and its determination shall be final, binding and conclusive. The Board may also, but need not, specify that other transactions or events constitute a Change in Control.
  - (c) "Involuntary Termination" shall include (i) any termination of Employee's employment by the Company (other than for Cause and other than as a result of Employee's death or Permanent Disability) or (ii) Employee's voluntary termination within sixty (60) days following the occurrence of any of the following events without Employee's written consent: (i) a material reduction or material change in job duties, responsibilities, authority and requirements inconsistent with Employee's position with the Company and Employee's prior duties, responsibilities and requirements or a material negative change in Employee's reporting relationship (in each case, excluding any changes as a result of the loss of any interim or temporary roles within the Company),

including, without limitation, the Employee ceasing to be the Chief Executive Officer of a publicly-traded company following the occurrence of a Change in Control; (ii) a material reduction of Employee's base compensation (other than in connection with a general decrease in base salaries for most officers of the Company or successor corporation); or (iii) Employee's refusal to relocate to a facility or location more than fifty (50) miles from the Company's current location, provided that Employee will not resign due to such change, reduction or relocation without first providing the Company with written notice of the event or events constituting the grounds for Employee's voluntary resignation within thirty (30) days of the initial existence of such grounds and a reasonable cure period of not less than thirty (30) days following the date of such notice.

- (d) "Ownership Change Event" means the occurrence of any of the following with respect to Apricus: (i) the direct or indirect sale or exchange in a single or series of related transactions by the shareholders of Apricus of more than fifty percent (50%) percent of the outstanding voting stock of Apricus; (ii) a merger or consolidation in which Apricus is a party, other than a change of domicile; or (iii) the sale, exchange, or transfer of all or substantially all of the assets of Apricus.
  - 6. Limitation and Conditions on Payments.
- (a) Parachute Payments. In the event that the severance and other benefits provided for in this Agreement to Employee: (i) constitute "parachute payments" within the meaning of Section 280G of the Code; and (ii) but for this Section, would be subject to the excise tax imposed by Section 4999 of the Code, then Employee's severance benefits under Section 4 shall be payable either:
  - (i) in full; or
  - (ii) as to such lesser amount which would result in no portion of such severance benefits being subject to excise tax under Section 4999 of the Code, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Employee on an after-tax basis, of the greatest amount of severance benefits under Section 4, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. Any determination required under this Section 6 shall be made in writing by independent public accountants selected by the Company (the "Accountants"), whose determination shall be conclusive and binding upon Employee and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Section 280G and 4999 of the Code. The Company and Employee shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 6. Any reduction in severance benefits required by this Section 6 shall occur in a manner necessary to provide Employee with the greatest economic benefit. If more than one manner of reduction of severance benefits is necessary to arrive at the reduced amount yields the greatest economic benefit to Employee, the payments and benefits shall be reduced pro rata.

- (b) Release Prior to Receipt of Benefits. Prior to the receipt of any benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c) of this Agreement, Employee (or, in the event of Employee's incapacity due to Permanent Disability, his legal representative) shall execute, and allow to become effective, a release of claims agreement in the form attached hereto as Exhibit A (the "Release") not later than fifty-two (52) days following Employee's employment termination. In no event will the Company have any obligation to pay any severance benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c) of this Agreement be provided to Employee until the Release becomes effective. In the event the Release does not become effective within fifty-two (52) days following Employee's employment termination, the Company shall not have any obligation to pay to Employee any severance benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c).
- Section 409A. All severance payments to be made upon a termination of employment under this Agreement may be made only upon a "separation of service" within the meaning of Section 409A of the Code and the Department of Treasury regulations and other guidance promulgated thereunder. Notwithstanding any provision to the contrary in this Agreement, subject to Employee's compliance with Section 6(b) and the other provisions of this Section 6(c), any amount payable under Section 4 that is deemed deferred compensation subject to Section 409A of the Code shall be paid on the sixtieth (60th) day following Employee's "separation from service." Notwithstanding any provision to the contrary in this Agreement, if Employee is deemed by the Company at the time of Employee's separation from service to be a "specified employee" for purposes of Code Section 401A(a)(2)(B)(i), to the extent delayed commencement of any portion of the benefits to which Employee is entitled under this Agreement is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i), such portion of Employee's benefits shall not be provided to Employee priorition distribution under Code Section 409A(a)(2)(B)(i), such portion of Employee's belief is sharf not be provided to Employee's prior to the earlier of (i) the expiration of the six-month period measured from the date of Employee's "separation of service" with the Company or (ii) the date of Employee's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 6(c) shall be paid in a lump sum to Employee, and any remaining payments due under the Agreement shall be paid as otherwise provided herein. For purposes of Code Section 409Å (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Employee's right to receive installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. It is intended that none of the severance payments and benefits to be provided hereunder will be subject to Section 409A of the Code and any ambiguities herein will be interpreted to be so exempt or, if not so exempt, to comply with Section 409A of the Code. Employee and the Company agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Employee under Section 409A of the Code. Notwithstanding anything to the contrary contained herein, to the extent that any amendment to this Agreement with respect to the payment of any severance payments or benefits would constitute under Code Section 409A a delay in a payment or a change in the form of payment, then such amendment must be done in a manner that complies with Code Section 409A(a)(4)(C). Any reimbursement of expenses or in-kind benefits payable under this Agreement shall be made in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv) and shall be paid on or before the last day of Employee's taxable year following the taxable year in which Employee incurred the expenses. The amount of expenses reimbursed or in-kind benefits payable during any taxable year of Employee's shall not affect the amount eligible for reimbursement or in-kind benefits payable in any other taxable year of Employee's, and Employee's right to reimbursement for such amounts shall not be subject to liquidation or exchange for any other benefit.

- 7. Proprietary Information and Inventions Agreement. Employee has executed and agrees to abide by the terms of the Company's form of Proprietary Information and Inventions Agreement, which shall survive termination of Employee's employment with the Company and the termination of this Agreement.
- 8. Conflicts. Employee represents that Employee's performance of all the terms of this Agreement will not breach any other agreement to which Employee is a party. Employee has not, and will not during the term of this Agreement, enter into any oral or written agreement in conflict with any of the provisions of this Agreement. Employee further represents that Employee is entering into or has entered into an employment relationship with the Company of Employee's own free will and that Employee has not been solicited as an employee in any way by the Company.
- 9. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Employee's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.
- 10. Notice. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Employee shall be addressed to Employee at the home address which Employee most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

#### 11. Miscellaneous Provisions.

- (a) No Duty to Mitigate. Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Employee may receive from any other source.
- (b) Waiver. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Employee and by an authorized officer of the Company (other than Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.
- (c) Whole Agreement. This Agreement replaces the Original Agreement in its entirety. Other than any indemnification agreement entered into between the Company and Employee in connection with Employee's employment, any outstanding stock option or other equity compensation award agreements and the Proprietary Information and Inventions Agreement executed by Employee, no agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes any agreement of the same title and concerning similar subject matter dated prior to the Effective Date, including any offer

letter between Employee and the Company, and by execution of this Agreement both parties agree that any such predecessor agreement shall be deemed null and void.

- (d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions.
- (e) Severability. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefore to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.
- Arbitration. Any dispute, claim or controversy based on, arising out of or relating to Employee's employment or the termination thereof or this Agreement shall be settled by final and binding arbitration in the County of San Diego, California, before a single neutral arbitrator in accordance with the National Rules for the Resolution of Employment Disputes (the "Rules") of the American Arbitration Association, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction. The Rules may be found online at www.adr.org. Arbitration may be compelled pursuant to the California Arbitration Act (Code of Civil Procedure §§ 1280 et seq.). If the parties are unable to agree upon an arbitrator, one shall be appointed by the AAA in accordance with its Rules. Each party shall pay the fees of its own attorneys, the expenses of its witnesses and all other expenses connected with presenting its case; however, the parties agree that, to the extent permitted by law, the arbitrator may, in his or her discretion, award reasonable attorneys' fees to the prevailing party; provided, further than the prevailing party; provided party par that the prevailing party shall be reimbursed for such fees, costs and expenses within forty-five (45) days following any such award, but in no event later than the last day of Employee's taxable year following the taxable year in which the fees, costs and expenses were incurred; provided, further, that the parties' obligations pursuant to this sentence shall terminate on the tenth (10th) anniversary of the date of the termination of my employment. Other costs of the arbitration, including the cost of any record or transcripts of the arbitration, AAA's administrative fees, the fee of the arbitrator, and all other fees and costs, shall be borne by the Company. This Section 11(f) is intended to be the exclusive method for resolving any and all claims by the parties against each other for payment of damages under the Agreement or relating to my employment or the termination thereof; provided, however, that Employee shall retain the right to file administrative charges with or seek relief through any government agency of competent jurisdiction, and to participate in any government investigation, including but not limited to (i) claims for workers' compensation, state disability insurance or unemployment insurance; (ii) claims for unpaid wages or waiting time penalties brought before the California Division of Labor Standards Enforcement; provided, however, that any appeal from an award or from denial of an award of wages and/or waiting time penalties shall be arbitrated pursuant to the terms of this paragraph; and (iii) claims for administrative relief from the United States Equal Employment Opportunity Commission and/or the California Department of Fair Employment and Housing (or any similar agency in any applicable jurisdiction other than California); provided, further, that Employee shall not be entitled to obtain any monetary relief through such agencies other than workers' compensation benefits or unemployment insurance benefits. This paragraph shall not limit either party's right to obtain any provisional remedy, including, without limitation, injunctive or similar relief, from any court of

competent jurisdiction as may be necessary to protect their rights and interests pending the outcome of arbitration, including without limitation injunctive relief, in any court of competent jurisdiction pursuant to California Code of Civil Procedure § 1281.8 or any similar statute of an applicable jurisdiction. Seeking any such relief shall not be deemed to be a waiver of such party's right to compel arbitration. Both the Company and Employee expressly waive their right to a jury trial.

- (g) Legal Fees and Expenses. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with this Agreement. Notwithstanding the foregoing, in the event of any dispute arising under or relating to this Agreement, the arbitrator or court may, but shall not be required to, award the prevailing party its fees and expenses, including reasonable attorneys' fees.
- (h) No Assignment of Benefits. The rights of Employee to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this Section 11(h) shall be void. This Agreement does not create, and shall not be construed as creating, any rights enforceable by any person not a party to this Agreement.
- (i) Employment Taxes. All payments made pursuant to this Agreement will be subject to withholding of applicable income and employment taxes.
- (j) Assignment by Company. The Company may assign its rights under this Agreement to an affiliate, and an affiliate may assign its rights under this Agreement to another affiliate of the Company or to the Company. In the case of any such assignment, the term "Company" when used in a section of this Agreement shall mean the corporation that actually employs Employee.
- (k) Non-Disparagement. Upon any termination of employment or service, Employee agrees that he/she will not, directly or indirectly through affiliates or associates, make any written or oral communications that could reasonably be considered to be disparaging of the Company in any respect, including, but not limited to, the Company's business, technology, products, executives, officers, directors, former executives, consultants, contractors or agents. Additionally, the Company agrees that the Board and the Company's executive officers will not make (or direct the Company to make) any written or oral communications that could reasonably be considered to be disparaging of Employee in any respect. Nothing in this Section shall preclude Employee or any representative of the Company from testifying truthfully in any deposition or judicial or administrative proceeding. Moreover, nothing in this Section applies to communications to Employee's immediate family or communications by Employee or representatives of the Company to their respective attorneys, or to pleadings or other documents in any proceeding to enforce this Agreement or between Employee and the Company.
- (l) Construction. The language in all parts of this Agreement shall in all cases be construed simply, according to its fair meaning, and not strictly for or against any of the parties hereto. Without limitation, there shall be no presumption against any party on the ground that such party was responsible for drafting this Agreement or any part thereof.
- (m) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(n)	Whistleblower								
directly with, co	operating with, o	r providing i	nformation to,	any feder	al, state or lo	ocal govern	nment regul	ator, includ	ing, but not
limited to, the U	J.S. Securities an	nd Exchange	Commission,	the U.S.	Commodity	Futures 7	Frading Co	mmission,	or the U.S.
Department of Ju	ıstice.	_			•				

[Signature page follows]

The parties have executed this Agreement on the date first written above.

# APRICUS BIOSCIENCES, INC.

By: /s/ Kleanthis G. Xanthopoulos
Name: Kleanthis G. Xanthopoulos, Ph.D.

Title: Chairman

**EMPLOYEE** 

Signature: <u>/s/ Richard W. Pascoe</u> Print Name: Richard W. Pascoe

## Exhibit A FORM OF RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the severance benefits to be provided me in connection with the involuntary termination of my employment, as set forth in Section 4[insert relevant subsection] of the Amended and Restated Employment Agreement between me and Apricus Biosciences, Inc. (the "Company"), dated December 20, 2016 (the "Agreement"), which are conditioned on my signing this Release of Claims and not revoking this Release of Claims as provided below, and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executors, administrators, beneficiaries, representatives and assigns, and all others connected with or claiming through me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, shareholders, employees, employee benefit plans, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns and all others connected with any of them (all of the foregoing, the "Company Released Parties"), both individually and in their official capacities, from any and all causes of action, rights or claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way related to, resulting from, arising out of or connected with my employment by or service to the Company or any of its subsidiaries or other affiliates or the termination of that employment or service or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act (the "ADEA Claims"), Employee Retirement Income Security Act, the Americans with Disabilities Act, and the wage and hour, wage payment, and fair employment practices laws of the state or states in which I have been employed by the Company or any of its subsidiaries or other affiliates, each as amended from time to time).

In signing this Release of Claims, I expressly waive and relinquish all rights and benefits afforded by Section 1542 of the Civil Code of the State of California, as well as under any other statutes or common law principles of similar effect, and do so understanding and acknowledging the significance of such specific waiver of Section 1542, which Section states as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

Thus, notwithstanding the provisions of Section 1542, and for the purpose of implementing a full and complete release and discharge of the Released, I expressly acknowledge that this Release of Claims is intended to include in its effect, without limitation, all Claims which I do not know or suspect to exist in my favor at the time of execution hereof, and that this Release of Claims contemplates the extinguishment of such Claim or Claims.

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement based on the Company's executory obligations under the Agreement after the effective date of this Release of Claim; (ii) any right of indemnification or contribution that I have pursuant to the articles of incorporation or by-laws of the Company, (iii) all rights to any outstanding options, restricted stock, restricted stock units or other awards to the extent vested and exercisable pursuant to the terms of the awards and the plans under which they were granted as of the termination of my employment; (iv) any right which cannot

be waived by operation of law, including claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims for workers' compensation insurance benefits under the terms of any workers' compensation insurance policy or fund of the Company or any claims pursuant to the terms and conditions of the federal law known as COBRA or any comparable state law, including Cal-COBRA; and (v) my right to bring to the attention of the Equal Employment Opportunity Commission or the California Department of Fair Employment and Housing or any other federal, state or local government agency claims of discrimination, or from participating in an investigation or proceeding conducted by the Equal Employment Opportunity Commission or any other federal, state or local government agency; provided, however, that I do release my right to secure any damages for alleged discriminatory treatment.

I hereby represent, warrant and agree that I have been paid in full all compensation due to me, whether for services rendered by me to the Company, its subsidiaries and other affiliates, or otherwise, through the date on which my employment with the Company terminated and that, exclusive only of the Company's provision to me of the severance benefits in accordance with the terms and conditions set forth in Section 4(a) of the Agreement, no further compensation of any kind shall be due to me from the Company or any of the other Company Released Parties as a result of my employment now ended. Without limiting the generality of the foregoing, I specifically acknowledge and agree that I have been paid in full all base salary, bonus compensation and pay for unused vacation due to me and that I have been reimbursed for all business expenses I incurred in the performance of my duties for the Company and the other Company Released Parties.

Effective as of the date of my termination of employment, I hereby confirm my resignation from all officer positions I hold or previously held with the Company or any subsidiary. I further agree that I will execute any additional documents that the Company may reasonably request in connection with the foregoing.

I understand that I must immediately return to the Company any and all documents, materials and information (whether in hardcopy, on electronic media or otherwise) related to the business (whether present or otherwise) of the Company, its subsidiaries and other affiliates and all keys, access cards, credit cards, computer hardware and software, telephones and other property of the Company, its subsidiaries and other affiliates and any copies thereof in my possession or control.

I have previously entered into the Company's standard proprietary information and inventions agreement (the "Proprietary Information and Inventions Agreement"). I agree to continue to perform my obligations thereunder.

Nothing in this Release of Claims shall be deemed to restrict my right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation.

This Release of Claims creates legally binding obligations and I acknowledge that I am hereby advised by the Company to seek the advice of an attorney prior to signing this Release of Claims.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to [twenty-one (21)][forty-five (45)] Forty-five days to be included in the event of a group termination. days from the date I receive it, provided that I sign and return it to the Company no later than the [twenty-first (21st)][forty-fifth (45th)] day after such receipt. I acknowledge that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing

before signing; and that I am signing this Release of Claims knowingly, voluntarily and with a full understanding of its terms. I represent and acknowledge that if I am executing this Release of Claims before the foregoing period has elapsed, I do so knowingly, voluntarily and upon the advice of and with the approval of my legal counsel (if any), and I voluntarily waive any remaining portion of the consideration period. I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth in writing expressly in the Agreement or this Release of Claims.

I understand that I may revoke this Release of Claims solely with respect to any potential ADEA Claims at any time within seven (7) days of the date of my signing by written notice to the Company c/o the Chief Executive Officer and that this Release of Claims will take full effect on the eighth calendar day after my signing and only if I have not revoked it during the preceding seven-day revocation period. Notwithstanding my election to revoke with respect to any potential ADEA Claims, I acknowledge that all other terms of this Release of Claims shall remain in full force and effect. I further acknowledge that I shall not be entitled to any payments under Section 4[insert relevant subsection] of the Agreement unless this Release of Claims is executed and becomes effective not later than [thirty (30)][fifty-two (52)] days following the date of my termination of employment.

[I acknowledge that I have been provided with a notice, as required by the Older Workers Benefit Protection Act of 1990, that contains information about the job titles and ages of all individuals eligible or selected to receive the severance package and the ages of all individuals in the same job classification or organizational unit who are not eligible or selected for the severance package. (See Attachment 1.)] To be included in the event of a group termination.

This Release of Claims, the Agreement and the Proprietary Information and Inventions Agreement constitute the entire agreement of the Company and me in respect of the subject matter contained herein and therein and supersede all prior or simultaneous representations, discussions, negotiations and agreements, whether written or oral. This Release of Claims may be amended or modified only with my written consent and the written consent of an authorized representative of the Company. No oral waiver, amendment or modification will be effective under any circumstances whatsoever.

The validity, interpretation, construction and performance of this Release of Claims shall be governed by the laws of the State of California without reference to conflict of laws provisions.

If any term or provision of this Release of Claims or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Release of Claims or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefore to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

This Release of Claims may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

Any dispute, claim or controversy based on, arising out of or relating to my employment or the termination thereof or the Agreement shall be settled by final and binding arbitration in the County of San Diego, California, before a single neutral arbitrator in accordance with the National Rules for the Resolution of Employment Disputes (the "Rules") of the American Arbitration Association, and judgment on the award

rendered by the arbitrator may be entered in any court having jurisdiction. The Rules may be found online at www.adr.org. Arbitration may be compelled pursuant to the California Arbitration Act (Code of Civil Procedure §§ 1280 et seq.). If the parties are unable to agree upon an arbitrator, one shall be appointed by the AAA in accordance with its Rules. Each party shall pay the fees of its own attorneys, the expenses of its witnesses and all other expenses connected with presenting its case; however, the parties agree that, to the extent permitted by law, the arbitrator may, in his or her discretion, award reasonable attorneys' fees to the prevailing party; provided, further, that the prevailing party shall be reimbursed for such fees, costs and expenses within forty-five (45) days following any such award, but in no event later than the last day of my taxable year following the taxable year in which the fees, costs and expenses were incurred; provided, further, that the parties' obligations pursuant to this sentence shall terminate on the tenth (10th) anniversary of the date of the termination of my employment. Other costs of the arbitration, including the cost of any record or transcripts of the arbitration, AAA's administrative fees, the fee of the arbitrator, and all other fees and costs, shall be borne by the Company. This paragraph is intended to be the exclusive method for resolving any and all claims by the parties against each other for payment of damages under the Agreement or relating to my employment or the termination thereof; provided, however, that I shall retain the right to file administrative charges with or seek relief through any government agency of competent jurisdiction, and to participate in any government investigation, including but not limited to (i) claims for workers' compensation, state disability insurance or unemployment insurance; (ii) claims for unpaid wages or waiting time penalties brought before the California Division of Labor Standards Enforcement; provided, however, that any appeal from an award or from denial of an award of wages and/or waiting time penalties shall be arbitrated pursuant to the terms of this paragraph; and (iii) claims for administrative relief from the United States Equal Employment Opportunity Commission and/or the California Department of Fair Employment and Housing (or any similar agency in any applicable jurisdiction other than California); provided, further, that I shall not be entitled to obtain any monetary relief through such agencies other than workers' compensation benefits or unemployment insurance benefits. This paragraph shall not limit either party's right to obtain any provisional remedy, including, without limitation, injunctive or similar relief, from any court of competent jurisdiction as may be necessary to protect their rights and interests pending the outcome of arbitration, including without limitation injunctive relief, in any court of competent jurisdiction pursuant to California Code of Civil Procedure § 1281.8 or any similar statute of an applicable jurisdiction. Seeking any such relief shall not be deemed to be a waiver of such party's right to compel arbitration. Both the Company and I expressly waive our right to a jury trial.

Intending to be legally bound, I have signed this Release of Claims as of the date written below.

Signature:

## **APRICUS BIOSCIENCES, INC.**

## AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (the "<u>Agreement</u>") is dated as of December 20, 2016 (the "Effective Date"), by and between Brian Dorsey ("<u>Employee</u>") and Apricus Biosciences, Inc., a Nevada corporation ("<u>Apricus</u>," and collectively with its subsidiaries, the "<u>Company</u>").

#### RECITALS

- A. Employee became a full-time employee of the Company on December 1, 2014 and Employee and Apricus entered into an Employment Agreement, dated December 1, 2014 (the "Original Agreement").
- B. The Board of Directors of Apricus (the "Board") believes it is in the best interests of the Company and its shareholders to retain Employee and provide incentives to Employee to serve the Company as set forth herein.
- C. The Board further believes that it is necessary to provide Employee with certain benefits upon certain terminations of Employee's employment, which benefits are intended to provide Employee with financial security and provide sufficient income and encouragement to Employee to remain employed with the Company, notwithstanding the possibility of a Change in Control.
- D. To accomplish the foregoing objectives, the Board has directed the Company, upon execution of this Agreement by Employee, to agree to the terms provided in this Agreement.

It is therefore agreed as follows:

- 1. At-Will Employment. The Company and Employee acknowledge that Employee's employment is and shall continue to be at-will, as defined under applicable law, and that Employee's employment with the Company may be terminated by either party at any time for any or no reason. This "at-will" nature of Employee's employment shall remain unchanged during Employee's tenure as an employee and may not be changed, except in an express writing signed by Employee and a duly authorized officer of the Company. If Employee's employment terminates for any reason, Employee shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law.
- Duties. Employee shall be employed by the Company as Senior Vice President, Chief Development Officer of the Company, and, as such, Employee shall faithfully perform for the Company the duties of said office and shall perform such other duties of an executive, managerial or administrative nature as shall be specified and designated from time to time by the Board or the Chief Executive Officer of Apricus ("CEO"). While employed by the Company, Employee shall not, without the prior consent of the CEO, (i) render to others services of any kind for compensation or engage in any other business activity that would materially interfere with the performance of Employee's duties under this Agreement, or (ii) directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. Employee shall not invest in any company or business that competes in any manner with the Company; provided that, Employee may, without violating this section, own as a passive investment, shares of capital stock of a publicly-traded corporation

that engages in competition if (i) such shares are actively traded on an established national securities market in the United States, (ii) the number of shares of such corporation's capital stock that are beneficially owned (directly or indirectly) by Employee represents less than one percent of the total number of shares of such corporation's outstanding capital stock, and (iii) Employee is not otherwise associated directly or indirectly with such corporation or with any affiliated of such corporation. Employee may also participate freely in the affairs of any recognized charitable organizations, non-profit or in any community affairs of Employee's choice. Employee shall be subject to and comply with the policies and procedures generally applicable to employees of the Company to the extent the same are not inconsistent with any term of this Agreement.

- 3. <u>Compensation</u>. As compensation for the services to be rendered by Employee to the Company pursuant to this Agreement, Employee shall be paid the following compensation and other benefits, which compensation and benefits may be paid or provided by Apricus or NexMed (U.S.A.), Inc., Apricus' wholly-owned subsidiary.
- (a) <u>Salary</u>. The Company shall pay Employee a salary at an initial rate of \$319,300 per annum, which may be adjusted by the Compensation Committee of the Board from time to time (the "<u>Annual Salary</u>"), and shall be paid in accordance with the customary payroll practices of the Company applicable to employees.
- (b) **Bonus**. For each fiscal year completed during the term hereof, Employee shall be eligible to participate in any annual bonus plan provided by the Company for its employees generally, as in effect from time to time. Employee's annual target bonus shall be 40% of the Annual Salary (the "<u>Target Bonus</u>"), with the actual amount of the bonus, if any, to be determined by the Board or the Compensation Committee in accordance with the terms of the bonus plan. Employee shall be required to be employed with the Company on the date that bonuses are paid in order to be entitled to receive such payment.
- Benefits. During the term hereof, Employee shall be eligible for inclusion, to the extent permitted by law, as a fultime employee of the Company or any of its subsidiaries, in any and all of the following plans, programs, and policies in effect at the time, subject to the terms and conditions of such plans, programs and policies: (i) pension, profit sharing, savings, and other retirement plans and programs, (ii) life and health (medical, dental, hospitalization, short-term and long-term disability) insurance plans and programs, (iii) stock option and stock purchase plans and programs, (iv) accidental death and dismemberment protection plans and programs, (v) travel accident insurance plans and programs, (vi) vacation policy (Employee shall accrue paid vacation per calendar year based on seniority in accordance with Company's policies), and (vii) other plans and programs sponsored by the Company or any subsidiary for employees generally, including any and all plans and programs that supplement any or all of the foregoing types of plans or programs. Nothing in this Agreement shall preclude the Company or any of its subsidiaries or affiliates from terminating or amending any employee benefit plan, program or policy from time to time after the date of this Agreement.
- (d) **Expenses.** The Company shall pay or reimburse Employee for all ordinary and reasonable out-of-pocket expenses actually incurred (and, in the case of reimbursement, paid) by Employee during the term of employment in the performance of Employee's services under this Agreement; *provided* that Employee submits proof of such expenses, with the properly completed forms as prescribed from time to time by the Company, no later than thirty (30) days after such expenses have been so incurred or as otherwise provided in accordance with the standard practices of the Company.

## 4. **Benefits Upon Termination of Employment.**

- (a) Severance Upon Involuntary Termination. In the event that Employee suffers an Involuntary Termination, and subject to the limitations set forth in Section 6, then in addition to any accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination, Employee will be entitled to receive severance benefits as follows: (i) the Company shall pay to Employee in one lump sum an amount equal to (A) twelve (12) months of Employee's Annual Salary that Employee was receiving immediately prior to the Involuntary Termination; plus (B) any accrued but unpaid bonus for the calendar year preceding Employee's termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee be employed on the date the bonus is to be paid) (as determined by the Compensation Committee of the Board in its discretion); plus (C) 100% of the Employee's Target Bonus for the year in which the date of Employee's Involuntary Termination occurs; (ii) full acceleration of the vesting of all equity awards held by Employee at the time of the Involuntary Termination, including any options, restricted stock, restricted stock units or other awards; and (iii) reimbursement for the cost of continuation of health insurance benefits provided to Employee immediately prior to the Involuntary Termination pursuant to the terms of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or other applicable law through the earliest to occur of (A) twelve (12) months following the Involuntary Termination, (B) the date Employee becomes eligible for such COBRA or other benefits under applicable law (the "COBRA Coverage Period"). If any of the Company's health benefits are self-funded as of the date of Employee's Involuntary Termination, or if the Company cannot provide the foregoing benefits in a manner that is exempt from Section 409A of the Internal Revenue Code of 1986, as amended (
- (b) **Disability or Death.** If Employee should suffer a Permanent Disability, the Company may terminate Employee's employment hereunder upon ten (10) or more days' prior written notice to Employee. If Employee should pass away during the term of this Agreement, Employee's employment shall be deemed terminated on Employee's date of death. For purposes of this Agreement, a "Permanent Disability" shall be deemed to have occurred only when Employee has qualified for benefits (including satisfaction of any applicable waiting period) under the Company's or a subsidiary's long-term disability insurance arrangement. In the event of the termination of Employee's employment hereunder by reason of Permanent Disability or death, the Employment Term shall end on the day of such termination and the Company shall pay, no later than the first payroll date following Employee's termination, to Employee or Employee's legal representative (in the event of Permanent Disability), or any beneficiary or beneficiaries designated by Employee to the Company in writing, or to Employee's estate if no such beneficiary has been so designated (in the event of Employee's death), a single lump sum payment of: (i) any accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination; and (ii) any amounts owing, but not yet paid, pursuant to Section 3(d) hereof. In addition, upon a termination under this Section 4(b): (1) Employee shall receive a pro rata bonus for the calendar year in which such termination occurs, equal to Employee's Target Bonus for the calendar year of said termination, and the denominator of which is three hundred sixty-five (365); (2) Employee shall receive any accrued but unpaid bonus for the calendar year preceding Employee's termination,

to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee be employed on the date the bonus is to be paid) (as determined by the Compensation Committee of the Board in its discretion); and (3) all of Employee's outstanding but unvested equity awards shall vest immediately and the expiration date for all of Employee's unvested stock option awards shall be extended so that they expire one year after the date of Employee's termination under this Section 4(b). Subject to Section 6(c), the amounts payable pursuant to clauses (1) and (2) above shall be paid within five (5) days following the date Employee's Release becomes effective and irrevocable (or, in the event of Employee's death, within five (5) days following the date of Employee's death).

- (c) Severance Upon a Change in Control. In the event that Employee suffers an Involuntary Termination within the 12-month period following the effective date of a Change in Control, then in addition to all accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of Employee's termination of employment, Employee will be entitled to receive severance benefits as follows: (i) the Company shall pay to Employee in one lump sum an amount equal to the greater of (A) eighteen (18) months of Employee's Annual Salary that Employee was receiving immediately prior to the Involuntary Termination or (B) eighteen (18) months of Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (iii) the Company shall pay to Employee in one lump sum (A) any accrued (with the exception of the requirement that Employee's termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee's Involuntary Termination Cours; (iii) full acceleration of the Vesting of all equity awards held by Employee at the time of the Involuntary Termination, including any options, restricted stock, restricted stock units or other awards; and (iv) reimbursement for the cost of continuation of health insurance benefits provided to Employee immediately prior to the Involuntary Termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of eighteen (18) months following the Involuntary Termination, or if the Company cannot provide the foregoing benefits
- (d) <u>Termination for Cause</u>. Notwithstanding any other provision of this Agreement, if Employee's employment is terminated for Cause at any time, then Employee shall not be entitled to receive payment of any severance benefits or any continuation or acceleration of stock award vesting and all of Employee's stock awards shall remain subject to all applicable forfeiture provisions and transfer restrictions. Employee will receive payment(s) for all accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination.
- (e) <u>Voluntary Resignation</u>. If Employee voluntarily resigns from the Company under circumstances which do not constitute an Involuntary Termination, then Employee shall not be entitled to receive payment of any severance benefits, or option acceleration, or relinquishment of forfeiture and transfer restrictions. Employee will receive payment(s) for all accrued but unpaid Annual Salary, including Annual

Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination.

- 5. **<u>Definition of Terms.</u>** The following terms referred to in this Agreement shall have the following meanings:
- (a) "Cause" means any of the following: (i) Employee's theft, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, or falsification of any Company or affiliate documents or records; (ii) Employee's material failure to abide by a Company's or affiliate's code of conduct or other policies (including without limitation, policies relating to confidentiality and reasonable workplace conduct); (iii) Employee's unauthorized use, misappropriation, destruction or diversion of any tangible or intangible asset or corporate opportunity of the Company or an affiliate (including, without limitation, Employee's improper use or disclosure of confidential or proprietary information); (iv) any intentional act by Employee which has a material detrimental effect on the Company or an affiliate's reputation or business; (v) Employee's repeated failure or inability to perform any reasonable assigned duties after written notice from the Company or an affiliate (including, without limitation, habitual absence from work for reasons other than illness), and a reasonable opportunity to cure, such failure or inability; (vi) any material breach by Employee of any employment or service agreement between Employee and the Company or an affiliate, which breach is not cured pursuant to the terms of such agreement; or (vii) Employee's conviction (including any plea of guilty or *nolo contendere*) of any criminal act involving fraud, dishonesty, misappropriation or moral turpitude, or which materially impairs Employee's ability to perform his duties with the Company or an affiliate.
- (b) "Change in Control" means the occurrence of any of the following:
  - (i) an Ownership Change Event or a series of related Ownership Change Events (collectively, a "<u>Transaction</u>") in which the shareholders of Apricus immediately before the Transaction do not retain immediately after the Transaction, in substantially the same proportions as their ownership of shares of Apricus' voting stock immediately before the Transaction, direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding voting securities of Apricus or such surviving entity immediately outstanding after the Transaction, or, in the case of an Ownership Change Event the entity to which the assets of Apricus were transferred (the "Transferee"), as the case may be; or
  - (ii) the liquidation or dissolution of Apricus.

For purposes of Section 5(b)(i), indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own Apricus or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Board shall have the right to determine whether multiple sales or exchanges of the voting securities in Apricus or multiple Ownership Change Events are related, and its determination shall be final, binding and conclusive. The Board may also, but need not, specify that other transactions or events constitute a Change in Control.

- (c) "Involuntary Termination" shall include (i) any termination of Employee's employment by the Company (other than for Cause and other than as a result of Employee's death or Permanent Disability) or (ii) Employee's voluntary termination within sixty (60) days following the occurrence of any of the following events without Employee's written consent: (i) a material reduction or material change in job duties, responsibilities, authority and requirements inconsistent with Employee's position with the Company and Employee's prior duties, responsibilities and requirements or a material negative change in Employee's reporting relationship (in each case, excluding any changes as a result of the loss of any interim or temporary roles within the Company); (ii) a material reduction of Employee's base compensation (other than in connection with a general decrease in base salaries for most officers of the Company or successor corporation); or (iii) Employee's refusal to relocate to a facility or location more than fifty (50) miles from the Company's current location, provided that Employee will not resign due to such change, reduction or relocation without first providing the Company with written notice of the event or events constituting the grounds for Employee's voluntary resignation within thirty (30) days of the initial existence of such grounds and a reasonable cure period of not less than thirty (30) days following the date of such notice.
- (d) "Ownership Change Event" means the occurrence of any of the following with respect to Apricus: (i) the direct or indirect sale or exchange in a single or series of related transactions by the shareholders of Apricus of more than fifty percent (50%) percent of the outstanding voting stock of Apricus; (ii) a merger or consolidation in which Apricus is a party, other than a change of domicile; or (iii) the sale, exchange, or transfer of all or substantially all of the assets of Apricus.
- 6. Limitation and Conditions on Payments.
- (a) Parachute Payments. In the event that the severance and other benefits provided for in this Agreement to Employee: (i) constitute "parachute payments" within the meaning of Section 280G of the Code; and (ii) but for this Section, would be subject to the excise tax imposed by Section 4999 of the Code, then Employee's severance benefits under Section 4 shall be payable either:
  - (i) in full; or
  - (ii) as to such lesser amount which would result in no portion of such severance benefits being subject to excise tax under Section 4999 of the Code, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Employee on an after-tax basis, of the greatest amount of severance benefits under Section 4, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. Any determination required under this Section 6 shall be made in writing by independent public accountants selected by the Company (the "Accountants"), whose determination shall be conclusive and binding upon Employee and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Section 280G and 4999 of the Code. The Company and Employee shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 6. Any reduction in severance benefits required by this Section 6 shall occur in a manner necessary to

provide Employee with the greatest economic benefit. If more than one manner of reduction of severance benefits is necessary to arrive at the reduced amount yields the greatest economic benefit to Employee, the payments and benefits shall be reduced pro rata.

- (b) Release Prior to Receipt of Benefits. Prior to the receipt of any benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c) of this Agreement, Employee (or, in the event of Employee's incapacity due to Permanent Disability, his legal representative) shall execute, and allow to become effective, a release of claims agreement in the form attached hereto as Exhibit A (the "Release") not later than fifty-two (52) days following Employee's employment termination. In no event will the Company have any obligation to pay any severance benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c) of this Agreement be provided to Employee until the Release becomes effective. In the event the Release does not become effective within fifty-two (52) days following Employee's employment termination, the Company shall not have any obligation to pay to Employee any severance benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c).
- Section 409A. All severance payments to be made upon a termination of employment under this Agreement may be made only upon a "separation of service" within the meaning of Section 409A of the Code and the Department of Treasury regulations and other guidance promulgated thereunder. Notwithstanding any provision to the contrary in this Agreement, subject to Employee's compliance with Section 6(b) and the other provisions of this Section 6(c), any amount payable under Section 4 that is deemed deferred compensation subject to Section 409A of the Code shall be paid on the sixtieth (60th) day following Employee's "separation from service." Notwithstanding any provision to the contrary in this Agreement, if Employee is deemed by the Company at the time of Employee's separation from service to be a "specified employee" for purposes of Code Section 401A(a)(2)(B)(i), to the extent delayed commencement of any portion of the benefits to which Employee is entitled under this Agreement is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i), such portion of Employee's benefits shall not be provided to Employee prior to the earlier of (i) the expiration of the six-month period measured from the date of Employee's "separation of service" with the Company or (ii) the date of Employee's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 6(c) shall be paid in a lump sum to Employee, and any remaining payments due under the Agreement shall be paid as otherwise provided herein. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Employee's right to receive installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. It is intended that none of the severance payments and benefits to be provided hereunder will be subject to Section 409A of the Code and any ambiguities herein will be interpreted to be so exempt or, if not so exempt, to comply with Section 409A of the Code. Employee and the Company agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Employee under Section 409A of the Code. Notwithstanding anything to the contrary contained herein, to the extent that any amendment to this Agreement with respect to the payment of any severance payments or benefits would constitute under Code Section 409A a delay in a payment or a change in the form of payment, then such amendment must be done in a manner that complies with Code Section 409A(a)(4)(C). Any reimbursement of expenses or in-kind benefits payable under this Agreement shall be made in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv) and shall be paid on or before the last day of Employee's taxable year following the taxable

year in which Employee incurred the expenses. The amount of expenses reimbursed or in-kind benefits payable during any taxable year of Employee's shall not affect the amount eligible for reimbursement or in-kind benefits payable in any other taxable year of Employee's, and Employee's right to reimbursement for such amounts shall not be subject to liquidation or exchange for any other benefit.

- 7. Proprietary Information and Inventions Agreement. Employee has executed and agrees to abide by the terms of the Company's form of Proprietary Information and Inventions Agreement, which shall survive termination of Employee's employment with the Company and the termination of this Agreement.
- 8. Conflicts. Employee represents that Employee's performance of all the terms of this Agreement will not breach any other agreement to which Employee is a party. Employee has not, and will not during the term of this Agreement, enter into any oral or written agreement in conflict with any of the provisions of this Agreement. Employee further represents that Employee is entering into or has entered into an employment relationship with the Company of Employee's own free will and that Employee has not been solicited as an employee in any way by the Company.
- 9. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Employee's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.
- 10. Notice. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Employee shall be addressed to Employee at the home address which Employee most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

#### 11. Miscellaneous Provisions.

- (a) No Duty to Mitigate. Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Employee may receive from any other source.
- (b) Waiver. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Employee and by an authorized officer of the Company (other than Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.
- (c) Whole Agreement. This Agreement replaces the Original Agreement in its entirety. Other than any indemnification agreement entered into between the Company and Employee in connection with Employee's employment, any outstanding stock option or other equity compensation

award agreements and the Proprietary Information and Inventions Agreement executed by Employee, no agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes any agreement of the same title and concerning similar subject matter dated prior to the Effective Date, including any offer letter between Employee and the Company, and by execution of this Agreement both parties agree that any such predecessor agreement shall be deemed null and void.

- (d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions.
- (e) Severability. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefore to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.
- Arbitration. Any dispute, claim or controversy based on, arising out of or relating to Employee's employment or the termination thereof or this Agreement shall be settled by final and binding arbitration in the County of San Diego, California, before a single neutral arbitrator in accordance with the National Rules for the Resolution of Employment Disputes (the "Rules") of the American Arbitration Association, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction. The Rules may be found online at www.adr.org. Arbitration may be compelled pursuant to the California Arbitration Act (Code of Civil Procedure §§ 1280 et seq.). If the parties are unable to agree upon an arbitrator, one shall be appointed by the AAA in accordance with its Rules. Each party shall pay the fees of its own attorneys, the expenses of its witnesses and all other expenses connected with presenting its case; however, the parties agree that, to the extent permitted by law, the arbitrator may, in his or her discretion, award reasonable attorneys' fees to the prevailing party; provided, further, that the prevailing party shall be reimbursed for such fees, costs and expenses within forty-five (45) days following any such award, but in no event later than the last day of Employee's taxable year following the taxable year in which the fees, costs and expenses were incurred; provided, further, that the parties' obligations pursuant to this sentence shall terminate on the tenth (10th) anniversary of the date of the termination of my employment. Other costs of the arbitration, including the cost of any record or transcripts of the arbitration, AAA's administrative fees, the fee of the arbitrator, and all other fees and costs, shall be borne by the Company. This Section 11(f) is intended to be the exclusive method for resolving any and all claims by the parties against each other for payment of damages under the Agreement or relating to my employment or the termination thereof; provided, however, that Employee shall retain the right to file administrative charges with or seek relief through any government agency of competent jurisdiction, and to participate in any government investigation, including but not limited to (i) claims for workers' compensation, state disability insurance or unemployment insurance; (ii) claims for unpaid wages or waiting time penalties brought before the California Division of Labor Standards Enforcement; provided, however, that any appeal from an award or from denial of an award of wages and/or waiting time penalties shall be arbitrated pursuant to the terms of this paragraph; and (iii) claims for administrative relief from the United States Equal Employment Opportunity Commission and/or the

California Department of Fair Employment and Housing (or any similar agency in any applicable jurisdiction other than California); provided, further, that Employee shall not be entitled to obtain any monetary relief through such agencies other than workers' compensation benefits or unemployment insurance benefits. This paragraph shall not limit either party's right to obtain any provisional remedy, including, without limitation, injunctive or similar relief, from any court of competent jurisdiction as may be necessary to protect their rights and interests pending the outcome of arbitration, including without limitation injunctive relief, in any court of competent jurisdiction pursuant to California Code of Civil Procedure § 1281.8 or any similar statute of an applicable jurisdiction. Seeking any such relief shall not be deemed to be a waiver of such party's right to compel arbitration. Both the Company and Employee expressly waive their right to a jury trial.

- (g) Legal Fees and Expenses. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with this Agreement. Notwithstanding the foregoing, in the event of any dispute arising under or relating to this Agreement, the arbitrator or court may, but shall not be required to, award the prevailing party its fees and expenses, including reasonable attorneys' fees.
- (h) No Assignment of Benefits. The rights of Employee to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this Section 11(h) shall be void. This Agreement does not create, and shall not be construed as creating, any rights enforceable by any person not a party to this Agreement.
- (i) Employment Taxes. All payments made pursuant to this Agreement will be subject to withholding of applicable income and employment taxes.
- (j) Assignment by Company. The Company may assign its rights under this Agreement to an affiliate, and an affiliate may assign its rights under this Agreement to another affiliate of the Company or to the Company. In the case of any such assignment, the term "Company" when used in a section of this Agreement shall mean the corporation that actually employs Employee.
- (k) Non-Disparagement. Upon any termination of employment or service, Employee agrees that he/she will not, directly or indirectly through affiliates or associates, make any written or oral communications that could reasonably be considered to be disparaging of the Company in any respect, including, but not limited to, the Company's business, technology, products, executives, officers, directors, former executives, consultants, contractors or agents. Additionally, the Company agrees that the Board and the Company's executive officers will not make (or direct the Company to make) any written or oral communications that could reasonably be considered to be disparaging of Employee in any respect. Nothing in this Section shall preclude Employee or any representative of the Company from testifying truthfully in any deposition or judicial or administrative proceeding. Moreover, nothing in this Section applies to communications to Employee's immediate family or communications by Employee or representatives of the Company to their respective attorneys, or to pleadings or other documents in any proceeding to enforce this Agreement or between Employee and the Company.
- (l) Construction. The language in all parts of this Agreement shall in all cases be construed simply, according to its fair meaning, and not strictly for or against any of the parties hereto. Without

limitation, there shall be no presumption against any party on the ground that such party was responsible for drafting this Agreement or any part thereof.

- (m) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.
- (n) Whistleblower Provision. Nothing herein is intended to or shall prevent Employee from communicating directly with, cooperating with, or providing information to, any federal, state or local government regulator, including, but not limited to, the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, or the U.S. Department of Justice.

[Signature page follows]

The parties have executed this Agreement on the date first written above.

# APRICUS BIOSCIENCES, INC.

By: <u>/s/ Richard W. Pascoe</u> Name: Richard W. Pascoe

Title: Chief Executive Officer & Secretary

**EMPLOYEE** 

Signature: /s/ Brian Dorsey
Print Name: Brian Dorsey

## Exhibit A FORM OF RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the severance benefits to be provided me in connection with the involuntary termination of my employment, as set forth in Section 4[insert relevant subsection] of the Amended and Restated Employment Agreement between me and Apricus Biosciences, Inc. (the "Company"), dated December 20, 2016 (the "Agreement"), which are conditioned on my signing this Release of Claims and not revoking this Release of Claims as provided below, and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executors, administrators, beneficiaries, representatives and assigns, and all others connected with or claiming through me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, shareholders, employees, employee benefit plans, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns and all others connected with any of them (all of the foregoing, the "Company Released Parties"), both individually and in their official capacities, from any and all causes of action, rights or claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way related to, resulting from, arising out of or connected with my employment by or service to the Company or any of its subsidiaries or other affiliates or the termination of that employment or service or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act (the "ADEA Claims"), Employee Retirement Income Security Act, the Americans with Disabilities Act, and the wage and hour, wage payment, and fair employment practices laws of the state or states in which I have been employed by the Company or any of its subsidiaries or other affiliates, each as amended from time to time).

In signing this Release of Claims, I expressly waive and relinquish all rights and benefits afforded by Section 1542 of the Civil Code of the State of California, as well as under any other statutes or common law principles of similar effect, and do so understanding and acknowledging the significance of such specific waiver of Section 1542, which Section states as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

Thus, notwithstanding the provisions of Section 1542, and for the purpose of implementing a full and complete release and discharge of the Released, I expressly acknowledge that this Release of Claims is intended to include in its effect, without limitation, all Claims which I do not know or suspect to exist in my favor at the time of execution hereof, and that this Release of Claims contemplates the extinguishment of such Claim or Claims.

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement based on the Company's executory obligations under the Agreement after the effective date of this Release of Claim; (ii) any right of indemnification or contribution that I have pursuant to the articles of incorporation or by-laws of the Company, (iii) all rights to any outstanding options, restricted stock, restricted stock units or other awards to the extent vested and exercisable pursuant to the terms of the awards and the plans under which they were granted as of the termination of my employment; (iv) any right which cannot

be waived by operation of law, including claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims for workers' compensation insurance benefits under the terms of any workers' compensation insurance policy or fund of the Company or any claims pursuant to the terms and conditions of the federal law known as COBRA or any comparable state law, including Cal-COBRA; and (v) my right to bring to the attention of the Equal Employment Opportunity Commission or the California Department of Fair Employment and Housing or any other federal, state or local government agency claims of discrimination, or from participating in an investigation or proceeding conducted by the Equal Employment Opportunity Commission or any other federal, state or local government agency; provided, however, that I do release my right to secure any damages for alleged discriminatory treatment.

I hereby represent, warrant and agree that I have been paid in full all compensation due to me, whether for services rendered by me to the Company, its subsidiaries and other affiliates, or otherwise, through the date on which my employment with the Company terminated and that, exclusive only of the Company's provision to me of the severance benefits in accordance with the terms and conditions set forth in Section 4(a) of the Agreement, no further compensation of any kind shall be due to me from the Company or any of the other Company Released Parties as a result of my employment now ended. Without limiting the generality of the foregoing, I specifically acknowledge and agree that I have been paid in full all base salary, bonus compensation and pay for unused vacation due to me and that I have been reimbursed for all business expenses I incurred in the performance of my duties for the Company and the other Company Released Parties.

Effective as of the date of my termination of employment, I hereby confirm my resignation from all officer positions I hold or previously held with the Company or any subsidiary. I further agree that I will execute any additional documents that the Company may reasonably request in connection with the foregoing.

I understand that I must immediately return to the Company any and all documents, materials and information (whether in hardcopy, on electronic media or otherwise) related to the business (whether present or otherwise) of the Company, its subsidiaries and other affiliates and all keys, access cards, credit cards, computer hardware and software, telephones and other property of the Company, its subsidiaries and other affiliates and any copies thereof in my possession or control.

I have previously entered into the Company's standard proprietary information and inventions agreement (the "Proprietary Information and Inventions Agreement"). I agree to continue to perform my obligations thereunder.

Nothing in this Release of Claims shall be deemed to restrict my right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation.

This Release of Claims creates legally binding obligations and I acknowledge that I am hereby advised by the Company to seek the advice of an attorney prior to signing this Release of Claims.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to [twenty-one (21)][forty-five (45)] Forty-five days to be included in the event of a group termination. days from the date I receive it, provided that I sign and return it to the Company no later than the [twenty-first (21st)][forty-fifth (45th)] day after such receipt. I acknowledge that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing

before signing; and that I am signing this Release of Claims knowingly, voluntarily and with a full understanding of its terms. I represent and acknowledge that if I am executing this Release of Claims before the foregoing period has elapsed, I do so knowingly, voluntarily and upon the advice of and with the approval of my legal counsel (if any), and I voluntarily waive any remaining portion of the consideration period. I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth in writing expressly in the Agreement or this Release of Claims.

I understand that I may revoke this Release of Claims solely with respect to any potential ADEA Claims at any time within seven (7) days of the date of my signing by written notice to the Company c/o the Chief Executive Officer and that this Release of Claims will take full effect on the eighth calendar day after my signing and only if I have not revoked it during the preceding seven-day revocation period. Notwithstanding my election to revoke with respect to any potential ADEA Claims, I acknowledge that all other terms of this Release of Claims shall remain in full force and effect. I further acknowledge that I shall not be entitled to any payments under Section 4[insert relevant subsection] of the Agreement unless this Release of Claims is executed and becomes effective not later than [thirty (30)][fifty-two (52)] days following the date of my termination of employment.

[I acknowledge that I have been provided with a notice, as required by the Older Workers Benefit Protection Act of 1990, that contains information about the job titles and ages of all individuals eligible or selected to receive the severance package and the ages of all individuals in the same job classification or organizational unit who are not eligible or selected for the severance package. (See Attachment 1.)] To be included in the event of a group termination.

This Release of Claims, the Agreement and the Proprietary Information and Inventions Agreement constitute the entire agreement of the Company and me in respect of the subject matter contained herein and therein and supersede all prior or simultaneous representations, discussions, negotiations and agreements, whether written or oral. This Release of Claims may be amended or modified only with my written consent and the written consent of an authorized representative of the Company. No oral waiver, amendment or modification will be effective under any circumstances whatsoever.

The validity, interpretation, construction and performance of this Release of Claims shall be governed by the laws of the State of California without reference to conflict of laws provisions.

If any term or provision of this Release of Claims or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Release of Claims or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefore to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

This Release of Claims may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

Any dispute, claim or controversy based on, arising out of or relating to my employment or the termination thereof or the Agreement shall be settled by final and binding arbitration in the County of San Diego, California, before a single neutral arbitrator in accordance with the National Rules for the Resolution of Employment Disputes (the "Rules") of the American Arbitration Association, and judgment on the award

rendered by the arbitrator may be entered in any court having jurisdiction. The Rules may be found online at www.adr.org. Arbitration may be compelled pursuant to the California Arbitration Act (Code of Civil Procedure §§ 1280 et seq.). If the parties are unable to agree upon an arbitrator, one shall be appointed by the AAA in accordance with its Rules. Each party shall pay the fees of its own attorneys, the expenses of its witnesses and all other expenses connected with presenting its case; however, the parties agree that, to the extent permitted by law, the arbitrator may, in his or her discretion, award reasonable attorneys' fees to the prevailing party; provided, further, that the prevailing party shall be reimbursed for such fees, costs and expenses within forty-five (45) days following any such award, but in no event later than the last day of my taxable year following the taxable year in which the fees, costs and expenses were incurred; provided, further, that the parties' obligations pursuant to this sentence shall terminate on the tenth (10th) anniversary of the date of the termination of my employment. Other costs of the arbitration, including the cost of any record or transcripts of the arbitration, AAA's administrative fees, the fee of the arbitrator, and all other fees and costs, shall be borne by the Company. This paragraph is intended to be the exclusive method for resolving any and all claims by the parties against each other for payment of damages under the Agreement or relating to my employment or the termination thereof; provided, however, that I shall retain the right to file administrative charges with or seek relief through any government agency of competent jurisdiction, and to participate in any government investigation, including but not limited to (i) claims for workers' compensation, state disability insurance or unemployment insurance; (ii) claims for unpaid wages or waiting time penalties brought before the California Division of Labor Standards Enforcement; provided, however, that any appeal from an award or from denial of an award of wages and/or waiting time penalties shall be arbitrated pursuant to the terms of this paragraph; and (iii) claims for administrative relief from the United States Equal Employment Opportunity Commission and/or the California Department of Fair Employment and Housing (or any similar agency in any applicable jurisdiction other than California); provided, further, that I shall not be entitled to obtain any monetary relief through such agencies other than workers' compensation benefits or unemployment insurance benefits. This paragraph shall not limit either party's right to obtain any provisional remedy, including, without limitation, injunctive or similar relief, from any court of competent jurisdiction as may be necessary to protect their rights and interests pending the outcome of arbitration, including without limitation injunctive relief, in any court of competent jurisdiction pursuant to California Code of Civil Procedure § 1281.8 or any similar statute of an applicable jurisdiction. Seeking any such relief shall not be deemed to be a waiver of such party's right to compel arbitration. Both the Company and I expressly waive our right to a jury trial.

Intending to be legally bound, I have signed this Release of Claims as of the date written below.

Signature: Name: Brian Dorsey
Date Signed:
Acknowledged and Agreed:
APRICUS BIOSCIENCES, INC.
G:
Signature:
Name:
Title:
Date Signed:

#### APRICUS BIOSCIENCES, INC.

#### SECOND AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Second Amended and Restated Employment Agreement (the "<u>Agreement</u>") is dated as of December 20, 2016 (the "Effective Date"), by and between Neil Morton ("<u>Employee</u>") and Apricus Biosciences, Inc., a Nevada corporation ("<u>Apricus</u>," and collectively with its subsidiaries, the "<u>Company</u>").

#### RECITALS

- A. Employee and Apricus entered into the Amended and Restated Employment Agreement, dated as of April 25, 2016 (the "Original Agreement").
- B. The Board of Directors of Apricus (the "Board") believes it is in the best interests of the Company and its shareholders to retain Employee and provide incentives to Employee to serve the Company as set forth herein.
- C. The Board further believes that it is necessary to provide Employee with certain benefits upon certain terminations of Employee's employment, which benefits are intended to provide Employee with financial security and provide sufficient income and encouragement to Employee to remain employed with the Company, notwithstanding the possibility of a Change in Control.
- D. To accomplish the foregoing objectives, the Board has directed the Company, upon execution of this Agreement by Employee, to agree to the terms provided in this Agreement.

It is therefore agreed as follows:

- 1. At-Will Employment. The Company and Employee acknowledge that Employee's employment is and shall continue to be at-will, as defined under applicable law, and that Employee's employment with the Company may be terminated by either party at any time for any or no reason. This "at-will" nature of Employee's employment shall remain unchanged during Employee's tenure as an employee and may not be changed, except in an express writing signed by Employee and a duly authorized officer of the Company. If Employee's employment terminates for any reason, Employee shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law.
- 2. **Duties.** Employee shall be employed by the Company as Senior Vice President, Chief Business Officer of the Company, and, as such, Employee shall faithfully perform for the Company the duties of said office and shall perform such other duties of an executive, managerial or administrative nature as shall be specified and designated from time to time by the Board or the Chief Executive Officer of Apricus ("CEO"). While employed by the Company, Employee shall not, without the prior consent of the CEO, (i) render to others services of any kind for compensation or engage in any other business activity that would materially interfere with the performance of Employee's duties under this Agreement, or (ii) directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. Employee shall not invest in any company or business that competes in any manner with the Company; *provided that*, Employee may, without violating this section, own as a passive investment, shares of capital stock of a publicly-traded corporation

that engages in competition if (i) such shares are actively traded on an established national securities market in the United States, (ii) the number of shares of such corporation's capital stock that are beneficially owned (directly or indirectly) by Employee represents less than one percent of the total number of shares of such corporation's outstanding capital stock, and (iii) Employee is not otherwise associated directly or indirectly with such corporation or with any affiliated of such corporation. Employee may also participate freely in the affairs of any recognized charitable organizations, non-profit or in any community affairs of Employee's choice. Employee shall be subject to and comply with the policies and procedures generally applicable to employees of the Company to the extent the same are not inconsistent with any term of this Agreement.

- 3. <u>Compensation</u>. As compensation for the services to be rendered by Employee to the Company pursuant to this Agreement, Employee shall be paid the following compensation and other benefits, which compensation and benefits may be paid or provided by Apricus or NexMed (U.S.A.), Inc., Apricus' wholly-owned subsidiary.
- (a) <u>Salary</u>. The Company shall pay Employee a salary at an initial rate of \$275,000.00 per annum, which may be adjusted by the Compensation Committee of the Board from time to time (the "<u>Annual Salary</u>"), and shall be paid in accordance with the customary payroll practices of the Company applicable to employees.
- (b) **Bonus**. For each fiscal year completed during the term hereof, Employee shall be eligible to participate in any annual bonus plan provided by the Company for its employees generally, as in effect from time to time. Employee's annual target bonus shall be 40% of the Annual Salary (the "<u>Target Bonus</u>"), with the actual amount of the bonus, if any, to be determined by the Board or the Compensation Committee in accordance with the terms of the bonus plan. Employee shall be required to be employed with the Company on the date that bonuses are paid in order to be entitled to receive such payment.
- Benefits. During the term hereof, Employee shall be eligible for inclusion, to the extent permitted by law, as a fultime employee of the Company or any of its subsidiaries, in any and all of the following plans, programs, and policies in effect at the time, subject to the terms and conditions of such plans, programs and policies: (i) pension, profit sharing, savings, and other retirement plans and programs, (ii) life and health (medical, dental, hospitalization, short-term and long-term disability) insurance plans and programs, (iii) stock option and stock purchase plans and programs, (iv) accidental death and dismemberment protection plans and programs, (v) travel accident insurance plans and programs, (vi) vacation policy (Employee shall accrue paid vacation per calendar year based on seniority in accordance with Company's policies), and (vii) other plans and programs sponsored by the Company or any subsidiary for employees generally, including any and all plans and programs that supplement any or all of the foregoing types of plans or programs. Nothing in this Agreement shall preclude the Company or any of its subsidiaries or affiliates from terminating or amending any employee benefit plan, program or policy from time to time after the date of this Agreement.
- (d) **Expenses.** The Company shall pay or reimburse Employee for all ordinary and reasonable out-of-pocket expenses actually incurred (and, in the case of reimbursement, paid) by Employee during the term of employment in the performance of Employee's services under this Agreement; *provided* that Employee submits proof of such expenses, with the properly completed forms as prescribed from time to time by the Company, no later than thirty (30) days after such expenses have been so incurred or as otherwise provided in accordance with the standard practices of the Company.

#### 4. **Benefits Upon Termination of Employment.**

- (a) Severance Upon Involuntary Termination. In the event that Employee suffers an Involuntary Termination, and subject to the limitations set forth in Section 6, then in addition to any accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination, Employee will be entitled to receive severance benefits as follows: (i) the Company shall pay to Employee in one lump sum an amount equal to (A) twelve (12) months of Employee's Annual Salary that Employee was receiving immediately prior to the Involuntary Termination; plus (B) any accrued but unpaid bonus for the calendar year preceding Employee's termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee be employed on the date the bonus is to be paid) (as determined by the Compensation Committee of the Board in its discretion); plus (C) 100% of the Employee's Target Bonus for the year in which the date of Employee's Involuntary Termination occurs; (ii) full acceleration of the vesting of all equity awards held by Employee at the time of the Involuntary Termination, including any options, restricted stock, restricted stock units or other awards; and (iii) reimbursement for the cost of continuation of health insurance benefits provided to Employee immediately prior to the Involuntary Termination pursuant to the terms of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or other applicable law through the earliest to occur of (A) twelve (12) months following the Involuntary Termination, (B) the date Employee becomes eligible for such COBRA or other benefits under applicable law (the "COBRA Coverage Period"). If any of the Company's health benefits are self-funded as of the date of Employee's Involuntary Termination, or if the Company cannot provide the foregoing benefits in a manner that is exempt from Section 409A of the Internal Revenue Code of 1986, as amended (
- mployment hereunder upon ten (10) or more days' prior written notice to Employee. If Employee should pass away during the term of this Agreement, Employee's employment shall be deemed terminated on Employee's date of death. For purposes of this Agreement, a "Permanent Disability" shall be deemed to have occurred only when Employee has qualified for benefits (including satisfaction of any applicable waiting period) under the Company's or a subsidiary's long-term disability insurance arrangement. In the event of the termination of Employee's employment hereunder by reason of Permanent Disability or death, the Employment Term shall end on the day of such termination and the Company shall pay, no later than the first payroll date following Employee's termination, to Employee or Employee's legal representative (in the event of Permanent Disability), or any beneficiary or beneficiaries designated by Employee to the Company in writing, or to Employee's estate if no such beneficiary has been so designated (in the event of Employee's death), a single lump sum payment of: (i) any accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination; and (ii) any amounts owing, but not yet paid, pursuant to Section 3(d) hereof. In addition, upon a termination under this Section 4(b): (1) Employee shall receive a pro rata bonus for the calendar year in which such termination occurs, equal to Employee's Target Bonus for the calendar year of said termination, and the denominator of which is three hundred sixty-five (365); (2) Employee shall receive any accrued but unpaid bonus for the calendar year preceding Employee's termination,

to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee be employed on the date the bonus is to be paid) (as determined by the Compensation Committee of the Board in its discretion); and (3) all of Employee's outstanding but unvested equity awards shall vest immediately and the expiration date for all of Employee's unvested stock option awards shall be extended so that they expire one year after the date of Employee's termination under this Section 4(b). Subject to Section 6(c), the amounts payable pursuant to clauses (1) and (2) above shall be paid within five (5) days following the date Employee's Release becomes effective and irrevocable (or, in the event of Employee's death, within five (5) days following the date of Employee's death).

- (c) Severance Upon a Change in Control. In the event that Employee suffers an Involuntary Termination within the 12-month period following the effective date of a Change in Control, then in addition to all accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of Employee's termination of employment, Employee will be entitled to receive severance benefits as follows: (i) the Company shall pay to Employee in one lump sum an amount equal to the greater of (A) eighteen (18) months of Employee's Annual Salary that Employee was receiving immediately prior to the Involuntary Termination or (B) eighteen (18) months of Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (ii) the Company shall pay to Employee's Annual Salary that Employee was receiving immediately prior to the Change in Control; (iii) the Company shall pay to Employee in one lump sum (A) any accrued (with the exception of the requirement that Employee's termination, to the extent that all criteria for such bonus have been met (with the exception of the requirement that Employee's Involuntary Termination Cours; (iii) full acceleration of the Vesting of all equity awards held by Employee at the time of the Involuntary Termination, including any options, restricted stock, restricted stock units or other awards; and (iv) reimbursement for the cost of continuation of health insurance benefits provided to Employee immediately prior to the Involuntary Termination pursuant to the terms of COBRA or other applicable law for a period continuing until the earlier of eighteen (18) months following the Involuntary Termination, or if the Company cannot provide the foregoing benefits
- (d) <u>Termination for Cause</u>. Notwithstanding any other provision of this Agreement, if Employee's employment is terminated for Cause at any time, then Employee shall not be entitled to receive payment of any severance benefits or any continuation or acceleration of stock award vesting and all of Employee's stock awards shall remain subject to all applicable forfeiture provisions and transfer restrictions. Employee will receive payment(s) for all accrued but unpaid Annual Salary, including Annual Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination.
- (e) <u>Voluntary Resignation</u>. If Employee voluntarily resigns from the Company under circumstances which do not constitute an Involuntary Termination, then Employee shall not be entitled to receive payment of any severance benefits, or option acceleration, or relinquishment of forfeiture and transfer restrictions. Employee will receive payment(s) for all accrued but unpaid Annual Salary, including Annual

Salary in respect of any accrued and accumulated but unpaid vacation, due to Employee at the date of such termination.

- 5. **Definition of Terms.** The following terms referred to in this Agreement shall have the following meanings:
- (a) "Cause" means any of the following: (i) Employee's theft, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, or falsification of any Company or affiliate documents or records; (ii) Employee's material failure to abide by a Company's or affiliate's code of conduct or other policies (including without limitation, policies relating to confidentiality and reasonable workplace conduct); (iii) Employee's unauthorized use, misappropriation, destruction or diversion of any tangible or intangible asset or corporate opportunity of the Company or an affiliate (including, without limitation, Employee's improper use or disclosure of confidential or proprietary information); (iv) any intentional act by Employee which has a material detrimental effect on the Company or an affiliate's reputation or business; (v) Employee's repeated failure or inability to perform any reasonable assigned duties after written notice from the Company or an affiliate (including, without limitation, habitual absence from work for reasons other than illness), and a reasonable opportunity to cure, such failure or inability; (vi) any material breach by Employee of any employment or service agreement between Employee and the Company or an affiliate, which breach is not cured pursuant to the terms of such agreement; or (vii) Employee's conviction (including any plea of guilty or *nolo contendere*) of any criminal act involving fraud, dishonesty, misappropriation or moral turpitude, or which materially impairs Employee's ability to perform his duties with the Company or an affiliate.
  - (b) "Change in Control" means the occurrence of any of the following:
    - (i) an Ownership Change Event or a series of related Ownership Change Events (collectively, a "<u>Transaction</u>") in which the shareholders of Apricus immediately before the Transaction do not retain immediately after the Transaction, in substantially the same proportions as their ownership of shares of Apricus' voting stock immediately before the Transaction, direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding voting securities of Apricus or such surviving entity immediately outstanding after the Transaction, or, in the case of an Ownership Change Event the entity to which the assets of Apricus were transferred (the "Transferee"), as the case may be; or
    - (ii) the liquidation or dissolution of Apricus.

For purposes of Section 5(b)(i), indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own Apricus or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Board shall have the right to determine whether multiple sales or exchanges of the voting securities in Apricus or multiple Ownership Change Events are related, and its determination shall be final, binding and conclusive. The Board may also, but need not, specify that other transactions or events constitute a Change in Control.

(c) "Involuntary Termination" shall include (i) any termination of Employee's employment by the Company (other than for Cause and other than as a result of Employee's death or Permanent Disability) or (ii) Employee's voluntary termination within sixty (60) days following

the occurrence of any of the following events without Employee's written consent: (i) a material reduction or material change in job duties, responsibilities, authority and requirements inconsistent with Employee's position with the Company and Employee's prior duties, responsibilities and requirements or a material negative change in Employee's reporting relationship (in each case, excluding any changes as a result of the loss of any interim or temporary roles within the Company); (ii) a material reduction of Employee's base compensation (other than in connection with a general decrease in base salaries for most officers of the Company or successor corporation); or (iii) Employee's refusal to relocate to a facility or location more than fifty (50) miles from the Company's current location, provided that Employee will not resign due to such change, reduction or relocation without first providing the Company with written notice of the event or events constituting the grounds for Employee's voluntary resignation within thirty (30) days of the initial existence of such grounds and a reasonable cure period of not less than thirty (30) days following the date of such notice.

- (d) "Ownership Change Event" means the occurrence of any of the following with respect to Apricus: (i) the direct or indirect sale or exchange in a single or series of related transactions by the shareholders of Apricus of more than fifty percent (50%) percent of the outstanding voting stock of Apricus; (ii) a merger or consolidation in which Apricus is a party, other than a change of domicile; or (iii) the sale, exchange, or transfer of all or substantially all of the assets of Apricus.
- 6. Limitation and Conditions on Payments.
- (a) Parachute Payments. In the event that the severance and other benefits provided for in this Agreement to Employee: (i) constitute "parachute payments" within the meaning of Section 280G of the Code; and (ii) but for this Section, would be subject to the excise tax imposed by Section 4999 of the Code, then Employee's severance benefits under Section 4 shall be payable either:
  - (i) in full; or
  - as to such lesser amount which would result in no portion of such severance benefits being subject to excise tax (ii) under Section 4999 of the Code, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Employee on an after-tax basis, of the greatest amount of severance benefits under Section 4, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. Any determination required under this Section 6 shall be made in writing by independent public accountants selected by the Company (the "Accountants"), whose determination shall be conclusive and binding upon Employee and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Section 280G and 4999 of the Code. The Company and Employee shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 6. Any reduction in severance benefits required by this Section 6 shall occur in a manner necessary to provide Employee with the greatest economic benefit. If more than one manner of reduction of severance benefits is necessary to arrive at the reduced amount yields the

greatest economic benefit to Employee, the payments and benefits shall be reduced pro rata.

- (b) Release Prior to Receipt of Benefits. Prior to the receipt of any benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c) of this Agreement, Employee (or, in the event of Employee's incapacity due to Permanent Disability, his legal representative) shall execute, and allow to become effective, a release of claims agreement in the form attached hereto as Exhibit A (the "Release") not later than fifty-two (52) days following Employee's employment termination. In no event will the Company have any obligation to pay any severance benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c) of this Agreement be provided to Employee until the Release becomes effective. In the event the Release does not become effective within fifty-two (52) days following Employee's employment termination, the Company shall not have any obligation to pay to Employee any severance benefits under Sections 4(a), 4(b) (in the event of a termination of Employee's employment by reason of Permanent Disability) or 4(c).
- (c) Section 409A. All severance payments to be made upon a termination of employment under this Agreement may be made only upon a "separation of service" within the meaning of Section 409A of the Code and the Department of Treasury regulations and other guidance promulgated thereunder. Notwithstanding any provision to the contrary in this Agreement, subject to Employee's compliance with Section 6(b) and the other provisions of this Section 6(c), any amount payable under Section 4 that is deemed deferred compensation subject to Section 409A of the Code shall be paid on the sixtieth (60th) day following Employee's "separation from service." Notwithstanding any provision to the contrary in this Agreement, if Employee is deemed by the Company at the time of Employee's separation from service to be a "specified employee" for purposes of Code Section 401A(a)(2)(B)(i), to the extent delayed commencement of any portion of the benefits to which Employee is entitled under this Agreement is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i), such portion of Employee's benefits shall not be provided to Employee prior to the earlier of (i) the expiration of the six-month period measured from the date of Employee's "separation of service" with the Company or (ii) the date of Employee's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 6(c) shall be paid in a lump sum to Employee, and any remaining payments due under the Agreement shall be paid as otherwise provided herein. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Employee's right to receive installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. It is intended that none of the severance payments and benefits to be provided hereunder will be subject to Section 409A of the Code and any ambiguities herein will be interpreted to be so exempt or, if not so exempt, to comply with Section 409A of the Code. Employee and the Company agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Employee under Section 409A of the Code. Notwithstanding anything to the contrary contained herein, to the extent that any amendment to this Agreement with respect to the payment of any severance payments or benefits would constitute under Code Section 409A a delay in a payment or a change in the form of payment, then such amendment must be done in a manner that complies with Code Section 409A(a)(4)(C). Any reimbursement of expenses or in-kind benefits payable under this Agreement shall be made in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv) and shall be paid on or before the last day of Employee's taxable year following the taxable year in which Employee incurred the expenses. The amount of expenses reimbursed or in-kind benefits payable during any taxable year of Employee's shall not affect the amount eligible for reimbursement or in-

kind benefits payable in any other taxable year of Employee's, and Employee's right to reimbursement for such amounts shall not be subject to liquidation or exchange for any other benefit.

- 7. Proprietary Information and Inventions Agreement. Employee has executed and agrees to abide by the terms of the Company's form of Proprietary Information and Inventions Agreement, which shall survive termination of Employee's employment with the Company and the termination of this Agreement.
- 8. Conflicts. Employee represents that Employee's performance of all the terms of this Agreement will not breach any other agreement to which Employee is a party. Employee has not, and will not during the term of this Agreement, enter into any oral or written agreement in conflict with any of the provisions of this Agreement. Employee further represents that Employee is entering into or has entered into an employment relationship with the Company of Employee's own free will and that Employee has not been solicited as an employee in any way by the Company.
- 9. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Employee's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.
- 10. Notice. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Employee shall be addressed to Employee at the home address which Employee most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

#### 11. Miscellaneous Provisions.

- (a) No Duty to Mitigate. Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Employee may receive from any other source.
- (b) Waiver. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Employee and by an authorized officer of the Company (other than Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.
- (c) Whole Agreement. This Agreement replaces the Original Agreement in its entirety. Other than any indemnification agreement entered into between the Company and Employee in connection with Employee's employment, any outstanding stock option or other equity compensation award agreements and the Proprietary Information and Inventions Agreement executed by Employee, no agreements, representations or understandings (whether oral or written and whether express or

implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes any agreement of the same title and concerning similar subject matter dated prior to the Effective Date, including any offer letter between Employee and the Company, and by execution of this Agreement both parties agree that any such predecessor agreement shall be deemed null and void.

- (d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions.
- (e) Severability. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefore to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.
- Arbitration. Any dispute, claim or controversy based on, arising out of or relating to Employee's employment or the termination thereof or this Agreement shall be settled by final and binding arbitration in the County of San Diego, California, before a single neutral arbitrator in accordance with the National Rules for the Resolution of Employment Disputes (the "Rules") of the American Arbitration Association, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction. The Rules may be found online at www.adr.org. Arbitration may be compelled pursuant to the California Arbitration Act (Code of Civil Procedure §§ 1280 et seq.). If the parties are unable to agree upon an arbitrator, one shall be appointed by the AAA in accordance with its Rules. Each party shall pay the fees of its own attorneys, the expenses of its witnesses and all other expenses connected with presenting its case; however, the parties agree that, to the extent permitted by law, the arbitrator may, in his or her discretion, award reasonable attorneys' fees to the prevailing party; provided, further, that the prevailing party shall be reimbursed for such fees, costs and expenses within forty-five (45) days following any such award, but in no event later than the last day of Employee's taxable year following the taxable year in which the fees, costs and expenses were incurred; provided, further, that the parties' obligations pursuant to this sentence shall terminate on the tenth (10th) anniversary of the date of the termination of my employment. Other costs of the arbitration, including the cost of any record or transcripts of the arbitration, AAA's administrative fees, the fee of the arbitrator, and all other fees and costs, shall be borne by the Company. This Section 11(f) is intended to be the exclusive method for resolving any and all claims by the parties against each other for payment of damages under the Agreement or relating to my employment or the termination thereof; provided, however, that Employee shall retain the right to file administrative charges with or seek relief through any government agency of competent jurisdiction, and to participate in any government investigation, including but not limited to (i) claims for workers' compensation, state disability insurance or unemployment insurance; (ii) claims for unpaid wages or waiting time penalties brought before the California Division of Labor Standards Enforcement; provided, however, that any appeal from an award or from denial of an award of wages and/or waiting time penalties shall be arbitrated pursuant to the terms of this paragraph; and (iii) claims for administrative relief from the United States Equal Employment Opportunity Commission and/or the California Department of Fair Employment and Housing (or any similar agency in any applicable jurisdiction other than California); provided, further, that Employee shall not be entitled to obtain

any monetary relief through such agencies other than workers' compensation benefits or unemployment insurance benefits. This paragraph shall not limit either party's right to obtain any provisional remedy, including, without limitation, injunctive or similar relief, from any court of competent jurisdiction as may be necessary to protect their rights and interests pending the outcome of arbitration, including without limitation injunctive relief, in any court of competent jurisdiction pursuant to California Code of Civil Procedure § 1281.8 or any similar statute of an applicable jurisdiction. Seeking any such relief shall not be deemed to be a waiver of such party's right to compel arbitration. Both the Company and Employee expressly waive their right to a jury trial.

- (g) Legal Fees and Expenses. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with this Agreement. Notwithstanding the foregoing, in the event of any dispute arising under or relating to this Agreement, the arbitrator or court may, but shall not be required to, award the prevailing party its fees and expenses, including reasonable attorneys' fees.
- (h) No Assignment of Benefits. The rights of Employee to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this Section 11(h) shall be void. This Agreement does not create, and shall not be construed as creating, any rights enforceable by any person not a party to this Agreement.
- (i) Employment Taxes. All payments made pursuant to this Agreement will be subject to withholding of applicable income and employment taxes.
- (j) Assignment by Company. The Company may assign its rights under this Agreement to an affiliate, and an affiliate may assign its rights under this Agreement to another affiliate of the Company or to the Company. In the case of any such assignment, the term "Company" when used in a section of this Agreement shall mean the corporation that actually employs Employee.
- (k) Non-Disparagement. Upon any termination of employment or service, Employee agrees that he/she will not, directly or indirectly through affiliates or associates, make any written or oral communications that could reasonably be considered to be disparaging of the Company in any respect, including, but not limited to, the Company's business, technology, products, executives, officers, directors, former executives, consultants, contractors or agents. Additionally, the Company agrees that the Board and the Company's executive officers will not make (or direct the Company to make) any written or oral communications that could reasonably be considered to be disparaging of Employee in any respect. Nothing in this Section shall preclude Employee or any representative of the Company from testifying truthfully in any deposition or judicial or administrative proceeding. Moreover, nothing in this Section applies to communications to Employee's immediate family or communications by Employee or representatives of the Company to their respective attorneys, or to pleadings or other documents in any proceeding to enforce this Agreement or between Employee and the Company.
- (l) Construction. The language in all parts of this Agreement shall in all cases be construed simply, according to its fair meaning, and not strictly for or against any of the parties hereto. Without limitation, there shall be no presumption against any party on the ground that such party was responsible for drafting this Agreement or any part thereof.

(m)	) (	Counterparts.	This A	greement	may b	e executed	in	counterparts,	each	of wh	ich :	shall	be o	deemed	an	original.
but all of w	hich togo	ether will con	stitute	one and th	ie sam	e instrumei	nt.	1								

(n) Whistleblower Provision. Nothing herein is intended to or shall prevent Employee from communicating directly with, cooperating with, or providing information to, any federal, state or local government regulator, including, but not limited to, the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading Commission, or the U.S. Department of Justice.

[Signature page follows]

The parties have executed this Agreement on the date first written above.

### APRICUS BIOSCIENCES, INC.

By: <u>/s/ Richard W. Pascoe</u> Name: Richard W. Pascoe

Title: Chief Executive Officer & Secretary

**EMPLOYEE** 

Signature: <u>/s/ Neil Morton</u> Print Name: Neil Morton

## Exhibit A FORM OF RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the severance benefits to be provided me in connection with the involuntary termination of my employment, as set forth in Section 4[insert relevant subsection] of the Second Amended and Restated Employment Agreement between me and Apricus Biosciences, Inc. (the "Company"), dated December 20, 2016 (the "Agreement"), which are conditioned on my signing this Release of Claims and not revoking this Release of Claims as provided below, and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executors, administrators, beneficiaries, representatives and assigns, and all others connected with or claiming through me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, shareholders, employees, employee benefit plans, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns and all others connected with any of them (all of the foregoing, the "Company Released Parties"), both individually and in their official capacities, from any and all causes of action, rights or claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way related to, resulting from, arising out of or connected with my employment by or service to the Company or any of its subsidiaries or other affiliates or the termination of that employment or service or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act (the "ADEA Claims"), Employee Retirement Income Security Act, the Americans with Disabilities Act, and the wage and hour, wage payment, and fair employment practices laws of the state or states in which I have been employed by the Company or any of its subsidiaries or other affiliates, each as amended from time to time).

In signing this Release of Claims, I expressly waive and relinquish all rights and benefits afforded by Section 1542 of the Civil Code of the State of California, as well as under any other statutes or common law principles of similar effect, and do so understanding and acknowledging the significance of such specific waiver of Section 1542, which Section states as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

Thus, notwithstanding the provisions of Section 1542, and for the purpose of implementing a full and complete release and discharge of the Released, I expressly acknowledge that this Release of Claims is intended to include in its effect, without limitation, all Claims which I do not know or suspect to exist in my favor at the time of execution hereof, and that this Release of Claims contemplates the extinguishment of such Claim or Claims.

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement based on the Company's executory obligations under the Agreement after the effective date of this Release of Claim; (ii) any right of indemnification or contribution that I have pursuant to the articles of incorporation or by-laws of the Company, (iii) all rights to any outstanding options, restricted stock, restricted stock units or other awards to the extent vested and exercisable pursuant to the terms of the awards and the plans under which they were granted as of the termination of my employment; (iv) any right which cannot

be waived by operation of law, including claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims for workers' compensation insurance benefits under the terms of any workers' compensation insurance policy or fund of the Company or any claims pursuant to the terms and conditions of the federal law known as COBRA or any comparable state law, including Cal-COBRA; and (v) my right to bring to the attention of the Equal Employment Opportunity Commission or the California Department of Fair Employment and Housing or any other federal, state or local government agency claims of discrimination, or from participating in an investigation or proceeding conducted by the Equal Employment Opportunity Commission or any other federal, state or local government agency; provided, however, that I do release my right to secure any damages for alleged discriminatory treatment.

I hereby represent, warrant and agree that I have been paid in full all compensation due to me, whether for services rendered by me to the Company, its subsidiaries and other affiliates, or otherwise, through the date on which my employment with the Company terminated and that, exclusive only of the Company's provision to me of the severance benefits in accordance with the terms and conditions set forth in Section 4(a) of the Agreement, no further compensation of any kind shall be due to me from the Company or any of the other Company Released Parties as a result of my employment now ended. Without limiting the generality of the foregoing, I specifically acknowledge and agree that I have been paid in full all base salary, bonus compensation and pay for unused vacation due to me and that I have been reimbursed for all business expenses I incurred in the performance of my duties for the Company and the other Company Released Parties.

Effective as of the date of my termination of employment, I hereby confirm my resignation from all officer positions I hold or previously held with the Company or any subsidiary. I further agree that I will execute any additional documents that the Company may reasonably request in connection with the foregoing.

I understand that I must immediately return to the Company any and all documents, materials and information (whether in hardcopy, on electronic media or otherwise) related to the business (whether present or otherwise) of the Company, its subsidiaries and other affiliates and all keys, access cards, credit cards, computer hardware and software, telephones and other property of the Company, its subsidiaries and other affiliates and any copies thereof in my possession or control.

I have previously entered into the Company's standard proprietary information and inventions agreement (the "Proprietary Information and Inventions Agreement"). I agree to continue to perform my obligations thereunder.

Nothing in this Release of Claims shall be deemed to restrict my right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation.

This Release of Claims creates legally binding obligations and I acknowledge that I am hereby advised by the Company to seek the advice of an attorney prior to signing this Release of Claims.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to [twenty-one (21)][forty-five (45)] Forty-five days to be included in the event of a group termination. days from the date I receive it, provided that I sign and return it to the Company no later than the [twenty-first (21st)][forty-fifth (45th)] day after such receipt. I acknowledge that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing

before signing; and that I am signing this Release of Claims knowingly, voluntarily and with a full understanding of its terms. I represent and acknowledge that if I am executing this Release of Claims before the foregoing period has elapsed, I do so knowingly, voluntarily and upon the advice of and with the approval of my legal counsel (if any), and I voluntarily waive any remaining portion of the consideration period. I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth in writing expressly in the Agreement or this Release of Claims.

I understand that I may revoke this Release of Claims solely with respect to any potential ADEA Claims at any time within seven (7) days of the date of my signing by written notice to the Company c/o the Chief Executive Officer and that this Release of Claims will take full effect on the eighth calendar day after my signing and only if I have not revoked it during the preceding seven-day revocation period. Notwithstanding my election to revoke with respect to any potential ADEA Claims, I acknowledge that all other terms of this Release of Claims shall remain in full force and effect. I further acknowledge that I shall not be entitled to any payments under Section 4[insert relevant subsection] of the Agreement unless this Release of Claims is executed and becomes effective not later than [thirty (30)][fifty-two (52)] days following the date of my termination of employment.

[I acknowledge that I have been provided with a notice, as required by the Older Workers Benefit Protection Act of 1990, that contains information about the job titles and ages of all individuals eligible or selected to receive the severance package and the ages of all individuals in the same job classification or organizational unit who are not eligible or selected for the severance package. (See Attachment 1.)] To be included in the event of a group termination.

This Release of Claims, the Agreement and the Proprietary Information and Inventions Agreement constitute the entire agreement of the Company and me in respect of the subject matter contained herein and therein and supersede all prior or simultaneous representations, discussions, negotiations and agreements, whether written or oral. This Release of Claims may be amended or modified only with my written consent and the written consent of an authorized representative of the Company. No oral waiver, amendment or modification will be effective under any circumstances whatsoever.

The validity, interpretation, construction and performance of this Release of Claims shall be governed by the laws of the State of California without reference to conflict of laws provisions.

If any term or provision of this Release of Claims or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Release of Claims or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefore to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

This Release of Claims may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

Any dispute, claim or controversy based on, arising out of or relating to my employment or the termination thereof or the Agreement shall be settled by final and binding arbitration in the County of San Diego, California, before a single neutral arbitrator in accordance with the National Rules for the Resolution of Employment Disputes (the "Rules") of the American Arbitration Association, and judgment on the award

rendered by the arbitrator may be entered in any court having jurisdiction. The Rules may be found online at www.adr.org. Arbitration may be compelled pursuant to the California Arbitration Act (Code of Civil Procedure §§ 1280 et seq.). If the parties are unable to agree upon an arbitrator, one shall be appointed by the AAA in accordance with its Rules. Each party shall pay the fees of its own attorneys, the expenses of its witnesses and all other expenses connected with presenting its case; however, the parties agree that, to the extent permitted by law, the arbitrator may, in his or her discretion, award reasonable attorneys' fees to the prevailing party; provided, further, that the prevailing party shall be reimbursed for such fees, costs and expenses within forty-five (45) days following any such award, but in no event later than the last day of my taxable year following the taxable year in which the fees, costs and expenses were incurred; provided, further, that the parties' obligations pursuant to this sentence shall terminate on the tenth (10th) anniversary of the date of the termination of my employment. Other costs of the arbitration, including the cost of any record or transcripts of the arbitration, AAA's administrative fees, the fee of the arbitrator, and all other fees and costs, shall be borne by the Company. This paragraph is intended to be the exclusive method for resolving any and all claims by the parties against each other for payment of damages under the Agreement or relating to my employment or the termination thereof; provided, however, that I shall retain the right to file administrative charges with or seek relief through any government agency of competent jurisdiction, and to participate in any government investigation, including but not limited to (i) claims for workers' compensation, state disability insurance or unemployment insurance; (ii) claims for unpaid wages or waiting time penalties brought before the California Division of Labor Standards Enforcement; provided, however, that any appeal from an award or from denial of an award of wages and/or waiting time penalties shall be arbitrated pursuant to the terms of this paragraph; and (iii) claims for administrative relief from the United States Equal Employment Opportunity Commission and/or the California Department of Fair Employment and Housing (or any similar agency in any applicable jurisdiction other than California); provided, further, that I shall not be entitled to obtain any monetary relief through such agencies other than workers' compensation benefits or unemployment insurance benefits. This paragraph shall not limit either party's right to obtain any provisional remedy, including, without limitation, injunctive or similar relief, from any court of competent jurisdiction as may be necessary to protect their rights and interests pending the outcome of arbitration, including without limitation injunctive relief, in any court of competent jurisdiction pursuant to California Code of Civil Procedure § 1281.8 or any similar statute of an applicable jurisdiction. Seeking any such relief shall not be deemed to be a waiver of such party's right to compel arbitration. Both the Company and I expressly waive our right to a jury trial.

Intending to be legally bound, I have signed this Release of Claims as of the date written below.

Name: Neil Morton	
Date Signed:	
Acknowledged and Agreed	1:
APRICUS BIOSCIENCE	S, INC.
Signature: Name: Title:	

Signature:

Date Signed:

#### 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

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 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, 333-105509, 333-96813, 333-46976 and 333-91957) and Form S-8 (Nos. 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. (the "Company") of our report dated March 13, 2017, relating to the 2016 consolidated financial statements 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 13, 2017

#### 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 13, 2017

/S/ RICHARD W. PASCOE

Richard W. Pascoe

Chief Executive Officer & Secretary

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

I, Richard W. Pascoe, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Apricus Biosciences, Inc. on Form 10-K for the year ended December 31, 2016 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 13, 2017 By: /S/ RICHARD W. PASCOE

Name: Richard W. Pascoe

Title: Chief Executive Officer & Secretary

#### Apricus Biosciences, Inc. and Subsidiaries Notes to Unaudited Pro Forma Condensed Consolidated Financial Information

#### **Explanatory Note**

On March 8, Apricus Biosciences, Inc. filed a Current Report on Form 8-K (the "Original Form 8-K") to report, among other things, Apricus Biosciences, Inc., NexMed (U.S.A.), Inc., NexMed Holdings, Inc. and NexMed International Limited (collectively, the "Company") entry into an asset purchase agreement, dated March 8, 2017 (the "Ferring Asset Purchase Agreement") with Ferring International Center S.A. ("Ferring"), pursuant to which, and on the terms and subject to the conditions thereof, among other things, the Company agreed to sell to Ferring the Company's 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"). 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 Original Form 8-K also reported that the Company and Ferring closed the transactions on March 8, 2017 (the "Closing"). The Original Form 8-K is amended by filing this Exhibit 99.2 and incorporated therein by reference.

As a closing condition of the Ferring Asset Purchase Agreement, the Company was required to unencumber the purchased assets and therefore, used approximately \$6.6 million of the proceeds from the sale to repay all outstanding amounts due and owed under its Loan and Security Agreement ("Credit Facility") with Oxford Finance, LLC ("Oxford") and Silicon Valley Bank ("SVB") (Oxford and SVB are referred to together as the "Lenders"). Accordingly, the repayment of the Credit Facility is also given pro forma effect in the accompanying pro forma condensed consolidated financial information.

As a result of this transaction, effective in the first quarter of 2017, the Company will classify its results of operations for all periods presented to reflect the Product Business as a discontinued operation. The unaudited pro forma condensed consolidated statements of operations for the years ended December 31, 2016 and 2015 are presented as if the Ferring Asset Purchase Agreement had occurred as of January 1, 2015. The unaudited pro forma condensed consolidated balance sheet as of December 31, 2016 is presented as if the sales transaction had occurred as of December 31, 2016. The pro forma condensed consolidated financial statements and the notes thereto should be read in conjunction with the Company's historical consolidated financial statements in its Annual Report on Form 10-K filed herein.

The unaudited pro forma condensed consolidated financial information has been prepared based upon available information and management estimates; actual amounts may differ from these estimated amounts. The unaudited pro forma condensed consolidated financial information is not necessarily indicative of the financial position or results of operations that might have occurred had the Asset Purchase Agreement occurred as of the dates stated above or for any period following the sale of the Product Business. The pro forma adjustments are described in the notes and the unaudited pro forma condensed consolidated financial information should be read in conjunction with the related notes.

#### Apricus Biosciences, Inc. and Subsidiaries Unaudited Pro Forma Condensed Consolidated Statements of Operations For The Fiscal Year Ended December 31, 2016 (In thousands, except per share data)

	Pro Forma Adjustments			
	As Previously Reported	Activity of Discontinued Operation (1)	Other Adjustments (2)	Pro Forma Statement of Operations for Continuing Operations
License fee revenue	\$ 4,000	\$ (3,950)	\$	\$ 50
Royalty revenue	1,088	(1,088)	_	_
Product sales	675	(675)	<u> </u>	
Total revenue	5,763	(5,713)	_	50
Cost of goods sold	511	(511)	_	_
Cost of Sandoz rights	3,380	(3,380)	_	
Gross profit	1,872	(1,822)	_	50
Operating expense				_
Research and development	6,831	_	_	6,831
General and administrative	8,434	_	_	8,434
Loss on disposal of assets	14			14
Total operating expense	15,279	_	_	15,279
Loss before other expense	(13,407)	(1,822)	_	(15,229)
Other income (expense)				_
Interest income (expense), net	(1,022)	40	988	6
Change in fair value of warrant liabilities	7,479	_	_	7,479
Other financing expenses	(461)	_	_	(461)
Other expense, net	(22)	_	_	(22)
Total other income	5,974	40	988	7,002
Net loss	\$ (7,433)	\$ (1,782)	\$ 988	\$ (8,227)
Basic and diluted loss per common share	\$ (1.14)			\$ (1.26)
Weighted average common shares outstanding used for basic and diluted loss per share	6,516,662			6,516,662

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

#### Apricus Biosciences, Inc. and Subsidiaries Unaudited Pro Forma Condensed Consolidated Statements of Operations For The Fiscal Year Ended December 31, 2015 (In thousands, except per share data)

		Pro Forma A			Adjust	ments	
	A	s Previously Reported		Activity of Discontinued Operation (1)	Othe	r Adjustments (2)	Pro Forma Statement of Operations for Continuing Operations
License fee revenue	\$	3,600	\$	(3,600)	\$	_	\$ _
Royalty revenue		650		(650)		_	
Product sales		589		(589)		<u> </u>	_
Total revenue		4,839		(4,839)		_	_
Cost of goods sold		922		(922)			 _
Gross profit		3,917		(3,917)		_	_
Operating expense							_
Research and development		14,649		_		_	14,649
General and administrative		10,516		_		_	10,516
Loss on disposal of assets		102					102
Total operating expense		25,267		_		_	25,267
Loss before other expense		(21,350)		(3,917)			(25,267)
Other income (expense)							_
Interest expense, net		(895)		_		827	(68)
Change in fair value of warrant liabilities		3,236		_		_	3,236
Other expense, net		(14)					(14)
Total other income		2,327		_		827	3,154
Net loss	\$	(19,023)	\$	(3,917)	\$	827	\$ (22,113)
Basic and diluted loss per common share	\$	(3.83)					\$ (4.45)
Weighted average common shares outstanding used for basic and diluted loss per share		4,972,858					4,972,858

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

#### Apricus Biosciences, Inc. and Subsidiaries Unaudited Pro Forma Condensed Consolidated Balance Sheet December 31, 2016 (In thousands)

				Pro Forma		
	As Previously Reported		Activity of Discontinued Operations (3)		Other Adjustments (2)	Pro Forma Balance Sheet
Assets						
Cash	\$	2,087	\$	11,500	\$ (6,650)	\$ 6,937
Accounts receivable		530		_	_	530
Inventories		764		(764)	_	_
Prepaid expenses and other current assets		253		_	_	253
Total current assets		3,634		10,736	(6,650)	7,720
Property and equipment, net		1,006		(842)	_	164
Other long term assets		60		_	_	60
Total assets	\$	4,700	\$	9,894	\$ (6,650)	\$ 7,944
Liabilities and stockholders' deficit						
Current liabilities						
Note payable, net	\$	6,650	\$	_	\$ (6,650)	\$ —
Accounts payable		960		_	_	960
Accrued expenses		3,070		(1,170)	43	1,943
Accrued compensation		614				614
Total current liabilities		11,294		(1,170)	(6,607)	3,517
Warrant liabilities		846		_	_	846
Other long term liabilities		76				76
Total liabilities		12,216		(1,170)	(6,607)	4,439
Commitments and contingencies						
Stockholders' equity (deficit)						
Common stock		8		_	_	8
Additional paid-in-capital		308,784		<u> </u>	_	308,784
Accumulated deficit		(316,308)		11,064	(43)	(305,287)
Total stockholders' equity (deficit)		(7,516)		11,064	(43)	3,505
Total liabilities and stockholders' equity (deficit)	\$	4,700	\$	9,894	\$ (6,650)	\$ 7,944

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

#### Apricus Biosciences, Inc. and Subsidiaries Notes to Unaudited Pro Forma Condensed Consolidated Financial Information

#### Note 1. Basis of Presentation

The accompanying unaudited pro forma condensed consolidated financial statements give effect to the pro forma adjustments necessary to reflect the sale of the Product Business in exchange for \$11.5 million and repayment of the Credit Facility with the Lenders as if they had occurred as of January 1, 2015 in the pro forma condensed consolidated statements of operations for the years ended December 31, 2016 and 2015, and as of December 31, 2016 in the pro forma condensed consolidated balance sheet. The Company is eligible to receive up to an additional \$0.7 million for the value of inventory related to the Purchased Assets, subject to certain customary adjustments and limitations. Additionally, the Company is eligible to receive two additional quarterly payments totaling \$0.5 million for transition services, subject to certain limitations. These amounts to be received are not reflected in the pro forma condensed consolidated financial statements because the payments have not been made and are contingent upon certain conditions being met. Beginning in the first quarter of 2017, the Company will classify its results of operations for all periods presented to reflect the Product Business as a discontinued operation.

#### Note 2. Pro Forma Adjustments

The unaudited pro forma condensed consolidated statements of earnings and balance sheet reflect the effect of the following pro forma adjustments:

(1) Reduction of revenue and expenses as a result of the sale of the Product Business to Ferring in the Ferring Asset Purchase Agreement. These amounts do not consider an allocation of general corporate overhead costs not specifically related to the Product Business and therefore, selling, general and administrative expenses do not reflect any potential reductions in corporate costs in response to this change in the Company.

The Company is also eligible to receive up to \$0.5 million in payments related to transition services, subject to certain limitations. This activity is nonrecurring and has not been adjusted within the pro forma condensed consolidated statements of earnings.

- (2) Other Adjustments. Other Adjustments reflect the payoff of the Credit Facility and elimination of the related interest expense.
- (3) The elimination of assets and liabilities associated with the Product Business included in the Company's historical condensed consolidated financial statements subject to the terms of the sales transaction. The increase in cash of \$11.5 million represents the proceeds received from Ferring upon closing of the Ferring Asset Purchase Agreement for the Purchased Assets, which includes, 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 is also eligible to receive up to \$0.7 million for the delivery of certain product-related inventory, which is not reflected in the cash proceeds above. The accounting for the gain on sale of the Product Business has not been finalized, as the estimated gain does not reflect final net income tax liability relating to the transaction, and other adjustments, as necessary, to account for the other concurrent transactions. The \$11.1 million gain reflected in the unaudited pro forma condensed consolidated balance sheet is based on the Company's effective tax rate (0%) and assumes the Company's net operating losses will be utilized. However, utilization of the loss carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred as required under Internal Revenue Code Section 382 as well as similar state and foreign provisions. Accordingly, these ownership changes may limit the amount of loss carryforwards that can be utilized to offset the taxable gain and the actual gain on sale may be less.