(Nasdaq: JNP)

2015 Annual Report

To my fellow shareholders,

Juniper had an exceptional year in 2015 both financially and operationally. Notable highlights included our return to proprietary drug development and the expansion of our proprietary product pipeline, the addition of talented leadership in several key positions, and the Company's strong financial performance.

Total revenues increased 16% year-over-year. This was driven by increasing sales of CRINONE® (progesterone gel) to Merck KGaA for ex-U.S. markets, and strong growth at Juniper Pharma Services, which provides high-end fee-for-service pharmaceutical development, analytics, and clinical trials manufacturing services to pharmaceutical and biotech customers. Revenue in these business segments grew 29% and 33%, respectively, over the prior year, providing important cash flow to support our drug development initiatives.

The team at Juniper Pharma Services also applies its pharmaceutical development expertise to our proprietary products. Their focused efforts and those of our world-class clinical team enable us to advance a robust pipeline, with four candidates aimed at unmet medical needs in large markets.

Since January 2015, Juniper has filed an Investigational New Drug (IND) application with the FDA; initiated a robust, well-designed Phase 2b clinical trial of COL-1077 in women undergoing a pipelle-directed endometrial biopsy with tenaculum placement; and rapidly advanced our new intravaginal ring (IVR) technology, with several products moving forward toward the clinic.

Candidate	Preclinical	Ph. 1	Ph. 2	Ph. 3
COL-1077 10% lidocaine vaginal gel	→	→	→	
JNP-0101 oxybutynin IVR	→			
JNP-0201 estradiol + progesterone IVR	→			
JNP-0301 progesterone IVR	→			

Our lead product candidate, COL-1077, is a 10% lidocaine vaginal gel being developed as a local analgesic for use in minimally invasive gynecologic outpatient procedures. In aggregate, over seven million of these procedures were performed in the U.S. alone in 2015.

The pain and cramping associated with these procedures is well documented; however, there is no standard of care to manage pain caused by minimally invasive gynecologic procedures. Based on the outcomes of four prior studies of COL-1077, we believe that COL-1077 holds great promise for these patients. We are eager to complete enrollment in the COL-1077 Phase 2b clinical trial very soon, with data read-out expected in the third quarter of 2016.

The Juniper IVR technology was acquired in early 2015 through an exclusive worldwide license. This technology was created in the laboratories of Dr. Robert Langer at MIT and Dr. William Crowley at Massachusetts General Hospital. Due to its unique, patented design, we believe our IVR has the capability to deliver poorly bioavailable drugs as well as a wide range of drugs with differing molecular weights. This technology can be utilized to deliver a single drug or multiple drugs at different doses, all within a single multi-segment ring.

We currently have three IVR candidates in preclinical development:

- JNP-0101, an oxybutynin IVR for overactive bladder (OAB) in women;
- JNP-0201, a combination progesterone and estradiol IVR for symptoms of menopause; and,
- JNP-0301, a natural progesterone IVR to help prevent preterm birth.

JNP-0101 is our most advanced IVR product candidate and we anticipate an IND submission later this year. OAB is a chronic urological condition affecting an estimated 20 million women in the U.S., with approximately nine million patients receiving pharmacologic therapy. The U.S. market for OAB therapeutics was $1.3 billion in 2014[i].

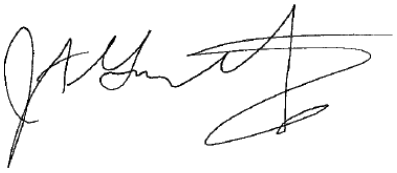
We believe that delivering oxybutynin using an IVR can provide an effective treatment for OAB while reducing side effects. JNP-0101 is also expected to improve compliance, as well as increase convenience for many patients and improve disease management and overall health outcomes. We look forward to submitting the IND for JNP-0101 once the ongoing animal PK study is complete, and expect to initiate a clinical trial thereafter.

Looking ahead, we expect ongoing growth in our core business. CRINONE® (progesterone gel) was launched in several new EU countries in the second half of 2015, and we understand that Merck KGaA expects to launch the product in Japan later this year. At Juniper Pharma Services, we have seen a marked increase in the U.S. client base and revenue, as well as a significant increase in volume of higher value clinical trial manufacturing projects. Juniper's contract development and manufacturing business is successfully establishing a strong reputation and subsequent demand for specialized formulation of challenging drug molecules.

With a strong management team, board of directors, and Scientific Advisory Board in place, and the Company making great forward progress on all fronts, Frank Condella recently announced his planned retirement as Juniper's President and CEO, although he will remain on our board of directors. The search for his successor is underway, and I am confident the Board will select the right candidate to lead this dynamic company as we advance to the next stage of our corporate development and continue to execute our strategy to build long-term value for our shareholders.

I want to thank our hardworking team for their dedication to Juniper's mission. We strive daily to do our best for our customers; for the patients on whose behalf we are developing new women's health therapeutics; and for our shareholders, whose ongoing support we deeply value.

Sincerely,



James A. Geraghty
Chairman of the Board

[i] Market data source: Technavio Insights, 2014. Global Overactive Bladder Therapeutics Market Report 2014-2018.

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

FORM 10-K

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

For the fiscal year ended December 31, 2015

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 1-10352

JUNIPER PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**59-2758596**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
33 Arch Street Boston, Massachusetts	**02110**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 639-1500

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

Common Stock, $0.01 par value	**NASDAQ Global Select Market**
(Title of each class)	**(Name of exchange on which registered)**

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐

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

The aggregate market value of Common Stock held by non-affiliates of the registrant on June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, based on the adjusted closing price on that date of $9.15, was $92,533,227.

Number of shares of Common Stock of Juniper Pharmaceuticals, Inc. issued and outstanding as of March 7, 2016 is 10,801,549.

Documents Incorporated By Reference

Portions of the Juniper Pharmaceuticals, Inc. ("Juniper" or the "Company") Proxy Statement for the 2016 Annual Meeting of Shareholders (the "Proxy Statement") are incorporated by reference into Part III of this Form 10-K.

Index to Annual Report on Form 10-K
Fiscal Year Ended December 31, 2015

Forward-Looking Information

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements, that involve risk and uncertainties. Generally, forward-looking statements can be identified by words such as "may," "will," "plan," "believe," "expect," "intend," "anticipate," "potential," "should," "estimate," "predict," "project," "would," and similar expressions, which are generally not historical in nature. However, the absence of these words or similar expressions does not mean that a statement is not forward-looking. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future – including statements relating to our future operating or financial performance or events, our strategy, goals, plans and projections regarding our financial position, our liquidity and capital resources, and our product development – are forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, caution should be taken not to place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. Our Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain known and unknown risks, uncertainties and factors that may cause actual results to differ materially from our Company's historical experience and our present expectations or projections.

Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. We have included important risk factors in the cautionary statements included in this Annual Report, particularly in Part 1 – Item 1A and in our other public filings with the Securities and Exchange Commission (the "SEC") that could cause actual results or events to differ materially from the forward-looking statements that we make.

You should read this Annual Report and the documents that we have filed as exhibits to the Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. While we may elect to update forward-looking statements at some point in the future, we do not undertake any obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise.

PART I

Item 1. ***Business***

OVERVIEW

We are a women's health therapeutic company focused on developing therapeutics that address unmet medical needs in women's health. Our marketed product and product development programs utilize our proprietary drug delivery technologies, which we believe are suited to applications in women's health. These technologies consist of our bioadhesive delivery system ("BDS"), a polymer designed to adhere to epithelial surfaces or mucosa and achieve sustained and controlled delivery of active drug product, and our novel intra-vaginal ring ("IVR") technology, a multi-segment IVR.

Our lead product candidate, COL-1077, is an investigational 10% lidocaine bioadhesive vaginal gel intended for use as a local anesthetic for pain from minimally invasive gynecological procedures. We expect to announce the results of our ongoing Phase 2b clinical trial of COL-1077 in the third quarter of 2016. We are also advancing three preclinical product development programs utilizing our IVR technology, which target overactive bladder, hormone replacement therapy in women, and prevention of preterm birth.

Historically, we have developed and brought to market several prescription and "over the counter" pharmaceutical products. We currently receive revenues from CRINONE®, an 8% progesterone bioadhesive vaginal gel designed for progesterone supplementation or replacement as part of an assisted reproductive technology ("ART") treatment for infertile women with progesterone deficiency. We supply CRINONE to Merck KGaA, Darmstadt, Germany, ("Merck KGaA") internationally, and sold the rights to CRINONE to Allergan, plc ("Allergan") in the United States.

Through our subsidiary, Juniper Pharma Services ("JPS") we also offer a range of sophisticated technical services to the pharmaceutical and biotechnology industry on a fee-for-services basis. Within our services offering, we provide our customers expertise on the characterization, development and manufacturing of small molecule compounds. Our services model allows us to take our customers drug candidates from early development through to Phase 2 clinical trials manufacturing. We also support our customers with advanced analytical and consulting services for intellectual property issues and we have particular expertise in problem solving for challenging compounds that are considered "difficult to progress".

We are applying the cash-flow generated from our CRINONE franchise and JPS to substantially fund the development of new therapeutic product candidates using our proprietary drug delivery technologies. We believe this strategy positions us well for capital-efficient growth as we advance these programs into clinical development. Internally-funded research and development expenditures were $6.9 million, $0.7 million and $0 for the fiscal years ended December 31, 2015, 2014 and 2013, respectively.

We expect to seek approval in the United States for our current pipeline of product candidates via the 505(b)(2) regulatory pathway. The 505(b)(2) pathway enables a potentially shorter development timeline compared to the development time for drugs that are new chemical entities by allowing us to rely, in part, on the U.S. Food and Drug Administration's ("FDA's") prior findings of safety and efficacy for a previously approved product, or published literature, in support of our new drug applications ("NDAs").

Our marketed product and product development programs are described below.

Program	Preclinical	Phase 1	Phase 2	Phase 3	Approved
CRINONE® 8% (progesterone gel)	Partnered with Merck KGaA outside the U.S. and Allergan in the U.S.				
COL-1077 (10% lidocaine gel)	Gynecologic procedure-related pain				
JNP-0101 (oxybutynin IVR)	Overactive bladder				
JNP-0201 (estrogen + progesterone IVR)	Hormone Replacement Therapy				
JNP-0301 (progesterone IVR)	Preterm birth				

- **CRINONE**, an 8% progesterone bioadhesive vaginal gel for progesterone supplementation or replacement as part of an ART treatment for infertile women with progesterone deficiency, is approved for marketing in the United States, Europe, and many additional countries around the world. CRINONE is the primary source of our commercial revenue. We have licensed CRINONE to our commercial partner, Merck KGaA, for all markets outside the United States, and we receive product revenues from the manufacture and sale of CRINONE to Merck KGaA internationally. We sold the U.S. intellectual property rights to CRINONE to Allergan in 2010, and receive royalty revenues from Allergan based on its U.S. sales.
- **COL-1077**, our lead product candidate, is an investigational 10% lidocaine bioadhesive vaginal gel intended for use as a local anesthetic for pain from minimally invasive gynecological procedures. In March 2015, we filed an Investigational New Drug ("IND") application with the FDA for COL-1077. In June 2015, we began enrolling patients in a multicenter, randomized, double-blinded, placebo-controlled Phase 2b clinical trial to evaluate the safety and efficacy of COL-1077 in women undergoing transvaginal pipelle-directed endometrial biopsy with tenaculum placement, a procedure to remove a tissue sample from the inner lining of the uterus. We currently expect to announce the results of this Phase 2b clinical trial in the third quarter of 2016 and, assuming positive results, to initiate a pivotal Phase 3 clinical trial of COL-1077 in early 2017.
- **JNP-0101** is an IVR product candidate designed to deliver oxybutynin for the treatment of overactive bladder ("OAB") in women. Oxybutynin is currently approved for the treatment of OAB, however, oral oxybutynin therapy is frequently discontinued by patients due to undesirable side effects including dry mouth, blurred vision, and constipation. We expect that the delivery of oxybutynin using our IVR technology will provide an improved side effect profile as the drug will be delivered to local tissues in higher concentrations, and will bypass first pass hepatic metabolism issues (where a drug is metabolized in the liver resulting in reduced drug availability and/or metabolites that can cause side effects). We expect this program to enter clinical trials in late 2016 or early 2017.
- **JNP-0201** is a segmented IVR product candidate containing both natural progesterone and natural estradiol to be used for hormone replacement therapy (HRT) in menopausal women. JNP-0201 has been designed to deliver natural hormones locally to vaginal tissue. We believe our delivery approach will provide an improved side effect profile when compared to the currently approved combination HRT therapies; these include orally administered formulations utilizing synthetic hormones, which have been associated in published clinical trials with higher risk of side effects including cardiovascular events. In addition, we believe that delivery using our IVR technology will improve patient compliance and convenience versus other routes of administration, including oral therapies and patches. This product candidate is currently in preclinical development.

- **JNP-0301** is a natural progesterone IVR product candidate for the prevention of preterm birth in women with a short cervical length. Short cervical length at mid-pregnancy is a critical predictor of preterm birth ("PTB") in women, and medical guidelines issued by the American College of Obstetricians and Gynecologists and the Society of Maternal Fetal Medicine, among others, support use of vaginal progesterone in women with a short cervical length at mid-pregnancy to reduce the risk of PTB. There is no FDA approved product to prevent PTB in women at risk due to short cervix. We believe JNP-0301 can enable the consistent local delivery of progesterone while facilitating patient compliance. This product candidate is currently in preclinical development.

OUR STRATEGY

Our objective is to be a leader in the discovery, development, and commercialization of therapeutics to treat unmet medical needs in women's health by utilizing our proprietary drug delivery technologies. Key elements of our strategy include:

- Advancing our lead product candidate, COL-1077, an investigational 10% lidocaine bioadhesive vaginal gel through clinical development and regulatory approval;
- Advancing preclinical product candidates utilizing our IVR technology to target overactive bladder, hormone replacement therapy, and preterm birth into clinical development;
- Supplying CRINONE to our commercial partner, Merck KGaA, for sale in over 90 countries around the world;
- Growing our pharmaceutical service business, JPS;
- Identifying and pursuing business development collaborations, including co-development opportunities that will take advantage of our proprietary drug delivery technologies and the pharmaceutical development capabilities of JPS for life-cycle management of existing commercial pharmaceutical products; and
- Supporting our customers with our formulation, analytical and product development capabilities allows us to efficiently deploy these same capabilities for our in-house proprietary product programs.

OUR PROPRIETARY DRUG DELIVERY TECHNOLOGIES

We have two key proprietary drug delivery technologies:

Bioadhesive Delivery System

Our BDS is a unique drug delivery technology that facilitates binding to mucosal surfaces (buccal and vaginal areas) upon administration, and allows release of the active drug in a controlled and sustained manner until the BDS gel is discharged upon normal cell turnover. This occurs every three to five days for the vaginal epithelium, and up to every 24 hours for the oral mucosa. Our BDS is utilized in both CRINONE and COL-1077.

The key BDS ingredient is polycarbophil, which is a non-immunogenic, hypo-allergenic, bioadhesive polymer. Polycarbophil bonds to the cells of the body's mucosal surfaces upon administration. This happens because polycarbophil mimics negatively charged mucin, the glycoprotein component of mucus that is responsible for its attachment to underlying epithelial surfaces.

Intra-vaginal Ring Technology

In March 2015, we obtained an exclusive worldwide license to the intellectual property rights for a novel segmented IVR technology. Due to its novel polymer and segmentation composition, we believe our IVR has the potential to deliver one or more drugs, including hormones and larger molecules such as peptides, at different dosages and release rates within a single segmented ring. Drugs such as progesterone and leuprolide have already been tested using the technology and demonstrated sustained release for up to three weeks.

We believe our proprietary multi-segment IVR may have advantages over currently available intravaginal rings for the reasons described below.

Homogenized, Membrane-Free-Design

Currently marketed intravaginal rings utilize a polymer membrane to control the delivery of a single drug to the patient from the ring. The two membrane ring types in use are reservoir-type and sandwich type. Reservoir rings utilize a drug-loaded core that is encapsulated by a polymer membrane and sandwich-type rings utilize a drug-loaded layer between a core, typically silicone, and a polymer membrane. The inherent risk associated with membrane rings is "drug dumping" which occurs if the membrane ruptures or tears.

By contrast, our IVR has a solid homogenous cross-section with drug and specific excipients distributed within an ethylene vinyl acetate ("EVA") polymer. The ring is manufactured using hot melt extrusion with no drug reservoirs or layers and active drug is released to the patient by diffusions through the polymer.

Molecular Weight Not Limited to Small Molecules

Reservoir and sandwich type rings are limited in the size of molecules, typically small molecules, they are able to deliver due to the use of a polymer membrane. By contrast, to date, no molecular weight limit has been identified for our IVR, and preclinical and clinical studies, such as a study by Kimball et al, submitted to *Journal Controlled Release* in 2016 have demonstrated its ability to deliver larger sized peptides and lipophilic hormones.

In a Phase 1 clinical trial, our IVR was used to administer leuprolide, a nine amino acid peptide and serum leuprolide levels rose within eight hours to levels typically seen following parenteral injections. This was the first demonstration of trans-epithelial delivery of leuprolide across the vaginal mucosa, and provided proof of concept demonstrating that we could achieve therapeutic levels with our IVRs.

Segmentation Capability

To date, membrane rings have been limited to delivering a single drug at a single dosage range. Our IVR technology allows a ring to be designed to deliver one or more drugs in a single ring using specific drug segments with each segment designed based on its own dose delivery criteria. Each segment is specifically designed and produced using hot melt extrusion and the segmented ring is assembled using proprietary know-how.

We believe our BDS and IVR technologies may provide the basis for developing products we could bring to market ourselves as well as products in which we expect there would be significant partnering interest.

OUR PRODUCT PIPELINE

COL-1077

COL-1077 is an investigational 10% lidocaine vaginal BDS gel intended as a local delivered anesthetic for pain from minimally invasive gynecological procedures.

Lidocaine is a drug substance approved by the FDA for use on skin or on ocular surfaces as a topical local anesthetic. Intravenous lidocaine solutions (0.4%, 0.8%, 1%, and 2%) are approved in the United States for use in the management of ventricular arrhythmias (abnormal rapid heartbeat). Lidocaine acts by temporarily blocking a pain signal pathway along nerves by stopping the sodium from entering the nerve ending at the site of the pain. This mechanism prevents an electrical signal from passing a pain message to the brain.

In March 2015, we filed an IND application with the FDA for COL-1077. In June 2015, we began enrolling patients in a multicenter, randomized, double-blinded, placebo-controlled Phase 2b clinical trial to evaluate the safety and efficacy of COL-1077 in women undergoing transvaginal pipelle-directed endometrial biopsy with tenaculum placement, a procedure to remove a tissue sample from the inner lining of the uterus. We currently expect to announce the results of this Phase 2b clinical trial in the third quarter of 2016.

Pain Associated with Gynecological Procedures

COL-1077 targets acute pain associated with gynecological procedures. Sources indicate that over seven million gynecological procedures are performed annually in the United States. The chart below shows the most common out-patient gynecological procedures.

Procedure	U.S. Annual Incidence 2015 (est., in millions)
IUD Placement/Removal	2.0
Cervical Biopsy	1.7
Endometrial Biopsy	1.5
Colposcopy	1.2
Diagnostic Hysteroscopy	0.8
Loop Electrosurgical Excision Procedures ("LEEP")	0.4
Endometrial Ablation	0.3
Total	7.9

We are focused on two primary pain issues associated with these procedures: procedure-related pain, and post-procedure pain and cramping. Current treatment approaches are not standardized and largely inadequate. These include:

- *Topical anesthetics*, including analgesic sprays and creams, which typically do not reach tissue beyond the vaginal epithelium. These require physician administration, and may therefore result in procedural delay.
- *Paracervical block*, an anesthetic procedure in which a local anesthetic is injected into two to six sites at a depth of 3–7 mm alongside the vaginal portion of the cervix in the vaginal fornices, is an expensive option which has been associated with adverse side effects including pain on injection, bleeding and risk of infection. The paracervical block procedure requires physician administration, and may therefore result in procedural delay.

  According to government statistics, in 2015 paracervical block was used in an estimated 30-35% of endometrial biopsy procedures, 40-45% of cervical biopsies, and nearly all LEEP procedures in the United States. Approximately 2.6 million paracervical block procedures were performed in conjunction with gynecological procedures in the United States in 2015.
- *Nonsteroidal anti-inflammatory drugs ("NSAIDs")*, which are taken orally, and have been associated with gastrointestinal side-effects and increased bleeding risk.

Our Solution – COL-1077

We believe COL-1077 may have the potential to be a preferred pretreatment option, offering patients an effective pain relief conveniently and cost-effectively. As a local anesthetic targeting acute pain from gynecological procedures, COL-1077 requires a single, self-administered dose approximately six hours prior to a scheduled gynecological procedure. COL-1077 adheres to the vaginal epithelium and provides sustained release of lidocaine into the endometrium to myometrium. This deep local tissue penetration is enabled by the BDS technology underlying COL-1077. The analgesic effect of COL-1077 is expected to last several hours, with peak concentration at approximately six hours post-dose, allowing patients to arrive at the physician office "procedure ready."

Clinical Trials

We believe that the four clinical trials of COL-1077 conducted to date have collectively demonstrated that BDS delivery of lidocaine is effectively absorbed through vaginal mucosa, penetrates tissues and reaches

myometrium, achieves serum lidocaine concentrations more than 100 below levels of IV-administered lidocaine and is well tolerated with no significant safety concerns.

Prior clinical trials evaluated the pharmacokinetics of single and multiple doses of our lidocaine BDS vaginal gel at 2.5%, 5%, and 10% concentrations. In these studies, collectively, COL-1077 was well tolerated with no safety concerns. These studies collectively demonstrated that treatment with COL-1077 achieved serum lidocaine concentrations below levels of intravenous-administered lidocaine commonly used to treat cardiac arrhythmias.

Phase 1 Clinical Pharmacokinetic Studies

Two Phase 1 pharmacokinetic ("PK") clinical trials have been conducted in healthy volunteers, both of which evaluated the pharmacokinetics of lidocaine following vaginal application of COL-1077 lidocaine bioadhesive gel at 2.5%, 5.0%, and 10.0% concentrations and placebo. Publication of these studies has been submitted by Mayer P. et al. to Drug Development in Clinical Pharmacology in 2016.

COL-1077-01 was a double-blind, randomized, single-dose clinical trial. Cmax (maximum concentration of drug in plasma) and AUC0-inf (area under the concentration-time curve from zero to infinity) increased dose-proportionally. Subjects receiving 10% lidocaine bioadhesive gel had mean values of 70.63 ng/mL and 1291.2 hr•ng/mL for Cmax and AUC0-inf, respectively.

COL-1077-02 was a double-blind, randomized, multiple-dose clinical trial. Subjects receiving treatment with vaginal COL-1077 at 2.5%, 5.0% and 10% concentrations or placebo for four consecutive days. On both Day 1 and Day 4, lidocaine exposure (AUC0-24; area under the concentration-time curve from zero to 24 hours) increased with increasing dosage. For the 2.5% and 5.0% strengths, there was a decrease in lidocaine exposure on Day 4 relative to Day 1, while a small increase in lidocaine exposure was seen on Day 4 with the 10% treatment; none of these differences were statistically significant.

Phase 2 Clinical Trial: Dysmenorrhea: Vasopressin-induced Cramping (COL-1077-IT01)

In October 2005, positive results were reported from a single-blind, randomized, parallel-group, placebo-controlled clinical trial conducted at a single center in Italy. This 24-patient clinical trial evaluated uterine contractile force, frequency of contractions, and pain after administration of 5% lidocaine vaginal gel or placebo bioadhesive gel during vasopressin-induced cramping.

Subjects eligible to participate were 18 to 44 years old and had a diagnosis of dysmenorrhea despite oral contraceptive ("OC") use. Women with ovarian cysts >2.5 mm in size; uterine fibroids; dysfunctional uterine bleeding; concurrent use of any device (e.g., IUD); medication use other than OCs and those allowed by the protocol; and/or a body mass index >30 were not allowed to participate in the clinical trial.

Cramping episodes were artificially triggered in all 24 subjects with an exogenous vasopressin ("VP)" infusion. Intrauterine pressure ("IUP") was monitored and pain assessed over 60 minutes. Subjects in whom basal tone IUP increased 40% or more from baseline during the pre-treatment VP challenge infusion were retained and considered evaluable in the clinical trial. Evaluable participants then received either COL-1077 5% lidocaine bioadhesive gel or placebo gel, and rested for 4 – 5 hours before undergoing a second VP test.

The 24 women enrolled in the clinical trial were randomized to receive either COL-1077 (n=12) or placebo (n=12). Of these 24 subjects, 19 had at least one change in basal tone IUP ≥40% during the pre-treatment VP challenge period, and were considered evaluable for efficacy analysis.

In this trial, administration of COL-1077 was associated with a statistically significant decrease in:

- Uterine pressure (p=0.012);
- Uterine contraction frequency (p<0.001);

- Pain (p=0.002); and,
- Number of uterine contractions (p=0.008).

Safety variables included incidence of adverse events and changes in vital signs (blood pressure and pulse rate) during the pre-treatment and post-treatment periods. These parameters were assessed during each period at baseline, time of VP challenge, VP + 10, VP + 20, and VP + 30 minutes. There were no adverse events reported for any of the subjects during this clinical trial.

Overall, the clinical trial demonstrated that in patients treated with COL-1077, objective measures of uterine contractile force and basaltone IUP tone decreased to a greater degree as compared with patients treated with placebo gel and as relative to pre-treatment levels. Correlatively, COL-1077 treated patients, subjectively reported that there was a greater decrease in measures of basal pain scores (absolute pain) and frequency of cramping pain scores (perceived pain) at most time points during the post-treatment VP challenge period (except for the frequency pain scores at the VP challenge + 30 minute time point) and for the AUC summary measures. Treatment with COL-1077 was well tolerated. There were no adverse events reported for any of the subjects during this clinical trial. Also, during the evaluable period, there were no notable differences between COL-1077 and placebo subjects for any of the vital sign parameters.

This clinical trial abstract, "Pretreating with Vaginal Lidocaine Reduces Induced Uterine Contractions and Pain in Chronic Dysmenorrhea," was presented at the American College of Obstetricians and Gynecologists ("ACOG") 2005 Annual Clinical Meeting and published in the April 2005 supplement to *Obstetrics & Gynecology*, the Journal of ACOG.

Outcomes of this clinical trial demonstrate proof of concept for the current ongoing Phase 2b clinical trial (COL-1077-07)

Phase 2 Clinical Trial: Cross-Over Dysmenorrhea Clinical Trial (COL-1077-04)

Given the positive results of the vasopressin challenge clinical trial (COL-1077-IT1), we conducted in 2008 a double-blind, placebo-controlled clinical trial evaluating COL-1077 10% lidocaine bioadhesive vaginal gel in reducing the severity and onset of pain in 70 women with a history of moderate-to-severe dysmenorrhea.

This clinical trial used a cross-over design in which each subject received either COL-1077 or placebo for four consecutive days starting one to two days before the expected Day one of menses. Participants were asked to record pain assessments using a four-point categorical scale and an 11-point numeric rating scale ("NPRS"). No significant difference was observed between the COL-1077 and placebo treatment arms for the primary efficacy endpoint (time-weighted average pain intensity over the four treatment days, using the four-point categorical scale), or for the secondary endpoints (including time-weighted average pain intensity over the seven treatment days, using the 4-point categorical scale and time-weighted average pain intensity over the seven treatment days, using the four-point categorical scale or NPRS).

This clinical trial did not reveal any significant adverse events and those adverse events that occurred were similar in both kind and frequency for lidocaine and placebo.

Based on these clinical trial outcomes and our strategic decision in 2011 to focus our resources on a different development program, the IND status for COL-1077 for use prophylactically in controlling pain during the peri-menstrual period in dysmenorrhea women was changed to 'inactive' in January 2011.

Ongoing Clinical Trial: COL-1077-07

In June 2015, we began enrolling patients in a multicenter, randomized, double-blinded, placebo-controlled Phase 2b clinical trial to evaluate the safety and efficacy of COL-1077 (10% (150 mg) lidocaine bioadhesive gel)

in women undergoing transvaginal pipelle-directed endometrial biopsy with tenaculum placement. This trial is designed to enroll up to 185 patients at approximately 25 U.S. sites.

The primary endpoint of the Phase 2b clinical trial is a reduction in pain intensity at the time of endometrial biopsy, with secondary endpoints assessing the reduction in post-procedural pain and cramping over a 24-hour time period. Additional endpoints will evaluate safety and need for rescue analgesic, as well as some exploratory patient-related outcome assessments such as ability to return to normal activities after the procedure is performed.

Subject to positive outcomes of this Phase 2b trial, we plan to initiate a Phase 3 trial for COL-1077 in 2017. We expect to seek approval for COL-1077 in the United States via the 505 (b)(2) regulatory pathway and will have an End of Phase 2 meeting with the FDA to determine the Phase 3 requirements needed for registration.

JNP-0101

JNP-0101 is an IVR designed to deliver oxybutynin to treat OAB in women. Oxybutynin is currently approved for the treatment of OAB and most successfully treats women with predominant urge (rather than stress) incontinence. The average age of presentation in women is in the mid 50s. We believe that the delivery of oxybutynin using our IVR technology will provide an improved side effect profile as the drug will be delivered to local tissues in higher concentrations, bypassing first pass hepatic metabolism. This program is expected to enter clinical trials in late 2016 or early 2017.

Overactive Bladder

OAB is a widespread, chronic condition caused by involuntary contraction of the detrusor muscles before the bladder is full. OAB affects approximately 20 million women in the United States, with an estimated nine million receiving pharmacotherapy to treat the condition. In 2014, the U.S. OAB market was estimated to be $1.3 billion, comprised of branded and generic products.

The most common prescription drug is generic oral oxybutynin; oxybutynin addresses OAB by decreasing muscle spasms of the bladder and the frequent urge to urinate caused by these spasms. Unfortunately, more than 70% of women discontinue oxybutynin within the first year due to adverse events (45-55%) or perceived inadequate efficacy (~25%). According to Technavio Insights, 7 to 9 million women are eligible for OAB treatment and approximately 6.8 million patients failed oral oxybutynin. Current branded therapies range from $3,000-4,000 per year. We believe that a new therapy that demonstrates improved side effect profile could support pricing above the current generic products.

Our Solution – JNP-0101

JNP-0101, our novel oxybutynin IVR, has the potential to address the most pressing unmet clinical needs in the treatment of overactive bladder. By delivering oxybutynin intra-vaginally, JNP-0101 leverages the region's shared vascular and lymphatic networks to achieve localized absorption of oxybutynin by relevant tissues in higher concentrations, while bypassing hepatic first pass metabolism. We anticipate an improvement in the side effect profile of oxybutynin using this delivery route, in addition to improved compliance afforded by a once monthly ring. We believe JNP-0101 has the potential to increase convenience in many patients and improve disease management and overall outcomes.

We plan to submit an IND application to the FDA for JNP-0101and initiate a Phase 2a bioavailability and dose finding clinical trial with JNP-0101 in the second half of 2016. Currently, pharmaceutical development work and pilot manufacturing for JNP-0101 is underway at our JPS facility. We expect to seek approval for JNP-0101 in the United States via the 505 (b)(2) regulatory pathway.

Supporting Data

Initial proof of concept for JNP-0101 was provided by multiple peer reviewed publications on the safety and efficacy of a once-monthly oxybutynin vaginal ring. The ring evaluated in these studies was a reservoir-type ring constructed of molded silicone with a cylindrical cavity into which the oxybutynin or placebo material was loaded. By contrast, JNP-0101 is constructed of ethylene vinyl acetate with the oxybutynin homogenized throughout.

In these studies, delivery of oxybutynin was found to offer women an effective, safe and well tolerated once-monthly treatment option for OAB. However, the molded silicone oxybutynin IVR evaluated was not brought to market by the sponsor due to factors including its decision to exit women's health.

JNP-0201

JNP-0201 is a segmented IVR containing both natural progesterone and estradiol for hormone replacement therapy (HRT) in menopausal women. This delivery approach is expected to provide an improved side effect profile as natural hormones will be delivered locally to vaginal tissue where they are needed. In addition, delivery using our IVR technology is expected to improve patient compliance and convenience versus other routes of administration, including oral and transdermal approaches. In addition a once monthly IVR is expected.

Hormone Replacement Therapy

In the United States, there is a large and growing market for HRT. In 2014, the U.S. HRT market was estimated at $2.2 billion. Of this market, 1.5 billion dollars is accounted for by compounding pharmaceutics that have come under increased FDA scrutiny with the recent passage of the 2013 Drug Quality and Security Law.

While there are nearly 40 FDA-approved HRT products on the market, the HRT combination therapies fall short. Currently, HRT combination therapies only occupy approximately 30% of the U.S. HRT market. All FDA-approved HRT combination products contain synthetic progestin rather than natural progesterone while recent studies suggest fewer cardiovascular adverse events are associated with natural progestogens. In addition, all current combination HRT products are orally administered, which cause extensive fist pass metabolism and require daily dosing.

In 2012, the North American Menopause Society (NAMS) issued a Consensus Statement which supports HRT in peri- and post-menopausal women. This statement endorsed use of hormone replacement therapy in women within 10 years of menopause, concluded that hormone treatment should be individualized based on each patient's personal risk factors, and identified a growing body of evidence that hormone replacement therapy formulation, route of administration, and the timing of therapy produces different biologic effects. We expect that as a result of the 2012 NAMS Statement, the percentage of the approximately 45 million American women who are menopausal or approaching menopause who receive HRT will increase.

Our Solution – JNP-0201

We believe that JNP-0201, our combination estrogen and progesterone IVR product candidate, has the potential to offer patients multiple benefits as compared with currently available therapies, including: integrated administration of natural progesterone and natural estrogen; improved patient compliance; improved side effect profile; and continuous local vaginal delivery of natural hormones, while eliminating the need for daily administration. We are in the process of developing the prototype of JNP-0201 and expect to submit an IND application to the FDA in 2017. We expect to seek approval for JNP-0201 in the United States via the 505 (b)(2) regulatory pathway.

Preclinical Data

Proof-of-concept work has been conducted, demonstrating the ability of our IVR to deliver progesterone and estradiol. Prototype development is underway, and further preclinical development will be conducted in 2016.

JNP-0301

JNP-0301 is a natural progesterone IVR for the prevention of preterm birth in women with a short cervical length. Short cervical length at mid pregnancy is a critical predictor of preterm birth in women and medical guidelines support use of vaginal progesterone for treatment of this condition. There is no FDA approved product to prevent preterm birth in women at-risk due to short cervix. We believe JNP-0301 has the potential to enable the consistent local delivery of progesterone improving patient compliance.

Preterm Birth due to Short Cervical Length

PTB is a significant public health issue. Each year, there are 4.3 million births in the United States. Approximately 11% of U.S. pregnancies deliver prior to 37 weeks gestation. A review of 39,000 cases of PTB found that short cervical length was the most important single predictor of PTB. Over 30% cases of PTB have short cervical length (1.0-3.0 cm) at mid-pregnancy. Approximately 1.3 million women in the United States are estimated to be at risk for PTB due to short cervical length.

Clinical data strongly supports the use of vaginal progesterone for prevention of PTB. Furthermore, there is clear consensus that vaginal progesterone should be used for prevention of PTB in women with short cervical length at mid-pregnancy, including Medical Practice Guidelines from the Society for Maternal-Fetal Medicine, an ACOG Committee Opinion, and an Issue Brief from Medicaid Health Plans of America. Despite the medical need and cost savings associated with prevention of PTB, there are currently no products that are FDA approved to prevent PTB in women at risk due to a short cervix.

Our Solution – JNP-0301

JNP-0301, our progesterone IVR may offer meaningful benefits to women with short cervical length. By providing continuous, consistent, local delivery of natural progesterone, this product candidate may increase patient compliance as compared to current off-label progestogens, which require daily administration, thereby potentially improving overall outcomes. We expect to have a pre-IND meeting with the FDA in the first half of 2016 to define a clinical and regulatory path for a vaginal progesterone therapy.

Preclinical Data

Proof-of-concept work has been conducted, demonstrating the ability of the IVR to deliver progesterone. Further preclinical development will be conducted in 2016.

COMMERCIAL PRODUCT

CRINONE

CRINONE is a progesterone gel designed to be used for progesterone supplementation or replacement as part of ART for infertile women with progesterone deficiency. CRINONE is approved for marketing in the United States, Europe, and certain other markets, and the primary source of our commercial revenue. We have licensed CRINONE to our commercial partner, Merck KGaA, for the markets outside the United States and we receive product revenues from the manufacture and sale of CRINONE internationally. We sold the U.S. intellectual property rights to CRINONE to Allergan in 2010, and receive royalty revenues from Allergan based on its U.S. sales.

CRINONE continues to be introduced in new countries by Merck KGaA. Under the terms of our current license and supply agreement with Merck KGaA, we sell CRINONE to Merck KGaA on a country-by-country basis at the greater of (i) cost plus 20% or (ii) a percentage of Merck KGaA's net selling price based on a tiered structure. As sales unit volumes increase, our percentage share of incremental sales decreases. Additionally, we are jointly cooperating with Merck KGaA to evaluate and implement clinical manufacturing cost reductions, with

both parties sharing any benefits realized from these initiatives. Our second amended and restated license and supply agreement with Merck KGaA was renewed in April 2013 for an additional five-year term, extending the expiration date to May 2020. If, at the end of the supply term, the parties cannot agree upon mutually acceptable terms for renewal of the supply arrangement, Merck KGaA will have the option of converting the agreement into a license agreement and will be free to manufacture, or have manufactured, the product pursuant to the terms set forth in the amendment agreement. See "– Collaboration Agreements – Merck KGaA."

PHARMACEUTICAL SERVICE BUSINESS

JPS, our pharmaceutical service business, offers a range of sophisticated technical services to the pharmaceutical and biotechnology industry. Our customers range from start-up biotechnology firms to global pharmaceutical companies.

Within our services offering, we provide to our customers expertise on the characterization, development, and manufacturing of pharmaceutical compounds for clinical trials. We believe we have particular expertise in problem solving for challenging compounds that are considered "difficult to progress." Our service model allows us to take our customers' product candidates from early development through clinical trials manufacturing. We also support our customers with advanced analytical and consulting services for intellectual property issues. We also deploy these same capabilities for our in-house proprietary product development activities, including managing the preclinical and clinical manufacturing stages for COL-1077 and our IVR programs.

Through JPS, we also manage the global supply chain and contract manufacturing of CRINONE, for our partner Merck KGaA.

MANUFACTURING AND COMMERCIALIZATION

We utilize our UK subsidiary, JPS, for the clinical supply manufacturing of COL-1077 and JNP-0101. We plan to use a third-party contract manufacturer for the clinical supply of JNP-0201 and JNP-0301 as those products contain hormones and required a specialized facility.

Our ability to conduct later-stage clinical trials, manufacture and commercialize our product candidates will depend on the ability of third-party manufacturers to manufacture our product candidates on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices ("cGMP"), and foreign regulatory requirements, if applicable.

Use of third party manufacturers limits our control over and ability to monitor the manufacturing process. As a result, we may not be able to detect a variety of problems that may arise in the manufacturing process and we may incur additional costs in the process of interfacing with and monitoring the progress of our contract manufacturers. If third party manufacturers fail to meet our manufacturing needs in an acceptable manner, we would face delays and additional costs while we develop internal manufacturing capabilities or find alternate third party manufacturers. It may not be possible to have multiple third party manufacturers ready to supply us with needed material at all or without incurring significant costs.

SOURCES OF SUPPLY

The major raw materials we use in our products and product candidates are polycarbophil and progesterone.

Medical grade, cross-linked polycarbophil, the polymer used in our BDS-based product and product candidate is currently available from only one supplier, Lubrizol, Inc. ("Lubrizol"). We believe that Lubrizol will supply as much of the material as we require because our product ranks among the highest value-added uses of the polymer. In the event that Lubrizol cannot or will not supply enough polycarbophil to satisfy our needs, however, we will be required to seek alternative sources of supply.

Only one supplier of progesterone for CRINONE is approved by regulatory authorities outside the United States. We have not experienced production delays due to shortages of progesterone. This supplier has notified us that it intends to materially increase the price for its progesterone and has requested that we enter into a long-term supply agreement. It is unclear what impact, if any, an increase in the cost of progesterone will have on our financial results or our demand for CRINONE, or whether we would be able to obtain progesterone from an alternate supplier in a timely manner.

As discussed in greater detail in Item 1A of this Annual Report, the loss of our single-source third-party suppliers of raw materials for our product and product candidates could impair our ability to manufacture and sell our products.

COMPETITION

We and our commercial partners compete against established pharmaceutical companies who market products and services addressing the same markets and patient needs. Further, numerous companies are developing, or may develop, enhanced delivery systems, products and services that compete with our present and proposed products and services. It is possible that we may not have the resources to withstand these and other competitive forces. Some of these competitors possess greater financial, research and technical resources than us or our partners. Moreover, these companies may possess greater marketing capabilities than we or our partners possess, including the resources to implement extensive advertising campaigns.

The pharmaceutical industry is subject to change as new delivery technologies are developed, new products enter the market, regulatory requirements change, generic versions of available drugs become available and treatment paradigms evolve to reflect these and other medical research discoveries. We face significant competition in all areas of our business. The rapid pace of change in the pharmaceutical industry continually creates new opportunities for competitors and start-ups and can quickly render existing products, technologies and services less valuable. Customer requirements and physician and patient preferences continually change as new treatment options emerge, are more or less heavily promoted, and become less expensive. As a result, our partners may not gain, and may lose, market share.

CRINONE

CRINONE, a natural progesterone product, competes in markets with other progestins, both synthetic and natural, that may be delivered by pharmacy-compounded injections or vaginal suppositories, including Prometrium® (oral micronized progesterone) marketed by Abbott Laboratories, and Endometrin® (progesterone vaginal insert) marketed by Ferring Pharmaceuticals, Inc. CRINONE and Endometrin are the only progestin products currently approved by the FDA for use in infertility.

COL-1077

COL-1077 is an investigational 10% lidocaine vaginal gel intended for use as an acute use anesthetic for pain from minimally invasive gynecological procedures. Although there is currently no FDA-approved product for this indication, and no standard of care for preventing pain from these procedures, there are a range of therapies currently being used by physicians, including nonsteroidal anti-inflammatory drugs (“NSAIDs”) topical anesthetic sprays and creams, and the paracervical block procedure, as well as opioids as rescue medication for post-procedural pain.

In 2015, the paracervical block procedure was used in an estimated 30-35% of endometrial biopsy procedures, 40-45% of cervical biopsies, and nearly all Loop Electrosurgical Excision Procedures (“LEEP”) procedures in the United States. Approximately 2.6 million paracervical block procedures were performed in conjunction with gynecological procedures in the United States in 2015.

In the United States there are currently ongoing clinical trials for several prospective therapies for use in pain related to various out-patient gynecologic procedures, including: EMLA® (5% lidocaine/ 25 mg-prilocaine 25 mg/g) cream; oral diclofenac plus lidocaine gel (non-bioadhesive); and 10% lidocaine spray.

JNP-0101

JNP-0101 is our IVR designed to deliver oxybutynin to treat OAB in women.

Oxybutynin is currently approved for the treatment of OAB in oral and transdermal gel formulations. Oral oxybutynin chloride tablets are the most widely prescribed formulation of this antimuscarinic agent, the first of which was approved in 2006. Gelnique® (oxybutynin chloride 10 % topical gel), marketed by Allergan, was approved by the FDA in 2009.

Additional antimuscarinics approved for the treatment of OAB include VESIcare® (solifenacin) marketed by Astellas Pharma Inc. ("Astellas") and Detrol LA® (tolterodine), Toviaz® (fesoterodine), and Enablex® (darifenacin), all marketed by Pfizer. Additionally, the beta agonist Mybetriq® (mirabegron) was approved by the FDA in 2012 and is marketed by Astellas.

There are currently ongoing clinical trials for several prospective OAB therapeutics, including Botox® (botulinum toxin type A), the Axonics Sacral Neuromodulation System, and Premarin® vaginal cream.

JNP-0201

JNP-0201 is our combination estrogen and progesterone IVR candidate.

Prempro® (conjugated estrogens/medroxyprogesterone acetate tablets), which is marketed by Pfizer®, is one of the currently approved drugs used for HRT in menopausal women. It was approved by the FDA in 1995 for use in women with an intact uterus for the treatment of moderate to severe vasomotor symptoms and/or vulvar and vaginal atrophy due to menopause, and for the prevention of postmenopausal osteoporosis.

There are currently ongoing clinical trials for several prospective products, both single-agent and combination therapies, for HRT in pre-, post- or menopausal women. These include an oral estradiol and progesterone combination product; ospemifene; and a vaginally-administered estradiol capsule for which an NDA is expected to be filed in 2016 for the treatment of vulvar and vaginal atrophy in postmenopausal women.

JNP-0301

JNP-0301 is our natural progesterone IVR designed to prevent preterm birth in women with short cervixes.

There is currently no FDA-approved product to prevent preterm birth in women at-risk due to short cervixes.

There are currently ongoing clinical trials evaluating use of cerclage to prevent preterm birth in women with short cervixes and a history of a prior preterm birth or mid-trimester miscarriage, and to compare the efficacy of two tocolytics, nifedipine versus indomethacin, in preventing preterm birth in women with short cervixes.

Juniper Pharma Services

There is a range of large and smaller scale competitors who compete with our JPS business, providing similar pharmaceutical development and consulting services. Some of these competitors have greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities, that are larger and more established than ours.

Additional competitors may also enter the market, and we are likely to compete with new companies in the future.

Competition among organizations providing pharmaceutical development and analytical services is characterized by technical expertise and reputation, breadth of technical services, budget considerations and the ability to timely deliver the customer's requirements. Accordingly, our success depends in part on establishing, maintaining and expanding a client base, offering new innovative services and maintaining regulatory and quality compliance.

Potential customers also may decide not to purchase our services, or to delay such purchases, due to technical, clinical, regulatory or financial considerations beyond our control. In addition, we expect that competitive pressures may result in price competition, which could affect our profitability.

COLLABORATION AGREEMENTS

Our primary revenue product is CRINONE. We have licensed CRINONE to Merck KGaA, outside the United States, and sold the rights to CRINONE to Allergan, in the United States.

Merck KGaA

During 2012 and 2013, we manufactured and sold CRINONE to Merck KGaA at a price determined on a country-by-country basis at the greater of (i) 30% of the net selling price in such country, or (ii) our direct manufacturing cost plus 20%. Certain quantity discounts were applied to annual purchases over 10 million, 20 million, and 30 million units.

In April 2013, our license and supply agreement with Merck KGaA for the sale of CRINONE outside the United States was renewed for an additional five year term, extending the expiration date from to May 19, 2020.

Under the terms of the amended license and supply agreement, we will sell CRINONE to Merck KGaA on a country-by-country basis at the greater of (i) direct manufacturing cost plus 20% or (ii) a percentage of Merck KGaA's net selling price. From 2014 through 2020, the percentage of net selling price will be determined based on a tiered structure, which is based on volume sold. As sales volumes increase our percentage share of each incremental tier decreases. Additionally, the parties are cooperating to evaluate and implement manufacturing cost reduction measures, with both parties sharing any reductions realized from these initiatives. If, at the end of the supply term, the parties cannot agree upon mutually acceptable terms for renewal of the supply arrangement, Merck KGaA may elect to retain a license to the product and will have an irrevocable fully paid up license to the product.

We are the exclusive supplier of CRINONE to Merck KGaA. Merck KGaA holds marketing authorizations for CRINONE in over 90 countries outside the United States.

The amended license and supply agreement requires Merck KGaA to provide a rolling 18-month forecast of its CRINONE requirements for each country in which the product is marketed. The first four months of each forecast are considered firm orders. Under the agreement, each party is responsible for new clinical trials and government registrations in its territory and the parties are obligated to consult from time to time regarding the studies. Each party has agreed to promptly provide the other party the data from its CRINONE studies free-of-charge. During the term of the agreement, we have agreed not to develop, license, manufacture or sell to another party outside the United States any product for the vaginal delivery of progesterone or progestational agents for hormone replacement therapy or other indications where progesterone or progestational agents are commonly used.

Allergan

Within the United States, CRINONE is marketed by Allergan (which changed its name from Actavis, Inc. in 2015 and from Watson Pharmaceuticals, Inc. in 2012, each as a result of an acquisition) pursuant to a Purchase and Collaboration Agreement dated March 2010. Pursuant to the terms of this agreement, Allergan purchased certain of our assets and we agreed to participate in joint development activities with Allergan with respect to the development of certain progesterone gel products. In December 2013, we and Allergan held our last joint development committee meeting and there have been no joint development activities since then. In July 2010, and in connection with this agreement, we entered into a License Agreement with Allergan, which provided Allergan with exclusive rights to develop, manufacture and offer to sell and commercialize these progesterone gel products in the United States. We also entered into a Supply Agreement with Allergan, dated July 2010, which made us the exclusive supplier to Allergan for CRINONE.

In April 2011, we filed NDA 22-139 to expand the labeled uses of progesterone vaginal gel 8% to include its use in the reduction of the risk of preterm birth in women with a singleton gestation and a short uterine cervical length in the mid-trimester of pregnancy. NDA 22-139 was reviewed by the FDA's Advisory Committee for Reproductive Health Drugs in January 2012. While the committee members generally agreed that progesterone vaginal gel 8% is safe, the committee stated that more information is needed to support approval. On February 10, 2012, we transferred NDA 22-139 to Allergan pursuant to the second closing of our sale of assets to Allergan under the Purchase and Collaboration Agreement. On February 24, 2012, Allergan received a Complete Response Letter ("CRL"), from the FDA indicating that the review cycle for NDA 22-139 was complete but the application was not ready for approval in its present form. The CRL stated that the effect of treatment with progesterone vaginal gel 8% in reducing the risk of preterm birth in women with a short uterine cervical length at ≤32 6/7 weeks gestation (p=0.022) did not meet the level of statistical significance generally expected to support the approval of the product in the U.S. market from a single trial. In the CRL, the FDA stated that additional clinical work would be required to support the approval. Allergan held an "End-of-Review" meeting with the FDA to discuss the issues outlined in the CRL. Allergan continued discussions with the FDA to determine a viable pathway forward and in August 2012 filed a Formal Dispute Resolution Request ("FDRR") related to this application. The FDA denied Allergan's FDRR in October 2012. Allergan discontinued further development of this program.

From July 2010 to November 2013 we manufactured and sold products to Allergan at direct manufacturing cost plus 10%; the revenues generated from these sales were recorded as product revenues from a related party. Since Allergan had sufficient inventories of CRINONE, there were no orders in 2013. In November 2013, we entered into an early termination of the exclusive Supply Agreement with Allergan. The early termination of the agreement, which would have otherwise terminated in May 2015, provided for a one-time payment by Allergan, as a termination fee, in addition to payment for all raw materials purchased by us to meet forecast requirements.

Pursuant to the Purchase and Collaboration Agreement, we will continue to be eligible to receive royalties until July 2, 2020 equal to a minimum of 10% of annual net sales of CRINONE by Allergan for annual net sales up to $150 million, 15% for sales above $150 million but less than $250 million, and 20% for annual net sales of $250 million and over. Royalties under the Purchase and Collaboration Agreement will be payable until the latest of (i) the last valid claim, (ii) expiration of regulatory exclusivity or (iii) the 10th anniversary of product launch.

Between February 1, 2012 and February 6, 2012, two putative securities class action complaints were filed against us and certain of our officers and directors in the United States District Court for the District of New Jersey. Both actions were consolidated into a single proceeding entitled *In Re Columbia Laboratories, Inc., Securities Litigation*, under which Allergan and three of its officers were added as defendants. The United States Court of Appeals for the Third Circuit affirmed, in March 2015, the prior decision of the United States District Court for the District of New Jersey dismissing this securities class action lawsuit.

Massachusetts General Hospital

On March 27, 2015 we entered into an Exclusive Patent License Agreement with Massachusetts General Hospital ("MGH") pursuant to which we licensed the exclusive worldwide rights to MGH's patent rights in a novel IVR technology for the delivery of one or more pharmaceuticals at different dosages and release rates in a single segmented ring.

Unless earlier terminated by the parties, the license agreement will remain in effect until the later of (i) the date on which all issued patents and filed patent applications within the licensed patent rights have expired or been abandoned and (ii) one year after the last sale for which a royalty is due under the license agreement or 10 years after such expiration or abandonment date referred to in (i), whichever is earlier. We have the right to terminate the license agreement by giving 90 day advance written notice to MGH. MGH has the right to terminate the license agreement based on our failure to make payments due under the license agreement, subject to a 15 day cure period, or our failure to maintain the insurance required by the license agreement. MGH may also terminate the license agreement based on our non-financial default under the license agreement, subject to a 60 day cure period.

Pursuant to the terms of the license agreement, we have agreed to reimburse MGH for all costs associated with the preparation, filing, prosecution and maintenance of the licensed patent rights and has agreed to pay MGH a $50,000 annual license fee on each of the first five year anniversaries of the effective date of the license agreement, and a $100,000 annual license fee beginning on the sixth anniversary of the effective date of the license agreement and on each subsequent anniversary thereafter. The annual license fee is creditable against any royalties or sublicense income payable in each calendar year.

Under the terms of the license agreement, we have agreed to use commercially reasonable efforts to develop and commercialize at least one product and/or process related to the IVR technology, which efforts will include the making of certain minimum annual expenditures in each of the first five years following the effective date of the license agreement. We have also agreed to pay MGH certain milestone payments totaling up to $1,200,000 tied to our achievement of certain development and commercialization milestones, and certain annual royalty payments based on net sales of any such patented products or processes developed by us.

INTELLECTUAL PROPERTY

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the composition of matter of our product candidates, their manufacture and methods of use, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect certain aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including certain aspects of our formulation and device development expertise and know-how.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for pharmaceutical companies like us are generally uncertain and can involve complex legal, scientific, and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

As of January 1, 2016, our patent estate, which includes patents and patent applications that we own or in-license, consisted of 16 issued U.S. patents, 1 pending U.S. patent application, over 120 issued foreign patents and 10 pending foreign patent applications.

With regard to our CRINONE product, all of our patents covering the product have expired in all countries other than Argentina.

With regard to COL-1077, we have two issued U.S. patents with composition of matter and method of use claims directed to COL-1077 and its use. The issued U.S. patents are expected to expire in 2018 and 2024. In addition, we have over 50 patents that have been granted by various countries in Europe, North America, and Asia, which are expected to expire from 2018 to 2024 and we have pending patent applications in various other countries in South America, Europe, and Asia, which, if issued, are expected to expire in 2022 and 2023.

With regard to our JNP-0101, JNP-0201, and JNP-0301product candidates, we have exclusively in-licensed from MGH (as discussed above) four issued U.S. patents with composition of matter, method of manufacture and method of use claims directed to the JNP-0101, JNP-0201, and JPN-0301 product candidates and their manufacture and use. These U.S. patents are scheduled to expire from 2024 to 2027. In addition, we have in-licensed counterpart patents that have been granted in Australia, Canada, Europe, and Japan, which are expected to expire in 2024. Allergan holds a United States method of use patent that would apply to JNP-0301 and expires 2028.

The term of any individual patent depends upon laws of the countries in which such patent is obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our formulation and device development expertise and know-how. However, trade secrets can be difficult to protect. Although we take reasonable steps to protect our proprietary information, including restricting access to our premises and to our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, third parties may independently develop the same or similar subject matter and know-how or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

GOVERNMENT REGULATIONS

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and subsequently maintaining compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines,

refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical study related regulations, sometimes referred to as good clinical practices ("GCPs") to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA;
- 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 facility or facilities where the drug is produced to assess compliance with the FDA's cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA; and,
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Nonclinical Studies and IND Submission

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Nonclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity, and drug product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLP regulations. Prior to commencing the first clinical trial with a product candidate, an IND sponsor must submit the results of the nonclinical tests and nonclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols, among other things, to the FDA as part of an IND. In the case of 505(b)(2) applications, though, some of the IND components may not be required. Some nonclinical testing may continue even after the IND is submitted.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose a clinical hold at any time before or during trials due to safety concerns or noncompliance. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other

things, the objectives of the trial, subject selection and exclusion criteria, the trial procedures, the parameters to be used in monitoring safety, the efficacy criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. In addition, an institutional review board ("IRB"), at each study site participating in the clinical trial or a central IRB must review and approve the plan for any clinical trial, informed consent forms, and communications to study subjects before a study commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the FDA for review, and to the IRB for approval. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk to humans exposed to the drug, findings from animal or in vitro testing that suggest a significant risk to human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health ("NIH"), for public dissemination on their clinicaltrials.gov website.

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 regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of trial subjects, enrollment of potential trial subjects, and the continuing validity and scientific merit of the clinical trial. The data safety monitoring board receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determined there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- Phase 1 – Studies are initially conducted in healthy human volunteers or subjects with the target disease or condition and test the investigational drug for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 clinical trials may also be used to gain early evidence on effectiveness.
- Phase 2 – Controlled studies are conducted in limited subject populations with a specified disease or condition to evaluate preliminary efficacy, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks.
- Phase 3 – These adequate and well-controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide evidence of clinical efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. Typically, two Phase 3 clinical trials are required by the FDA for product approval.

The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved. These so-called Phase 4 clinical trials may be made a condition to be satisfied after

approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information.

In the case of a 505(b)(2) NDA, which is a marketing application in which sponsors may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted, some of the above-described studies and nonclinical studies may not be required or may be abbreviated. Bridging studies may be needed, however, to demonstrate the applicability of the studies that were previously conducted by other sponsors to the drug that is the subject of the marketing application.

Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Regulatory authorities or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, or the clinical trial is not being conducted in accordance with the FDA's requirements. Similarly, an IRB can suspend or terminate approval of a trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to subjects.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and the manufacturer, among other things, must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and nonclinical testing, the results of non-clinical studies and clinical trials, including negative or ambiguous results, and information about the manufacturing process and facilities, are all submitted to the FDA, along with the proposed labeling, as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances including where the applicant employs fewer than 500 employees (including employees of affiliates) where the applicant does not have a drug product that has been approved and introduced or delivered for introduction into interstate commerce, and where the applicant (including its affiliates) is submitting its first marketing application. Product candidates that are designated as orphan drugs, which are further described below, are also not subject to application user fees unless the application includes an indication other than the orphan indication.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. The FDA also may require submission of a risk evaluation and mitigation strategy, ("REMS") to ensure that the benefits of the drug outweigh the risks of the drug. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if

new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has set the goal of completing its review of 90% of all applications within 10 months from the 60-day filing date for its initial review of a standard NDA for a New Molecular Entity ("NME"). For non-NME standard applications, the FDA has set the goal of completing its review of 90% of all applications within 10 months from the submission date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides substantial additional information or clarification regarding the submission.

The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of its reasons for not referring the application to an advisory committee. The FDA may also refer drugs to advisory committees when it is determined that an advisory committee's expertise would be beneficial to the regulatory decision-making process, including the evaluation of novel products and the use of new technology. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, safety, potency, and purity. Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA the FDA will inspect one or more clinical trial sites to assure compliance with GCPs.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a CRL. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval and describes all of the specific deficiencies that the FDA identified in the NDA. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA, and may require additional clinical or nonclinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring

additional clinical trials. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

The FDA may withdraw the product approval if compliance with the pre- and post-marketing regulatory requirements is not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling, or FDA notification may be required.

505(b)(2) Approval Process

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and permits the filing of an NDA where at least one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The applicant may rely upon the FDA's prior findings of safety and effectiveness for a previously approved product or on published scientific literature, in support of its application. The FDA may also require 505(b)(2) applicants to perform additional trials to support the changes from the previously approved drug and to further demonstrate the new drug's safety and effectiveness. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Orange Book Listing

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application in which the applicant, in part, relies on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics, and intended use, among other things, to a previously approved product. Limited changes must be pre-approved by the FDA via a suitability petition. ANDAs are termed "abbreviated" because they are generally not required to include nonclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

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 and method of use. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

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 make patent certifications to the FDA that: (1) no patent information on the drug or method of use that is the subject of the application has been submitted to the FDA; (2) the patent has expired; (3) the date on which the patent has expired and approval will not be sought until after the patent expiration; or (4) the 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. The last certification is known as a paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a paragraph IV certification or if the applicant is not seeking approval of a patented method of use. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the competitor has provided a paragraph IV certification to the FDA, the competitor must also send notice of the paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner within 20 days after the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a paragraph IV certification notice prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay.

In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owners regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Exclusivity

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDA provides periods of regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug. Five years of exclusivity are available to New Chemical Entities ("NCEs"). An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent derivatives, such as a complex, chelate, or clathrate, of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review and approve an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a paragraph IV certification is filed.

If a product is not eligible for NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation or indication 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 or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, the three year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will also not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy. Moreover, even if a product receives a period of exclusivity, a physician may prescribe the reference listed drug or a generic version of the reference listed drug off-label for the same use as the newly approved drug.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity period described above. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. Moreover, pediatric exclusivity attaches to all formulations, dosage forms, and indications for products with existing marketing exclusivity or patent life that contain the same active moiety as that which was studied.

Post-approval Requirements

Any drug manufactured or distributed pursuant to FDA approvals is subject to pervasive and continuing regulation by the FDA, including, among other things: requirements related to manufacturing, recordkeeping, and reporting, including adverse experience reporting, drug shortage reporting, and periodic reporting; product sampling and distribution; advertising; marketing; promotion; certain electronic records and signatures; and post-approval obligations imposed as a condition of approval, such as Phase 4 clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and list their drug products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMP and other requirements, which impose certain procedural and documentation requirements upon the company and third-party manufacturers.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and specifications, and impose reporting and documentation requirements upon the manufacturer and any third-party manufacturers that the NDA holder may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA also strictly regulates marketing, labeling, advertising, including direct to consumer advertising, and promotion of drug products that are placed on the market. A company can make only those claims relating to

safety and efficacy, purity, and potency that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Pharmaceutical companies, however, are required to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, and refusal of government contracts.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the Drug Quality and Security Act ("DQSA"), enacted in 2013, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing, which are being implemented over a 10 year period. Among the requirements of this legislation, manufacturers are or will be required to provide certain information regarding the drug products to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers are also required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufactures have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, voluntary product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, debarment from receiving government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties including fines and imprisonment, and may result in adverse publicity, among other adverse consequences.

Regulation of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated by different regulatory authorities, and frequently by different centers within the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually-specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FFDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations changed or what the effect of such changes, if any, may be.

Pricing and Reimbursement

Sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government healthcare program administrative authorities, managed care organizations, private health insurers, and other entities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. 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. Therefore, our products, once approved, may not obtain market acceptance unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved. Moreover, a third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved or that any required patient cost-sharing amount will be acceptable to the patient. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ

significantly from payor to payor and among the insured lives of an individual payor depending upon the benefits applicable to the insured person. One third-party payor's decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for drug products and medical services, examining the medical necessity and reviewing the cost effectiveness of drug products and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health develop research plans and periodically report on the status of the research and related expenditures to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for governmental or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates, once approved.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be priced significantly lower.

Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the United States, among other things, the research, manufacturing, distribution, sale and promotion of drug products are potentially subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General and the Health Resources and Services Administration), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state attorneys general and other state and local government agencies. Our current and future business activities, including for example, sales, marketing and scientific/educational grant programs must comply with healthcare regulatory laws, including the Federal Anti-Kickback Statute, the Federal False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act ("HIPAA"), as amended, physician payment transparency laws, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration,

additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The Federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the intent standard under the Federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law 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. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, and the potential for additional legal or regulatory change in this area, it is possible that our future business activities, including our sales and marketing practices and/or our future relationships with healthcare providers might be challenged under anti-kickback laws, which could harm us.

The Federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent. This statute has been interpreted to prohibit presenting claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the Federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the Federal False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

Although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may further prosecute conduct constituting a false claim under the criminal False Claims Act, which prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Additionally, HIPAA created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors 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.

Payment or reimbursement of prescription drugs by Medicaid or Medicare requires manufacturers of the drugs to submit pricing information to CMS. The Medicaid Drug Rebate statute requires manufacturers to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for the drug. For drugs paid under Medicare Part B, manufacturers must also calculate and report their Average Sales Price, which is used to determine the Medicare Part B payment rate for the drug. Drugs that are approved under an NDA, including 505(b)(2) drugs, are subject to an additional inflation penalty which can substantially increase rebate payments. In addition, for NDA drugs, the Veterans Health Care Act ("VHCA"), requires manufacturers to calculate and report to the Veterans Administration ("VA"), a different price called the Non-Federal Average Manufacturing Price, which is used to determine the maximum price that can be charged to certain federal agencies, referred to as the Federal Ceiling Price ("FCP"). Like the Medicaid rebate amount, the FCP includes an inflation penalty. A Department of Defense regulation requires manufacturers to provide this discount on drugs dispensed by retail pharmacies when paid by the TRICARE Program. All of these price reporting requirements create risk of submitting false information to the government, and potential False Claims Act liability.

The VHCA also requires manufacturers of covered drugs participating in the Medicaid program to enter into Federal Supply Schedule contracts with the VA through which their covered drugs must be sold to certain federal agencies at FCP and to report pricing information. This necessitates compliance with applicable federal procure laws and regulations and subjects us to contractual remedies as well as administrative, civil, and criminal sanctions. In addition, the VHCA requires manufacturers participating in Medicaid to agree to provide different mandatory discounts to certain Public Health Service grantees and other safety net hospitals and clinics.

The Affordable Care Act included a provision commonly referred to as the Sunshine Act, which requires certain pharmaceutical manufacturers to track and report annually certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" provided, as well as any ownership or investment interests held by physicians and their immediate family members. Covered manufacturers are required to submit reports to CMS by the 90th day of each subsequent calendar year. The information reported is publicly available on a searchable website. There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us.

In addition, we may 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 for

Economic 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 certain of 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 created four new tiers of civil monetary penalties 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 attorneys' 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 and may not have the same effect, thus complicating compliance efforts.

The failure to comply with applicable regulatory requirements subjects us to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, injunctions, voluntary recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, refusal to allow us to enter into supply contracts, including government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Should we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we will develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the law and program requirements to which we will or may become subject.

To the extent that our products are sold in a foreign country, we or our collaborators may be subject to similar foreign laws and regulations, which may include, for instance, clinical trial and pre- and post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Affordable Care Act and Other Reform Initiatives

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare and containing or lowering the cost of healthcare.

The Affordable Care Act was enacted in March 2010. The Affordable Care Act includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. The Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs to 23.1% of average manufacturer price ("AMP") and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP.

- The Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. The Affordable Care Act imposed a requirement on manufacturers of branded drugs to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i.e., "donut hole").
- The Affordable Care Act imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs.
- The Affordable Care Act established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- The Affordable Care Act created the Independent Payment Advisory Board which has the authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.
- The Affordable Care Act established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019.

Many of the details regarding the implementation of the Affordable Care Actare yet to be determined, and at this time, it remains unclear the full effect that the Affordable Care Act would have on our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

OUR REPORTING SEGMENTS

We currently operate in two segments: product and service. The product segment oversees the supply chain and manufacturing of CRINONE, our sole commercialized product to our commercial partner, Merck KGaA, internationally. The product segment also includes the royalty stream we receive from Allergan, for CRINONE sales in the United States as well as the development of new product candidates. The service segment includes pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services provided to the Company's customers, as well as characterizing and developing pharmaceutical product candidates for our internal programs and managing the preclinical and clinical manufacturing of COL-1077 and our IVR technology.

We view the development and clinical trial manufacturing of drug product for our pharmaceutical company clients and the manufacturing of CRINONE for our commercial partner to be similar activities. Accordingly, we have integrated all operational activities for the CRINONE business into JPS. These activities, including management of CRINONE manufacturing, quality assurance and logistics and, management of our intellectual property estate are now managed out of our Nottingham, U.K. facility.

Segment information is consistent with the financial information regularly reviewed by our chief operating decision maker, who we have determined to be the chief executive officer, for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting future periods. Our chief operating decision maker evaluates the performance of our product and service segments based on revenue and gross profit. Our chief operating decision maker does not review our assets, operating expenses or non-operating income and expenses by business segment at this time.

See Note 12 to our consolidated audited financial statements included in Item 8 of this Annual Report for certain financial information related to our two operating segments and for certain selected financial information by geographic area, which is incorporated by reference into Item 1 of this Annual Report.

EMPLOYEES

As of February 29, 2016, we had 105 employees, including four executive officers, 16 employees in supply chain management and quality, four employees in sales and marketing functions, 57 employees in technical and other production functions, four employees in research and development functions and 20 employees in other administrative functions. We also use consultants as necessary to support key functions.

Our success is highly dependent on our ability to attract and retain qualified employees. Competition for employees is intense in the pharmaceutical industry. We believe we have been successful in our efforts to recruit qualified employees, but we cannot guarantee that we will continue to be as successful in the future. None of the Company's employees are represented by a labor union or are subject to collective bargaining agreements. We believe that our relationship with our employees is good.

ADDITIONAL INFORMATION

We were incorporated as a Delaware corporation in 1986. Our principal executive offices are located at 33 Arch Street, Suite 3110, Boston Massachusetts 02110, and our telephone number is (617) 639-1500. In April 2015 we changed our name from Columbia Laboratories, Inc. to Juniper Pharmaceuticals, Inc. and also changed our ticker symbol from CBRX to JNP. Our wholly-owned subsidiaries are Columbia Laboratories (Bermuda) Ltd. ("Columbia Bermuda"), Juniper Pharmaceuticals (France) SA ("Juniper France"), Juniper Pharmaceuticals (U.K.) Limited ("Juniper U.K."), and Juniper Pharma Services Ltd (U.K.).

Our Internet address is *www.juniperpharma.com*. Through a link on the "Investor Relations" section of this website, *ir.juniperpharma.com*, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, proxy statement on Form DEF 14A, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material or furnish them to the Securities and Exchange Commission ("SEC"). In addition, we will provide electronic or paper copies of our filings free of charge upon request. Information contained on our corporate website or any other website is not incorporated into this Annual Report and does not constitute a part of this Annual Report.

In addition, the public may read and copy any materials filed by the Company with the SEC at the SEC's Reference Room, which is located at 100 F Street NE, Washington, D.C., 20549. Interested parties may call (800) SEC-0330 for further information on the Reference Room. The SEC also maintains a website containing reports, proxy materials and information statements, among other information, at *http://www.sec.gov*.

We post our code of business conduct and ethics, which applies to all employees, including all executive officers, senior financial officers and directors, in the "Corporate Governance" sub-section of the "Investor Relations" section (*ir.juniperpharma.com*) of our corporate website at *www.juniperpharma.com*. Our code of business conduct and ethics complies with Item 406 of SEC Regulation S-K and the rules of NASDAQ. We intend to disclose any changes to the code that affect the provisions required by Item 406 of Regulation S-K, and any waivers of the code of ethics for our executive officers, senior financial officers or directors, on our corporate website.

Item 1A. *Risk Factors*

Certain factors may have a material adverse effect on our business, financial condition, and results of operations. You should carefully consider the risks and uncertainties described below, in addition to other information contained in this Annual Report, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. The occurrence of any of the risks described below could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to the Clinical Development, Regulatory Review, Approval and Commercialization of Our Product Candidates

Clinical drug development is a lengthy and expensive process with an uncertain outcome.

In order to obtain FDA approval to market a new drug product we must demonstrate proof of safety and efficacy in humans. To meet these requirements we will have to conduct extensive preclinical testing and "adequate and well-controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting preclinical studies or clinical trials may cause us to incur additional operating expenses. Moreover, we may continue to be affected by delays associated with the preclinical testing and clinical trials of certain product candidates conducted by our potential partners over which we have no control. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites, particularly those in foreign jurisdictions;
- slower than expected rates of patient recruitment due to narrow screening requirements;
- the inability of patients to meet FDA or other regulatory authorities' imposed protocol requirements;
- the inability to retain patients who have initiated participation in a clinical trial but may be prone to withdraw due to various clinical or personal reasons, or who are lost to further follow-up;
- the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices, or cGMPs, for use in clinical trials;
- shortages of the active pharmaceutical ingredient, or API;
- the need or desire to modify our manufacturing processes;
- the inability to adequately observe patients after treatment;
- changes in regulatory requirements for clinical trials;
- the lack of effectiveness during the clinical trials;
- unforeseen safety issues, or adverse drug reactions;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site;
- insufficient financial resources;
- government or regulatory delays or "clinical holds" requiring suspension or termination of the trials; and
- non-compliance with GLP, GCP or GMP regulatory standards.

Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

Clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate statistically sufficient safety and efficacy to obtain the requisite regulatory approvals for any of our product candidates or product candidates employing our technology. We expect to commence a Phase 3 trial for COL-1077 in 2017, to initiate clinical trials for JNP-0101, JNP-0201 and JNP-0301 in 2016 or 2017, and to commence new clinical trials from time to time in the course of our business as our product development work continues. The failure of clinical trials to demonstrate the safety and effectiveness of a product candidate for its desired indications could harm the development of such product candidate as well as our other product candidates. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

Delays in clinical trials are common for many reasons, and any such delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales as currently contemplated.

We may experience delays in clinical trials for our product candidates, including COL-1077, which is currently in a Phase 2b trial. Our planned clinical trials, including those for COL-1077, JNP-0101, JNP-0201 and JNP-0301, might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the Data and Safety Monitoring Board ("DSMB"), the FDA, or the Institutional Review Board ("IRB"), or us;
- imposition of a clinical hold by the FDA or other regulatory authorities because of significant problems with a product candidate in the same class as one of our product candidates;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in identifying, recruiting, and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including suitable API; or,
- delays resulting from negative or equivocal findings of DSMB for a trial.

Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process, and jeopardize our ability to commence product sales and generate revenue.

Failure to recruit, enroll, and retain patients for clinical trials may cause the development of our product candidates to be delayed or development costs to increase substantially.

We have experienced, and expect to experience in the future, delays in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends,

among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and,
- competition for patients by clinical trial programs for other competitive treatments.
- Clinician's and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating

Our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, because some patients who might have opted to enroll in our trials opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which reduces the number of patients who are available for our clinical trials in such clinical trial site. Delays in patient enrollment in the future as a result of these and other factors may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent us from completing these trials and adversely affect our ability to advance the development of our product candidates.

Our clinical trials may be halted at any time for a variety of reasons.

Our clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA, or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the DSMB or the IRB for a clinical trial. An IRB may also suspend or terminate our clinical trials for failure to protect patient safety or patient rights. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe the clinical trials are not being conducted in accordance with applicable regulatory requirements or present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any proposed product that we develop, the commercial prospects of such proposed product will be harmed and our ability to generate product revenue from any of these proposed products will be delayed or eliminated. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly.

Additionally, our current and/or future product candidates may demonstrate serious adverse side effects in clinical trials. These adverse side effects could interrupt, delay, or halt clinical trials of product candidates and could result in FDA or other regulatory authorities denying approval of product candidates for any or all targeted indications. An IRB or independent data safety monitoring board, the FDA, other regulatory authorities, or we ourselves or our customers may suspend or terminate clinical trials at any time. Product candidates may prove not to be safe for human use. In such circumstances, we may not be able to complete development and successful licensing or partnering of our own internal programs.

Our product development efforts may not be successful.

None of our current product candidates have received regulatory approval. All of our product candidates are in research, preclinical, and clinical stages of development. If the results from any of our clinical trials are not positive, those results may adversely affect our ability to obtain regulatory approval to conduct additional clinical trials or possibly raise additional capital, which will affect our ability to continue research and development activities. In addition, our product candidates may take longer than anticipated to progress through clinical trials, or patient enrollment in the clinical trials may be delayed or prolonged significantly, thus delaying the clinical trials.

Even if we obtain regulatory approval for our product candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval for one or more of our product candidates in the United States, the FDA may still impose significant restrictions on a product's indicated uses or marketing or to the conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including phase 4 clinical trials or post-market surveillance. As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for our hormone therapy product candidates, if approved, may include restrictions on use or warnings. The Food and Drug Administration Amendments Act of 2007 ("FDAAA"), gives the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved Risk Evaluation and Mitigation Strategies ("REMS) programs. If approved, our product candidates will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of its authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our product candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases or conditions to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

The holder of an approved NDA also is subject to obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. Legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's cGMPs regulations or comparable foreign requirements. If we or a regulatory agency discovers previously unknown problems with a

product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us. Such restrictions may include requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the drug, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS program. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- conduct an investigation into our practices and any alleged violation of law;
- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall; or,
- exclude us from providing our products to those participating in government health care programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

The occurrence of any of the foregoing events or penalties may force us to expend significant amounts of time and money and may significantly inhibit our ability to bring to market or continue to market our products and generate revenue. Similar regulations apply in foreign jurisdictions.

The manufacture and packaging of pharmaceutical products are subject to FDA requirements and those of similar foreign regulatory bodies. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercial efforts may be harmed.

The manufacture and packaging of pharmaceutical products, if approved, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory bodies. There are a limited number of commercial manufacturers that operate under these cGMP regulations who are both capable of manufacturing COL-1077 and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations or requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions, any of which could harm our business. The same requirements and risks are applicable to the suppliers of the key raw material used to manufacture the API for CRINONE and COL-1077.

Only one supplier of progesterone for CRINONE is approved by regulatory authorities outside the United States. We have not experienced production delays due to shortages of progesterone. This supplier has notified us

that it intends to materially increase the price for its progesterone and has requested that we enter into a long-term supply agreement. It is unclear what impact, if any, an increase in the cost of progesterone will have on our financial results or the demand for CRINONE, and what our ability is to obtain progesterone from an alternate supplier in a timely manner.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's cGMPs. Any new facility is subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the launch of a product.

Furthermore, in order to obtain approval of our product candidates, by the FDA and foreign regulatory agencies, we will be required to consistently produce the API, and the finished product in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation. Each of our potential API suppliers will likely use a different method to manufacture API, which has the potential to increase the risk to us that our manufacturers will fail to meet applicable regulatory requirements. We also need to complete process validation on the finished product in the packaging we propose for commercial sales. This includes testing of stability, measurement of impurities and testing of other product specifications by validated test methods. If the FDA does not consider the result of the process validation or required testing to be satisfactory, we may not obtain approval to launch the product or approval, launch or commercial supply after launch may be delayed.

The FDA and similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing requirements, for the manufacturing, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory, civil actions or penalties which could harm our business.

Our development, regulatory and commercialization strategy for our product candidates depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products containing lidocaine.

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or Section 505(b)(2). Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA also requires companies to perform additional clinical trials to support any difference from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the listed drug has been approved, as well as for any new indication(s) sought by the Section 505(b)(2) applicant as supported by additional data. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the listed drug's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions.

We have designed our clinical programs to advance COL-1077, JNP-0101, and JNP-0201 for registration filing in the United States using the FDA's 505(b)(2) regulatory pathway and the hybrid application pathway, which is analogous to the 505(b)(2) regulatory pathway, in Europe. As such, our NDAs in the United States will rely, and our marketing authorization applications ("MAA") in Europe will rely, in part, on previous findings of safety and efficacy for other similar but approved products and published scientific literature. Even though we expect to be able to take advantage of Section 505(b)(2) and the hybrid application pathway to support potential

regulatory approval of our product candidates in the United States and Europe, the relevant regulatory authorities may require us to perform additional clinical trials to support approval over and above the clinical trials that we have already completed, that are underway, and the additional clinical trials we currently plan to commence. The relevant regulatory authorities also may determine that we have not provided sufficient data to justify reliance on prior investigations involving the approved active ingredients in our product candidates.

In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), in the past some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). For example, parties have filed citizen petitions objecting to the FDA approving a Section 505(b)(2) NDA on both scientific and legal and regulatory grounds. Scientific arguments have included the assertions that for the FDA to determine the similarity of the drug in the 505(b)(2) NDA to the listed drug, the agency would need to reference proprietary manufacturing information or trade secrets in the listed drug's NDA; that it would be scientifically inappropriate for the FDA to rely on public or nonpublic information about the listed drug because it differs in various ways from the drug in the 505(b)(2) NDA; or that differences between the listed drug and the drug in the 505(b)(2) NDA may impair the latter's safety and effectiveness. Legal and regulatory arguments have included the assertion that Section 505(b)(2) NDAs must contain a full report of investigations conducted on the drug proposed for approval, and that approving a drug through the 505(b)(2) regulatory pathway would lower the approval standards. In addition, citizen petitions have made patent-based challenges against 505(b)(2) NDAs. For example, petitioners have asserted that the FDA should refuse to file a 505(b)(2) NDA unless it references a specific NDA as the listed drug, because it is "most similar" to the proposed drug, and provides appropriate patent certification to all patents listed for that NDA; or that when a 505(b)(2) NDA is pending before the agency, but before it is approved, where the FDA approves an NDA for a drug that is pharmaceutically equivalent to the drug that is the subject of the 505(b)(2) NDA, then the FDA should require that the 505(b)(2) NDA be resubmitted referencing the approved NDA as the listed drug and certifying to the listed patents for that approved drug. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of COL-1077 or any future product candidates we may develop.

The commercial success of CRINONE and any current or future product candidates that are approved for marketing and sale, will depend upon gaining and retaining significant market acceptance of these products among physicians and payors, including perceptions related to pricing and access.

Physicians may not prescribe our products, including any current or future product candidates that are approved by the appropriate regulatory authorities for marketing and sale, which would prevent us from generating revenue or becoming profitable. Market acceptance of our products by physicians, patients, and payors, will depend on a number of factors, many of which are beyond our control, including the following:

- the clinical indications for which our product candidates are approved, if at all;
- acceptance by physicians and payors of each product as safe and effective treatment;
- the cost of treatment in relation to alternative treatments, including numerous generic drug products;
- the relative convenience and ease of administration of our products in the treatment of the symptoms for which they are intended;
- the availability and efficacy of competitive and generic drugs;
- the effectiveness of our sales force and marketing efforts;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the availability of coverage and adequate reimbursement by third parties, such as insurance companies and other health care payors, or by government health care programs, including Medicare and Medicaid;

- limitations or warnings contained in a product's FDA-approved labeling; and,
- prevalence and severity of adverse side effects.

Even if the medical community accepts that our products are safe and efficacious for their approved indications, physicians may not immediately be receptive to their use or may be slow to adopt our products as an accepted treatment for the symptoms for which they are intended. We cannot assure you that any labeling approved by the FDA will permit us to promote our products as being superior to competing products. If our products, once approved, do not achieve an adequate level of acceptance by physicians and payors, we may not generate sufficient or any revenue from these products and we may not become profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

If our product candidates, are approved for sale, and the actual number of patients in the applicable market is smaller than we estimate, our revenue could be adversely affected, possibly materially.

There is no patient registry or other method for establishing with precision the actual number of patients that might benefit from our product candidates. There is no guarantee that our assumptions and estimates are correct. The number of patients our product candidates could benefit, if approved for use, could actually be significantly lower than our estimates.

We believe that the actual size of the total addressable markets for our product candidates, if approved, will be determined only after we have substantial history as a commercial company. If the total addressable market for our products is smaller than we expect, our revenue could be adversely affected, possibly materially.

The longer term growth of our business depends on our efforts to utilize our proprietary delivery technologies to expand our portfolio of product candidates, which may require substantial financial resources and may ultimately be unsuccessful.

The longer term growth of our business depends upon our ability to utilize our proprietary delivery technologies to develop and commercialize therapeutic products. In addition to our development and commercialization of COL-1077, JNP-0101, JNP-0201, and JNP-0301, we intend to pursue the development and commercialization of other product candidates that leverage our IVR technology. A significant portion of the research that we are conducting involves our IVR technology.

Research programs to identify new disease targets or conditions and product candidates require substantial technical, financial, and human resources whether or not we ultimately identify any additional product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including that:

- the research methodology used may not be successful in identifying potential product candidates; or,
- potential product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

There are a number of FDA requirements that we must satisfy before we can commence a clinical trial. If we are able to identify additional potential product candidates, satisfaction of these regulatory requirements will entail substantial time, effort, and financial resources. We may never satisfy these requirements. The effort, and financial resources we expend on the development of additional product candidates may impair our ability to continue development, obtain regulatory approval, and commercialize our current product candidates and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of other product candidates, these product candidates may never demonstrate sufficient safety and efficacy to be approved by the FDA or other regulatory authorities. If any of these events occur, we may be forced to abandon our development efforts for such program or programs, which would harm our business.

Healthcare insurers and other payors may not pay for our products or may impose limits on reimbursement.

The ability of us or our partners to commercialize our prescription products will depend, in part, on the extent to which reimbursement for our products is available from third-party payors, such as health maintenance organizations, health insurers and other public and private payors. If we or our partners succeed in bringing new prescription products to market or expand the approved label for existing products, we cannot be assured that third-party payors will pay for such products, or establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development.

Government health agencies, private health maintenance organizations and other third-party payors may use one or more tools including price controls, profit or reimbursement caps, and use of formularies, or lists of drugs for which coverage is provided under a healthcare benefit plan, to control the costs of prescription drugs. Each payor that maintains a drug formulary makes its own determination as to whether a new drug will be added to the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the same class. This determination often involves an assessment of the clinical appropriateness of the drug and, in some cases, the cost of the drug in comparison to alternative products. Our products marketed by us or our partners from which we derive sales revenues and royalties may not be added to payors' formularies, our products may not have preferred status to alternative therapies, and formulary decisions may not be conducted in a timely manner. Once reimbursement at an agreed level is approved by a payor organization, reimbursement may be lost entirely or be reduced compared to competitive products. As reimbursement is often approved for a period of time, this risk is greater at the end of the time period, if any, for which the reimbursement was approved. Our partners may also decide to enter into discount or formulary fee arrangements with payors, which could result in lower or discounted prices for CRINONE or future products.

If our products do not have the effects intended or cause undesirable side effects, our business may suffer.

Although many of the ingredients in our current product candidates are approved generics, human hormones, and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. Our product or product candidates could have certain undesirable side effects, including if not taken as directed or if taken by a consumer who has certain medical conditions. In addition, our product and product candidates may not have the effect intended, including if they are not taken in accordance with certain instructions. Furthermore, there can be no assurance that our product or product candidates, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations, and prospects would be harmed significantly.

Our products could demonstrate hormone replacement risks.

In the past, certain studies of female hormone replacement therapy products, such as conjugated equine estrogen, have reported an increase in health risks. Progesterone is a natural female hormone present at normal levels in most women throughout their lifetimes. However, some women require progesterone supplementation due to a natural or chemical-related progesterone deficiency. It is possible that data suggesting risks or problems may come to light in the future that could demonstrate a health risk associated with progesterone or progestin supplementation or CRINONE or our product candidates. It is also possible that future study results for hormone replacement therapy could be negative and could result in negative publicity about the risks and benefits of hormone replacement therapy. As a result, physicians and patients may not wish to prescribe or use progesterone or other hormones, including CRINONE.

We may be exposed to product liability claims.

We could be exposed to future product liability claims by consumers. Although we presently maintain product liability insurance coverage at what we believe is a commercially reasonable level, such insurance may

not be sufficient to cover all possible liabilities. An award against us in an amount greater than our insurance coverage could have a material adverse effect on our operations.

We face substantial competition from larger companies with considerable resources that already have comparable treatments available in the market, and they or others may also discover, develop or commercialize additional products before or more successfully than we do.

Our industry is highly competitive and subject to rapid and significant technological change as researchers learn more about diseases and develop new technologies and treatments. Our potential competitors include primarily large pharmaceutical, biotechnology, and specialty pharmaceutical companies. In attempting to achieve the widespread commercialization of our product candidates, we will face competition from established drugs and major brand names and also generic versions of these products. In addition, new products developed by others could emerge as competitors to our future products.

Our services business competes directly with the in-house research departments of pharmaceutical companies and biotechnology companies, as well as contract research companies, and research and academic institutions. We also experience significant competition from foreign companies operating under lower cost structures. Many of our competitors have greater financial and other resources than we have. We expect to face increased competition as new companies enter the market and as more advanced technologies become available. In the future, any one of our competitors may develop technological advances that render the services that we provide obsolete. While we plan to develop technologies, which will give us competitive advantages, our competitors plan to do the same. We may not be able to develop the technologies we need to successfully compete in the future, and our competitors may be able to develop such technologies before we do or provide those services at a lower cost. Consequently, we may not be able to successfully compete in the future.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. These companies also have long-established relationships within the medical and patient community, including patients, physicians, nurses and commercial third-party payors and government payors. Our ability to compete successfully will depend largely on our ability to:

- discover and develop product candidates that are superior to other products in the market;
- obtain required regulatory approvals;
- adequately communicate the benefits of our product candidates, if approved;
- attract and retain qualified personnel;
- obtain and maintain patent and/or other proprietary protection for our product candidates and any future product candidates we may develop; and,
- obtain collaboration arrangements to commercialize our product candidates and any future product candidates we may develop.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval of drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates or any future product candidates we may develop obsolete or non-competitive before we can recover the expenses of developing and commercializing our product candidates or any future product candidates we may develop. Our competitors may also obtain FDA or other regulatory approval of their products more rapidly than we may obtain approval of ours. We anticipate that we will face intense and increasing competition as new drugs enter the market and more advanced technologies

become available. For example, a competitor could develop therapies that are more efficacious or convenient than our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our product candidates or any future product candidates we may develop, if approved, could be impaired.

Legislative or regulatory reform of the health care system and other regulatory or statutory changes in the United States and foreign jurisdictions may adversely impact our business, operations, or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations, or financial results. In particular, in March 2010 the Patient Protection and Affordable Care Act and a related reconciliation bill (collectively the "Affordable Care Act") were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

- Mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans.
- The definition of "average manufacturer price" was revised for reporting purposes, which could increase the amount of Medicaid drug rebates by state.
- The 340B Drug Pricing Program under the Public Health Service Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities.
- Pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the "donut hole."
- Pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs. The aggregated industry-wide fee is expected to total $28 billion through 2019. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

Despite initiatives to invalidate the Affordable Care Act, the U.S. Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate, and a provision that provides federal premium tax credits to individuals purchasing coverage through health insurance exchanges. Additionally, there are legal challenges to the Affordable Care Act in lower courts on other grounds. We will not know the full effects of the Affordable Care Act until applicable federal and state agencies issue regulations or guidance under the law. Although it is too early to determine the effect of the Affordable Care Act, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which began in 2013, which will remain in effect until 2024 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to

five years. We expect that additional 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, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products. Other legislative and regulatory initiatives have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. For example, the Drug Supply Chain Security Act of 2013 imposes new obligations on manufacturers of certain pharmaceutical products related to product tracking and tracing. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance documents or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Further, in some foreign jurisdictions, including the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval and product launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further, federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from our current and future products and may affect our overall financial condition and ability to develop product candidates.

Risks Related to Our Business and Industry

Our product revenue is dependent on the continued sale of CRINONE to Merck KGaA.

Our operating results are dependent on the product revenues from Merck KGaA derived from the sale of CRINONE in countries outside the U.S. Revenues from sales to Merck KGaA during the years ended December 31, 2015, 2014 and 2013 constituted approximately 59%, 53% and 73% of our total revenues, respectively. We do not control the amount and timing of marketing resources that Merck KGaA may or may not devote to our product. The failure of Merck KGaA to effectively market CRINONE and maintain licensure in marketed countries could have a material adverse effect on our business, financial condition and results of operations. Our current supply agreement with Merck KGaA has an expiration date of May 19, 2020.

We may fail to obtain new customer projects, renew existing customers or have customer project cancellations at our wholly-owned subsidiary, JPS, which may adversely affect our service revenue and gross margin.

The majority of our customer projects at JPS are short-term in duration. As a result, we must maintain a robust backlog of customer programs to replace projects as they are completed. In the event we are unable to

replace these customer projects in a timely manner or at all, our revenues may not be able to be sustained or may decline. In addition, customer projects may be cancelled or delayed by clients for any reason upon notice and this can materially impact our business. While we intend to seek new or extended agreements, if new contracts cannot be completed or existing contracts cannot be extended on terms acceptable to us or at all, our business, results of operation and financial condition could be materially adversely affected.

We have made significant capital investments in our JPS business to meet growth expectations. If we are unable to utilize the facilities' expected capacity, our margins could be adversely affected.

We have made substantial investments in our Nottingham, U.K. facilities and equipment to support increased development and contract manufacturing activity. If new customer agreements are not executed or do not generate expected revenues, we may have excess fixed costs capacity that may require an impairment charge that will negatively affect our financial performance.

Foreign governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market our product candidates in both the U.S. and foreign jurisdictions either directly or through a future collaboration partner. If we or a potential future collaboration partner obtain approval in one or more foreign jurisdictions, we or such collaboration partner will be subject to rules and regulations in those jurisdictions relating to our product candidates. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we or a potential future collaboration partner may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

If our products are marketed or distributed in a manner that violates federal, state or foreign healthcare fraud and abuse laws, marketing disclosure laws or other federal, state or foreign laws and regulations, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements in the U.S. and abroad, our general operations, and the research, development, manufacture, sale and marketing of our products, are subject to extensive additional federal, state and foreign healthcare regulation, including the FCA, the Federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, and their state analogues, and similar laws in countries outside of the U.S., laws, such as the U.K. Bribery Act of 2010 and governing sampling and distribution of products, and government price reporting laws.

Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws and private individuals have been active in bringing lawsuits on behalf of the government under the FCA and similar laws in other countries. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry; however, these laws are broad in scope and there may not be regulations, guidance or court decisions that definitively interpret these laws in the context of particular industry practices. We cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all federal, state and foreign regulations. If we or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us, including, but not limited to, restrictions on how we market and sell our products, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations. Such investigations or suits may also result in related shareholder lawsuits, which can also have an adverse effect on our business.

Further, the FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. For drug products that are approved by the FDA under the FDA's accelerated approval regulations, unless otherwise informed by the FDA, the sponsor must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the promotional materials, which delays and may negatively impact our commercial team's ability to implement changes such product's marketing materials, thereby negatively impacting revenues. Moreover, under Subpart H, the FDA may also withdraw approval of such product if, among other things, the promotional materials are false or misleading, or other evidence demonstrates that such product is not shown to be safe or effective under its conditions of use.

The U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that can impose significant restrictions and other burdens on the affected companies. If we are found to have promoted such off-label uses, we may become subject to similar consequences.

In recent years, several U.S. states have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or to file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. In addition, as part of the Affordable Care Act, manufacturers of drugs are required to publicly report gifts and other payments or transfers of value made to U.S. physicians and teaching hospitals. Several states have also adopted laws that prohibit certain marketing-related activities, including the provision of gifts, meals or other items to certain healthcare providers. Many of these requirements are new and uncertain, and the likely extent of penalties for failure to comply with these requirements is unclear; however, compliance with these laws is difficult, time consuming and costly, and if we are found to not be in full compliance with these laws, we may face enforcement actions, fines and other penalties, and we could receive adverse publicity which could have an adverse effect on our business, financial condition, and results of operations.

If we fail to comply with any federal, state, or foreign laws or regulations governing our industry, we could be subject to a range of regulatory actions that could adversely affect our ability to commercialize our products, harm or prevent sales of our products, or substantially increase the costs and expenses of commercializing and marketing our products, all of which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, incentives exist under applicable U.S. law that encourage employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so-called "whistleblower" lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies as a result of, for example, promotion of pharmaceutical products beyond labeled claims. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.

As a pharmaceutical development and services company, we are subject to a large body of legal and regulatory requirements. In addition, as a publicly traded company we are subject to significant regulations. We cannot assure you that we are or will be in compliance with all potentially applicable laws and regulations. Failure to comply with all potentially applicable laws and regulations could lead to the imposition of fines, cause the value of our common stock to decline, impede our ability to raise capital, or lead to the de-listing of our stock.

We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing, and marketing the products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from expected synergies. We cannot assure that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

The loss of our key executives could have a significant impact on us.

Our success depends in large part upon the abilities and continued service of our executive officers and other key employees. Our employment agreements with our executive officers are terminable by either party on short notice. The loss of key employees may result in a significant loss in the knowledge and experience that we, as an organization, possess, and could cause significant delays in, or outright failure of, the management of our supply chain, our pharmaceutical development, analytical, and consulting services business and/ or, our development of future products and product candidates. If we are unable to attract and retain qualified and talented senior management personnel, our business may suffer.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of February 29, 2016, we had 105 employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. Our future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate new employees. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to increase revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth in our organization.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, acts of terrorism and other natural or man-made disasters or business interruptions. The occurrence of any business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to produce clinical supplies of COL-1077, JNP-0101, JNP-0201, JNP-0301 and other potential product candidates could be disrupted if the operations of JPS or our other suppliers are affected by a man-made or natural disaster or other business interruption.

Our internal computer systems, or those used by our third-party collaborators, CROs, or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our third-party collaborators, CROs, and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party collaborators and other third parties for research and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or suffer substantial reputational harm and the further development and commercialization of our product candidates could be delayed.

Our operations involve hazardous materials and are subject to environmental, health, and safety controls and regulations.

We are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials, and we spend considerable time complying with such laws and regulations. Our business activities involve the controlled use of hazardous materials and although we take precautions to prevent accidental contamination or injury from these materials, we cannot completely eliminate the risk of using these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may materially harm our business, financial condition and results of operations.

Risks Related to Our Reliance on Third Parties

We rely on third-parties to conduct our clinical trials and many of our preclinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our product candidates may not advance in a timely manner or at all.

In the course of our discovery, preclinical testing, and clinical trials, we rely on third parties, including universities, investigators, and CROs, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our preclinical studies. CROs and investigators are responsible for many aspects of the trials, including finding and enrolling patients for testing and administering the trials. We therefore must rely on third parties to conduct our clinical trials, but their failure to comply with all regulatory and contractual requirements, or to perform their services in a timely and acceptable manner, may compromise our clinical trials in particular or our business in general. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial patients are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner. Any failings by these third parties may compromise our clinical trials in particular or our business in general. Similarly, we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. For example, if such third parties fail to perform their obligations in compliance with our clinical trial protocols, our clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control. These risks also apply to the development activities of

our collaborators, and we do not control our collaborators' research and development, clinical trials or regulatory activities. We do not expect any drugs resulting from our collaborators' research and development efforts to be commercially available for at least two (2) or more years, if ever.

In addition, we have prepaid research and development expenses to third parties that have been deferred and capitalized as pre-payments to secure the receipt of future preclinical and clinical research and development services. These pre-payments are recognized as an expense in the period that the services are performed. We assess our prepaid research and development expenses for impairment when events or changes in circumstances indicate that the carrying amount of the prepaid expense may not be recoverable or provide a future economic benefit, including the risk of third party nonperformance. If there are indicators that the third parties are unable to perform the research and development services, we may be required to take an impairment charge.

Our research and development activities rely on technology licensed from third parties, and termination of any of those licenses would result in loss of significant rights to develop and market our products, which would impair our business, prospects, financial condition and results of operations.

We have been granted rights to a technology necessary for our research and development activities from third parties through license agreements. The license generally may be terminated by the licensor if we fail to perform our obligations under the agreement, including obligations to develop the product candidates under license. If terminated, we would lose the right to develop the product candidates, which could adversely affect our business, prospects, financial condition and results of operations. The license agreements also generally require us to meet specified milestones or show reasonable diligence in development of the technology. If disputes arise over the definition of these requirements or whether we have satisfied the requirements in a timely manner, or if any other obligations in the license agreements are disputed by the other party, the other party could terminate the agreement, and we could lose our rights to develop the licensed technology.

In addition, if new technology is developed from these licenses, we may be required to negotiate certain key financial and other terms, such as milestone and royalty payments, for the licensing of this future technology with the third party licensors, and it might not be possible to obtain any such license on terms that are satisfactory to us, or at all.

We are completely dependent on third parties to manufacture our commercial products and any difficulties, disruptions, or delays, or the need to find alternative sources, could adversely affect our profitability and future business prospects.

We do not currently own or operate, and currently do not plan to own or operate, facilities for the commercial manufacture of our products. We currently rely solely on third-party contract manufacturers to manufacture CRINONE and will rely on third-party contract manufacturers to manufacture any product candidates that are approved for marketing and sale. We do not currently have an alternative manufacturer for our drug substance and finished drug product, and we may not be able to enter into agreements with second source manufacturers whose facilities and procedures comply with cGMP, regulations and other regulatory requirements on a timely basis and with terms that are favorable to us, if at all.

Our ability to have our commercial products manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of our third-party contract manufacturing facilities. Any difficulties, disruptions or delays in the manufacturing process could result in product defects or shipment delays, suspension of manufacturing or sale of the product, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand in a timely and cost-effective manner. Furthermore, our current third-party manufacturers do not manufacture for us exclusively and may exhaust some or all of their resources meeting the demand of other customers. In addition, securing additional third-party contract manufacturers for our products will require significant time for transitioning the necessary manufacturing

processes, gaining regulatory approval, and for having the appropriate oversight and may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture our products in accordance with cGMP.

Further, we and our third-party manufacturers currently purchase certain raw and other materials used to manufacture our products from third-party suppliers and, at present, do not have long-term supply contracts with most of these third parties. These third-party suppliers may cease to produce the raw or other materials used in our product or product candidates or otherwise fail to supply these materials to us or our third-party manufacturers or fail to supply sufficient quantities of these materials to us or our third-party manufacturers in a timely manner for a number of reasons, including but not limited to the following:

- unexpected demand for or shortage of raw or other materials;
- adverse financial developments at or affecting the supplier;
- regulatory requirements or action;
- an inability to provide timely scheduling and/or sufficient capacity;
- manufacturing difficulties;
- changes to the specifications of the raw materials such that they no longer meet our standards;
- lack of sufficient quantities or profit on the production of raw materials to interest suppliers;
- labor disputes or shortages; or,
- import or export problems.

Any other interruption in our third-party supply chain could adversely affect our ability to satisfy commercial demand and our clinical development needs for our products and product candidates. In addition, we or our third-party manufacturers sometimes obtain raw or other materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high-quality standards imposed on our raw or other materials, we or our third-party manufacturers may not be able to obtain such materials of the quality required to manufacture our products and product candidates from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

If we are unable to have our products and product candidates manufactured on a timely or sufficient basis because of the factors discussed above, we may not be able to meet commercial demand or our clinical development needs for our products and product candidates, or may not be able to manufacture our products and product candidates in a cost-effective manner. As a result, we may lose sales, fail to generate increased revenues or suffer regulatory setbacks, any of which could have an adverse impact on our profitability and future business prospects.

Our IVR technology utilizes medical grade ethlyene vinyl acetate polymers for which there are a limited number of vendors. If we are unable to reach acceptable financial terms for research and commercial supplies with one of these vendors, our ability to commercialize products using the technology will be significantly delayed or prohibited.

We are dependent on single-source third-party suppliers of raw materials for our product and product candidate, the loss of whom could impair our ability to manufacture and sell our products.

Medical grade, cross-linked polycarbophil, the polymer used in our BDS-based product and product candidate is currently available from only one supplier, Lubrizol, Inc. (“Lubrizol”). We believe that Lubrizol will supply as much of the material as we require because our product ranks among the highest value-added uses of

the polymer. In the event that Lubrizol cannot or will not supply enough of the product to satisfy our needs, we will be required to seek alternative sources of polycarbophil. An alternative source of polycarbophil may not be available on satisfactory terms or at all, which would impair our ability to manufacture and sell our product. While we purchase polycarbophil from Lubrizol from time to time, we do not have an agreement with them concerning future purchases. Our policy is to have in inventory at least a 12 month supply of polycarbophil.

Only one supplier of progesterone is approved by regulatory authorities outside the United States If this supplier is unable or unwilling to satisfy our needs, we will be required to seek alternative sources of supply. While alternative sources of progesterone exist, the time needed to obtain regulatory approvals for new suppliers may impair our ability to manufacture and sell our products.

We are dependent upon single-source third-party manufacturers for our sale of CRINONE, the loss of which could result in a loss of revenues.

We rely on third parties to manufacture CRINONE, including Fleet, which manufacturers CRINONE in bulk, Maropack, which fills CRINONE into applicators, and Central Pharma, which packages CRINONE in final containers. These third parties may not be able to satisfy our needs in the future, and we may not be able to find or obtain approval from regulatory authorities of alternate developers and manufacturers. Delays in the manufacture of CRINONE could have a material adverse effect on our business. This reliance on third parties could have an adverse effect on our profit margins. Any interruption in the manufacture of CRINONE would impair our ability to deliver our product to customers on a timely and competitive basis, and could result in the loss of revenues.

Only one supplier of progesterone for CRINONE is approved by regulatory authorities outside the United States. We have not experienced production delays due to shortages of progesterone. This supplier has notified us that it intends to materially increase the price for its progesterone and has requested that we enter into a long-term supply agreement. It is unclear what impact, if any, an increase in the cost of progesterone will have on our financial results or the demand for CRINONE, and what our ability is to obtain progesterone from an alternate supplier in a timely manner.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will incur continued losses for the next several years and thus may never achieve or maintain profitability.

We expect to incur increasing operating losses over the next several years. Expected future operating losses will have an adverse effect on our cash resources, stockholders' equity and working capital. If we obtain regulatory approval of COL-1077, JNP-0101, JNP-0201, JNP-0301 or any future product candidates, we may incur significant sales, marketing, and outsourced manufacturing expenses, as well as continued research and development expenses. In addition, we expect our research and development expenses to significantly increase in connection with our planned Phase 3 clinical trial for COL-1077, our potential clinical trials for JNP-0101, JNP-0201 and JNP-0301, and as we explore additional product candidates for our drug pipeline. We will also continue to incur costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our stock and impair our ability to raise capital, expand our business, maintain our development efforts, obtain regulatory approvals, diversify our portfolio of product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We may not be able to complete the development and commercialization of our product candidates if we fail to obtain additional financing.

We need substantial amounts of cash to complete the clinical development of our product candidates. Although we have existing cash and cash equivalents, and future cash is expected from the ongoing results of our core operations, it may not be sufficient to fund our requirements in an expeditious manner. In addition, changing circumstances may cause us to consume funds significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may attempt to raise additional capital from the issuance of equity or debt securities, collaborations with third parties, licensing of rights to these products, or other means, or a combination of any of the foregoing. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from our day-to-day activities, which may adversely affect our ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to take one or more of the following actions:

- significantly delay, scale back, or discontinue our product development and commercialization efforts;
- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be the case; and,
- license, potentially on unfavorable terms, our rights to our product candidates that we otherwise would seek to develop or commercialize ourselves.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or proposed products, or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing discovery, development, and commercialization efforts, and our ability to generate revenue and achieve or sustain profitability will be substantially harmed.

Impairment of our intangible assets could result in significant charges that would adversely impact our future operating results.

We have significant intangible assets, including goodwill and intangibles with useful lives ranging from three to seven years, which are susceptible to valuation adjustments as a result of changes in various factors or conditions. The most significant intangible assets we have is goodwill as well as developed technology, customer relationships, and trade names. We amortize our intangible assets that have finite lives using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. Amortization is recorded over the estimated useful lives ranging from three to seven years. We assess the potential impairment of intangible assets on an annual basis, as well as whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment of such assets include the following:

- significant underperformance relative to historical or projected future operating results;
- significant changes in the manner of or use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends;

- significant decline in our stock price for a sustained period;
- changes in our organization or management reporting structure that could result in additional reporting units, which may require alternative methods of estimating fair values or greater disaggregation in our analysis by reporting unit; and
- a decline in our market capitalization below net book value.

Future adverse changes in these or other unforeseeable factors could result in an impairment charge that would impact our results of operations and financial position in the reporting period identified.

We are exposed to market risk from foreign currency exchange rates.

With four international subsidiaries and third party manufacturers in Europe, economic and political developments in the European Union can have a significant impact on our business. All of our products are currently manufactured in Europe. We are exposed to currency fluctuations related to payment for the manufacture of our products in Euros, Pounds Sterling, Swiss Francs, and other currencies and selling them in U.S. dollars and other currencies.

Risks Related to Our Intellectual Property

The patent protection for our CRINONE product has expired, and our competitors may develop and commercialize generic or otherwise competitive products, the sales of which may materially affect the revenue we receive based on the sale of our CRINONE product around the world.

Although our CRINONE product is the primary source of our commercial revenue, the patents covering CRINONE have expired in all the major jurisdictions where CRINONE is currently being sold. As a result, we may face significant competition in those markets. Our competitors may develop and commercialize products that compete with CRINONE, and the sales of such products may materially affect the revenue we receive from our strategic partners, Merck KGaA and Allergan, based on sales of CRINONE in the United States and in other countries around the world.

If we are unable to obtain and maintain adequate patent protection for our product candidates, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected; also the term of our or our licensor's issued patents may be inadequate to protect our competitive position for our product candidates for an adequate amount of time.

The success of our COL-1077, JPN-0101, JPN-0201, and JPN-0301 product candidates depends, in part, upon our and our licensors ability to obtain and maintain patent protection in the United States and other countries for our product candidates. If we do not receive adequate intellectual property protection, our competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we or our licensors have filed and, when appropriate, will file patent applications in the United States and abroad to seek protection for innovations relating to our novel product candidates that are important to our business. The patent application and approval process, however, is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position of pharmaceutical companies generally is highly uncertain. In addition, the determination of patent rights with respect to pharmaceutical products commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming that the other requirements

for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our or our licensor's patent rights. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Our pending and future patent applications may not result in patents being issued which protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection and prevent competitors from competing with us or otherwise provide us with any competitive advantage. For example, our competitors may be able to circumvent our patents by developing alternative formulations that have biological activities the same as or similar to our product candidates but fall outside the scope of the claims of our issued patents. Also, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our competitors may be able to commercialize products that compete with our product candidates, which may have a material adverse effect on our business position, business prospects, and financial condition.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke those parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

Even if we prevail in our infringement action, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our and our strategic partner's ability to develop, manufacture, market and sell our product candidates and to sell the CRINONE product without infringing the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our product candidates or their methods of use, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the pharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could have a material adverse effect on our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

While we have obtained composition of matter patents with respect to some of our product candidates, we also rely on trade secret protection for certain aspects of our technology platform, including certain aspects of our formulation and device development expertise and know-how. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Furthermore, even if the information were to become available to the public by improper means, once released, we will not be able to stop other innocent parties from using the released information. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us or from disclosing the information widely. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. Furthermore, certain foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties under certain circumstances. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of our employees, including members of our senior management, were previously employed at other pharmaceutical companies, and some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from that third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. Even if we enter into such agreements, we cannot prevent the other party from, for example, attempting to challenge the ownership or inventorship of the proprietary rights that was intended to be covered by the agreement. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Risks Related to Ownership of Our Common Stock

The price of our common stock has been and may continue to be volatile.

The market prices and volume of securities of small specialty pharmaceutical companies, including ours, from time to time experience significant price and volume fluctuations. Historically, the market price of our common stock has fluctuated over a wide range. Between 2013 and 2015, our common stock traded in a range from $4.48 to $15.44 per share. During the twelve months ended December 31, 2015, our common stock traded in a range from $5.09 to $15.44 per share. It is likely that the price of our common stock will continue to fluctuate. In particular, the market price of our common stock may fluctuate significantly due to a variety of factors, including: the results of our operations, our ability to develop additional products and services, and general market conditions. In addition, the occurrence of any of the risks described in these “Risk Factors” could have a material and adverse impact on the market price of our common stock.

Sales of large amounts of our common stock may adversely affect our market price. The issuance of preferred stock or convertible debt may adversely affect the rights of our common stockholders.

As of December 31, 2015, we had 10,801,549 shares of common stock outstanding, of which 10,113,924 shares were freely tradable. As of that date, approximately 687,625 shares of our common stock were held by affiliates. We also have the following securities outstanding: series B convertible preferred stock, contingently redeemable series C convertible preferred stock, treasury shares, and options. If all of these securities are exercised or converted, an additional 1.1 million shares of our common stock will be outstanding, all of which will be available for resale under the Securities Act, subject in some cases to applicable volume limitations under Rule 144 of the Securities Act. The exercise and conversion of these securities would likely dilute the book value per share of our common stock. In addition, the existence of these securities may adversely affect the terms on which we can obtain additional equity financing.

In March 2002, our Board of Directors authorized shares of series D junior participating preferred stock in connection with its adoption of a stockholder rights plan which plan was amended and restated on November 29, 2010 and subsequently on January 28, 2015), under which we issued rights to purchase series D convertible preferred stock to holders of our common stock. Upon certain triggering events, such rights become exercisable to purchase shares of our common stock (or, in the discretion of our Board of Directors, series D convertible preferred stock) at a price substantially discounted from the then current market price of our common stock.

Under our certificate of incorporation, our Board of Directors has the authority to issue up to 1.0 million shares of preferred stock and to determine the price, rights, preferences and privileges of those shares without any further vote or action by our stockholders. In addition, we may issue convertible debt without shareholder approval. The rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any shares of preferred stock or convertible debt that may be issued in the future. While we have no present intention to authorize or issue any additional series of preferred stock or convertible debt, such preferred stock or convertible debt, if authorized and issued, may have other rights, including economic rights senior to our common stock, and, as a result, their issuance could have a material adverse effect on the market value of our common stock.

Anti-takeover provisions could impede or discourage a third-party acquisition of the Company. This could prevent stockholders from receiving a premium over market price for their stock.

We are a Delaware corporation. Anti-takeover provisions of Delaware law impose various obstacles to the ability of a third party to acquire control of our company, even if a change in control would be beneficial to our existing stockholders. In addition, our Board of Directors has adopted a stockholder rights plan (as discussed above, this plan was amended and restated on November 29, 2010 and subsequently on January 28, 2015) and has designated a series of preferred stock that could be used defensively if a takeover is threatened. Our incorporation under Delaware law, our stockholder rights plan, and our ability to issue additional series of preferred stock, could impede a merger, takeover or other business combination involving our company or discourage a potential acquirer from making a tender offer for our common stock. This could reduce the market value of our common stock if investors view these factors as preventing stockholders from receiving a premium for their shares.

We may be limited in our use of our net operating loss carryforwards.

As of December 31, 2015, we had certain net operating loss carryforwards of approximately $157 million that may be used to reduce our future U.S. federal income tax liabilities, if we become profitable on a federal income tax basis. If unused, these tax loss carryforwards will begin to expire between 2018 and 2034. Our ability to use these loss carryforwards to reduce our future U.S. federal income tax liabilities could also be lost if we were to experience more than a 50% change in ownership within the meaning of Section 382(g) of the Internal Revenue Code of 1986, as amended, the "Code"). If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected.

On January 22, 2015, our Board of Directors adopted an amendment and restatement of the Amended and Restated Rights Agreement, dated as of November 29, 2010, (the "Rights Plan"), between the Company and American Stock Transfer & Trust Company, LLC, as successor rights agent as (amended and restated, the "Amended Rights Plan"). We adopted the Rights Plan to preserve the value of our net operating loss carry forwards by reducing the likelihood that we would experience an ownership change by discouraging any person (together with such person's affiliates and associates), without the approval of the Board of Directors, (i) from acquiring 4.99% or more of the outstanding Voting Stock (as defined in the Rights Plan) and (ii) that currently beneficially owns 4.99% or more of the outstanding Voting Stock from acquiring more shares of Voting Stock, other than by exercise or conversion of currently existing warrants, convertible securities or other equity-linked securities. In general, the Amended Rights Plan leaves the Rights Plan unchanged in all material respects, other than increasing from 4.99% or more to 9.99% or more the percentage of outstanding shares of Voting Stock that

a Person must Beneficially Own (as defined in the Amended Rights Plan) in order to qualify as an "Acquiring Person" for purposes of triggering the Rights (as defined in the Amended Rights Plan) under the Amended Rights Plan. The Amended Rights Plan expires on July 3, 2016.

There is no guarantee that the Rights Plan will prevent an ownership change within the meaning of Section 382(g) of the Internal Revenue Code and, therefore, no guarantee that the value of our net operating loss carryforwards will be preserved.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting.

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles, or GAAP. We are likewise required, on an annual basis, to evaluate the effectiveness of our disclosure controls and to disclose any changes and material weaknesses in our internal controls.

As described in Item 9A of this Annual Report, our management identified a material weakness in our internal control over financial reporting, relating to our evaluation of revenue recognition for services transactions and contractual arrangements during the year ended December 31, 2014. We developed a remediation plan designed to address the material weakness in our internal control over financial reporting. Our plan included additional staffing, enhancing policies and procedures relating to revenue recognition and other areas reflected in the material weakness, and implementing a series of incremental software solutions. This material weakness has been remediated as of December 31, 2015.

We cannot assure you that that additional material weaknesses in our internal control over financial reporting will not be identified in the future. Any failure to implement and document new and more precise monitoring controls or to implement organizational changes including skillset enhancements through resource changes or education to improve detection and communication of financial misstatements across all levels of the organization could result in additional material weaknesses, result in material misstatements in our financial statements and cause us to fail to meet our reporting obligations, which in turn could cause the trading price of our common stock to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings, if any, for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to holders of our common stock would therefore be limited to the appreciation of their stock.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

We lease a 7,050 square foot facility in Boston, Massachusetts, which houses our executive offices and certain administrative functions. The lease on this facility expires in February 2019. We own two facilities in Nottingham, United Kingdom. The first is an 8,000 square foot facility containing administrative offices and laboratories for analytical and development services. The second building is a 30,000 square foot facility containing laboratories and clean rooms primarily used for pharmaceutical development, analytical and manufacturing activities.

Item 3. ***Legal Proceedings***

Claims and lawsuits are filed against the Company from time to time. Although the results of pending claims are always uncertain, the Company believes that it has adequate reserves or adequate insurance coverage in respect of these claims, but no assurance can be given as to the sufficiency of such reserves or insurance coverage in the event of any unfavorable outcome resulting from these actions.

Item 4. ***Mine Safety Disclosures***

Not Applicable.

PART II

Item 5. *Market for the Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities*

Market Price of Our Common Stock.

Our common stock is traded on the Nasdaq Global Market under the symbol "JNP." The following table sets forth for the periods indicated the high and low sales prices of our common stock on the Nasdaq Global Market.

	High	Low
Fiscal Year Ended December 31, 2015		
First Quarter	$ 8.40	$5.09
Second Quarter	9.75	6.10
Third Quarter	15.44	7.55
Fourth Quarter	13.49	9.52
Fiscal Year Ended December 31, 2014		
First Quarter	$ 7.50	$6.37
Second Quarter	7.33	6.20
Third Quarter	6.84	5.59
Fourth Quarter	6.34	5.21

Holders of Record

At February 29, 2016, there were approximately 200 shareholders of record of our common stock, one shareholder of record of our Series B convertible preferred stock ("Series B Preferred Stock") and two shareholders of record of our Series C Convertible Preferred Stock ("Series C Preferred Stock"). We estimate that there were approximately 4,000 beneficial owners of our common stock on such date.

At December 31, 2015, 130 shares of our Series B Preferred Stock remain outstanding. Each share of Series B Preferred Stock is convertible into 2.5 shares of common stock. Upon our liquidation, the holders of the Series B Preferred Stock are entitled to $100 per share. The Series B Preferred Stock will be automatically converted into common stock upon the occurrence of certain events. Holders of the Series B Preferred Stock are entitled to one vote for each share of common stock into which the preferred stock is convertible.

Our contingently redeemable series C Preferred Stock has a stated value of $1,000 per share, and is convertible into common stock at the lower of: (i) $28.00 per share of common stock; or, (ii) 100% of the average of the closing prices during the three trading days immediately preceding the conversion notice, not to exceed 294,045 shares as of December 31, 2015. The Series C Preferred Stock pays a 5% dividend, payable quarterly in arrears on the last day of each quarter. The security holders of Series C Preferred Stock have certain redemption rights due to events beyond our control such as delisting, dividend defaults and certain other defaults. The terms of the Series C Preferred Stock have remained the same since inception.

Dividend Policy

We have never paid a cash dividend on our common stock and do not anticipate the payment of cash dividends in the foreseeable future. We intend to retain any earnings for use in the development and expansion of our business. We are required to pay a 5% dividend on our Series C Preferred Stock on the last day of each quarter. We are current on our dividend payments.

Applicable provisions of the Delaware General Corporation Law may affect our ability to declare and pay dividends on our common stock as well as on our Series C Preferred Stock. In particular, pursuant to the

Delaware General Corporation Law, a company may pay dividends out of its surplus, as defined, or out of its net profits, for the fiscal year in which the dividend is declared and/or the preceding year. Surplus is defined in the Delaware General Corporation Law to be the excess of our net assets over capital. Capital is defined to be the aggregate par value of shares issued unless otherwise established by the Board of Directors.

Issuer Purchases of Equity Securities.

Period	Total Number of Shares Purchased[1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 through October 30, 2015	2,283	$9.68	—	—
November 1 through November 30, 2015			—	—
December 1 through December 30, 2015			—	—
Total	2,283	$9.68		

(1) During the fourth quarter of 2015, an employee delivered 2,283 shares of restricted stock to us upon vesting, to satisfy tax withholding requirements.

Recent Sales of Unregistered Securities.

None.

Equity Compensation Plan Information

See Part III, Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters," for information regarding securities authorized for issuance under our equity compensation plans.

Shelf Registration

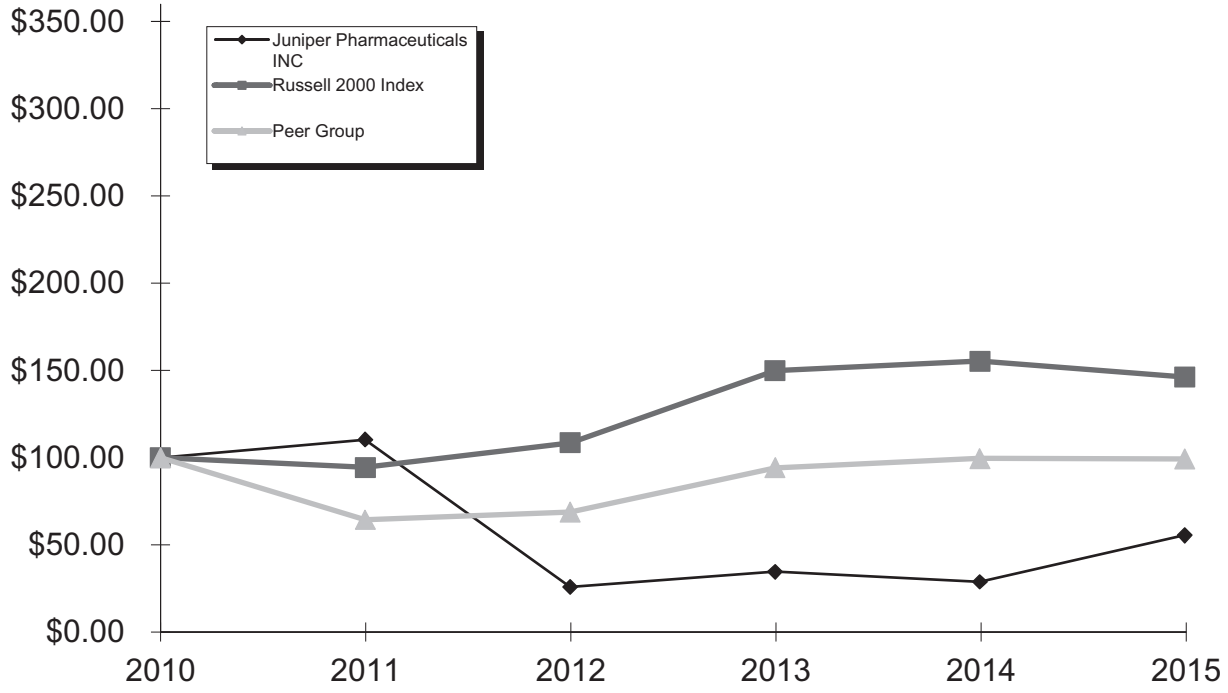
On September 14, 2015, we filed an S-3 registration statement with the SEC using a "shelf" registration process, file number 333-206928, which became effective September 23, 2015. Under this shelf registration process, we may from time to time sell any combination of the securities described in the prospectus in one or more offerings for an aggregate offering price of up to $100,000,000. The amount to be registered under the shelf registration consists of up to $100,000,000 of an indeterminate amount of common stock and/or preferred stock, warrants, rights and/or units to purchase certain securities. We have not issued any securities under this registration statement.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Exchange Act.

The table below shows the cumulative total stockholder return of an investment of $100 on December 31, 2010 in our common stock, the Russell 2000 Index, and Peer Group. Our stock price performance shown in the table below is not indicative of future stock price performance.

Comparison of Five-Year Cumulative Total Return
Juniper Pharmaceuticals, Inc., Russell 2000 Index and Peer Group*
(Performance Results Through 12/31/2015)



	December 31,				
	2011	2012	2013	2014	2015
Juniper Pharmaceuticals, Inc.	$110.13	$ 28.00	$ 36.40	$ 30.84	$ 56.72
Russell 2000 Index	$ 94.55	$108.38	$148.49	$153.73	$144.95
Peer Group	$ 65.39	$ 69.68	$ 94.48	$ 99.50	$ 99.32

* Peer Group Companies are Alimera Sciences, Inc., Antares Pharma, Inc., BioDelivery Sciences International, Inc., Pain Therapeutics, Caladrius Biosciences, Inc., Codexis, Inc., CTI BioPharma Corp., Cytokinetics, Athersys, Inc., Elite Pharmaceuticals, Inc., Eprius Biopharma, OncoGenex Pharmaceuticals, Inc., Paratek Pharmaceuticals, Inc., Pozen, Inc., Rigel Pharmaceuticals, Inc., XOMA Corp., and Zogenix.

Note: Factual material is obtained from sources believed to be reliable, but the publisher is not responsible for any errors or omissions contained herein.

Item 6. ***Selected Financial Data***

The following selected financial data are derived from our audited consolidated financial statements and are qualified in their entirety by reference to, and should be read in conjunction with, such consolidated financial statements and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report. The consolidated statement of operations data for the years ended December 31, 2015, 2014, 2013, 2012, and 2011 and consolidated balance sheet data as of December 31, 2015, 2014, 2013, 2012, and 2012 have been derived from audited consolidated financial statements. The historical results are not necessarily indicative of the results to be expected for any future period.

	Year Ended December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Consolidated Statement of Operations Data:					
(000's except per share data)					
Revenues	$37,558	$32,464	$29,226	$25,828	$43,062
Gross profit	16,144	14,775	15,976	13,040	31,371
Operating expenses	18,655	10,960	10,101	10,231	8,442
Interest expense	106	118	25	—	12
Net (loss) income	$ (2,134)	$ 3,390	$ 6,704	$ 9,917	$20,527
(Loss) income per common share-basic and diluted					
Basic	$ (0.20)	$ 0.31	$ 0.59	$ 0.91	$ 1.90
Diluted	$ (0.20)	$ 0.27	$ 0.52	$ 0.26	$ 1.73
Weighted average number of common shares outstanding:					
Basic	10,774	10,992	11,259	10,914	10,791
Diluted	10,774	11,007	11,273	11,063	11,569
Consolidated Balance Sheet Data:					
(000's)					
Working capital	$19,000	$20,438	$25,930	$32,157	$27,500
Total assets	51,379	52,208	60,092	36,869	36,083
Notes payable	3,135	3,532	3,995	—	—
Contingently redeemable series C preferred stock	550	550	550	550	600
Shareholders' equity	39,417	40,868	46,878	31,365	20,631

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is intended to provide a reader of our consolidated financial statements with a narrative from the perspective of our management on our financial condition, results of operations, liquidity and certain other factors that may affect our future results. You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial data included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review Item 1A of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Company Overview

We are a women's health therapeutic company focused on developing therapeutics that address unmet medical needs in women's health. Our pipeline of product and product development programs utilizes proprietary drug delivery technologies that we believe are uniquely suited to applications in women's health. These technologies consist of our BDS, a polymer designed to adhere to epithelial surfaces or mucosa and achieve sustained and controlled delivery of active drug product, and our novel IVR technology, a multi-segment IVR which we believe is advantageous compared to existing ring technologies.

The Company currently operates in two segments: product and service. The product segment oversees the supply chain and manufacturing of CRINONE, the Company's sole commercialized product to our commercial partner, Merck KGaA, internationally. The product segment also includes the royalty stream the Company receives from Allergan for CRINONE sales in the United States as well as the development of new product candidates. The service segment includes product development, clinical trial manufacturing, and advanced analytical and consulting services for the Company's customers, as well as characterizing and developing pharmaceutical product candidates for the Company's internal programs and managing the preclinical and clinical manufacturing COL-1077 and our IVR technology.

Our objective is to be a leader in the discovery, development, and commercialization of therapeutics designed to treat unmet medical needs in women's health by utilizing our proprietary drug delivery technologies. Key elements of our strategy include:

- Advancing our lead product candidate, COL-1077, an investigational 10% lidocaine bioadhesive vaginal gel through clinical development and regulatory approval;
- Advancing preclinical product candidates utilizing our IVR technology to target overactive bladder, hormone replacement therapy, and preterm birth into clinical development;
- Supplying CRINONE to our commercial partner, Merck KGaA, for sale in over 90 countries around the world;
- Growing our pharmaceutical service business, JPS;
- Identifying and pursuing business development collaborations, including co-development opportunities that will take advantage of our proprietary drug delivery technologies and the pharmaceutical development capabilities of JPS for life-cycle management of existing commercial pharmaceutical products; and
- Supporting our customers with our formulation, analytical and product development capabilities allows us to efficiently deploy these same capabilities for our in-house proprietary product programs.

We are applying the revenue generated from our CRINONE franchise and our pharmaceutical service business to partially fund the commercialization of new therapeutics using our proprietary drug delivery technologies. We believe this strategy, in concert with our product and product development programs, positions us well for effective and capital-efficient growth.

Our lead product candidate, COL-1077, is an investigational 10% lidocaine bioadhesive vaginal gel intended as a local anesthetic for pain from minimally invasive gynecological procedures. We currently expect to announce the results of our ongoing Phase 2b clinical trial of COL-1077 in the third quarter of 2016. We are also advancing three preclinical product development programs that target overactive bladder, hormone replacement therapy in women, and prevention of preterm birth.

Collaboration Agreements

Our primary revenue product is CRINONE. We have licensed CRINONE to Merck KGaA, outside the United States, and sold the rights to CRINONE to Allergan, in the United States.

Merck KGaA

During 2012 and 2013, we manufactured and sold CRINONE to Merck KGaA at a price determined on a country-by-country basis at the greater of (i) 30% of the net selling price in such country, or (ii) our direct manufacturing cost plus 20%. Certain quantity discounts were applied to annual purchases over 10 million, 20 million, and 30 million units.

In April 2013, our license and supply agreement with Merck KGaA for the sale of CRINONE outside the United States was renewed for an additional five year term, extending the expiration date from to May 19, 2020.

Under the terms of the amended license and supply agreement, we will sell CRINONE to Merck KGaA on a country-by-country basis at the greater of (i) direct manufacturing cost plus 20% or (ii) a percentage of Merck KGaA's net selling price. From 2014 through 2020, the percentage of net selling price will be determined based on a tiered structure, which is based on volume sold. As sales volumes increase our percentage share of each incremental tier decreases. Additionally, the parties are cooperating to evaluate and implement manufacturing cost reduction measures, with both parties sharing any reductions realized from these initiatives. If, at the end of the supply term, the parties cannot agree upon mutually acceptable terms for renewal of the supply arrangement, Merck KGaA may elect to retain a license to the product and will have an irrevocable fully paid up license to the product.

We are the exclusive supplier of CRINONE to Merck KGaA. Merck KGaA holds marketing authorizations for CRINONE in over 90 countries outside the United States. The patent for CRINONE has expired in all countries other than Argentina.

The amended license and supply agreement requires Merck KGaA to provide a rolling 18-month forecast of its CRINONE requirements for each country in which the product is marketed. The first four months of each forecast are considered firm orders. Under the agreement, each party is responsible for new clinical trials and government registrations in its territory and the parties are obligated to consult from time to time regarding the studies. Each party has agreed to promptly provide the other party the data from its CRINONE studies free-of-charge. During the term of the agreement, we have agreed not to develop, license, manufacture or sell to another party outside the United States any product for the vaginal delivery of progesterone or progestational agents for hormone replacement therapy or other indications where progesterone or progestational agents are commonly used.

Allergan

Within the United States, CRINONE is marketed by Allergan (which changed its name from Actavis, Inc. in 2015 and from Watson Pharmaceuticals, Inc. in 2012, each as a result of an acquisition) pursuant to a Purchase and Collaboration Agreement dated March 2010. Pursuant to the terms of this agreement, Allergan purchased certain of our assets and we agreed to participate in joint development activities with Allergan with respect to the development of certain progesterone gel products. In December 2013, we and Allergan held our last joint

development committee meeting and there have been no joint development activities since then. In July 2010, and in connection with this agreement, we entered into a License Agreement with Allergan, which provided Allergan with exclusive rights to develop, manufacture and offer to sell and commercialize these progesterone gel products in the United States. We also entered into a Supply Agreement with Allergan, dated July 2010, which made us the exclusive supplier to Allergan for CRINONE.

In April 2011, we filed NDA 22-139 to expand the labeled uses of progesterone vaginal gel 8% to include its use in the reduction of the risk of preterm birth in women with a singleton gestation and a short uterine cervical length in the mid-trimester of pregnancy. NDA 22-139 was reviewed by the FDA's Advisory Committee for Reproductive Health Drugs in January 2012. While the committee members generally agreed that progesterone vaginal gel 8% is safe, the committee stated that more information is needed to support approval. On February 10, 2012, we transferred NDA 22-139 to Allergan pursuant to the second closing of our sale of assets to Allergan under the Purchase and Collaboration Agreement. On February 24, 2012, Allergan received a Complete Response Letter ("CRL"), from the FDA indicating that the review cycle for NDA 22-139 was complete but the application was not ready for approval in its present form. The CRL stated that the effect of treatment with progesterone vaginal gel 8% in reducing the risk of preterm birth in women with a short uterine cervical length at ≤32 6/7 weeks gestation (p=0.022) did not meet the level of statistical significance generally expected to support the approval of the product in the U.S. market from a single trial. In the CRL, the FDA stated that additional clinical work would be required to support the approval. Allergan held an "End-of-Review" meeting with the FDA to discuss the issues outlined in the CRL. Allergan continued discussions with the FDA to determine a viable pathway forward and in August 2012 filed a Formal Dispute Resolution Request ("FDRR") related to this application. The FDA denied Allergan's FDRR in October 2012. Allergan discontinued further development of this program.

From July 2010 to November 2013 we manufactured and sold products to Allergan at direct manufacturing cost plus 10%; the revenues generated from these sales were recorded as product revenues from a related party. Since Allergan had sufficient inventories of CRINONE, there were no orders in 2013. In November 2013, we entered into an early termination of the exclusive Supply Agreement with Allergan. The early termination of the agreement, which would have otherwise terminated in May 2015, provided for a one-time payment by Allergan, as a termination fee, in addition to payment for all raw materials purchased by us to meet forecast requirements.

Pursuant to the Purchase and Collaboration Agreement, we will continue to be eligible to receive royalties until July 2, 2020 equal to a minimum of 10% of annual net sales of CRINONE by Allergan for annual net sales up to $150 million, 15% for sales above $150 million but less than $250 million, and 20% for annual net sales of $250 million and over. Royalties under the Purchase and Collaboration Agreement will be payable until the latest of (i) the last valid claim, (ii) expiration of regulatory exclusivity or (iii) the 10th anniversary of product launch.

Between February 1, 2012 and February 6, 2012, two putative securities class action complaints were filed against us and certain of our officers and directors in the United States District Court for the District of New Jersey. Both actions were consolidated into a single proceeding entitled *In Re Columbia Laboratories, Inc., Securities Litigation*, under which Allergan and three of its officers were added as defendants. The United States Court of Appeals for the Third Circuit affirmed, in March 2015, the prior decision of the United States District Court for the District of New Jersey dismissing this securities class action lawsuit.

Sale of Legatrin P.M. Intellectual Property Rights and Technology to Lil' Drug Store

In August 2014, Lil' Drug Store Products exercised its option to purchase the intellectual property rights and technology related to Legatrin P.M. The Company previously licensed this product to Lil Drug Store Products and received annual royalties. Based on a predetermined formula, the Company received approximately $2.2 million from the sale.

Exclusive patent license agreement with The Massachusetts General Hospital Corporation

On March 27, 2015 we entered into an Exclusive Patent License Agreement with Massachusetts General Hospital ("MGH") pursuant to which we licensed the exclusive worldwide rights to MGH's patent rights in a novel IVR technology for the delivery of one or more pharmaceuticals at different dosages and release rates in a single segmented ring.

Unless earlier terminated by the parties, the license agreement will remain in effect until the later of (i) the date on which all issued patents and filed patent applications within the licensed patent rights have expired or been abandoned and (ii) one year after the last sale for which a royalty is due under the license agreement or 10 years after such expiration or abandonment date referred to in (i), whichever is earlier. We have the right to terminate the license agreement by giving 90 day advance written notice to MGH. MGH has the right to terminate the license agreement based on our failure to make payments due under the license agreement, subject to a 15 day cure period, or our failure to maintain the insurance required by the license agreement. MGH may also terminate the license agreement based on our non-financial default under the license agreement, subject to a 60 day cure period.

Pursuant to the terms of the license agreement, we have agreed to reimburse MGH for all costs associated with the preparation, filing, prosecution and maintenance of the licensed patent rights and have agreed to pay MGH a $50,000 annual license fee on each of the first five year anniversaries of the effective date of the license, and a $100,000 annual license fee beginning on the sixth anniversary of the effective date of the license and on each subsequent anniversary thereafter. The annual license fee is creditable against any royalties or sublicense income payable in each calendar year.

Under the terms of the license agreement, we have agreed to use commercially reasonable efforts to develop and commercialize at least one product and/or process related to the IVR technology, which efforts will include the making of certain minimum annual expenditures in each of the first five years following the effective date of the license. We have also agreed to pay MGH certain milestone payments totaling up to $1,200,000 tied to our achievement of certain development and commercialization milestones, and certain annual royalty payments based on net sales of any such patented products or processes developed by us.

Workforce Reduction and Corporate Office Relocation

During the year ended December 31, 2013, we relocated our corporate facilities from Livingston, New Jersey to Boston, Massachusetts. In March 2013, we entered into a lease agreement for our new facilities in Boston. The new lease provided a significant cost saving to the Company as compared to our lease in Livingston, which expired in October 2013. We incurred a charge of $0.7 million for the year ended December 31, 2013, related to severance and other relocation costs associated with the elimination of certain positions at the Livingston location. In addition as a result of the Company's relocation, certain state carryover attributes were remeasured and reduced in 2014 and the Company realized a current one-time clawback expense under a New Jersey Economic Development Authority program of $0.3 million relating to the recapture of previously granted state incentives.

In October, 2015, we relocated our corporate facilities to 33 Arch Street in Boston, Massachusetts.

Revenues

We generate revenues primarily from the sale of our products and services and from a royalty stream and certain other revenues. During the year ended December 31, 2015, we derived approximately 59% of our revenues from the sale of our products, 31% from the sale of our services and 10% from our royalty stream and certain other revenues. During the year ended December 31, 2014, we derived approximately 54% of our revenues from the sale of our products, 27% from the sale of our services and 19% of our revenues from royalty stream and certain other revenues. During the year ended December 31, 2013, we derived approximately 73% of our revenues from the sale of our products, 13% from the sale of our services and 14% of our revenues from royalty stream and certain other revenues. Generally, we recognize revenues from the sales of our products upon delivery to our customers and revenues from service as the work is performed.

We sell our products directly to our partner Merck KGaA and use a sales force to sell our services worldwide. During the years ended December 31, 2015, 2014 and 2013, we derived 80%, 68% and 81% of our total revenues, respectively, from sales outside North America.

Our services business is supported by sales and business development activities by both company executives and a dedicated business development team. At December 31, 2015, we had three dedicated sales employees based in the United Kingdom covering territories worldwide and in January 2015, we filled an open position for a U.S. based sales employee. A technical support team, that covers the scientific aspects of customer programs, supports this sales team.

We expect that future recurring revenues will be derived from product sales to Merck KGaA, a royalty stream from Allergan and from offering pharmaceutical development, clinical trial manufacturing, and analytical and consulting services. Quarterly sales results can vary widely and affect comparisons with prior periods because (i) products shipped to Merck KGaA occur only in full batches, and may not correlate to Merck KGaA's in-market sales and (ii) service revenues are driven by obtaining and retaining our customer contracts, which may vary widely from quarter to quarter.

Cost of Product Revenues

Our cost of product revenues consists primarily of material, labor, consulting, manufacturing overhead expenses, cost of components and subassemblies supplied by third party suppliers. Cost of revenues also includes depreciation expense for certain equipment used for the manufacturing of our products.

Cost of Service Revenues

Our cost of service revenues consists primarily of labor, consulting, overhead expenses associated with the production and service projects undertaken by our scientists and laboratory employees. Cost of service revenues also includes depreciation expense for the utilization of manufacturing and laboratory equipment and facilities and amortization expense for developed technology, an intangible asset identified as a part of the JPS acquisition.

Sales and Marketing Expenses

Our sales and marketing expenses consist of costs including personnel and other administrative costs associated with employees directly focused on sales and marketing activities for our services business.

Research and Development Expenses

Research and development expenses include costs for product and clinical development, which were a combination of internal and third-party costs, and regulatory fees. There were no research and development expenses in 2013 because we eliminated our research and development activities as part of our workforce reduction and office relocation. In 2014, we resumed research and development activities for COL-1077, a sustained-release vaginal lidocaine gel for which the target indication is an acute use anesthetic for minimally invasive gynecological procedures. In 2015, we entered into a phase 2b clinical trial for COL-1077. We are also advancing three preclinical product development programs that target overactive bladder, hormone replacement therapy in women, and prevention of preterm birth. In 2016, we expect our research and development expenses to increase significantly as a percentage of revenue as a result of our further research and development efforts related to COL-1077, JNP-0101, JNP-0201 and JNP-0301.

Acquisition-Related Expenses

Our acquisition-related expenses for 2013 were costs associated with our acquisition of JPS as well as a failed transaction in 2013. We did not incur any acquisition-related expenses in 2014 and 2015.

General and Administrative Expenses

General and administrative costs include payroll, employee benefits, equity compensation, and other personnel-related costs associated with administrative and support staff, as well as legal costs, insurance costs, bad debt expense and other administrative fees.

Interest (Expense) Income, net

Historically interest income consists primarily of interest earned on our short-term marketable securities consisting of U.S. Treasury and agency securities. In 2013, the company sold its short-term marketable securities. Subsequent interest income is derived from interest bearing bank accounts. Interest expense consists of interest payments associated with the debt assumed as a part of the acquisition of JPS in 2013. The debt assumed is secured by a mortgage on the facilities that we own in Nottingham.

Change in the Fair Value of Common Stock Warrants

We account for our warrants in accordance with "ASC 815-40" Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock," which requires warrants to be classified as permanent equity, temporary equity or as assets or liabilities. Our warrants are classified as liabilities because they include a provision that specifies that we must deliver freely tradable shares upon exercise by the warrant holder. Because there are circumstances, irrespective of likelihood that they may not be within our control, that could prevent delivery of registered shares, ASC 815-40 requires the warrants be recorded as a liability at fair value, with subsequent changes in fair value recorded as income or expense in our Consolidated Statements of Operations. The fair value of our warrants is determined using a Black-Scholes option pricing model, and is affected by changes in inputs to that model including our stock price, expected stock price volatility and contractual term. In 2009 we issued warrants to purchase 681,275 shares of common stock with an exercise price of $12.16 per share. These warrants expired in April 2015 and therefore, had no fair value at December 31, 2015.

Other Income (Expense), net

Other income (expense), net consists primarily of foreign currency re-measurement gains or losses and other miscellaneous income and expense items.

Provision for Income Taxes

The Company operates in multiple countries and has evaluated the need for a valuation allowance on a separate jurisdiction basis. Valuation allowances are provided if, based on the weight of available evidence, it is more-likely-than-not that some or all of the deferred tax assets will not be realized. In the fourth quarter of 2014, it was determined that the utilization of our tax loss carryforwards in the United Kingdom was not likely to be realized based on updated forecasts and projections of product development efforts the Company is beginning to undertake. Consequently, we have recorded a full valuation allowance against our net deferred tax assets in that jurisdiction, resulting in deferred tax expense of $0.5 million in 2014. Currently, we have a full valuation allowance offsetting our net domestic deferred tax asset.

We will continue to monitor the need for valuation allowances in each jurisdiction, and may adjust our positions in the future based on actual results.

Results of Operations

Years Ended December 31, 2015 and 2014

The following tables contain selected statement of operations information, which serves as the basis of the discussion surrounding our results of operations for the years ended December 31, 2015 and 2014 (in thousands):

	Year Ended December 31,					
	2015		2014			
	Amount	As a % of Total Revenues	Amount	As a % of Total Revenues	$ Change	% Change
Product revenues	$22,162	59%	$17,381	54%	$ 4,781	28%
Service revenues	11,651	31	8,770	27	2,881	33
Royalties	3,745	10	6,313	19	(2,568)	(41)
Total revenues	37,558	100	32,464	100	5,094	16
Cost of product revenues	13,053	35	10,470	32	2,583	25
Cost of service revenues	8,361	22	7,219	22	1,142	16
Total cost of revenues	21,414	57	17,689	54	3,725	21
Gross profit	16,144	43	14,775	46	1,369	9
Operating expenses:						
Sales and marketing	1,249	3	1,708	5	(459)	(27)
Research and development	6,948	18	663	2	6,285	948
General and administrative	10,458	28	8,589	26	1,869	22
Total operating expenses	18,655	50	10,960	34	7,695	70
(Loss) income from operations	(2,511)	(7)	3,815	12	(6,326)	(166)
Interest (expense) income, net	(106)	—	(118)	—	12	(10)
Change in fair value of common stock warrant liability	—	—	379	1	(379)	(100)
Other income (expense), net	488	1	302	1	186	62
(Loss) income before income taxes	(2,129)	(6)	4,378	13	(6,507)	(149)
Provision for income taxes	5	—	988	3	(983)	(99)
Net (loss) income	$ (2,134)	(6)%	$ 3,390	11%	$(5,524)	(163)%

Revenues

	Year Ended December 31,			
	2015	2014	$ Change	% Change
Product revenues	$22,162	$17,381	$ 4,781	28%
Service revenues	11,651	8,770	2,881	33
Royalties	3,745	6,313	(2,568)	(41)
Total revenues	$37,558	$32,464	$ 5,094	16%

Revenues for the year ended December 31, 2015 increased by $5.1 million, or 16%, as compared to the year ended December 31, 2014. The increase was primarily attributable to the following factors by segment:

Product

- Revenues from the sale of products increased by approximately $4.8 million, or 28%, from the 2014 period primarily due to the resumption of normalized shipments of CRINONE in a key market in the third quarter of 2014, along with in-market growth coupled and entry into new markets.
- Royalty revenues decreased $2.6 million, or 41%, for the year ended December 31, 2015 as compared to the year ended December 31, 2014 driven by the one-time benefit of $2.2 million from the sale of intellectual property rights and technology for Legatrin P.M. to Lil' Drug Store in the third quarter of 2014, eliminating recurring royalties (approximately $0.1 million per quarter). Royalties for 2015 are based solely on Allergan's sales of CRINONE.

Service

- Service revenues increased approximately $2.9 million, or 33%, from the 2014 period primarily due to increases in customer volume across our service offering.

Cost of revenues

	Year Ended December 31,		$	%
	2015	2014	Change	Change
Cost of product revenues	$13,053	$10,470	$2,583	25%
Cost of service revenues	8,361	7,219	1,142	16
Total cost of revenues	$21,414	$17,689	$3,725	21%
Total cost of revenues (as a percentage of total revenues)	57%	54%		
Product gross margin	50%	56%		
Service gross margin	28%	18%		

Total cost of revenues was $21.4 million and $17.7 million for the years ended December 31, 2015 and 2014, respectively. The increase in total cost of revenues in 2015 was largely driven by the resumption of shipments of CRINONE in a key market, in-market growth and entry into new markets. Accordingly, cost of product revenues increased due to a 31% increase in units shipped in the 2015 period as compared to the 2014 period. In addition, costs were impacted by several process improvements for CRINONE initiated during the year ended December 31, 2015.

Cost of service revenues are largely fixed and consist mainly of personnel and facility costs, external consultant fees, depreciation and materials used in connection with generating our service revenues.

Product gross margin, including royalty income, decreased in 2015 as compared to 2014 due to the reduction in royalty income. Excluding the intellectual property sale, the product gross profit percentage would be 51% for the year ended December 31, 2014. In addition, pricing discounts granted to Merck KGaA based on volume purchases pursuant to the license and supply agreement also contributed to the decline. Service gross margin increased in 2015 as compared to 2014 due to increased customer volumes and a change in mix of revenue type within the service segment.

Sales and marketing

	Year Ended December 31,		$	%
	2015	2014	Change	Change
Sales and marketing	$1,249	$1,708	$(459)	(27)%
Sales and marketing (as a percentage of total revenues)	3%	5%		

Sales and marketing expenses incurred during the year ended December 31, 2015 and 2014 were attributable to our services business and consist of personnel costs for our sales force as well as marketing costs for certain tradeshows and conference fees. The decrease in sales and marketing expenses in 2015 primarily relates to costs associated with certain organizational changes within JPS that were incurred in 2014.

Research and development

	Year Ended December 31,		$	%
	2015	2014	Change	Change
Research and development	$6,948	$663	$6,285	948%
Research and development (as a percentage of total revenues)	18%	2%		

Research and development costs incurred during the year ended December 31, 2015 were primarily associated with the development of COL-1077. These costs mainly consist of personnel-related expenses for employees directly involved in product development as well as professional service consultants. Drs. Robert Langer and William Crowley joined our Company as strategic advisors in March 2015 and we incurred $1.1 million of stock compensation expense for the year ended December 31, 2015 in connection with their engagement. As we continue to advance COL-1077 and other potential proprietary product programs, we expect corresponding increases in research and development costs.

General and administrative

	Year Ended December 31,		$	%
	2015	2014	Change	Change
General and administrative	$10,458	$8,589	$1,869	22%
General and administrative (as a percentage of total revenues)	28%	26%		

General and administrative expenses increased by $1.9 million to $10.5 million for the year ended December 31, 2015, compared with $8.6 million for the year ended December 31, 2014. This increase was attributable principally to costs associated with certain organizational changes within JPS, higher legal and audit expenses related to our annual audit process, and higher corporate recruitment and annual meeting expenses.

Non-operating income and expense

	Year Ended December 31,		$	%
	2015	2014	Change	Change
Interest (expense) income, net	$(106)	$(118)	$ 12	(10)%
Change in fair value of common stock warrant liability	$ —	$ 379	$(379)	(100)%
Other income (expense), net	$ 488	$ 302	$ 186	62%

The decrease in interest (expense) income, net, primarily relates to the weakening of the British pound in 2015 versus 2014 for the interest paid on the debt related to our Nottingham facility.

The fair value of the common stock warrant liability as of March 31, 2015 was zero, and the warrants expired in April 2015. Therefore, during the year ended December 31, 2015, no income or expense was recorded. The income of $0.4 million recognized for 2014 is associated with the change in fair value of common stock warrant liability for the year ended December 31, 2014.

Other income (expense), net, for the year ended December 31, 2015 increased primarily due to the income associated with the Regional Growth Fund offset by net foreign currency transaction losses related to the weakening of the Euro and the British Pound against the U.S dollar in the 2015 period.

Provision for income taxes

	Year Ended December 31,		$	%
	2015	2014	Change	Change
Provision for income taxes	$ 5	$988	$(983)	(99)%
Provision for income taxes (as a percentage of income before income taxes)	(0.2)%	23%		

The 2015 tax expense represents state minimum taxes owed. In the fourth quarter of 2014, we determined that the utilization of our tax loss carryforwards in the United Kingdom was not likely to be realized. This was due to updated forecasts and projections on product development efforts the Company is beginning to undertake. Consequently, we have recorded a full valuation allowance against our net deferred tax assets in this jurisdiction, resulting in deferred tax expense of $0.5 million. The remainder of our 2014 tax expense represents federal alternative minimum tax, state minimum taxes owed, and a one-time clawback provision under a New Jersey Economic Development Authority program relating to the sale of our state net operating losses. Currently, we have a full valuation allowance offsetting our net domestic deferred tax asset.

Years Ended December 31, 2014 and 2013

The following tables contain selected statement of operations information, which serves as the basis of the discussion surrounding our results of operations for the years ended December 31, 2013 and 2012 (in thousands):

	Year Ended December 31,					
	2014		2013			
	Amount	As a % of Total Revenues	Amount	As a % of Total Revenues	$ Change	% Change
Product revenues	$17,381	54%	$21,336	73%	$(3,955)	(19)%
Service revenues	8,770	27	3,640	13	5,130	141
Royalties	6,313	19	3,831	13	2,482	65
Other revenues	—	—	419	1	(419)	(100)
Total revenues	32,464	100	29,226	100	3,238	11
Cost of product revenues	10,470	32	10,903	37	(433)	(4)
Cost of service revenues	7,219	22	2,347	8	4,872	208
Total cost of revenues	17,689	54	13,250	45	4,439	34
Gross profit	14,775	46	15,976	55	(1,201)	(8)
Operating expenses:						
Sales and marketing	1,708	5	439	2	1,269	289
Research and development	663	2	—	—	663	100
Acquisition-related expenses	—	—	1,623	6	(1,623)	(100)
General and administrative	8,589	26	8,039	28	550	7
Total operating expenses	10,960	34	10,101	35	859	9
Income from operations	3,815	12	5,875	20	(2,060)	(35)
Interest (expense) income, net	(118)	—	71	—	(189)	(266)
Change in fair value of common stock warrant liability	379	1	794	3	(415)	(52)
Other income (expense), net	302	1	(14)	—	316	2,257
Income before income taxes	4,378	13	6,726	23	(2,348)	(35)
Provision for income taxes	988	3	22	—	966	4,391
Net income	$ 3,390	11%	$ 6,704	23%	$(3,314)	(49)%

Revenues

	Year Ended December 31,			
	2014	2013	$ Change	% Change
Product revenues	$17,381	$21,336	$(3,955)	(19)%
Service revenues	8,770	3,640	5,130	141
Royalties	6,313	3,831	2,482	65
Other revenues	—	419	(419)	(100)
Total revenues	$32,464	$29,226	$ 3,238	11%

Revenues for the year ended December 31, 2014 increased by $3.2 million, or 11%, as compared to the year ended December 31, 2013. The increase was primarily attributable to the following factors by segment:

Product

- Product revenues decreased by approximately $4.0 million, or 19%, from the 2013 period primarily due to reduced shipments of CRINONE in the year ended December 31, 2014 to one of Merck KGaA's higher-volume, higher margin markets during a routine license renewal in that market.
- Royalty revenues increased $2.5 million, or 65%, for the year ended December 31, 2014 as compared to the year ended December 31, 2013 driven by the one-time benefit of $2.2 million from the sale of intellectual property rights and technology for Legatrin P.M. to Lil' Drug Store and higher sales of progesterone products by Allergan. Royalty revenue associated with Legatrin P.M. in the 2013 period was $0.4 million as compared with $0.2 million in the 2014 period prior to the sale. Due to the sale of the intellectual property rights of Legatrin P.M., we no longer expect any further revenues from this royalty stream.
- Other revenues in the year ended December 31, 2013 primarily relate to a one-time payment associated with the termination of the supply agreement with Allergan in the fourth quarter of 2013. There were no other revenues for the year ended December 31, 2014.

Service

- Service revenues from our pharmaceutical development, clinical trial manufacturing, consulting and analytic services business increased approximately $5.1 million in the 2014 period compared to 2013. Our acquisition of JPS was completed in September 2013, resulting in only three and a half months of service revenue in the 2013 period compared to a full year in 2014.

Cost of revenues

	Year Ended December 31,		$	%
	2014	2013	Change	Change
Cost of product revenues	$10,470	$10,903	$ (433)	(4)%
Cost of service revenues	7,219	2,347	4,872	208
Total cost of revenues	$17,689	$13,250	$4,439	34%
Total cost of revenues (as a percentage of total revenues)	54%	45%		
Product gross margin	56%	57%		
Service gross margin	18%	36%		

Total cost of revenues was $17.7 million and $13.3 million for the years ended December 31, 2014 and 2013, respectively. Cost of product revenues decreased due to a 2% reduction in units shipped in the 2014 period as compared to the 2013 period. Cost of service revenues consist mainly of personnel costs, external consultant fees, depreciation and materials used in connection with generating our service revenues. The increase in total cost of revenues in 2014 was driven by a full-year of service costs for our Nottingham operations versus a shortened period in 2013. Product gross margin decreased in 2014 as compared to 2013 due to reduced shipments of CRINONE to one of Merck KGaA's higher-volume higher margin markets during a routine license renewal in the market. Service gross margin decreased in 2014 as compared to 2013 due to a change in mix of revenue type within the service segment. Fiscal year 2013 had a higher concentration of clinical trial manufacturing revenue that generally carries a higher margin.

Sales and marketing

	Year Ended December 31,		$	%
	2014	2013	Change	Change
Sales and marketing	$1,708	$439	$1,269	289%
Sales and marketing (as a percentage of total revenues)	5%	2%		

Sales and marketing expenses incurred during the year ended December 31, 2014 and 2013 represented the sales and marketing activities associated with our services offerings, which we acquired in September 2013 with our acquisition of JPS. These expenses consist of personnel costs for our sales force as well as marketing costs consisting of tradeshows and conference fees. The increase was attributable to having a full year of service revenues in 2014 compared to three and one-half months of service revenues in 2013.

Research and development

	Year Ended December 31,		$	%
	2014	2013	Change	Change
Research and development	$663	$—	$663	100%
Research and development (as a percentage of total revenues)	2%	— %		

Research and development costs incurred during the year ended December 31, 2014 were primarily attributable to activities associated with COL-1077. These costs mainly consist of personnel-related expenses for employees directly involved in product development as well as professional service consultants. There were no research and development expenses in the year ended December 31, 2013.

Acquisition-related expenses

	Year Ended December 31,		$	%
	2014	2013	Change	Change
Acquisition-related expenses	$—	$1,623	$(1,623)	(100)%
Acquisition-related expenses (as a percentage of total revenues)	— %	6%		

There were no acquisition-related expenses during the year ended December 31, 2014. Acquisition-related expenses for the year ended December 31, 2013 primarily related to legal fees, accounting services and other transaction costs associated with our acquisition of JPS in September 2013, as well as the costs associated with a failed transaction in the 2013 period.

General and administrative

	Year Ended December 31,		$	%
	2014	2013	Change	Change
General and administrative	$8,589	$8,039	$550	7%
General and administrative (as a percentage of total revenues)	26%	28%		

General and administrative expenses increased by $0.6 million to $8.6 million for the year ended December 31, 2014, compared with $8.0 million for the year ended December 31, 2013. This increase mainly relates to costs associated with certain organizational charges in addition to the effect of reporting a full-year of administrative costs related to our services business, which we acquired in September 2013.

Non-operating income and expense

	Year Ended December 31,		$	%
	2014	2013	Change	Change
Interest (expense) income, net	$(118)	$ 71	$(189)	(266)%
Change in fair value of common stock warrant liability	$ 379	$794	$(415)	(52)%
Other income (expense), net	$ 302	$ (14)	$ 316	2,257%

The decrease in interest (expense) income, net, primarily relates to interest paid in the 2014 period on the debt assumed in connection with the JPS acquisition, compared to the realized gain recognized on the sale of our marketable securities during the 2013 period. The debt assumed is secured by a mortgage on the facilities in Nottingham, U.K.

The change in fair value of common stock warrant liability during the twelve months ended December 31, 2014 and 2013 of $0.4 million and $0.8 million, respectively, is related to the 2009 stock and warrant issuance and resulted from the stabilization of the volatility rate used in our Black-Scholes model as the warrants approached their expiration in April 2015.

Other income (expense), net, for the year ended December 31, 2014 increased primarily due to income associated with the Regional Growth Fund recognized in 2014; offset partially by, net foreign currency transaction losses related to the strengthening of the euro and the British pound against the U.S. dollar in 2013.

Provision for income taxes

	Year Ended December 31,		$	%
	2014	2013	Change	Change
Provision for income taxes	$988	$ 22	$966	4,391%
Provision as a percentage of income before provision for income taxes	23%	0.3%		

In the fourth quarter of 2014, we determined that the utilization of our tax loss carryforwards in the United Kingdom was not likely to be realized. This was due to updated forecasts and projections on product development efforts the Company is beginning to undertake. Consequently, we recorded a full valuation allowance against our net deferred tax assets in this jurisdiction, resulting in deferred tax expense of $0.5 million. The remainder of our 2014 tax expense represents federal alternative minimum tax, state minimum taxes owed, and a one-time clawback provision under a New Jersey Economic Development Authority program relating to the sale of our state net operating losses. The 2013 tax expense represents state minimum tax expenses. Currently, we have a full valuation allowance offsetting our net domestic deferred tax asset.

Liquidity and Capital Resources

We require cash to fund operating expenses and working capital needs, finance research and development and product development efforts, make capital expenditures and fund acquisitions.

At December 31, 2015, our cash and cash equivalents were $13.9 million. Our cash and cash equivalents are highly liquid investments with original maturities of 90 days or less at date of purchase, and consist of cash in operating accounts.

In March 2014 we acquired all of our common stock that was beneficially owned by Allergan at that time, which represented 11.5% of our outstanding common stock. Immediately following the closing of the stock repurchase and as of December 31, 2014, Allergan ceased to own any of our outstanding common stock. We purchased the 1.4 million shares held by Allergan at a price of $6.08 per share, which represented a 10.75% discount to the market closing price on March 6, 2014. The total purchase price was approximately $8.5 million, which is included in treasury stock at December 31, 2014.

Our future capital requirements depend on a number of factors, including the rate of market acceptance of our current and future products and services and the resources we devote to developing and supporting the same. Our capital expenditures decreased for the twelve months ended December 31, 2015, as compared to the twelve months ended December 31, 2014, due primarily to investments in capital equipment made at our Nottingham, U.K. site and our contract manufacturer sites in prior year. We expect our capital expenditures to increase in the year ending December 31, 2016, as compared to the year ended December 31, 2015, primarily due to investments made related to research and development.

Research and development expenses include costs for product and clinical development, which were a combination of internal and third-party costs, and regulatory fees. There were no research and development expenses in 2013 because we eliminated our research and development activities as part of our workforce reduction and office relocation in 2013. In 2014, we resumed research and development activities for COL-1077, an investigational sustained-release vaginal lidocaine gel, for which the target indication is an acute use anesthetic for minimally invasive gynecological procedures. In 2016, we expect our research and development expenses to increase as a percentage of revenue as we advance research and development efforts related to COL-1077, JNP-0101, JNP-0201 and JNP-0301.

As of December 31, 2015, we had 319,429 exercisable options outstanding which, if exercised, would result in approximately $2.7 million of additional capital and would cause the number of shares outstanding to increase. There can be no assurance that any such options will be exercised. The intrinsic value of exercisable options for the years ended December 31, 2015 and 2014 were $1.1 million and $14,656, respectively.

On August 9, 2013, the Company effected a 1-for-8 reverse stock split, which was previously approved by the Board of Directors on July 26, 2013. Our reverse stock split was approved by our stockholders at our annual meeting of stockholders on May 1, 2013. All share and per share amounts relating to the common stock, stock options and warrants included in the financial statements and accompanying footnotes have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an equal amount to the reduction in par value of common stock to additional paid-in capital. The reverse stock split did not result in a retroactive adjustment to the share amounts for any of the classes of our preferred stock.

We believe that our current cash and cash equivalents, as well as cash generated from operations, will be sufficient to meet our anticipated cash needs for working capital, including advancing our product candidates, and capital expenditures for the foreseeable future.

Cash Flows

Net cash used in operating activities for the year ended December 31, 2015 was $0.9 million and resulted primarily from a $2.1 million net loss for the period, offset by $3.7 million in depreciation and amortization and stock-based compensation expense. Net changes in working capital items reduced cash from operating activities by approximately $2.4 million, primarily due to an increase in accounts receivable, inventories, other non-current assets and prepaid and other current assets of $3.6 million associated with increased product shipments and a

decrease in accounts payable and deferred revenue of $1.2 million offset by an increase in accrued expenses of $2.4 million. Net cash used in investing activities was $1.7 million for the year ended December 31, 2015, which resulted primarily from the purchase of property plant and equipment. Net cash used in financing activities was partially offset by approximately $0.2 million for the year ended December 31, 2015, primarily relating to the principal payments on the note (Lloyds Loan Agreement) offset by proceeds from the exercise of common stock options.

Net cash provided by operating activities for the year ended December 31, 2014 was $6.9 million and resulted primarily from $3.4 million of net income for the period, inclusive of a one-time benefit from the sale of intellectual property rights and technology for Legatrin P.M., increased by approximately $2.6 million in depreciation and amortization and stock-based compensation expense, and partially offset by $0.4 million from the change in fair value of stock warrants. Net changes in working capital items increased cash from operating activities by approximately $0.8 million, primarily driven by decreases to accounts receivable (including due from related party); offset partially by, increases in inventories and prepaid expenses and decreases in accrued expenses and deferred revenues. Net cash used in investing activities was $2.0 million for the year ended December 31, 2014, which resulted primarily from the purchase of property plant and equipment. Net cash used in financing activities was approximately $8.7 million for the year ended December 31, 2014, primarily relating to the $8.5 million stock buyback from Allergan and $0.2 million of principal payments on notes payable.

Net cash provided by operating activities for the year ended December 31, 2013 was $7.1 million and resulted primarily from $6.7 million of net income for the period, increased by approximately $1.4 million in depreciation and amortization and stock-based compensation expense, and partially offset by $0.8 million from the change in fair value of stock warrants. Net changes in working capital items reduced cash from operating activities by approximately $0.3 million, primarily due to an increase in accounts receivable of $2.4 million associated with increased product shipments and a decrease in accrued expense of $0.8 million, offset by a decrease in amounts due from related party totaling $1.3 million primarily related to the absence of product shipments to Allergan and a decrease in prepaid expenses and other current assets of $1.4 million. Net cash provided by investing activities was $0.3 million for the year ended December 31, 2013, which resulted primarily from the proceeds from the sale of short-term investments totaling $15.4 million partially offset by the net cash paid for the JPS acquisition of $14.5 million and the purchase of property and equipment of $0.5 million. Net cash used in financing activities was $0.1 million for the year ended December 31, 2013, primarily due to $0.1 million of principal payments on notes payable.

Contractual Obligations

In October 2009, we raised approximately $11.8 million in gross proceeds from the issuance and sale of 1,362,500 shares of our common stock at a price of $8.64 per share and warrants to purchase 681,275 shares of our common stock with an exercise price of $12.16 per share in a registered offering. The warrants became exercisable on April 30, 2010, and expired on April 30, 2015.

In July 2010, we purchased approximately $40 million in aggregate principal amount of our outstanding Notes. The aggregate purchase price for the Notes was approximately $26 million in cash (plus accrued and unpaid interest through but excluding the date of the closing of the Note purchases), warrants to purchase 968,750 shares of common stock with an exercise price of $10.80 per share and 925,925 shares of our common stock. The warrants issued under the Note Purchase Agreements were exercisable, subject to the limitations set forth therein and expired on July 2, 2015.

Our significant outstanding contractual obligations relate to operating leases for our facilities that are not owned and debt assumed as a result of the acquisition of JPS on September 12, 2013. Our facility leases are non-cancellable and contain renewal options. Our future contractual obligations include the following:

Contractual Obligations

	Payments Due by Period				
	Total	1 year or less	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$1,323	$370	$ 879	$ 74	$ —
Loan principal repayments	3,135	238	498	529	1,870
Total	$4,458	$608	$1,377	$603	$1,870

In September 2013, we assumed debt of $3.9 million in connection with our acquisition of JPS. JPS had entered into a Business Loan Agreement ("Loan Agreement") covering three loan facilities with Lloyds TSB Bank ("Lloyds") as administrative agent. JPS had drawn down $3.9 million under the Loan Agreement and as of December 31, 2015 owed a principal balance of $3.1 million. The three loan facilities are each repayable in monthly installments: one started repayment in February 2013, and the remaining two commenced in October 2013. All facilities are due for repayment over 15 years from the date of drawdown. Two of the facilities bear interest at the Bank of England's base rate plus 1.95% and 2.55%, respectively. The interest rate at December 31, 2015 for these two facilities was 2.45% and 3.05%, respectively. The third facility is a fixed rate agreement bearing interest at 3.52% per annum. The weighted average interest rate for the three loan facilities for the twelve months ending December 31, 2015 was 3.00%. The Loan Agreement is secured by the mortgaged property and other assets of JPS. The Loan Agreement contains financial covenants that limit the amount of indebtedness we may incur, requires us to maintain certain levels of net worth, and restricts our ability to materially alter the character of JPS' business. As of December 31, 2015, JPS remained in compliance with all of the covenants under the Loan Agreement.

In September 2013, we assumed a $2.5 million obligation under a grant arrangement with the Regional Growth Fund on behalf of the Secretary of State for Business, Innovation, and Skills in the United Kingdom. JPS used this grant to fund the building of their second facility, which includes analytical labs, office space, and a clinical manufacturing facility. As a part of the arrangement, JPS is required to create and maintain certain full-time equivalent personnel levels through October 2017. As of December 31, 2015, we remained in compliance with the covenants of the arrangement.

The income from the Regional Growth Fund will be recognized on a decelerated basis over the next two years. As of December 31, 2015, the obligation is valued at $1.5 million and is recorded as deferred revenue on the consolidated balance sheets. The amount of other income on the obligation that will be recognized provided we remain in compliance with the covenants will be the following:

Year	Total
2016	770
2017	710
Total	$1,480

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations set forth above are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those described below. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities, and the reported amounts of revenues and expenses, that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies require significant judgment and estimates by us in the preparation of our financial statements.

Revenue Recognition

We derive our revenues from the sale of product, the performance of professional services and royalties.

We recognize our product revenues under written contracts at the time goods are shipped to our customer and collection from our customer is reasonably assured.

The professional service contracts that we enter into and operate under specify whether the engagement will be billed on a time-and-materials or a fixed-price basis. These engagements generally last three to six months, although some of our engagements can be much longer in duration. Each contract must be approved by one of our officers.

We recognize substantially all of our professional services revenues under written contracts when the fee is fixed or determinable, as the services are provided, and only in those situations where collection from the client is reasonably assured. In certain cases we bill clients prior to work being performed, which requires us to defer revenue in accordance with U.S. GAAP. In these cases, these amounts are fully reserved until all criteria for recognizing revenue are met.

Our professional services revenue is derived from fixed price and time-and-materials service contracts. Revenues from time-and-materials service contracts are recognized as the services are performed based upon hours worked and contractually agreed-upon hourly rates, as well as indirect fees based upon hours worked.

Professional services revenues from a majority of our fixed-price engagements are recognized on a proportional performance method based on the ratio of costs incurred, substantially all of which are labor-related, to the total estimated project costs. In general, project costs are classified in costs of services and are based on the direct salary of the employees on the engagement plus all direct expenses incurred to complete the engagement, including any amounts billed to us by our vendors. The proportional performance method is used for fixed-price contracts because reasonably dependable estimates of the revenues and costs applicable to various stages of a contract can be made, based on historical experience and the terms set forth in the contract, and are indicative of the level of benefit provided to our clients. In the event of a termination, fixed-price contracts generally provide for payment for services rendered up to termination. Our management maintains contact with project managers to discuss the status of the projects. In cases where we may be required to commit unanticipated additional resources to complete projects, which may result in lower than anticipated income or losses on those contracts.

Professional service revenues also include reimbursements, which include reimbursement for travel and other out-of-pocket expenses, outside consultants, and other reimbursable expenses. Our project managers and finance personnel monitor payments from our customers and assess any collection issues. We maintain accounts receivable allowances for estimated losses resulting from disputed amounts or the inability of our customers to

make required payments. We base our estimates on our historical collection experience, current trends, and credit policy. In determining these estimates, we examine historical write-offs of our receivables and review client accounts to identify any specific customer collection issues. If the financial condition of our customers were to deteriorate or disputes were to arise regarding the services provided, resulting in an impairment of their ability or intent to make payment, additional allowances may be required. A failure to estimate accurately the accounts receivable allowances and ensure that payments are received on a timely basis could have a material adverse effect on our business, financial condition, and results of operations.

Royalty revenues, based on sales by licensees, are recorded as revenues when those sales are made by the licensees.

Inventories and Allowance for Excess and Obsolescence

We state all inventories at the lower of cost or market value, determined on a first-in, first-out method. We monitor standard costs on a monthly basis and update them annually and as necessary to reflect changes in raw material costs and labor and overhead rates. Our inventory balance as of December 31, 2015 was $3.6 million and as of December 31, 2014 was $3.2 million.

We provide inventory allowances when conditions indicate that the selling price could be less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. We balance the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when we sell products. Our inventory allowance as of December 31, 2015 was $0.3 million and as of December 31, 2014 was $36,000.

Segments

We currently operate in two segments: product and service. Our product segment oversees the supply chain and manufacturing of CRINONE, our sole commercialized product. The product segment also includes the royalty stream we receive from Allergan for CRINONE sales in the United States as well as the development of new product candidates. Our service segment includes pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services we provide to our customers as well as characterizing and developing pharmaceutical product candidates for our internal programs and managing the preclinical and clinical manufacturing of COL-1077 and our IVR. In September 2013, we acquired JPS, a U.K.-based provider of pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry. We have integrated our supply chain management for our sole commercialized product, CRINONE into those operations and have therefore sought to capture synergies by transferring all operational activities related to its historic business.

The Chief Executive Officer, who is the Company’s Chief Operating Decision Maker (CODM), currently manages the business based on our revenue and gross profit and as such we have concluded that we are two segments, which consists of product and service. Segment information is consistent with the financial information regularly reviewed by our chief operating decision maker, for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting future periods. Our chief operating decision maker does not review our assets, operating expenses or non-operating income and expenses by business segment at this time.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination. We do not amortize our goodwill, but instead test for impairment annually and more frequently whenever events or changes in circumstances indicate that the fair value of the asset may be less than its carrying value of the asset. Our annual test for impairment occurs on the first day in the fourth quarter.

In accordance with Accounting Standards Codification, or ASC 350, Goodwill and Other Intangibles ("ASC 350"), we use the two step approach for each reporting unit. The first step compares the carrying amount of the reporting unit to its estimated fair value (Step 1) utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated using a risk-adjusted discount rate. To the extent that the carrying value of the reporting unit exceeds its estimated fair value, a second step is performed, wherein the reporting unit's carrying value is compared to the implied fair value (Step 2). To the extent that the carrying value of goodwill exceeds the implied fair value of goodwill, impairment exists and must be recognized.

We have concluded that our business represents two reporting units for goodwill impairment testing, which are product and service. Our goodwill is assigned to our service reporting unit. We have performed our annual test for impairment and have determined that our goodwill is not impaired as of December 31, 2015.

Intangible Assets

We capitalize and include in intangible assets the costs of developed technology, customer relationships and trade names. Intangible assets are recorded at fair value and are stated net of accumulated amortization and impairments. We amortize our intangible assets that have finite lives using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. Amortization is recorded over the estimated useful lives ranging from three to seven years. We evaluate the realizability of our definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, we estimate the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk adjusted discount rate. To estimate the fair value of the assets, we use market participant assumptions pursuant to ASC 820, *Fair Value Measurements*. If the estimate of an intangible asset's remaining useful life is changed, we will amortize the remaining carrying value of the intangible asset prospectively over the remaining useful life.

Research and Development Expenses

Research and development consist of consultants, material costs, salaries and other personnel related expenses including stock-based compensation of employees and non-employees primarily engaged in research and development activities and materials used and other overhead expenses incurred. All research and development costs are expensed as incurred. Research and development costs that are paid in advance of performance are capitalized as prepaid expenses until incurred.

Clinical trial expenses include expenses associated with clinical research organizations. The invoicing from clinical research organizations for services rendered can lag several months. We accrue the cost of services rendered in connection with clinical research organizations activities based on our estimate of costs incurred. We maintain regular communication with our clinical research organizations to assess the reasonableness of our estimates. Differences between actual expenses and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

Sales Returns

Up to July 2013, we were responsible for sales returns for CRINONE and PROCHIEVE products sold prior to the Allergan transaction on July 2, 2010, and for STRIANT products sold prior to the sale of the product to Auxilium in April 2011. We are not and were not responsible for returns for international sales. Our policy for sales to the trade made prior to the Allergan and Auxilium transactions allows product to be returned for a period that began three months prior to the product expiration date and ended twelve months after the product expiration date. Provisions for returns on sales to wholesalers, distributors and retail chain stores were estimated based on a percentage of sales, using such factors as historical sales information, distributor inventory levels and product prescription data, and were recorded as a reduction to sales in the same period as the related sales were

recognized. We assumed that our customers were using the first-in, first-out method in filling orders so that the oldest saleable product was used first. We recorded a provision for returns on a quarterly basis using an estimated rate and adjusted the provision when necessary. Currently there is no sales returns reserve as the return rights obligation has elapsed for all products for which Juniper provided a right of return.

Accounting for Fair Value for Common Stock Warrant Liabilities

The estimated fair value of the common stock warrant liability is determined by using the Black-Scholes option pricing model which is based on our stock price at the measurement date, exercise price of the warrant, risk-free rate and historical volatility, and is classified as a Level 2 measurement. The common stock warrant liability expired in April 2015.

Share-Based Compensation

We recognize employee share-based compensation expense in accordance with ASC 718, *"Share Based Payment"* ("ASC 718"), for all stock-based awards made to employees and directors including employee stock options based on estimated fair values. ASC 718 requires companies to estimate the fair value of stock-based awards on the date of grant using an option pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our Consolidated Statements of Operations.

We recognize non-employee share-based compensation expense in accordance with ASC Subtopic 505-50, *Equity – Equity Based Payments to Nonemployees*. Non-employee share-based compensation expense is re-measured over the graded vesting term resulting in periodic adjustments to stock-based compensation expense.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, 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 the impact of its pending adoption of the new standard on its consolidated financial statements.

In January 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-01, Financial Instruments – Recognition and Measurement of Financial Assets and Financial Liabilities, which provides new guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. The standard becomes effective for Juniper beginning in the first quarter of 2018 and early adoption is permitted. Juniper is currently evaluating the effect, if any, that the standard will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements – Going Concern. The provisions of ASU No. 2014-15 require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial

statements are issued (or available to be issued). The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company does not believe this ASU will have an impact on the Company's financial statements.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" ("ASU 2014-09"), which provides guidance for revenue recognition. ASU 2014-09 affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets and supersedes the revenue recognition requirements in Topic 605, "Revenue Recognition," and most industry-specific guidance. This ASU also supersedes some cost guidance included in Subtopic 605-35, "Revenue Recognition-Construction-Type and Production-Type Contracts." The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company beginning January 1, 2018 and, at that time the Company may adopt the new standard under the full retrospective approach or the modified retrospective approach. Early adoption is not permitted. The Company is currently evaluating the method and impact that the adoption of ASU 2014-09 will have on the Company's consolidated financial statements and related disclosures.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risks*

Market Rate Risk

We do not believe that we have material exposure to market rate risk. We may, however, require additional financing to fund future obligations and no assurance can be given that the terms of future sources of financing will not expose us to material market risk.

Foreign Currency Exchange

A significant portion of our operations are conducted through operations in countries other than the United States. Revenues from our international operations that were recorded in U.S. dollars represented approximately 66% of our total international revenues during the year ended December 31, 2015. The remaining 34% of our international revenues were in British pounds. Since we conduct our business in U.S. dollars, our main exposure, if any, results from changes in the exchange rate between the British pound and the U.S. dollar. Our policy is to reduce exposure to exchange rate fluctuations by having most of our assets and liabilities, as well as most of our revenues and expenditures, designated in U.S. dollars, or U.S. dollar linked. We have not historically engaged in hedging activities relating to our non-U.S. dollar-based operations. We may be exposed to exchange rate fluctuations that occur from certain intercompany transactions with our subsidiaries, which we recognize as unrealized gains and losses in our statements of operations. Upon settlement of these payments, we may record realized foreign exchange gains and losses. We may incur negative foreign currency translation charges as a result of changes in currency exchange rates.

Item 8. *Financial Statements and Supplementary Data*

The financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15, set forth in this Annual Report.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

Not Applicable.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive and principal financial officers, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. We maintain disclosure controls and procedures, (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2015, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Evaluation of Changes in Internal Control over Financial Reporting

Our internal controls over financial reporting are designed to:

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

During the year ended December 31, 2015, we implemented new internal control procedures to address a previously identified material weakness related to revenue recognition for services transactions and contractual arrangements. After completing our testing of the design and operating effectiveness of our control enhancements, we concluded that we have remediated the previously identified material weakness as of December 31, 2015.

Except for the remediation efforts noted above we have determined that, during the fourth quarter of fiscal 2015, there were no changes in our internal control over financial reporting that have affected, or are reasonably likely to affect, materially our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with United States generally accepted accounting principles.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the guidelines established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, our President and Chief Executive Officer and our Chief Financial Officer concluded that our internal control over financial reporting was effective as of December 31, 2015 to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Our independent registered public accounting firm, BDO USA, LLP, an independent registered public accounting firm, has issued an audit report on their assessment of our internal control over financial reporting. The audit report is included herein.

Limitations on Effectiveness of Controls and Procedures

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company have been detected.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Juniper Pharmaceuticals, Inc.
Boston, Massachusetts

We have audited Juniper Pharmaceuticals Inc.'s (formerly Columbia Laboratories, Inc.) internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Juniper Pharmaceuticals Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting". Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, 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.

In our opinion, Juniper Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Juniper Pharmaceuticals, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive (loss) income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2015 and our report dated March 10, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
Boston, Massachusetts
March 10, 2016

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this item with respect to our directors and executive officers will be contained in our 2016 Proxy Statement, under the caption "Board of Directors and Corporate Governance – The Board in General" and "– Executive Officers" and is incorporated by reference into Item 10 of this Annual Report.

The information required by this item with respect to Section 16(a) beneficial ownership reporting compliance will be contained in our 2016 Proxy Statement under the caption "Ownership of the Company – Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated by reference into Item 10 of this Annual Report.

The information required by this item with respect to Audit Committee matters will be contained in our 2016 Proxy Statement under the caption "Board of Directors and Corporate Governance – Audit Committee" and is incorporated by reference into Item 10 of this Annual Report.

Code of Ethics

Our Board of Directors has adopted a Code of Business Conduct and Ethics applicable to all Board members, executive officers and all employees. The Code of Business Conduct and Ethics is available on our website ("www.Juniperpharma.com"), under the investor relations tab. We will provide an electronic or paper copy of this document free of charge upon request. If amendments to the Code of Business Conduct and Ethics are executed, or if waivers are granted with respect to the Company's Chief Executive Officer, Chief Financial Officer, Controller or persons performing similar functions, the Company will post and disclose the nature of such amendments or waivers on our website or in a report on Form 8-K.

Item 11. ***Executive Compensation***

The information required by this item will be contained in our 2016 Proxy Statement under the caption "Compensation Discussion and Analysis" and "Executive and Director Compensation" and is incorporated by reference into Item 11 of this Annual Report.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item will be contained in our 2016 Proxy Statement under the caption "Ownership of the Company – Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated by reference into Item 12 of this Annual Report.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item will be contained in our 2016 Proxy Statement under the caption "Board of Directors and Corporate Governance – Certain Relationships and Related Party Transactions" and "– Director Independence" and is incorporated by reference into Item 13 of this Annual Report.

Item 14. ***Principal Accountant Fees and Services***

The information required by this item will be contained in our 2016 Proxy Statement under the caption "Relationship With Independent Registered Public Accounting Firm" and is incorporated by reference into Item 14 of this Annual Report.

PART IV

Item 15. ***Exhibits and Financial Statement Schedule*** **(a)(1)(2) Financial Statements and Financial Statement Schedules**

Exhibit	Index Description of Exhibit
2.1	Purchase and Collaboration Agreement, dated March 3, 2010, by and between Juniper Pharmaceuticals, Inc. and Coventry Acquisition, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on March 4, 2010)
2.2	Share Purchase Agreement, dated September 2013, between the Sellers, Juniper Pharmaceuticals, Inc. and Juniper Pharma Services Limited (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on September 18, 2013)
2.3	Stock Purchase Agreement, dated March 6, 2014, by and between Juniper Pharmaceuticals, Inc. and Coventry Acquisition, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on March 7, 2014)
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2005, filed on March 13, 2006)
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on July 6, 2010)
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on August 8, 2013)
3.4	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on April 3, 2015)
3.5	Amended and Restated By-laws of Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on January 12, 2015)
3.6	Amendment No. 1 to the Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on April 3, 2015)
4.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of the Company, dated as of January 7, 1999 (incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 1998, filed on March 25, 1999)
4.2*	Form of Option Agreement (incorporated by reference to Exhibit 4.10 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2008, filed on March 16, 2009)
4.3	Amended and Restated Rights Agreement by and between Juniper Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC dated January 28, 2015 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on January 30, 2015)
10.1*	1996 Long-term Performance Plan, as amended, of the Company (incorporated by reference to Annex A to the Registrant's Proxy Statement (File No. 001-10352), filed on May 10, 2000)

Exhibit	Index Description of Exhibit
10.2*	Form of Restricted Stock Agreement under the 1996 Long-Term Performance Plan (incorporated by reference to Exhibit 10.62 of the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on May 17, 2006)
10.3	License Agreement, dated April 18, 2000, between the Company and Lil' Drug Store Products, Inc. (incorporated by reference to Exhibit 10.23 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352) for the quarter ended March 31, 2000, filed on May 15, 2000)
10.4*	Form of Indemnification Agreement for Officers and Directors (incorporated by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2003, filed on March 15, 2004)
10.5	Packaging Agreement, dated October 28, 1993, between Juniper Pharmaceuticals (Ireland) Ltd. and Maropack AG (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2007, filed on March 28, 2008)
10.6*	Juniper Pharmaceuticals, Inc. Amended and Restated 2008 Long-Term Incentive Plan (incorporated by reference to Appendix B to the Registrant's Proxy Statement (File No. 001-10352), filed on March 22, 2013)
10.7*	Form of Award Agreement under the Amended and Restated 2008 Long-term Incentive Plan of Juniper Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-8 (File No. 333-18647), filed on May 16, 2013)
10.8*	Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-8 (File No. 333-205723), filed on July 17, 2015)
10.9*	Form of Nonqualified Stock Option Award Agreement under the Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352), filed on August 4, 2015)
10.10*	Form of Incentive Stock Option Award Agreement under the Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352), filed on August 4, 2015)
10.11*	Form of Restricted Stock Award Agreement under the Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352), filed on August 4, 2015)
10.12*	Form of Executive Change of Control Severance Agreement (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2008, filed on March 16, 2009)
10.13	Manufacturing and Supply Agreement, dated December 8, 2009, between Fleet Laboratories and Juniper Pharmaceuticals (Bermuda), Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on December 9, 2009)
10.14	Note Purchase and Amendment Agreement, dated March 3, 2010, by and between Juniper Pharmaceuticals, Inc. and holders listed on Schedule I thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on March 4, 2010)
10.15*	Amended and Restated Employment Agreement, dated May 4, 2010, by and between Juniper Pharmaceuticals, Inc. and Frank C. Condella, Jr. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on May 5, 2010)

Exhibit	Index Description of Exhibit
10.16*	Addendum to Amended and Restated Employment Agreement, dated March 1, 2011, by and between Juniper Pharmaceuticals, Inc., and Frank C. Condella, Jr. (incorporated by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2010, filed on March 10, 2011)
10.17	Second Amended and Restated License and Supply Agreement, dated May 14, 2010, between Juniper Pharmaceuticals, Inc. and Ares Trading S.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on May 18, 2010)
10.18	Amendment No. 1 to the Second Amended and Restated License and Supply Agreement, dated April 4, 2013, between Juniper Pharmaceuticals, Inc. and Ares Trading S.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on April 9, 2013)
10.19	Parent Guarantee of Juniper Pharmaceuticals, Inc., dated September 12, 2013 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on September 18, 2013)
10.20*	Employment Agreement, dated September 12, 2013, between Dr. Nikin Patel and Juniper Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on September 18, 2013)
10.21	Bank Loan Agreement, dated January 6, 2012, between Juniper Pharma Services Limited and Lloyds TSB Bank plc (incorporated by reference to Exhibit 10.3 the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352) for the quarter ended September 30, 2013, filed on November 7, 2013)
10.22	Amendment letter, dated September 16, 2013, between Juniper Pharma Services Limited and Lloyds TSB Bank plc (incorporated by reference to Exhibit 10.4 the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352) for the quarter ended September 30, 2013, filed on November 7, 2013)
10.23	Amendment to Manufacturing and Supply Agreement, effective as of December 31, 2013, between Juniper Pharmaceuticals (Bermuda) Ltd., and Fleet Laboratories Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on February 6, 2014)
10.24*	Employment Agreement, dated September 23, 2014, by and between Juniper Pharmaceuticals, Inc. and George O. Elston (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (Filed No. 001-10352), filed on September 26, 2014)
10.25	Exclusive Patent License Agreement, dated as of March 27, 2015, by and between Juniper Pharmaceuticals, Inc. (f/k/a Columbia Laboratories, Inc.) and The General Hospital Corporation, d/b/a Massachusetts General Hospital (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (Filed No. 001-10352), filed on May 6, 2015)
10.26	Office Lease by and between T-C 33 Arch Street LLC and Juniper Pharmaceuticals, Inc. dated October 15, 2015 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (Filed No. 001-10352), filed on November 12, 2015)
21	Subsidiaries of the Company
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm
31(i).1	Certification of Chief Executive Officer of the Company
31(i).2	Certification of Chief Financial Officer of the Company
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Exhibit	Index Description of Exhibit
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Juniper Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets at December 31, 2015 and December 31, 2014, (ii) Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013, (iii) Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2015, 2014 and 2013, (iv) Consolidated Statements of Shareholders' Equity for the years ended December 31, 2015, 2014 and 2013, (v) Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013, and (vi) Notes to Consolidated Financial Statements.
†	Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
*	Management contract or compensatory plans or arrangements

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

JUNIPER PHARMACEUTICALS, INC.

Date: March 10, 2016

By: /s/ George O. Elston
George O. Elston
Chief Financial Officer and Treasurer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Frank C. Condella and George O. Elston, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

/s/ Frank C. Condella, Jr. Frank C. Condella, Jr.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2016
/s/ George O. Elston George O. Elston	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 10, 2016
/s/ Nikin Patel Nikin Patel	Chief Operating Officer and Director	March 10, 2016
/s/ Frank Armstrong Frank Armstrong	Director	March 10, 2016
/s/ Cristina Csimma Cristina Csimma	Director	March 10, 2016
/s/ James A. Geraghty James A. Geraghty	Chairman of the Board of Directors	March 10, 2016
/s/ Donald H. Hunter Donald H. Hunter	Director	March 10, 2016
/s/ Ann C. Merrifield Ann C. Merrifield	Director	March 10, 2016

JUNIPER PHARMACEUTICALS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Juniper Pharmaceuticals, Inc.
Boston, Massachusetts

We have audited the accompanying consolidated balance sheets of Juniper Pharmaceuticals, Inc. (formerly Columbia Laboratories, Inc.) as of December 31, 2015 and 2014 and the related consolidated statements of operations, comprehensive (loss) income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. 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. An audit 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 Juniper Pharmaceuticals at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015**,** in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Juniper Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 10, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
Boston, Massachusetts
March 10, 2016

Juniper Pharmaceuticals, Inc.

Consolidated Balance Sheets
(in thousands, except per share data)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 13,901	$ 16,762
Accounts receivable, net of allowances of $263 and $358 at December 31, 2015 and 2014, respectively	7,538	5,289
Inventories	3,623	3,201
Prepaid expenses and other current assets	1,674	1,134
Total current assets	26,736	26,386
Property and equipment, net	12,850	13,041
Intangible assets, net	1,598	2,182
Goodwill	10,010	10,503
Other assets	185	96
Total assets	$ 51,379	$ 52,208
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,004	$ 2,873
Accrued expenses	4,158	1,918
Deferred revenue	1,336	914
Notes payable	238	243
Total current liabilities	7,736	5,948
Deferred revenue, net of current portion	710	1,553
Notes payable, net of current portion	2,897	3,289
Deferred rent	69	—
Total liabilities	11,412	10,790
Commitments and contingencies (Note 8)		
Contingently redeemable series C preferred stock, 0.55 shares issued and outstanding (liquidation preference of $550)	550	550
Shareholders' equity:		
Preferred stock, $.01 par value; 1,000 shares authorized		
Series B convertible preferred stock, 0.13 shares issued and outstanding (liquidation preference of $13)	—	—
Common stock $.01 par value; 150,000 shares authorized; 12,215 issued and 10,802 outstanding at December 31, 2015 and 12,186 shares issued and 10,775 outstanding at December 31, 2014	122	122
Additional paid-in capital	289,464	287,660
Treasury stock (at cost), 1,413 and 1,411 shares at December 31, 2015 and 2014, respectively	(8,601)	(8,579)
Accumulated deficit	(240,406)	(238,272)
Accumulated other comprehensive income	(1,162)	(63)
Total shareholders' equity	39,417	40,868
Total liabilities and shareholders' equity	$ 51,379	$ 52,208

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

Juniper Pharmaceuticals, Inc.

Consolidated Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,		
	2015	2014	2013
Revenues			
Product revenues	$22,162	$17,214	$21,336
Product revenues from related party	—	167	—
Service revenues	11,651	8,770	3,640
Royalties	3,745	5,599	395
Royalties from related party	—	714	3,436
Other revenues	—	—	119
Other revenues from related party	—	—	300
Total revenues	37,558	32,464	29,226
Cost of product revenues	13,053	10,470	10,903
Cost of service revenues	8,361	7,219	2,347
Total cost of revenues	21,414	17,689	13,250
Gross profit	16,144	14,775	15,976
Operating expenses			
Sales and marketing	1,249	1,708	439
Research and development	6,948	663	—
Acquisition-related expenses	—	—	1,623
General and administrative	10,458	8,589	8,039
Total operating expenses	18,655	10,960	10,101
(Loss) income from operations	(2,511)	3,815	5,875
Interest (expense) income, net	(106)	(118)	71
Change in fair value of common stock warrant liability	—	379	794
Other income (expense), net	488	302	(14)
(Loss) income before income taxes	(2,129)	4,378	6,726
Provision for income taxes	5	988	22
Net (loss) income	$ (2,134)	$ 3,390	$ 6,704
Basic net (loss) income per common share	$ (0.20)	$ 0.31	$ 0.59
Diluted net (loss) income per common share	$ (0.20)	$ 0.27	$ 0.52
Basic weighted average common shares outstanding	10,774	10,992	11,259
Diluted weighted average common shares outstanding	10,774	11,007	11,273

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

Juniper Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive (Loss) Income
(in thousands)

	Year Ended December 31,		
	2015	2014	2013
Net (loss) income	$(2,134)	$ 3,390	$6,704
Other comprehensive (loss) income components:			
Foreign currency translation	(1,099)	(1,433)	1,184
Unrealized loss on short term investments	—	—	(80)
Reclassification adjustment for gains included in net income	—	—	(17)
Total other comprehensive (loss) income	(1,099)	(1,433)	1,087
Comprehensive (loss) income	$(3,233)	$ 1,957	$7,791

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

Juniper Pharmaceuticals, Inc.

Consolidated Statements of Shareholders' Equity
(in thousands, except per share amounts)

	Series B Convertible Preferred Stock		Series E Convertible Preferred Stock		Common Stock			Treasury Stock				
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Capital in Excess of Par Value	Number of Shares	Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance, December 31, 2012	—	$—	23	$—	10,943	$109	$279,464	(5)	$ (125)	$(248,366)	$ 283	$31,365
Options exercised and restricted shares vested	—	—	—	—	27	1	11	—	—	—	—	11
Issuance of common stock in connection with the acquisition of Juniper Pharma Services	—	—	—	—	1,051	11	7,284	—	—	—	—	7,295
Conversion of series E preferred stock	—	—	(23)	—	131	1	(157)	11	156	—	—	—
Purchase of treasury stock	—	—	—	—	—	—	—	(6)	(31)	—	—	(31)
Share based compensation expense	—	—	—	—	—	—	475	—	—	—	—	476
Dividends on preferred stock	—	—	—	—	—	—	(28)	—	—	—	—	(28)
Reverse stock split – cash in lieu	—	—	—	—	—	—	(1)	—	—	—	—	(1)
Translation adjustment	—	—	—	—	—	—	—	—	—	—	1,184	1,184
Unrealized loss on short term investments	—	—	—	—	—	—	—	—	—	—	(80)	(80)
Reclassification adjustment for gains included in net income	—	—	—	—	—	—	—	—	—	—	(17)	(17)
Net income	—	—	—	—	—	—	—	—	—	6,704	—	6,704
Balance, December 31, 2013	—	—	—	—	12,152	122	$287,048	—	—	(241,662)	1,370	46,878
Options exercised and restricted shares vested	—	—	—	—	34	—	33	—	—	—	—	33
Purchase of treasury stock	—	—	—	—	—	—	—	(1,411)	(8,579)	—	—	(8,579)
Share based compensation expense	—	—	—	—	—	—	607	—	—	—	—	607
Dividends on preferred stock	—	—	—	—	—	—	(28)	—	—	—	—	(28)
Translation adjustment	—	—	—	—	—	—	—	—	—	—	(1,433)	(1,433)
Net income	—	—	—	—	—	—	—	—	—	3,390	—	3,390
Balance, December 31, 2014	—	—	—	—	12,186	122	287,660	(1,411)	(8,579)	(238,272)	(63)	40,868
Options exercised and restricted shares vested	—	—	—	—	29	—	82	(2)	(22)	—	—	60
Share based compensation expense	—	—	—	—	—	—	1,750	—	—	—	—	1,750
Dividends on preferred stock	—	—	—	—	—	—	(28)	—	—	—	—	(28)
Translation adjustment	—	—	—	—	—	—	—	—	—	—	(1,099)	(1,099)
Net loss	—	—	—	—	—	—	—	—	—	(2,134)	—	(2,134)
Balance, December 31, 2015	—	$—	—	$—	12,215	$122	$289,464	(1,413)	$(8,601)	$(240,406)	$(1,162)	$39,417

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

Juniper Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2015	2014	2013
Operating activities:			
Net (loss) income	$ (2,134)	$ 3,390	$ 6,704
Reconciliation of net income to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,911	1,992	919
Change in fair value of common stock warrants	—	(379)	(794)
Provision for sales returns	—	—	(26)
Stock-based compensation expense	1,750	607	475
Gain on sale of short-term investments	—	—	(17)
Deferred income taxes	—	542	57
Loss on disposal of fixed assets	—	—	37
Changes in operating assets and liabilities:			
Accounts receivable	(2,499)	1,705	(2,347)
Due from related party	—	900	1,295
Inventories	(424)	(619)	46
Prepaid expenses and other current assets	(543)	(331)	1,439
Other non-current assets	(89)	(5)	(50)
Accounts payable	(925)	91	315
Accrued expenses	2,302	(559)	(830)
Deferred revenue	(309)	(405)	(150)
Deferred rent	69	—	—
Net cash (used in) provided by operating activities	(891)	6,929	7,073
Investing activities:			
Purchase of property and equipment	(1,708)	(2,048)	(522)
Cash paid for acquisition, net of cash received	—	—	(14,516)
Proceeds from the sale of short-term investments	—	—	15,353
Net cash (used in) provided by investing activities	(1,708)	(2,048)	315
Financing activities:			
Proceeds from exercise of stock options	82	33	11
Principal payments on notes payable	(238)	(245)	(72)
Payments for the purchase of treasury stock	(22)	(8,509)	—
Dividends paid	(28)	(28)	(28)
Net cash used in financing activities	(206)	(8,749)	(89)
Effect of exchange rate changes on cash and cash equivalents	(56)	(85)	212
Net (decrease) increase in cash and cash equivalents	(2,861)	(3,953)	7,511
Cash and cash equivalents, beginning of period	16,762	20,715	13,204
Cash and cash equivalents, end of period	$13,901	$16,762	$ 20,715
Supplemental cash flow information			
Cash paid for interest	$ 101	$ 120	$ 25
Cash paid for income taxes	$ 2	$ 3	$ 3
Supplemental noncash investing and financing activities			
Purchases of equipment through accounts payable	$ 95	$ —	$ —
Common stock issued in connection with the acquisition of Juniper Pharma Services	$ —	$ —	$ 7,295
Conversion of series E convertible preferred stock into common stock	$ —	$ —	$ 158

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

Juniper Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

1. Organization

Juniper Pharmaceuticals, Inc. (the "Company" or "Juniper"), formerly known as Columbia Laboratories, Inc., was incorporated as a Delaware corporation in December 1986. The Company has historically been in the business of developing, manufacturing, licensing and selling pharmaceutical products that utilize proprietary drug delivery technologies to treat various medical conditions to commercial partners. In September 2013, the Company acquired Nottingham, U.K. based Juniper Pharma Services Ltd. ("Juniper Pharma Services") formerly known as Molecular Profiles Ltd, a pharmaceutical services company. Juniper Pharma Services provides a range of drug development and consulting services to the pharmaceutical industry and has provided Juniper with an additional revenue source and in-house expertise for internal pharmaceutical programs.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries; Columbia Laboratories Bermuda Ltd., Juniper Pharmaceuticals France SA, Juniper Pharmaceuticals UK Ltd, and Juniper Pharma Services Ltd. All significant intercompany balances and transactions have been eliminated in consolidation.

Basis of Presentation

On July 26, 2013, Juniper's Board of Directors set a ratio of 1-for-8 for its previously approved reverse stock split which took effect on August 9, 2013. The reverse stock split was approved by Juniper's shareholders at its annual meeting of shareholders on May 1, 2013. All share and per share amounts relating to the common stock, stock options and common stock warrants included in the financial statements and accompanying footnotes have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an equal amount to the reduction in par value of common stock to additional paid-in capital. The reverse stock split did not result in a retroactive adjustment to the share amounts for any of the classes of the Company's preferred stock.

Segments

The Company and its subsidiaries currently operate in two segments: product and service. The product segment includes supply chain management for CRINONE, the Company's sole commercialized product. The product segment also includes the royalty stream the Company receives from Allergan for CRINONE sales in the United States as well as the development of new product candidates. The service segment includes pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services for the Company's customers as well as characterizing and developing pharmaceutical product candidates for the Company's internal programs and managing the preclinical and clinical manufacturing of COL-1077 and the Company's IVR. In September 2013, the Company acquired Juniper Pharma Services, a U.K.-based provider of pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services to the pharmaceutical industry. The Company has integrated its supply chain management for its sole commercialized product, CRINONE into those operations and have therefore sought to capture synergies by transferring all operational activities related to its historic business.

The Chief Executive Officer, who is the Company's Chief Operating Decision Maker (CODM), currently manages the business based on revenue and gross profit and as such the Company has concluded that it is two segments, which consists of product and service. Segment information is consistent with the financial information regularly reviewed by our CODM, who we have determined to be the chief executive officer, for

purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting future periods. Juniper's CODM does not review our assets, operating expenses or non-operating income and expenses by business segment at this time.

Management Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures at the date of the financial statements during the reporting period. Significant estimates are used for, but are not limited to revenue recognition, sales return reserves, allowance for doubtful accounts, inventory reserve, impairment analysis of goodwill and intangibles including their useful lives, research and development accruals, deferred tax assets, liabilities and valuation allowances, common stock warrant valuations, and fair value of stock options. On an ongoing basis, management evaluates its estimates. Actual results could differ from those estimates.

Foreign Currency

The assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars at current exchange rates and revenue and expense items are translated at average rates of exchange prevailing during the period. The functional currency of Juniper's foreign subsidiaries is considered to be the local currency for each entity and, accordingly, translation adjustments for these subsidiaries are included in accumulated other comprehensive income within stockholders' equity. Certain intercompany and third party foreign currency-denominated transactions generated foreign currency re-measurement losses of approximately $70,000, $33,000 and $47,000 during the years ended December 31, 2015, 2014 and 2013, respectively, which are included in other expense, net in the consolidated statements of operations.

Cash Equivalents

The Company considers all investments purchased with an original maturity of three months or less to be cash equivalents.

Fair Value of Financial Instruments

U.S. GAAP establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the amount that would be received for an asset or paid to transfer a liability (i.e., an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1: Quoted prices in active markets for identical assets and liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value of cash and cash equivalents are classified as Level 1 at December 31, 2015 and 2014.

The estimated fair value of the common stock warrant liability resulting from the October 2009 registered direct offering of 1,362,500 shares of the common stock and warrants to purchase 681,275 shares of common stock was $0.4 million as of December 31, 2013. There was no value associated with the common stock warrant liability as of December 31, 2015. There was no value associated with the common stock warrant liability as of December 31, 2014 as the Company neared the expiration of these warrants in April 2015. These values were determined by using the Black-Scholes option pricing model which is based on the Company's stock price at measurement date, exercise price of this common stock warrant, risk-free rate and historical volatility, and are classified as a Level 2 measurement. During the years ended December 31, 2014 and 2013, the Company recorded income of $0.4 million and $0.8 million, respectively, to adjust the value of the common stock warrant liability to market. The fair value of the common stock warrant liability as of December 31, 2015 was zero, as the warrants expired in April 2015. Therefore, during the year ended December 31, 2015, no income or expense was recorded.

	2015	2014
Stock Price	$—	$ 5.60
Exercise Price	$—	$ 12.16
Risk free interest rate	—	0.030%
Expected term	—	0.25 years
Dividend yield	—	—
Expected volatility	—	22.76%

The fair value of accounts receivable and accounts payable approximate their carrying amount. The Company's long-term debt is carried at amortized cost, which approximates fair value based on current market pricing available to the Company for similar debt instruments and is categorized as a Level 2 measurement.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. Components of inventory cost include materials, labor and manufacturing overhead. Inventories consist of the following (in thousands):

	December 31,	
	2015	2014
Raw materials	$1,410	$ 761
Work in process	1,840	1,095
Finished goods	373	1,345
Total	$3,623	$3,201

Reserves for excess and obsolete inventory were $0.3 million and $36,000 at December 31, 2015 and 2014, respectively.

Juniper provides inventory allowances when conditions indicate that the selling price could be less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. Juniper balances the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact Juniper's gross margins. Conversely, favorable changes in demand could result in higher gross margins when the Company sells products.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at their outstanding unpaid principal balances reduced by allowances for doubtful accounts. The Company estimates doubtful accounts based on our historical bad debts, factors related to specific customers' ability to pay and current economic trends. The Company writes off accounts receivable against the allowance when a balance is determined to be uncollectable.

Accounts receivable allowance activity consisted of the following for the years ended December 31 (in thousands):

	2015	2014	2013
Balance at beginning of year	$358	$112	$100
Additions	—	246	12
Deductions	(95)	—	—
Balance at end of year	$263	$358	$112

Juniper's accounts receivable balance, net of allowance for doubtful accounts, was $7.5 million as of December 31, 2015, and $5.3 million as of December 31, 2014. Included in the accounts receivable balance at December 31, 2015 and 2014 were $1.9 million and $0.7 million of unbilled accounts receivable, respectively. Juniper's unbilled accounts receivable is derived from services performed that have not been billed as of the balance sheet date.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Leasehold improvements are amortized over the lesser of the useful life or the term of the leases. Depreciation is computed on the straight-line basis over the estimated useful lives of the respective assets, as follows:

	Years
Machinery and equipment	3-10
Furniture and fixtures	3-5
Computer equipment and software	3-5
Buildings	Up to 39
Land	Indefinite

Costs of major additions and improvements are capitalized and expenditures for maintenance and repairs that do not extend the life of the assets are expensed. Upon sale or disposition of property and equipment, the cost and related accumulated depreciation are eliminated from the accounts and any resultant gain or loss is credited or charged to operations.

Juniper continually evaluates whether events or circumstances have occurred that indicate that the remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. Juniper evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets. Based on this evaluation, Juniper believes, as of each balance sheet date presented, none of Juniper's long-lived assets were impaired.

Concentration of Risk

The Company has two major customers – Allergan and Merck KGaA. See Note 12 of our consolidated financial statements for customer and product concentrations.

The Company depends on one supplier for a key excipient (ingredient) used in its products and one supplier for one of the active pharmaceutical ingredients.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination. The Company does not amortize its goodwill, but instead tests for impairment annually in the fourth quarter and more frequently whenever events or changes in circumstances indicate that the fair value of the asset may be less than its carrying value of the asset.

In accordance with Accounting Standards Codification, or ASC 350, Goodwill and Other Intangibles ("ASC 350"), we use the two step approach for each reporting unit. The first step compares the carrying amount of the reporting unit to its estimated fair value (Step 1) utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated using a risk-adjusted discount rate. To the extent that the carrying value of the reporting unit exceeds its estimated fair value, a second step is performed, wherein the reporting unit's carrying value is compared to the implied fair value (Step 2). To the extent that the carrying value of goodwill exceeds the implied fair value of goodwill, impairment exists and must be recognized.

We have concluded that our business represents two reporting units for goodwill impairment testing, which are product and service. Our goodwill is assigned to our service reporting unit. We have performed our annual test for impairment as of October 1, 2015 and have determined that our goodwill is not impaired as of December 31, 2015.

Intangible Assets

The Company capitalizes and includes in intangible assets the costs of trademark, developed technology and customer relationships. Intangible assets are recorded at fair value at the time of their acquisition and stated net of accumulated amortization. The Company amortizes its intangible assets that have finite lives using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. Amortization is recorded over the estimated useful lives ranging from 3 to 7 years. The Company evaluates the realizability of its definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group. If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair value of the assets, generally utilizing a discounted cash flow analysis based on the present value of estimated future cash flows to be generated by the assets using a risk-adjusted discount rate. To estimate the fair value of the assets, the Company uses market participant assumptions pursuant to ASC 820, *Fair Value Measurements*. If the estimate of an intangible asset's revised useful life is changed, the Company will amortize the remaining carrying value of the intangible asset prospectively over the revised useful life.

Income Taxes

Deferred tax assets or liabilities are determined based on timing differences between when income and expense items are recognized for financial statement purposes versus when they're recognized for tax purposes, as measured by enacted tax rates expected to apply to taxable income in the fiscal years in which those temporary differences are expected to be settled. A valuation allowance is provided against deferred tax assets in circumstances where management believes it is more likely than not that all or a portion of the assets will not be realized. The Company has provided a full valuation allowance against its net domestic deferred tax assets as of December 31, 2015 and 2014. The Company has provided a full valuation allowance against its net foreign deferred tax assets as of December 31, 2015 and 2014.

Accumulated Other Comprehensive (Loss) Income

Changes to accumulated other comprehensive income during the year ended December 31, 2014 were as follows (in thousands):

	Translation Adjustment
Balance – December 31, 2014	$ (63)
Current period other comprehensive income	(1,099)
Balance – December 31, 2015	$(1,162)

Revenue Recognition and Sales Returns Reserves

Revenues include product revenues, which primarily consist of sales of CRINONE to Merck KGaA, royalty revenues, which primarily consist of royalty revenues from Allergan on sales of CRINONE, service revenues, which primarily consist of analytical and consulting services, pharmaceutical development and clinical trial manufacturing services and other revenues.

Revenues from the sale of products are recorded at the time goods are shipped to customers, except in the case of product shipments to Allergan, which were recognized when received at Allergan' warehouse. Sales to Merck KGaA for CRINONE (progesterone gel) are determined on a country-by-country basis and are the greater of (i) a percentage of Merck KGaA's net selling price, or (ii) Juniper's direct manufacturing cost plus 20%. Juniper estimates net selling prices based on historical experience and other current information from Merck KGaA; the amounts are reconciled on a quarterly basis when information is received from Merck KGaA. In 2012 and 2013, certain quantity discounts applied to annual purchases over 10 million, 20 million, and 30 million units. Juniper accrues an estimated volume discount on a quarterly basis and reconciles it on an annual basis.

In April 2013, Juniper's license and supply agreement with Merck KGaA for the sale of CRINONE outside the United States was renewed for an additional five year term, extending the expiration date from to May 19, 2020.

Under the terms of the amended license and supply agreement, Juniper will sell CRINONE to Merck KGaA on a country-by-country basis at the greater of (i) direct manufacturing cost plus 20% or (ii) a percentage of Merck KGaA's net selling price. From 2014 through 2020, the percentage of net selling price will be determined based on a tiered structure, which is based on volume sold. As sales volumes increase Juniper's percentage share of each incremental tier decreases.

Juniper derives its revenues from the sale of product, the performance of professional services and royalties.

Juniper recognizes its product revenues under written contracts at the time goods are shipped to its customer and collection from its customer is reasonably assured.

The professional service contracts that Juniper enters into and operates under specifies whether the engagement will be billed on a time-and-materials or a fixed-price basis. These engagements generally last three to six months, although some of Juniper's engagements can be much longer in duration. Each contract must be approved by one of Juniper's officers.

Juniper recognizes substantially all of the Company's professional services revenues under written contracts when the fee is fixed or determinable, as the services are provided, and only in those situations where collection from the client is reasonably assured. In certain cases Juniper bills clients prior to work being performed, which requires Juniper to defer revenue in accordance with U.S. GAAP. In these cases, these amounts are fully reserved until all criteria for recognizing revenue are met.

Juniper's professional services revenue is derived from fixed price and time-and-materials service contracts. Revenues from time-and-materials service contracts are recognized as the services are performed based upon hours worked and contractually agreed-upon hourly rates, as well as indirect fees based upon hours worked.

Professional service revenues from a majority of Juniper's fixed-price engagements are recognized on a proportional performance method based on the ratio of costs incurred, substantially all of which are labor-related, to the total estimated project costs. In general, project costs are classified in costs of services and are based on the direct salary of the employees on the engagement plus all direct expenses incurred to complete the engagement, including any amounts billed to Juniper by its vendors. The proportional performance method is used for fixed-price contracts because reasonably dependable estimates of the revenues and costs applicable to various stages of a contract can be made, based on historical experience and the terms set forth in the contract, and are indicative of the level of benefit provided to Juniper's clients. In the event of a termination, fixed-price contracts generally provide for payment for services rendered up to termination. Juniper's management maintains contact with project managers to discuss the status of the projects. In cases where the Company may be required to commit unanticipated additional resources to complete projects, which may result in lower than anticipated income or losses on those contracts.

Professional service revenues also include reimbursements, which include reimbursement for travel and other out-of-pocket expenses, outside consultants, and other reimbursable expenses. Juniper's project managers and finance personnel monitor payments from its customers and assess any collection issues. The Company maintains accounts receivable allowances for estimated losses resulting from disputed amounts or the inability of Juniper's customers to make required payments. Juniper bases its estimates on the Company's historical collection experience, current trends, and credit policy. In determining these estimates, Juniper examines historical write-offs of its receivables and review client accounts to identify any specific customer collection issues. If the financial condition of Juniper's customers were to deteriorate or disputes were to arise regarding the services provided, resulting in an impairment of their ability or intent to make payment, additional allowances may be required. A failure to estimate accurately the accounts receivable allowances and ensure that payments are received on a timely basis could have a material adverse effect on Juniper's business, financial condition, and results of operations.

Royalty revenues, based on sales by licensees, are recorded as revenues when those sales are made by the licensees.

Juniper collects value added tax from its customers for revenues generated out of the United Kingdom for which the customer is not tax exempt and remits such taxes to the appropriate governmental authorities. Juniper presents its value added tax on a net basis; therefore, these taxes are excluded from revenues.

Up to July 2013, Juniper was responsible for sales returns for CRINONE and PROCHIEVE products sold prior to the Allergan transaction on July 2, 2010, and for STRIANT products sold prior to the sale of the product to Auxilium in April 2011. The Company is not and were not responsible for returns for international sales. The Company's policy for sales to the trade made prior to the Allergan and Auxilium transactions allows product to be returned for a period that began three months prior to the product expiration date and ended twelve months after the product expiration date. Provisions for returns on sales to wholesalers, distributors and retail chain stores were estimated based on a percentage of sales, using such factors as historical sales information, distributor inventory levels and product prescription data, and were recorded as a reduction to sales in the same period as the related sales were recognized. Juniper assumed that the Company's customers were using the first-in, first-out method in filling orders so that the oldest saleable product was used first. Juniper recorded a provision for returns on a quarterly basis using an estimated rate and adjusted the provision when necessary. Currently there is no sales returns reserve as the return rights obligation has elapsed for all products for which Juniper provided a right of return.

An analysis of the reserve for sales returns at December 31, 2014 and 2015 is as follows (in thousands):

	Total
Balance – December 31, 2013	$ 138
Provision:	
Related to current period sales	—
Related to prior period sales	(136)
	(136)
Returns:	
Related to prior period sales	(2)
	(2)
Balance – December 31, 2014	$ —

Deferred Revenue

As part of the acquisition of Juniper Pharma Services, Juniper assumed a $2.5 million obligation under a grant arrangement with the Regional Growth Fund on behalf of the Secretary of State for Business, Innovation, and Skills in the United Kingdom. Juniper Pharma Services used this grant to fund the building of its second facility, which includes analytical labs, office space, and a manufacturing facility. As a part of the arrangement, Juniper Pharma Services is required to create and maintain certain full-time equivalent personnel levels through October 2017. As of December 31, 2015, the Company is in compliance with the covenants of the arrangement.

The income from the Regional Growth Fund will be recognized on a decelerated basis through September 30, 2017. As of December 31, 2015, and 2014, the obligation is valued at $1.5 million and $2.1 million, respectively and is recorded in deferred revenue on the consolidated balance sheets.

Amounts paid but not yet earned on a sale are recorded as deferred revenue until such time as performance is rendered or the obligation to perform the service is completed.

Research and Development Costs

Research and development consist of consultants, material costs, salaries and other personnel related expenses including stock-based compensation of employees and non-employees primarily engaged in research and development activities and materials used and other overhead expenses incurred. All research and development costs are expensed as incurred. Research and development costs that are paid in advance of performance are capitalized as prepaid expenses until incurred.

Clinical trial expenses include expenses associated with clinical research organizations. The invoicing from clinical research organizations for services rendered can lag several months. Juniper accrues the cost of services rendered in connection with clinical research organizations activities based on our estimate of costs incurred. Juniper maintains regular communication with its clinical research organizations to assess the reasonableness of its estimates. Differences between actual expenses and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

Juniper entered into an agreement with Allergan to collaborate on the development of progesterone products, specifically the PREGNANT study. The PREGNANT study expenses consisted of fees for preparation, filing and approval process of the related drug application. Under the terms of the agreement, Juniper performed certain research and development activities, the cost of which was partially funded by Allergan.

In 2015, 2014, and 2013, there were no research and development expenses or reimbursements from Allergan.

In 2014, the Company completed its commercial and intellectual property assessment and clinical and regulatory diligence on COL-1077, extended-release lidocaine vaginal gel in addition to performing initial assessments of other potential proprietary product candidates. The target indication for COL-1077 is an acute use anesthetic for minimally invasive gynecological procedures. The Company is leveraging the technical capabilities of its Nottingham site to advance the COL-1077 development program.

In March 2015, the Company entered into an exclusive patent license agreement with The General Hospital Corporation, d/b/a Massachusetts General Hospital, pursuant to which Juniper has licensed the exclusive worldwide rights to Massachusetts General Hospital patent rights in a novel intra-vaginal ring (IVR) technology for delivery of one or more pharmaceutical dosages and release rates in a single segmented ring. The Company is leveraging the technology to advance JNP-0101, JNP-0201 and JNP-0301.

Stock-based compensation

Juniper follows the fair value recognition provisions of ASC 718, *Stock Compensation Topic* (ASC 718) and ASC Subtopic 505-50, *Equity – Equity Based Payments to Nonemployees*. Juniper expenses the fair value of stock options over the requisite service period. Juniper records its stock-based compensation expense without a forfeiture rate. Accordingly, Juniper reviews its actual forfeitures and aligns its stock compensation expense with the options that are vesting.

Juniper recorded stock-based compensation expense of $1.8 million, $0.6 million and $0.5 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Total stock-based compensation expense was recorded to cost of revenues, and operating expenses based upon the functional responsibilities of the individuals holding the respective options as follows (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Cost of revenues	$ 79	$ 44	$ 14
Sales and marketing	38	28	—
Research and development	1,126	2	—
General and administrative	507	533	461
Total employee stock-based compensation	$1,750	$607	$475

As of December 31, 2015, total unamortized share-based compensation cost related to non-vested stock options was $2.6 million, which is expected to be recognized on a straight-line basis over a weighted average period of 2.6 years.

Cash received from option exercises was $0.1 million, $33,000 and $11,000 during the years ending December 31, 2015, 2014 and 2013, respectively.

Juniper granted 387,000, 312,000 and 88,749 stock options to employees during the years ended December 31, 2015, 2014 and 2013, respectively.

The Company records stock-based compensation expense for stock options granted to non-employees based on the fair value of the stock options, which is re-measured over the graded vesting term resulting in periodic adjustments to stock-based compensation expense. During 2015, 243,000 stock options were granted by the Company to non-employees. During the twelve months ended December 31, 2015, the Company recorded stock-based compensation expense of $1.1 million related to these awards. The stock-based compensation expense recorded for non-employees is primarily reflected in the research and development line of the statement of operations. The 240,000 options reflected in the research and development line will be re-measured over a 1.25 year period from the date of grant versus the remaining 3,000 options will be re-measured over a 3.75 year period

from the date of grant. There was no stock-based compensation expense recorded for consultants in years ended December 31, 2014 and 2013, respectively. No tax benefit has been recognized due to the net tax losses during the periods presented.

The Company uses the Black-Scholes option pricing model to determine the estimated fair value for stock-based awards. Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. Accordingly the weighted-average fair value of the options granted to employees during the years ended December 31, 2015, 2014 and 2013 was $4.38, $4.27 and $3.52, respectively based on the following assumptions:

	Years Ended December 31,		
	2015	2014	2013
Risk free interest rate	0.87%-1.20%	0.93%-1.64%	0.71%-0.76%
Expected term	4.56-4.75 years	4.75 years	4.75 years
Dividend yield	—	—	—
Expected volatility	76.86%-83.09%	78.27%-81.36%	96.52%-97.02%

The weighted-average fair value of the options granted to non-employees during the years ended December 31, 2015, 2014 and 2013 was $4.52, $0 and $0, respectively based on the following assumptions:

	Years Ended December 31,		
	2015	2014	2013
Risk free interest rate	1.47%-1.54%	—	—
Expected term	7 years	—	—
Dividend yield	—	—	—
Expected volatility	82.88%-83.09%	—	—

Juniper's estimated expected stock price volatility is based on its own historical volatility. Juniper's expected term of options granted in the years ended December 31, 2015, 2014 and 2013 was derived from the simplified method for employee grants and the contractual term is used for non-employee grants. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

Net (Loss) Income Per Common Share

The calculation of basic and diluted income per common and common equivalent share is as follows (in thousands except for per share data):

	Years Ended December 31,		
	2015	2014	2013
Basic net (loss) income per common share			
Net (loss) income	$ (2,134)	$ 3,390	$ 6,704
Less: Preferred stock dividends	(28)	(28)	(28)
Net (loss) income applicable to common stock	$ (2,162)	$ 3,362	$ 6,676
Basic weighted average number of common shares outstanding	10,774	10,992	11,259
Basic net (loss) income per common share	$ (0.20)	$ 0.31	$ 0.59
Diluted net (loss) income per common share			
Net (loss) income applicable to common stock	$ (2,162)	$ 3,362	$ 6,676
Add: Preferred stock dividends	—	28	28
Less: Fair value of stock warrants for dilutive warrants	—	(379)	(794)
Net (loss) income applicable to dilutive common stock	$ (2,162)	$ 3,011	$ 5,910
Basic weighted average number of common shares outstanding	10,774	10,992	11,259
Effect of dilutive securities			
Dilutive stock awards	—	15	14
	—	15	14
Diluted weighted average number of common shares outstanding	10,774	11,007	11,273
Diluted net (loss) income per common share	$ (0.20)	$ 0.27	$ 0.52

Basic (loss) income per common share is computed by dividing the net (loss) income, less preferred dividends by the weighted-average number of shares of common stock outstanding during a period. The diluted (loss) income per common share calculation gives effect to dilutive options, warrants, convertible notes, convertible preferred stock, and other potential dilutive common stock including selected restricted shares of common stock outstanding during the period. Diluted (loss) income per common share is based on the treasury stock method and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options, assuming the exercise of all in-the-money stock options. Common share equivalents have been excluded where their inclusion would be anti-dilutive.

Shares to be issued upon the exercise of the outstanding options and warrants, convertible preferred stock and selected restricted shares of common stock excluded from the income per share calculation amounted to 1,087,308, 1,692,180 and 1,599,551 for the years ended December 31, 2015, 2014 and 2013, respectively, because the awards were anti-dilutive.

Acquisition-Related Expenses

The Company's acquisition-related expenses for 2013 were costs associated with the acquisition of Juniper Pharma Services and a failed transaction in the 2013 period. There were no acquisition-related expenses during the 2015 or 2014 periods.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, 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 the impact of its pending adoption of the new standard on its consolidated financial statements.

In January 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-01, Financial Instruments – Recognition and Measurement of Financial Assets and Financial Liabilities, which provides new guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. The standard becomes effective for Juniper beginning in the first quarter of 2018 and early adoption is permitted. Juniper is currently evaluating the effect, if any, that the standard will have on its consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements – Going Concern. The provisions of ASU No. 2014-15 require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this ASU are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company does not believe this ASU will have an impact on the Company's financial statements.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" ("ASU 2014-09"), which provides guidance for revenue recognition. ASU 2014-09 affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets and supersedes the revenue recognition requirements in Topic 605, "Revenue Recognition," and most industry-specific guidance. This ASU also supersedes some cost guidance included in Subtopic 605-35, "Revenue Recognition-Construction-Type and Production-Type Contracts." The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company beginning January 1, 2018 and, at that time the Company may adopt the new standard under the full retrospective approach or the modified retrospective approach. Early adoption is not permitted. The Company is currently evaluating the method and impact that the adoption of ASU 2014-09 will have on the Company's consolidated financial statements and related disclosures.

3. ***Goodwill and Intangible Assets***

Changes to goodwill during the year ended December 31, 2015 and 2014 were as follows (in thousands):

	Total
Balance – December 31, 2013	$11,152
Translation adjustment	(649)
Balance – December 31, 2014	10,503
Translation adjustment	(493)
Balance – December 31, 2015	$10,010

Intangible assets consist of the following at December 31, 2015 and December 31, 2014 (in thousands):

	Trademark	Developed Technology	Customer Relationships	Total
Gross carrying amount – December 31, 2015	$ 300	$1,370	$1,240	$ 2,910
Translation adjustment	(19)	(83)	(76)	(178)
Accumulated amortization	(215)	(538)	(381)	(1,134)
Balance – December 31, 2015	$ 66	$ 749	$ 783	$ 1,598

	Trademark	Developed Technology	Customer Relationships	Total
Gross carrying amount – December 31, 2014	$ 300	$1,370	$1,240	$2,910
Translation adjustment	(5)	(20)	(18)	(43)
Accumulated amortization	(127)	(333)	(225)	(685)
Balance – December 31, 2014	$ 168	$1,017	$ 997	$2,182

Amortization expense related to the developed technology is classified as a component of cost of service revenues in the consolidated statements of operations. Amortization expense related to trademark and customer relationships is classified as a component of general and administrative expenses in the consolidated statements of operations.

Acquired intangible assets are amortized over their estimated useful lives based on either the pattern in which the economic benefits of the intangible asset are consumed or on a straight-line method. The estimated useful life represents the anticipated term of the acquired intangible assets. The estimated useful lives for the trademark, developed technology and customer relationships are 3 years, 7 years and 7 years, respectively. The weighted average amortization period in total is 6.6 years.

Amortization expense for the years ended December 31, 2015 and 2014, was $0.4 million and $0.7 million, respectively. As of December 31, 2015, amortization expense on existing intangible assets for the next five years and beyond is as follows (in thousands):

Year	Total
2016	$ 436
2017	346
2018	317
2019	287
2020	212
Total	$1,598

4. ***Debt and other Contractual Obligations***

In September 2013, Juniper assumed debt of $3.9 million in connection with its acquisition of Juniper Pharma Services. Juniper Pharma Services entered into a Business Loan Agreement ("Loan Agreement") covering three loan facilities with Lloyds TSB Bank ("Lloyds"), as administrative agent. Juniper Pharma Services had withdrawn $3.9 million and as of December 31, 2015 owed $3.1 million. The three loan facilities are each repayable by monthly installments, one started repayment in February 2013 and the remaining two commenced in October 2013. All facilities are due for repayment over 15 years from the date of drawdown. Two of the facilities bear interest at the Bank of England's base rate plus 1.95% and 2.55%, respectively. The interest rate at December 31, 2015 for these two facilities was 2.45% and 3.05%, respectively. The third facility is a fixed rate agreement bearing interest at 3.52% per annum. The weighted average interest rate for the three loan facilities for the year ending December 31, 2015 was 3.00%. The Loan Agreement is secured by the mortgaged property and an unlimited lien on the other assets of Juniper Pharma Services. The Loan Agreement contains financial covenants that limit the amount of indebtedness Juniper Pharma Services may incur, requires Juniper Pharma Services to maintain certain levels of net worth, and restricts Juniper Pharma Service's ability to materially alter the character of its business. As of December 31, 2015 the Company is in compliance with all of the covenants under the Loan Agreement.

The Company's significant outstanding contractual obligations relate to operating leases for the Company's facilities and loan agreements. The Company's facility leases are non-cancellable and contain renewal options. The Company's future contractual obligations include the following (in thousands):

	Total	2015	2016	2017	2018	2019	Thereafter
Operating lease obligations	$1,323	$370	$436	$443	$ 74	$—	$ —
Loan principal repayments	3,135	238	245	253	261	268	1,870
Total	$4,458	$608	$681	$696	$335	$268	$1,870

Rent expense was $0.3 million for December 31, 2015, $0.1 million for December 31, 2014, and $0.3 million for December 31, 2013.

Interest expense, net was $0.1 million for the years ended December 31, 2015 and 2014, respectively. Interest expense, net was $25,000 for the year ended December 31, 2013.

As part of the acquisition of Juniper Pharma Services, Juniper assumed a $2.5 million obligation under a grant arrangement with the Regional Growth Fund on behalf of the Secretary of State for Business, Innovation, and Skills in the United Kingdom. Juniper Pharma Services used this grant to fund the building of its second facility, which includes analytical labs, office space, and a manufacturing facility. As a part of the arrangement, Juniper Pharma Services is required to create and maintain certain full-time equivalent personnel levels through October 2017. As of December 31, 2015, the Company is in compliance with the covenants of the arrangement.

The income from the Regional Growth Fund will be recognized on a decelerated basis over the next three years. As of December 31, 2015, the obligation is valued at $1.5 million and is recorded in deferred revenue within the consolidated balance sheets. The amount of other income on the obligation that will be recognized provided the Company remains in compliance with the covenants would be the following (in thousands):

Year	Total
2016	770
2017	710
Total	$1,480

5. ***Property and Equipment***

Property and equipment consists of the following:

	Estimated Useful Life (Years)	December 31, 2015 Cost	December 31, 2014 Cost
Machinery and equipment	3-10	$ 7,175	$ 6,080
Furniture and fixtures	3-5	1,030	1,019
Computer equipment and software	3-5	625	188
Buildings	Up to 39	8,771	9,062
Land	Indefinite	562	590
Construction in-process		9	107
		18,172	17,046
Less: Accumulated depreciation		(5,322)	(4,005)
Total		$12,850	$13,041

Depreciation expense for the years ended December 31, 2015, 2014, and 2013 was $1.5 million, $1.4 million and $0.7 million, respectively.

The net book value of property and equipment subject to lien is $7.1 million and $7.2 million as of December 31, 2015 and 2014, respectively.

6. ***Accrued Expenses***

Accrued expenses consist of the following:

	December 31, 2015	December 31, 2014
Payroll	$1,495	$ 660
Professional fees	952	610
Clinical studies	835	—
Other	876	648
Total	$4,158	$1,918

7. ***Income Taxes***

(Loss) income before income taxes consists of the following (in thousands):

	Year Ended December 31, 2015	2014	2013
Domestic	$(8,771)	$ (489)	$ (4,091)
Foreign	6,642	4,867	10,817
(Loss) income before income taxes	$(2,129)	$4,378	$ 6,726

As of December 31, 2015, the Company does not maintain accumulated earnings and profits in the foreign jurisdictions that it currently does business. The company has repatriated current earnings from its foreign subsidiaries to the United States in 2014 and 2015. To the extent the Company has positive accumulated foreign earnings in the future, we will further assess our global business needs and decide whether or not it will permanently reinvest those earnings.

The components of the provision (benefit) for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Current:			
Federal	$ (9)	$134	$ (20)
State	14	323	(2)
Foreign	—	531	—
Total current	5	988	(22)
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	44
Total deferred	—	—	44
Provision for income taxes	$ 5	$988	$ 22

The reconciliation of the federal statutory rate to Juniper's effective tax rate is as follows:

	2015	2014	2013
Federal income tax rate	34.0%	34.0%	34.0%
Foreign rate differential	106.1%	(31.6)%	(53.9)%
State tax, net of federal benefit	(2.4)	77.8	8.5
Permanent Items:			
Change in fair value of redeemable warrants	—	—	—
Change in fair market value of stock warrants	—	(3.0)	(4.0)
Incentive stock options	(10.4)	2.4	—
Dividend from foreign subsidiary	(55.9)	54.9	—
Subpart F inclusion	—	—	8.9
Acquisition costs capitalized	—	—	3.3
Amortization of technical rights	16.4	(8.0)	(5.2)
Deferred adjustments	4.8	2.6	(6.0)
Discrete prior year New Jersey liability	—	7.3	—
Other	(0.5)	0.8	1.1
Effect of permanent differences	(45.5)	57.0	(1.9)
Effective income tax rate	92.1	137.2	(13.3)
Change in valuation allowance	(92.3)	(114.6)	13.6
Effective income tax rate	(0.2)%	22.6%	0.3%

The Company follows the provisions of FASB ASC 740, "Accounting for Uncertainty in Income Taxes – An Interpretation of FASB No. 109." FASB ASC 740 provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the financial statements in accordance with ASC 740-20. Tax positions must meet a "more-likely-than-not" recognition threshold at the effective date to be recognized upon the adoption of FASB ASC 740 and in subsequent periods. Juniper recognizes interest and penalties, if any, related to uncertain tax positions in general and administrative expenses. No uncertain tax positions or interest and penalties related to uncertain tax positions were accrued at December 31, 2015.

The Company operates in multiple countries. Accordingly, separate tax filings are required based on jurisdiction. Due to the separate tax filings of our U.S. and U.K jurisdictions, we have evaluated the need for a

valuation allowance on a separate jurisdiction basis. As of December 31, 2015, we continue to maintain a full valuation allowance against all net deferred tax assets.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Management believes it is more likely than not that the results of future operations will not generate sufficient taxable income in the U.S. and the U.K., in order to realize the full benefits of the deferred tax assets in the respective jurisdictions.

As of December 31, 2015, the Company has U.S. tax net operating loss carryforwards of approximately $157 million, which expire through 2035. The Company also has unused tax credits of approximately $1.9 million, which expire at various dates through 2035. Utilization of the tax net operating loss carryforwards may be limited in any year due to limitations in the Internal Revenue Code. U.S. net operating loss carryforwards include no excess tax benefits from the exercise of share based awards due to the full valuation allowance that remains on the net domestic deferred tax assets. As of December 31, 2015, the Company had U.K. tax net operating loss carryforwards of approximately $15 million, which will not expire.

The Company files federal income tax returns as well as multiple state, local and foreign jurisdiction tax returns. Tax years ended December 31, 2013 or later remain subject to examination by the IRS. State and local jurisdiction tax returns remain subject to examination for tax years ended December 31, 2013 or later.

As of December 31, 2015, the Company's open tax years subject to audit are 2013, 2014 and 2015. The Internal Revenue Service has concluded their audit of the 2011 and 2012 tax years. There were no material findings resulting from their audit.

The components of Juniper's net deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2015	December 31, 2014
Share based awards compensation	$ 1,502	$ 1,085
Allowance for returns	—	—
Inventory reserve	—	—
Book accumulated depreciation net of tax	(1,386)	(1,475)
Other deferred revenue	249	335
Patents	1,396	1,290
Federal net operating loss	53,700	52,050
State net operating loss	912	1,133
Foreign losses	2,929	2,368
R&D credit carryover	1,723	1,723
Write-up of intangibles	(337)	(443)
Other	162	201
Net deferred tax assets	60,850	58,267
Less: valuation allowance:		
Federal	(60,850)	(58,267)
Deferred tax asset	$ —	$ —

8. ***Shareholders' Equity***

Preferred Stock

Authorized Preferred Stock is 1,000,000 shares at a par value of 0.01 per share.

Each share of Series B Preferred Stock is convertible into 20 shares of common stock. At December 31, 2015, 130 shares remain outstanding. Upon liquidation of the Company, the holders of the Series B Preferred Stock are entitled to $100 per share. The Series B Preferred Stock will be automatically converted into common stock upon the occurrence of certain events. Holders of the Series B Preferred Stock are entitled to one vote for each share of common stock into which the preferred stock is convertible.

The Series C Preferred Stock has a stated redemption value of $1,000 per share. The Series C Preferred Stock is convertible into common stock at the lower of: (i) $28.00 per common share or (ii) 100% of the average of the closing prices during the three trading days immediately preceding the conversion notice (not to exceed 294,045 shares). The Series C Preferred Stock pays a 5% dividend, payable quarterly in arrears on the last day of the quarter. In 2012, 50 shares of Series C Preferred Stock were redeemed for cash. Each holder of Series C Preferred Stock has the right to redeem all or a portion of their shares in cash and upon the occurrence of certain events under the Series C Preferred Stock certificate of designations.

In September 2012, a holder of 50 shares of the Company's contingently redeemable Series C Convertible Preferred Stock redeemed those shares pursuant to Section 6.5 of the Certificate of Designations for the Series C Preferred ("Certificate of Designations"), which provides that following a "Triggering Event," as defined therein, the holders of the Company's shares of Series C Preferred have the right to require us to redeem their shares in cash plus all accrued and unpaid dividends thereon on the date such redemption is demanded. The Allergan Transactions were a Triggering Event. There is no deadline following a Triggering Event by which a holder is required to make a redemption request. As a result, the Company redeemed the 50 shares for $50,000 (the "Mandatory Redemption Price" as defined in the Certificate of Designations) plus accrued and unpaid dividends. Five hundred fifty (550) shares of Series C Convertible Preferred Stock remain outstanding.

The Series E Preferred Stock has a stated value of $100 per share. In November 2013, 22,740 shares of Series E Preferred Stock were converted into 142,125 shares of common stock. As of December 31, 2015 and 2014 there are no shares outstanding.

In March 2002, the Company adopted a Stockholder Rights Plan (the "Rights Plan") designed to protect company stockholders in the event of takeover activity that would deny them the full value of their investment. The Rights Plan was not adopted in response to any specific takeover threat. In adopting the Rights Plan, the Board declared a dividend distribution of one preferred stock purchase right for each outstanding share of common stock of the Company, payable to stockholders of record at the close of business on March 22, 2002. The rights will become exercisable only in the event, with certain exceptions, a person or group of affiliated or associated persons acquires a specified amount (the "Specified Amount") (originally 15%) or more of the Company's voting stock, or a person or group of affiliated or associated persons commences a tender or exchange offer which, if successfully consummated, would result in such person or group owning the Specified Amount or more of the Company's voting stock. Each right, once exercisable, will entitle the holder (other than rights owned by an acquiring person or group) to buy one one-thousandth of a share of a series of the Company's Series D Junior Participating Preferred Stock at a price of $30 per one-thousandth of a share, subject to adjustments. In addition, upon the occurrence of certain events, holders of the rights (other than rights owned by an acquiring person or group) would be entitled to purchase either the Company's preferred stock or shares in an "acquiring entity" at approximately half of market value. Further, at any time after a person or group acquires the Specified Amount or more (but less than 50%) of the Company's outstanding voting stock, subject to certain exceptions, the Board of Directors may, at its option, exchange part or all of the rights (other than rights held by an acquiring person or group) for shares of the Company's common stock having a fair market value on the date of such acquisition equal to the excess of (i) the fair market value of preferred stock issuable upon exercise of the

rights over (ii) the exercise price of the rights. The Company generally will be entitled to redeem the rights at $0.01 per right at any time prior to the close of business on the tenth day after there has been a public announcement of the beneficial ownership by any person or group of the Specified Amount or more of the Company's voting stock, subject to certain exceptions.

In November 2010, the Board of Directors of the Company adopted an amendment and restatement (the "Amendment") of the Rights Plan, dated as of March 13, 2002 (the "Original Rights Agreement"), between the Company and American Stock Transfer & Trust Company, LLC, as successor rights agent (as amended, the "Rights Plan"). In general, the Amendment leaves the Original Rights Agreement unchanged in all material respects, other than changing the trigger for the Rights becoming exercisable from 15% to 4.99% of the outstanding Voting Rights (as defined in the Rights Plan), expanding the concept of "beneficial ownership" to include shares owned (including those owned indirectly and constructively) under Section 382 of the Code and modifying the provisions relating to the exchange of Rights for common stock.

The Company adopted the Amendment to preserve the value of the Company's net operating loss carry forwards (the "Tax Benefits"), because its ability to fully use the Tax Benefits on an annual basis to offset future income may be substantially limited if the Company experiences an "ownership change" for purposes of Section 382 of the Internal Revenue Code of 1986 (the "Code"). Generally, the Company would experience an "ownership change" under Section 382 of the Code if a greater than 50 percentage point change in ownership of the Voting Stock (as defined in the Rights Plan and described below) by stockholders who beneficially own (or who are deemed to own) 5% or more of the Company's Voting Stock occurs over a rolling three year period.

In September 2011, the Company and American Stock Transfer and Trust Company, LLC, as rights agent, further amended the Rights Plan to extend the expiration date of the rights from March 12, 2012 to July 3, 2013. In March 2013, the Company further amended the Rights Plan to extend the expiration date from July 3, 2013, to July 3, 2016. Except for the extension of the expiration date, the Rights Plan otherwise remained unmodified. The extension was made to preserve the value of the Tax Benefits.

In January 2015, the Company's Board of Directors approved an amendment that increases the threshold ownership trigger from 4.99% to 9.99%. Accordingly, the Rights Plan is presently designed to reduce the likelihood that the Company will experience an ownership change by discouraging any person (together with such person's affiliates and associates), without the approval of the Board, (i) from acquiring 9.99% or more of the outstanding Voting Stock and (ii) that currently beneficially owns 9.99% or more of the outstanding Voting Stock from acquiring more shares of Voting Stock, other than by exercise or conversion of currently existing warrants, convertible securities or other equity-linked securities. There is no guarantee that the Rights Plan will prevent the Company from experiencing an ownership change.

Common Stock

The Company granted 13,106 shares of restricted stock to the Company's independent Directors during the year ended December 31, 2015.

The Company granted 23,562 shares of restricted stock to the Company's independent Directors during the year ended December 31, 2014.

The Company granted 28,083 shares of restricted stock to the Company's independent Directors during the year ended December 31, 2013. On September 12, 2013, as part of the total consideration paid for the acquisition of Juniper Pharma Services, the Company issued 1,051,323 shares of common stock.

Warrants

During the year ended December 31, 2015, the following warrants expired:

Weighted Average Exercise Price	Warrants	Expiration Date
$10.80	502,907	07/02/2015
$12.16	621,275	04/30/2015
$11.55	1,124,182	

During the years ended December 31, 2015 and 2014, there were no warrants issued or exercised.

9. ***Stock-based Compensation***

Stock Option Plans

In May of 2008, the Company adopted the 2008 Long-term Incentive Plan ("2008 Plan") which provides for the grant of stock options, stock appreciation rights and restricted stock to certain designated employees of the Company, Non-Employee directors of the Company and certain other persons performing significant services for the Company as designated by the Compensation Committee of the Board of Directors. At December 31, 2014, the number of common shares reserved for issuance under the 2008 plan was 1,250,000. Options granted under the plan vest either (i) over a 48-month period at the rate of 25% each year until fully vested or (ii) over a vesting period determined by the Board of Directors. As of December 31, 2014, there were 558,859 shares available for future grant under the 2008 plan.

In April of 2015, the Company adopted the 2015 Long-term Incentive Plan ("2015 Plan") which provides for the grant of stock options, stock appreciation rights and restricted stock to certain designated employees of the Company, Non-Employee directors of the Company and certain other persons performing significant services for the Company as designated by the Compensation Committee of the Board of Directors. At December 31, 2015, the number of common shares and restricted stock reserved for issuance under the 2015 plan was 1,000,000 and 200,000, respectively. Options granted under the plan vest either (i) over a 48-month period at the rate of 25% each year until fully vested or (ii) over a 48-month period at the rate pf 6.25% each quarter until fully vested or (ii) over a vesting period determined by the Board of Directors. As of December 31, 2015, there were 745,375 shares available for future grant under the 2015 plan.

The Company's stock options have a maximum term of 10 years from the date of grant. Options granted prior to 2006 have a 10-year term. Since 2006, the Company has been granting stock options with a seven-year term.

A summary of the status of the Company's stock option plans as of December 31, 2015 is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2014	445,684	8.28	5.11 years	45,625
Granted	630,000	6.80		
Exercised	(15,625)	5.28		21,436
Forfeited	(40,375)	11.18		
Outstanding, December 31, 2015	1,019,684	$ 7.30	5.46 years	$3,607,077
Vested	319,429	8.30	4.33 years	1,060,969
Unvested	700,255	6.84		2,546,108
Vested or expected to vest, December 31, 2015	1,019,684	$ 7.30	5.46 years	$3,607,077
Exercisable, December 31, 2015	319,429	$ 8.30	4.33 years	$1,060,969

The intrinsic value of options exercised in 2015, 2014, and 2013, respectively, were $21,436, $10,161, and $4,380.

Restricted stock grants consist of grants of the Company's common stock that may vest in the future. The Board has set a one, two, or four year vesting period for most of the issued restricted shares except annual grants to independent Directors which vest at the next annual meeting of stockholders. The fair value of each restricted share grant is equal to the market price of the Company's common stock at the date of grant. Expense relating to restricted shares is at the closing price amortized ratably over the vesting period. As of December 31, 2015, there were 225,720 restricted shares available for future grant under the 2015 plan.

Included in the table above are 243,000 options granted to non-employees during 2015 with a weighted average exercise price of $6.10.

A summary of the Company's restricted stock activity and related information for the year ended December 31, 2015 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2014	22,830	$ 6.47
Granted	13,106	$11.71
Vested	(23,291)	$ 6.49
Forfeited	—	$ —
Unvested, December 31, 2015	12,645	$11.86

As of December 31, 2015, there was $0.1 million of total unrecognized compensation costs related to non-vested restricted share-based compensation. The remaining cost is expected to be recognized over a weighted average period of 0.43 years. The total fair value of shares vested during the year ended December 31, 2015 was $0.2 million.

10. ***Related Party Transactions***

From July 2010 to November 2013, the Company manufactured and sold products to Allergan at Juniper's cost plus 10%; the revenues generated from these sales were recorded within product revenues from related party. Pursuant to the Purchase and Collaboration Agreement dated July 2, 2010, Juniper receives royalties equal to a minimum of 10% of annual net sales of CRINONE by Allergan for annual net sales up to $150 million, 15% for sales above $150 million but less than $250 million; and 20% for annual net sales of $250 million and over.

On March 7, 2014 the Company acquired all of its common stock beneficially owned by Allergan, which represented approximately 11.5% of the Company's outstanding common stock. Immediately following the closing of the stock repurchase and as of December 31, 2014, Allergan did not own any of the Company's outstanding common stock. Juniper purchased the 1.4 million shares held by Allergan at a price of $6.08 per share, which represented a 10.75% discount to the market closing price on March 6, 2014. The total purchase price was approximately $8.5 million. At December 31, 2013, Allergan owned 11.5% of the Company's outstanding common stock.

The table below presents the related party transactions between the Company and Allergan for the years ended, December 31, 2014 and 2013 (in thousands):

	2014	2013
Revenues:		
Product revenues	$167	$ —
Royalties	714	3,436
Other revenues	—	300
Total revenues	881	3,736
Cost of product revenues:		
Cost of product revenues	—	—
Gross profit	$881	$3,736

As of December 31, 2015 and December 31, 2014, nothing was due from related party for these sales. There were no amounts due to Allergan as of December 30, 2015 and December 31, 2014.

Other revenues for the year ended December 31, 2013, consisted of a $0.3 million one-time payment associated with the termination of the supply agreement with Allergan in fourth quarter of 2013.

11. ***Legal Proceedings***

Claims and lawsuits are filed against the Company from time to time. Although the results of pending claims are always uncertain, the Company believes that it has adequate reserves or adequate insurance coverage in respect of these claims, but no assurance can be given as to the sufficiency of such reserves or insurance coverage in the event of any unfavorable outcome resulting from these actions.

12. ***Segments and Geographic Information***

The Company currently operates in two segments; product and service. The product segment includes supply chain management for CRINONE, the Company's sole commercialized product. The product segment also includes the royalty stream the Company receives from Allergan for CRINONE sales in the United States as well as the development of new product candidates. The service segment includes pharmaceutical development, clinical trial manufacturing, and advanced analytical and consulting services for the Company's customers as well as characterizing and developing pharmaceutical product candidates for the Company's internal programs and managing the preclinical and clinical manufacturing of COL-1077 and the Company's IVR. The Company has consolidated and runs all of its operational functions in one location in Nottingham, United Kingdom. The Company owns certain plant and equipment physically located at third party contractor facilities in the United Kingdom and Switzerland. The Company conducts its advanced formulation, analytical and consulting services through its subsidiary, Juniper Pharma Services.

The Company's largest customer, Merck KGaA, utilizes a Switzerland-based subsidiary to acquire product from the Company, which it then sells throughout the world excluding the U.S. The Company's primary

domestic customer, Allergan, is responsible for the commercialization and sale of progesterone products in the United States. The following tables show selected information by geographic area:

Revenues:

	Year Ended December, 31		
	2015	2014	2013
United States	$ 7,677	$10,374	$ 5,463
Switzerland	22,410	17,860	21,729
United Kingdom	4,422	2,180	825
Other countries	3,049	2,050	1,949
Subtotal international	29,881	22,090	23,763
Total	$37,558	$32,464	$29,226

Total assets:

	December 31,	
	2015	2014
United States	$16,256	$18,212
Switzerland	1,570	1,661
United Kingdom	33,335	32,140
Other countries	218	195
Total	$51,379	$52,208

Long-lived assets:

	December 31,	
	2015	2014
United States	$ 765	$ 245
Switzerland	49	529
United Kingdom	13,817	12,361
Other countries	2	2
Total	$14,633	$13,137

The following summarizes other information by segment for the year ended December 31, 2015 (in thousands):

	Product	Service	Total
Revenues			
Product revenues	$22,162	$ —	$22,162
Service revenues	—	11,651	11,651
Royalties	3,745	—	3,745
Other revenues	—	—	—
Total revenues	25,907	11,651	37,558
Cost of product revenues	13,053	—	13,053
Cost of service revenues	—	8,361	8,361
Total cost of revenues	13,053	8,361	21,414
Gross profit	12,854	3,290	16,144
Total operating expenses			18,655
Total non-operating income			382
(Loss) income before income taxes			(2,129)

The following summarizes other information by segment for the year ended December 31, 2014 (in thousands):

	Product	Service	Total
Revenues			
Product revenues	$17,381	$ —	$17,381
Service revenues	—	8,770	8,770
Royalties	6,313	—	6,313
Other revenues	—	—	—
Total revenues	23,694	8,770	32,464
Cost of product revenues	10,470	—	10,470
Cost of service revenues	—	7,219	7,219
Total cost of revenues	10,470	7,219	17,689
Gross profit	13,224	1,551	14,775
Total operating expenses			10,960
Total non-operating income			563
Income before income taxes			4,378

The following summarizes other information by segment for the year ended December 31, 2013 (in thousands):

	Product	Service	Total
Revenues			
Product revenues	$21,336	$ —	$21,336
Service revenues	—	3,640	3,640
Royalties	3,831	—	3,831
Other revenues	419	—	419
Total revenues	25,586	3,640	29,226
Cost of product revenues	10,903	—	10,903
Cost of service revenues	—	2,347	2,347
Total cost of revenues	10,903	2,347	13,250
Gross profit	14,683	1,293	15,976
Total operating expenses			10,101
Total non-operating income			851
Income before income taxes			6,726

Our chief operating decision maker evaluates the performance of our product and service segments based on revenue and gross profit. Our chief operating decision maker does not review our assets, operating expenses or non-operating income and expenses by business segment at this time. Therefore, such allocations by segment are not provided.

Customer Concentration

The following table presents information about Juniper's revenues by customer, including product sales, royalty and license revenue and service revenues for each customer accounting for 10% or more of consolidated revenues in any of the three years ended December 31 (in thousands) by segment:

Product

	Year Ended December, 31		
	2015	2014	2013
Merck KGaA	86%	73%	83%
Allergan	14	17	15
Lil' Drug Store	—	10	2
Total	100%	100%	100%

Service

Two of our customers in our service segment represented 11% and 10%, respectively, of total service revenue for the year ended December 31, 2014. Three customers in our service segment represented 15%, 13% and 12% of total service revenue for the year ended December 31, 2013. No other customers accounted for 10% or more of total service revenue for the years ended December 31, 2015, 2014 and 2013.

At December 31, 2015 Merck KGaA and Allergan accounted for 58% and 42% of the product segment accounts receivable, respectively. At December 31, 2014 Merck KGaA and Allergan accounted for 54% and 46% of the product segment accounts receivable, respectively. At December 31, 2015 one customer accounted for 18% of total service segment net accounts receivable. At December 31, 2014 two customers accounted for 18%

and 11% of total service segment accounts receivable. No other customers accounted for greater than 10% of the product or service segment accounts receivable.

Patent Expiration

Juniper is a pharmaceutical company focused on developing novel intra-vaginal therapeutics that address unmet medical needs in women's health. All of the Company's product sales are outside the United States. The patent for CRINONE has expired in all countries other than Argentina. This product accounts for approximately 59% of the Company's revenues and a higher percentage of gross profit.

Sources of Supply

The major raw materials the Company uses in our products and product candidates are polycarbophil and progesterone. Medical grade, cross-linked polycarbophil, the polymer used in our BDS-based product and product candidate is currently available from only one supplier, Lubrizol. We believe that Lubrizol will supply as much of the material as we require because our product ranks among the highest value-added uses of the polymer. In the event that Lubrizol cannot or will not supply enough polycarbophil to satisfy our needs, however, we will be required to seek alternative sources of supply.

Only one supplier of progesterone for CRINONE is approved by regulatory authorities outside the United States. Juniper has not experienced production delays due to shortages of progesterone. This supplier has notified the Company that it intends to materially increase the price for its progesterone and has requested that Juniper enters into a long-term supply agreement. It is unclear what impact, if any, an increase in the cost of progesterone will have on Juniper's financial results or Juniper's demand for CRINONE, or whether the Company would be able to obtain progesterone from an alternate supplier in a timely manner.

13. ***Quarterly Financial Information (Unaudited)***

The following table sets forth specific unaudited consolidated quarterly statement of operations data for the eight quarters ended December 31, 2015 (in thousands). This information is unaudited, but in the opinion of management, it has been prepared on the same basis as the audited consolidated financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to state fairly the unaudited consolidated quarterly results of operations. The results of operations for any quarter are not necessarily indicative of the results of operations for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2015				
Revenues	$8,326	$10,213	$11,455	$ 7,564
Gross profit	3,448	4,643	5,025	3,028
Operating expenses	4,279	4,976	4,156	5,244
(Loss) income from operations	(831)	(333)	869	(2,216)
Net (loss) income	(692)	(326)	953	(2,069)
(Loss) income per common share:				
Basic	$ (0.06)	$ (0.03)	$ 0.09	$ (0.19)
Diluted	$ (0.06)	$ (0.03)	$ 0.09	$ (0.19)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2014				
Revenues	$7,016	$6,654	$11,537	$7,259
Gross profit	2,744	2,785	6,437	2,811
Operating expenses	2,852	2,706	2,851	2,551
Income from operations	(108)	79	3,586	260
Change in fair value of common stock warrants	309	70	1	—
Net (loss) income	152	(10)	3,744	(494)
Income (loss) per common share:				
Basic	$ 0.01	$ (0.00)	$ 0.35	$ (0.05)
Diluted	$ (0.01)	$ (0.01)	$ 0.35	$ (0.05)

The explanations for major variances from the fourth quarters for the years ended December 31, 2015 and 2014 are:

1. In the fourth quarter of 2015, the Company increased personnel and temp labor as a VP of Business Development, and Two VP's of Product Development were hired.

2. In the fourth quarter of 2014, the Company recorded an income tax provision for approximately $0.9 million, associated with recording a valuation allowance of its net deferred tax assets in the United Kingdom jurisdiction.

EXHIBIT INDEX

Exhibit	Index Description of Exhibit
2.1	Purchase and Collaboration Agreement, dated March 3, 2010, by and between Juniper Pharmaceuticals, Inc. and Coventry Acquisition, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on March 4, 2010)
2.2	Share Purchase Agreement, dated September 2013, between the Sellers, Juniper Pharmaceuticals, Inc. and Juniper Pharma Services Limited (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on September 18, 2013)
2.3	Stock Purchase Agreement, dated March 6, 2014, by and between Juniper Pharmaceuticals, Inc. and Coventry Acquisition, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on March 7, 2014)
3.1	Restated Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2005, filed on March 13, 2006)
3.2	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on July 6, 2010)
3.3	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on August 8, 2013)
3.4	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on April 3, 2015)
3.5	Amended and Restated By-laws of Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on January 12, 2015)
3.6	Amendment No. 1 to the Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on April 3, 2015)
4.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock of the Company, dated as of January 7, 1999 (incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 1998, filed on March 25, 1999)
4.2*	Form of Option Agreement (incorporated by reference to Exhibit 4.10 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2008, filed on March 16, 2009)
4.3	Amended and Restated Rights Agreement by and between Juniper Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC dated January 28, 2015 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on January 30, 2015)
10.1*	1996 Long-term Performance Plan, as amended, of the Company (incorporated by reference to Annex A to the Registrant's Proxy Statement (File No. 001-10352), filed on May 10, 2000)
10.2*	Form of Restricted Stock Agreement under the 1996 Long-Term Performance Plan (incorporated by reference to Exhibit 10.62 of the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on May 17, 2006)

Exhibit	Index Description of Exhibit
10.3	License Agreement, dated April 18, 2000, between the Company and Lil' Drug Store Products, Inc. (incorporated by reference to Exhibit 10.23 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352) for the quarter ended March 31, 2000, filed on May 15, 2000)
10.4*	Form of Indemnification Agreement for Officers and Directors (incorporated by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2003, filed on March 15, 2004)
10.5	Packaging Agreement, dated October 28, 1993, between Juniper Pharmaceuticals (Ireland) Ltd. and Maropack AG (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2007, filed on March 28, 2008)
10.6*	Juniper Pharmaceuticals, Inc. Amended and Restated 2008 Long-Term Incentive Plan (incorporated by reference to Appendix B to the Registrant's Proxy Statement (File No. 001-10352), filed on March 22, 2013)
10.7*	Form of Award Agreement under the Amended and Restated 2008 Long-term Incentive Plan of Juniper Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-8 (File No. 333-18647), filed on May 16, 2013)
10.8*	Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-8 (File No. 333-205723), filed on July 17, 2015)
10.9*	Form of Nonqualified Stock Option Award Agreement under the Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352), filed on August 4, 2015)
10.10*	Form of Incentive Stock Option Award Agreement under the Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352), filed on August 4, 2015)
10.11*	Form of Restricted Stock Award Agreement under the Juniper Pharmaceuticals, Inc. 2015 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352), filed on August 4, 2015)
10.12*	Form of Executive Change of Control Severance Agreement (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2008, filed on March 16, 2009)
10.13	Manufacturing and Supply Agreement, dated December 8, 2009, between Fleet Laboratories and Juniper Pharmaceuticals (Bermuda), Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on December 9, 2009)
10.14	Note Purchase and Amendment Agreement, dated March 3, 2010, by and between Juniper Pharmaceuticals, Inc. and holders listed on Schedule I thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on March 4, 2010)
10.15*	Amended and Restated Employment Agreement, dated May 4, 2010, by and between Juniper Pharmaceuticals, Inc. and Frank C. Condella, Jr. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on May 5, 2010)
10.16*	Addendum to Amended and Restated Employment Agreement, dated March 1, 2011, by and between Juniper Pharmaceuticals, Inc., and Frank C. Condella, Jr. (incorporated by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K (File No. 001-10352) for the year ended December 31, 2010, filed on March 10, 2011)

Exhibit	Index Description of Exhibit
10.17	Second Amended and Restated License and Supply Agreement, dated May 14, 2010, between Juniper Pharmaceuticals, Inc. and Ares Trading S.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on May 18, 2010)
10.18	Amendment No. 1 to the Second Amended and Restated License and Supply Agreement, dated April 4, 2013, between Juniper Pharmaceuticals, Inc. and Ares Trading S.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on April 9, 2013)
10.19	Parent Guarantee of Juniper Pharmaceuticals, Inc., dated September 12, 2013 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on September 18, 2013)
10.20*	Employment Agreement, dated September 12, 2013, between Dr. Nikin Patel and Juniper Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on September 18, 2013)
10.21	Bank Loan Agreement, dated January 6, 2012, between Juniper Pharma Services Limited and Lloyds TSB Bank plc (incorporated by reference to Exhibit 10.3 the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352) for the quarter ended September 30, 2013, filed on November 7, 2013)
10.22	Amendment letter, dated September 16, 2013, between Juniper Pharma Services Limited and Lloyds TSB Bank plc (incorporated by reference to Exhibit 10.4 the Registrant's Quarterly Report on Form 10-Q (File No. 001-10352) for the quarter ended September 30, 2013, filed on November 7, 2013)
10.23	Amendment to Manufacturing and Supply Agreement, effective as of December 31, 2013, between Juniper Pharmaceuticals (Bermuda) Ltd., and Fleet Laboratories Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-10352), filed on February 6, 2014)
10.24*	Employment Agreement, dated September 23, 2014, by and between Juniper Pharmaceuticals, Inc. and George O. Elston (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (Filed No. 001-10352), filed on September 26, 2014)
10.25	Exclusive Patent License Agreement, dated as of March 27, 2015, by and between Juniper Pharmaceuticals, Inc. (f/k/a Columbia Laboratories, Inc.) and The General Hospital Corporation, d/b/a Massachusetts General Hospital (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (Filed No. 001-10352), filed on May 6, 2015)
10.26	Office Lease by and between T-C 33 Arch Street LLC and Juniper Pharmaceuticals, Inc. dated October 15, 2015 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (Filed No. 001-10352), filed on November 12, 2015)
21	Subsidiaries of the Company
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm
31(i).1	Certification of Chief Executive Officer of the Company
31(i).2	Certification of Chief Financial Officer of the Company
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Exhibit	Index Description of Exhibit
101	The following materials from the Juniper Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets at December 31, 2015 and December 31, 2014, (ii) Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013, (iii) Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2015, 2014 and 2013, (iv) Consolidated Statements of Shareholders' Equity for the years ended December 31, 2015, 2014 and 2013, (v) Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013, and (vi) Notes to Consolidated Financial Statements.
†	Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
*	Management contract or compensatory plans or arrangements

Exhibit 21

Subsidiaries of the Company

Columbia Laboratories (Bermuda) Ltd.

Juniper Pharmaceuticals (France) SA

Juniper Pharmaceuticals (UK) Limited

Juniper Pharma Services Limited (UK)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Juniper Pharmaceuticals, Inc.
Boston, Massachusetts

We hereby consent to the incorporation by reference in the Registration Statement on Forms S-3 (Nos. 333-206928, 333-169599, 333-75275, 333-125671, 333-132803, 333-140107, and 333-37976) and Forms S-8 (Nos. 333-152008, 333-188647 and 333-205723) of Juniper Pharmaceuticals, Inc. (formerly Columbia Laboratories, Inc.) of our report dated March 10, 2016, relating to the consolidated financial statements which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP
Boston, Massachusetts

March 10, 2016

Exhibit 31(i).1

Certification Pursuant to Rule 13a-14(a)/15d-14(a)
of the Securities Exchange Act of 1934

I, Frank C. Condella, Jr. certify that:

1. I have reviewed this Annual Report on Form 10-K of Juniper Pharmaceuticals, 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 periods 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 function):

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.

/s/ Frank C. Condella Jr.

Frank C. Condella Jr.
President and Chief Executive Officer
(Principal Executive Officer)
DATE: March 10, 2016

Exhibit 31(i).2

Certification Pursuant to Rule 13a-14(a)/15d-14(a)
of the Securities Exchange Act of 1934

I, George O. Elston, certify that:

1. I have reviewed this Annual Report on Form 10-K of Juniper Pharmaceuticals, 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 periods 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 function):

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.

/s/ George O. Elston

George O. Elston
Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)
DATE: March 10, 2016

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Juniper Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Frank C. Condella, Jr., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ Frank C. Condella, Jr.

Frank C. Condella, Jr.
President and Chief Executive Officer
(Principal Executive Officer)
Date: March 10, 2016

Exhibit 32.2

Certification Pursuant to
18 U.S.C. Section 1350
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Juniper Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George O. Elston, Vice President, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

/s/ George O. Elston

George O. Elston
Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)
DATE: March 10, 2016

Board of Directors

James A. Geraghty
Chairman of the Board

Dr. Frank M. Armstrong
Director

Frank C. Condella, Jr.[1]
President and Chief Executive Officer, Juniper Pharmaceuticals, Inc.

Dr. Cristina Csimma
Director

Dr. Mary Ann Gray
President, Gray Strategic Advisors LLC

Ann Merrifield
Director

Dr. Nikin Patel
Chief Operating Officer, Juniper Pharmaceuticals, Inc.

Advisor to the Board

Dr. Martyn Davies
Professor of Biomedical Surface Chemistry, University of Nottingham

Corporate Officers

Frank C. Condella, Jr. [1]
President and Chief Executive Officer

Dr. Nikin Patel
Chief Operating Officer

George O. Elston
Chief Financial Officer, Treasurer and Secretary

Dr. Bridget Martell
Chief Medical Officer

Scientific Advisory Board

Dr. Martyn Davies, Chair
University of Nottingham

Dr. Ginger D. Constantine
Former VP of Women's Health & Bone Repair Medical Research, Wyeth Research

Dr. William F. Crowley, Jr.
Massachusetts General Hospital / Harvard Medical School

Dr. Linda Giudice
University of California, San Francisco, School of Medicine

Dr. Robert S. Langer
Massachusetts Institute of Technology

Dr. Marilyn Mann
Past Deputy Director, FDA Division of Reproductive and Urologic Drug Products

Corporate Headquarters

Juniper Pharmaceuticals, Inc.
33 Arch Street, Suite 3110
Boston, MA 02110
(617) 639-1500 (phone)
(866) 566-5636 (toll-free)

http://www.juniperpharma.com

Independent Auditors

BDO USA, LLP[2]
Boston, MA 02110

Registrar and Stock Transfer

American Stock Transfer & Trust Company, LLC
59 Maiden Lane
New York, New York 10038
(800) 937-5449 (toll-free)

2016 Annual Meeting of Stockholders

The 2016 annual meeting of stockholders will be held Wednesday, July 27, 2016 at 9:00 am EDT at The Godfrey Hotel, 505 Washington Street, Boston, MA 02111. The record date for the meeting will be June 13, 2016.

Stockholder Inquiries

Questions regarding stock transfer requirements, lost certificates, and changes of address should be directed to the transfer agent listed herein. Other stockholder or investor inquiries, including requests for our filings with the SEC, investor packets, or other inquiries, should be directed to George Elston, CFO, at the Company's headquarters or by email at IR@juniperpharma.com.

Securities and Related Information

Juniper's Common Stock trades on the Nasdaq Global Select Market under the ticker symbol "JNP". It traded on the Nasdaq National Market from Apr. 13, 2015 to Oct. 20, 2015 under "JNP" and, prior to the Company's name change, from Feb. 13, 2004 to Apr. 13, 2015 under the symbol "CBRX". It previously traded on the American Stock Exchange under the symbol "COB".

Dividend Policy

The Company has never declared or paid a cash dividend on its Common Stock, and expects that its earnings will continue to be retained for use in operating and growing its business for the foreseeable future.

(1) Mr. Condella intends to retire as Juniper's President and CEO when his successor is appointed.
(2) BDO USA, LLP conducted the audit of the Company's accounts for the fiscal years ending December 31, 2015 and 2014. The Audit Committee has selected PricewaterhouseCoopers LLP, as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2016, and the Board is asking stockholders to ratify that selection at the 2016 Annual Meeting of Stockholders.

Safe Harbor Statement

This annual report contain forward-looking statements regarding Juniper Pharmaceuticals' strategic direction, prospects and future results, which statements are indicated by the words "may," "will," "plans," "believes," "expects," "potential," "should," and similar expressions. These include all statements relating to expected financial performance and future business or product developments. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. These statements are based on management's current expectations and Juniper Pharmaceuticals does not undertake any responsibility to revise or update any forward-looking statements contained herein, except as expressly required by law. For a discussion of certain risks and uncertainties associated with Juniper Pharmaceuticals' forward-looking statements, please review Juniper Pharmaceuticals' reports filed with the SEC, including, but not limited to, its Annual Report on Form 10-K for the period ended December 31, 2015 and Quarterly Report on Form 10-Q for the period ended March 31, 2016.

Juniper Pharmaceuticals, Inc.
(Nasdaq: JNP)
33 Arch Street, Suite 3110
Boston, MA 02110
(617) 639-1500 (phone)
(866) 566-5636 (toll-free)

http://www.juniperpharma.com