FORM 10-K

BIODELIVERY SCIENCES INTERNATIONAL INC - BDSI

Filed: March 10, 2016 (period: December 31, 2015)

Annual report with a comprehensive overview of the company

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

☐ **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 001-31361

BioDelivery Sciences International, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4131 ParkLake Avenue, Suite #225 Raleigh, NC	**27612**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number: 919-582-9050

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

Title of each class	Name of exchange on which registered
Common stock, par value $.001	**Nasdaq Capital Market**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 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 definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2015 was approximately $294,870,280 based on the closing sale price of the company's common stock on such date of $7.96 per share, as reported by the NASDAQ Capital Market.

As of March 7, 2016, there were 53,482,697 shares of company common stock issued and 53,467,206 shares of company common stock outstanding.

BioDelivery Sciences International, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2015

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Unless we have indicated otherwise, or the context otherwise requires, references in this Report to "BDSI," the "Company," "we," "us" and "our" or similar terms refer to BioDelivery Sciences International, Inc., a Delaware corporation and its consolidated subsidiaries.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report and the documents we have filed with the Securities and Exchange Commission (which we refer to herein as the SEC) that are incorporated by reference herein contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (or the Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (or the Exchange Act), that involve significant risks and uncertainties. Any statements contained, or incorporated by reference, in this Report that are not statements of historical fact may be forward-looking statements. When we use the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements.

A variety of factors, some of which are outside our control, may cause our operating results to fluctuate significantly. They include:

- our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® (as defined below) drug delivery technology platform and any of our approved products or product candidates;
- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including: (i) the timing, status and results of our or our commercial partners' filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies, including regulatory review thereof and (ii) the heavily regulated industry in which we operate our business generally;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates;
- our ability, or the ability of our commercial partners, to actually develop, commercialize, manufacture or distribute our products and product candidates, including for BUNAVAIL®, which is the first product we are self-commercializing;
- our ability to generate commercially viable products and the market acceptance of our BEMA® technology platform and our proposed products and product candidates;
- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- our expectations about the potential market sizes and market participation potential for our approved or proposed products;
- the protection and control afforded by our patents or other intellectual property, and any interest patents or other intellectual property that we license, of our or our partners' ability to enforce our rights under such owned or licensed patents or other intellectual property;
- the outcome of ongoing or potential future litigation (and related activities, including inter partes reviews and inter partes reexaminations) or other claims or disputes relating to our business, technologies, patents, products or processes;
- our expected revenues (including sales, milestone payments and royalty revenues) from our products or product candidates and any related commercial agreements of ours;
- the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to address any regulatory issues that have arisen or may in the future arise;
- our ability to retain members of our management team and our employees; and
- competition existing today or that will likely arise in the future.

The foregoing does not represent an exhaustive list of risks that may impact the forward-looking statements used herein or in the documents incorporated by reference herein. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance and related forward-looking statements.

Moreover, new risks regularly emerge and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Report are based on information available to us on the date hereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Report and the documents we have filed with the SEC.

PART I

Item 1. Description of Business.

Overview

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of approved therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. We have developed and are continuing to develop pharmaceutical products aimed principally in the areas of pain management and addiction. We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002.

Our approved products utilize the novel, patent protected and proprietary *BioErodible MucoAdhesive* (or BEMA®) drug delivery technology, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek). Our first U.S. Food and Drug Administration (which we refer to as the FDA) approved product, ONSOLIS® (fentanyl buccal soluble film), as well as our approved products BUNAVAIL® (buprenorphine and naloxone) buccal film and BELBUCA™ (buprenorphine) buccal film, utilize our BEMA® technology.

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we have licensed, and will continue to seek to acquire or license, additional drug delivery technologies or drugs utilizing the delivery or other technologies of other companies. Clonidine Topical Gel, which we licensed from Arcion Therapeutics (or Arcion) in 2013, and our 2015 agreement with Evonik Corporation (or Evonik) to develop a buprenorphine depot injection formulation, do not utilize the BEMA® technology and allowed us to diversify our portfolio while maintaining a focus in pain and addiction. As we gain access to such technologies, we seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace.

Our current development strategy focuses primarily on our ability to utilize the FDA's 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into our drug delivery technology. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and expeditious and have less regulatory approval risk than other FDA approval approaches.

An overview of our approved products and key products in development is set out below:

BUNAVAIL® (buprenorphine and naloxone) buccal film

We believe that the widespread use of buprenorphine for the treatment of opioid dependence and the need for improved means of delivery to address existing administration challenges present an important commercial opportunity. Therefore, we developed a BEMA® formulation of buprenorphine and naloxone specifically for the treatment of opioid dependence. The product combines a "high dose" of buprenorphine along with an abuse deterrent agent, naloxone. BUNAVAIL® provides us with an opportunity to compete in the growing opioid dependence market which, according to Symphony Health, exceeded $2.0 billion in sales in the U.S in 2015.

In September 2012, we announced the positive outcome of the pivotal pharmacokinetic study comparing BUNAVAIL® to Suboxone® sublingual tablets. The study was designed to compare the relative bioavailability of buprenorphine and naloxone between BUNAVAIL® and the reference product, Suboxone® tablets. The results demonstrated that the two key pharmacokinetic parameters, maximum drug plasma concentration (Cmax) and total drug exposure (AUC), for buprenorphine were comparable to Suboxone® sublingual tablet, and that the same parameters for naloxone were similar or less than Suboxone® tablet. This was followed by initiation of the safety study requested by FDA, assessing the safety and tolerability of BUNAVAIL® in patients converted from a stable dose of Suboxone® (buprenorphine and naloxone) sublingual tablets or films. A total of 249 patients were enrolled in the study, (191 patients completed) which completed in December 2012. Results of the study showed a very favorable safety and tolerability profile along with strong study subject retention and high dose form acceptability ratings. Data showed that over 91% of patients who switched from Suboxone® film or tablets considered the taste of BUNAVAIL® to be very pleasant, pleasant or neutral and over 82% rated the ease of use of BUNAVAIL® as very easy, easy or neutral. The study also showed a decrease in the incidence of constipation symptoms from 41% at baseline, before conversion of patients from Suboxone tablets or films to BUNAVAIL®, to 13% following 12 weeks of treatment with BUNAVAIL®.

On July 31, 2013, we submitted the NDA for BUNAVAIL® to the FDA for review, and on June 6, 2014, we announced the FDA approval of BUNAVAIL® for the maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support.

Following thorough review and analysis of a variety of commercialization strategies, which included entertaining commercial partnerships, a decision was made to commercialize BUNAVAIL® utilizing both internal and external resources. In March 2014, we announced we had entered into an agreement with Quintiles to support the launch and commercialization of BUNAVAIL®. Under terms of the agreement, Quintiles provides a range of services to support the commercialization of BUNAVAIL® in the U.S., including recruiting and training a field sales force. Separately, we entered into an agreement with Ashfield Market Access to provide managed markets and trade support for BUNAVAIL®. Ashfield Market Access, which is led by industry veterans including those who led GlaxoSmithKline's managed markets group for more than 20 years, took responsibility for executing a payer strategy aimed at maximizing patient access to BUNAVAIL®.

On November 3, 2014, we announced the availability of BUNAVAIL® in the U.S. where it is being supported by a 65-person field sales force and a full marketing effort targeting the nearly 5,000 physicians who, according to Symphony Health, are responsible for approximately 90% of prescriptions for buprenorphine products for the treatment of opioid dependence.

Through the end of 2015, over 79,000 prescriptions were dispensed for BUNAVAIL®. Prescription sales for BUNAVAIL® increased steadily quarter over quarter throughout 2015. Importantly, we were granted a contract which initiated on October 1, 2015 which provided exclusive preferred formulary status for BUNAVAIL® for Medicaid patients in the state of Tennessee. This contributed to growth from the third to fourth quarter of 2015 of 66% as patients on other buprenorphine-containing products switched to BUNAVAIL®.

BELBUCA™ (buprenorphine) buccal film for Chronic Pain

BELBUCA™ is a partial mu-opioid agonist and a treatment indicated for the management of pain severe enough to require daily, around the clock, long-term opioid treatment for which alternative treatment options are inadequate. As described further below, our commercial partner, Endo Pharmaceuticals Inc. (or Endo), received approval of the New Drug Application (or NDA) for BELBUCA™ on October 23, 2015.

In September 2011, we announced that a Phase 3 efficacy study of BELBUCA™ that we conduced failed to meet its primary endpoint, but that overall results from the study supported continued development of the product. In January 2012, we announced the signing of a worldwide licensing and development agreement for BELBUCA™ (which we refer to herein as the Endo Agreement) with Endo under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BELBUCA™ for the treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront, non-refundable license fee, which we received in January 2012; (ii) $95 million in milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events (which we have received following receipt of a $50 million milestone payment associated with the FDA approval of BELBUCA™); (iii) $55 million in potential sales threshold payments upon achievement of designated sales levels; and (iv) a tiered, mid- to upper-teen royalty on net sales of BELBUCA™ in the United States and a mid- to high-single digit royalty on net sales of BELBUCA™ outside the United States. Endo is one of the premier companies in the area of pain management and has demonstrated significant achievements in the pain space, particularly with the development, launch and commercialization of a portfolio of pain therapeutics including Opana® ER, Lidoderm®, Percocet® and Voltaren® Gel. We believe BELBUCA™ is an excellent fit with Endo's pain portfolio and adds a Schedule III opioid to their pain franchise. BELBUCA™ complements Endo's pain therapeutics portfolio providing the company with an opportunity to offer a "ladder" of pain products, aligned with pain severity and opioid scheduling. In particular, BELBUCA™ is well aligned with the needs of pain specialists and primary care physicians who seek an alternative to Schedule II opioids for the treatment of moderate to severe chronic pain that is not adequately controlled with commonly prescribed first-line therapies (e.g., short acting opioids).

One of the key intellectual property milestones under our Endo Agreement was achieved in February 2012, when the U.S. Patent and Trademark Office (or USPTO) issued a Notice of Allowance regarding one of our patent applications (No. 13/184306) which, once the patent was granted in April 2012, extended the exclusivity of the BEMA® drug delivery technology for BELBUCA™ (as well as BUNAVAIL®, as discussed below) from 2020 to 2027. As a result, we received a milestone payment from Endo in the amount of $15 million in May 2012, and also related to the issuance of the patent, received an additional milestone payment of $20 million paid at the time of approval of the NDA by the FDA for BELBUCA™ for the treatment of chronic pain, resulting in a total milestone payment at FDA approval of $50 million. Such amounts are included in the aforementioned $95 million in potential milestone payments based on intellectual property and clinical development and regulatory events. The aforementioned $20 million patent-related payment has been deferred for future revenue recognition and will be earned over the extended patent period from 2020 to 2027 as the payment is contingently refundable in the event a generic product is commercially launched during the patent extension period. In May 2012, in close collaboration with Endo, we initiated two Phase 3 clinical studies – one in opioid naïve and one in opioid experienced populations. The Phase 3 clinical trials were enriched-enrollment, double-blind, randomized withdrawal studies to evaluate the efficacy and safety of BELBUCA™ in the treatment of chronic lower back pain in opioid naive and opioid experienced populations. Patients titrated to a well-tolerated, effective dose were randomized to either continue on that dose of BELBUCA™, or receive placebo (BEMA® film with no active drug), with treatment continuing for 12 weeks. The primary efficacy endpoint was the mean change in the daily average pain numerical rating scale (NRS-Pain) scores from baseline (just prior to randomization) to week twelve of the double-blind treatment period. Pain was self-reported daily on an 11-point numeric rating scale (daily NRS; 0=no pain, 10=worst possible pain).

On January 23, 2014, we announced with Endo positive top-line results from the Phase 3 efficacy study of BELBUCA™ in opioid-"naïve" subjects. The trial successfully met its primary efficacy endpoint in demonstrating that BELBUCA™ resulted in significantly (p=0.0012) improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BELBUCA™ compared to placebo. The most commonly reported adverse events in patients treated with BELBUCA™ compared to placebo during the double blind portion of the study were nausea (10% vs. 7%, respectively), vomiting (4% vs. <1%, respectively) and constipation (4% vs. 3%, respectively). The locking of the database for the opioid naïve study triggered a $10 million milestone payment from Endo per the terms of the license agreement, which we received in February 2014.

On July 7, 2014, we announced with Endo positive top-line results from the Phase 3 efficacy study of BELBUCA™ in opioid-"experienced" subjects. The trial successfully met its primary efficacy endpoint in demonstrating that BELBUCA™ resulted in significantly (p<0.00001) improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BELBUCA™ compared to placebo. The most commonly reported adverse events in patients treated with BELBUCA™ compared to placebo were nausea (7% vs. 7%, respectively), vomiting (5% vs. 2%, respectively) and constipation (3% vs. 1%, respectively). Locking of the database for the opioid experienced study triggered an additional $10 million milestone payment from Endo per the terms of the license agreement, which we received July 2014.

On December 23, 2014, we and Endo announced the NDA submission for BELBUCA™, which was accepted by FDA in February 2015. Acceptance of the filing of the NDA by FDA triggered and we received an additional $10 million milestone payment from Endo.

On October 26, 2015, we and Endo announced the FDA approval of BELBUCA™ for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The approval of BELBUCA™ was based on the two double-blind, placebo-controlled, enriched-enrollment Phase 3 studies. A total of 1,559 opioid experienced (study BUP-307) and opioid naïve (BUP-308) patients received study drug. In both studies, BELBUCA™ demonstrated a consistent, statistically significant improvement in patient-reported pain relief at every week from baseline to week 12, compared to placebo. BELBUCA™ is available in seven dose strengths, allowing for flexible dosing ranging from 75 mcg to 900 mcg every 12 hours. This enables physicians to individualize titration and treatment based on the optimally effective and tolerable dose for each patient. The FDA's approval of BELBUCA™ triggered a milestone payment to us from Endo of $50 million, of which $20 million has been deferred for future revenue recognition. BELBUCA™ became commercially available from Endo in February 2016 and is supported by a competitively sized sales force and a related marketing effort.

ONSOLIS® (fentanyl buccal soluble film)

On July 16, 2009, we announced the U.S. approval of our first product, ONSOLIS® (fentanyl buccal soluble film). ONSOLIS® is indicated for the treatment of breakthrough pain (i.e., pain that "breaks through" the effects of other medications being used to control persistent pain) in opioid tolerant patients with cancer. In May 2010, regulatory approvals were granted for Canada, and in October 2010, approval was obtained in the European Union (which we refer to herein as E.U.) through the E.U.'s Decentralized Procedure, with Germany acting as the reference member state. ONSOLIS® is marketed in Europe under the trade-name BREAKYL™.

The FDA approval of ONSOLIS®, together with our satisfactory preparation of launch supplies of ONSOLIS®, triggered the payment to us by our commercial partner, Meda AB, a leading international specialty pharmaceutical company based in Sweden (which we refer to herein as Meda), of approval milestones aggregating $26.8 million. The first national approval of BREAKYL™ in the E.U. resulted in a milestone payment of $2.5 million from Meda. A second milestone payment of $2.5 million was subsequently realized at the time of first commercial sale in the E.U. in October 2012. We began receiving royalties from Meda on net sales of ONSOLIS® in the U.S. and Canada following launch and from BREAKYL™ following launch in the E.U. Our royalty revenue from this product remains below original projections due to certain regulatory conditions in the U.S., which are discussed below.

We granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Meda's U.S. subsidiary, Meda Pharmaceuticals, based in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets and sells branded prescription therapeutics. Meda secured access to additional markets through acquisition of European businesses from Valeant Pharmaceuticals International, Inc.

In 2010, we secured commercialization rights for ONSOLIS® for the remaining worldwide territories through execution of licensing agreements with KUNWHA Pharmaceutical Co., Ltd. (or Kunwha), for South Korea and TTY Biopharm Co., Ltd. (or TTY) for Taiwan where the product will be marketed as PAINKYL™. The Kunwha License Agreement was terminated on August 31, 2015.

Although we have generated licensing-related and other revenue to date from the commercial sales of an approved product — ONSOLIS®/BREAKYL™/PAINKYL™ — such revenue has been minimal to date due to multiple factors, including a highly restrictive Risk Evaluation and Mitigation Strategy (REMS) imposed by the FDA and certain formulation issues described below. The lack of approved REMS programs for our direct competitors resulted in an un-level playing field, which created an unfavorable selling environment for ONSOLIS® into 2012. In the E.U., BREAKYL™ was launched on a country by country basis starting in the fourth quarter of 2012 and continues to be sold by Meda. PAINKYL™ was launched by TTY during 2015.

On December 29, 2011, the FDA approved a "class-wide" REMS program covering all transmucosal fentanyl products under a single risk management program. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The TIRF REMS program was implemented in March 2012. The approved program covers all marketed transmucosal fentanyl products under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program also ended the disparity in prescribing requirements for ONSOLIS® compared to similar products and provided ONSOLIS® with the opportunity for retail and inpatient facility access.

On March 12, 2012, we announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide REMS until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, raised by the FDA during an inspection of our North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. (or Aveva) which is now a subsidiary of Apotex (or Apotex). While the appearance issues did not affect the product's underlying integrity, safety or performance, the FDA believed that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of ONSOLIS® was found to be specific to a buffer used in its formulation. In August 13, 2015 we announced approval by FDA of a Supplemental New Drug Application (sNDA) for a new formulation of ONSOLIS®.

On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Meda to return to us the marketing authorizations for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. We modified the formulation and submitted a prior approval supplement that responded to FDA questions and led to approval of the new formulation of ONSOLIS® in August 2015. We plan to relaunch ONSOLIS® upon completion of transfer of manufacturing to our new supplier and the securing of a U.S. partner. As of the date of this Report, we are working to complete such manufacturing transfer and partnering discussions are ongoing.

Clonidine Topical Gel

In March 2013, we announced our entry into a worldwide Exclusive License Agreement (which we refer to as the Arcion Agreement) with privately held Arcion, under which we will develop and commercialize Clonidine Topical Gel (formerly ARC4558) for the treatment of painful diabetic neuropathy (or PDN) and potentially other indications. Under the terms of the agreement, we made an upfront payment of $2 million to Arcion in the form of unregistered shares of our common stock. Additional financial terms of the licensing agreement include a milestone payment to Arcion of $2.5 million in unregistered shares of our common stock upon acceptance by the FDA of a NDA for Clonidine Topical Gel and a cash payment to Arcion of between $17.5 and $35 million upon NDA approval, depending on certain regulatory and commercial considerations. In addition, the licensing agreement includes sales milestones and low single-digit royalties on net worldwide sales.

We believe that the PDN market is highly under-served by existing products and therefore there is a strong scientific rationale for developing a topical treatment for PDN that delivers analgesia in a way that avoids systemic side effects. Evidence has shown that clonidine stimulates an inhibitory receptor in the skin associated with pain fibers. Arcion has assessed its effectiveness in reducing pain in PDN in a double-blind, placebo-controlled, Phase 2 study where the primary study endpoint was the change in pain intensity over a 3 month treatment period in diabetic foot pain. A significant treatment difference was seen in the planned subset analysis of diabetic patients who had documented evidence of "functioning pain receptors" in the skin of the lower leg (p=0.01, n=63) thus, at a minimum, supporting the effectiveness of topical clonidine in diabetic patients with functioning pain receptors of the skin. In the overall population that included patients without "functioning nerve receptors", there was a trend favoring topical Clonidine Topical Gel (p=0.07, n= 182), though the overall results did not reach statistical significance.

Oral medications that are approved for the treatment of PDN include anticonvulsants such as Lyrica (pregabalin), the antidepressant Cymbalta® (duloxetine) and the opioid Nucynta® ER (tapentadol ER), with sales for the treatment of neuropathic pain totaling over $3 billion in the U.S. according to Datamonitor. These treatments are modestly effective in relieving symptoms and their use can be limited by adverse effects and drug interactions.

We met with representatives of the FDA on November 21, 2013 to discuss the development program for Clonidine Topical Gel for the treatment of PDN. The FDA agreed with the proposed clinical program which included two placebo-controlled studies and one long term safety study in patients suffering from painful diabetic neuropathy, the number of treated subjects required for the safety assessment and the plan for data integration of previously performed and planned clinical studies. The discussion provided us with the input and clarity needed to move the program directly to Phase 3. It also appears that the FDA recognizes the need for new treatment options for PDN by confirming Fast Track designation for the program that could potentially lead to a priority review.

In early April 2014, we announced enrollment of the first patient in the Phase 3 clinical study of Clonidine Topical Gel for PDN, and in early August 2014, we announced that we completed a pre-specified interim analysis of the study. The interim analysis was performed on data from the first 50% of patients who completed the study. The purpose of the interim analysis was to allow for a

sample size adjustment if necessary to maintain appropriate statistical power to detect a treatment effect between Clonidine Topical Gel and placebo. As a result of the interim analysis, a total of approximately 80 additional patients were to be added to the trial in an effort to maintain 90% percent power to detect a statistically significant difference between Clonidine Topical Gel and placebo. The analysis was conducted by an independent biostatistician.

In March 2015, we announced that the primary efficacy endpoint in the Phase 3 study of Clonidine Topical Gel compared to placebo did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement (n=158; $p<0.02$) in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, we initiated a second study. Such study incorporates significant learnings from previously conducted studies and involves tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. The final study subject is expected to complete treatment by the end of 2016.

Buprenorphine Depot Injection

In 2014, we entered into an exclusive agreement with Evonik to develop and commercialize a proprietary, injectable microparticle formulation of buprenorphine potentially capable of providing 30 days of continuous therapy following a single subcutaneous injection. Microsphere-based, long acting, buprenorphine injectable depot has the ability to change the treatment paradigm in opioid dependence. Such a dosage form has the opportunity to improve therapy compliance through continuous delivery of drug for up to 30 days and addresses challenges regarding patient adherence to long-term buprenorphine treatment, which is critical to successfully manage opioid dependence and the potential for misuse and diversion.

While we plan to pursue an indication for the maintenance treatment of opioid dependence, we have also secured the rights and plans to develop a product for the treatment of chronic pain in patients requiring continuous opioid therapy. As part of the agreement, we will have the right to license the product(s) following the attainment of Phase 1 ready formulations. At that point, Evonik could receive downstream payments for milestones related to regulatory filings and subsequent NDA approvals as well as product royalties. Evonik has the exclusive rights to develop the formulation and manufacture the product(s).

In 2015, we completed initial development work and preclinical studies which have resulted in the identification of a formulation we believe is capable of providing 30 days of continuous buprenorphine treatment. During a pre-IND meeting with FDA in November 2015, FDA requested an additional study to assess the fate of the polymers used in the formulation. Upon completion of the study, we plan to submit an Investigational New Drug application (or IND) for this product candidate to FDA in the third quarter of 2016.

Additional Overview Information

From our inception through December 31, 2015, we have recorded accumulated losses totaling approximately $243.2 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for our product candidates, our goal will be to augment our current sources of revenue and, as applicable, deferred revenue (principally licensing fees), with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- commercializing our approved products such as BUNAVAIL®;
- partnering with other pharmaceutical companies such as Endo and Meda to assist in the distribution of our products like BELBUCA™ and ONSOLIS®, for which we would expect to receive an upfront payment, milestones and royalty payments; and
- securing proceeds from public and private financings and other strategic transactions.

We have based our estimates of development costs, market size estimates, peak annual sales projections and similar matters described below and elsewhere in this Report on our market research, third party reports and publicly available information which we consider reliable. However, readers are advised that the projected dates for filing and approval of our INDs or NDAs with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding BUNAVAIL®, BELBUCA™, ONSOLIS®, Clonidine Topical Gel, Buprenorphine Depot Injection or any other product candidates discussed below and elsewhere in this Report are merely estimates and subject to many factors, many of which may be beyond our control, which will likely cause us to revise such estimates. Readers are also advised that our projected sales figures do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our management's reasonable judgments given the information available and their previous experiences, although such estimates may not prove to be accurate.

The BEMA® Drug Delivery Technology

Our BEMA® drug delivery technology consists of a small, bi-layered erodible polymer film for application to the buccal mucosa (the lining inside the cheek). BEMA® films have the capability to deliver a rapid, reliable dose of drug across the buccal mucosa for time-critical conditions such as "breakthrough" cancer pain or in situations where gastrointestinal absorption of an oral drug is not practical or reliable, or in facilitating the administration of drugs with poor oral bioavailability.

We believe that the BEMA® technology permits control of two critical factors allowing for better dose-to-dose reproducibility: (i) the contact area for mucosal drug delivery, and (ii) the time the drug is in contact with that area, known as residence time. In contrast to competing transmucosal delivery systems like lozenges, buccal tablets and matrix-based delivery systems placed under the tongue or sprayed in the oral cavity, BEMA® products are designed to:

- adhere to buccal mucosa in seconds and dissolve in minutes;
- permit absorption without patients being required to move the product around in the mouth for absorption, thus avoiding patient intervariability;
- provide a reproducible delivery rate, not susceptible to varying or intermittent contact with oral membranes; and
- dissolve completely, leaving no residual product or waste and avoiding patient removal, and the possibility for diversion or disposal of partially used product.

We currently own the BEMA® drug delivery technology. We previously licensed the BEMA® drug delivery technology on an exclusive basis from Atrix Laboratories (previously known as QLT USA, Inc., now known as TOLMAR Therapeutics, Inc., which we refer to herein as Tolmar).

Overview of "Specialty Pharmaceuticals" and the 505(b)(2) Regulatory Pathway

Our corporate focus is "specialty pharmaceuticals" with characteristics that provide substantial points of differentiation from existing products. Our product portfolio is based on the application of drug delivery technologies and/or new dosage forms/indications to existing drugs for the creation of novel products. We then seek proprietary protection and FDA approval, and subsequently commercialize these products ourselves or through partners. We believe that research and development efforts focused on novel dose forms of FDA approved drugs is less risky than attempting to discover new drugs, sometimes called new chemical entities (known as NCEs). Our corporate focus came to initial fruition with the FDA's approval of ONSOLIS® (fentanyl buccal soluble film) in 2009 and was replicated in 2014 with the approval of BUNAVAIL® (buprenorphine and naloxone) buccal film and again in 2015 with the approval of BELBUCA™ (buprenorphine) buccal film. It is our goal to replicate this success with our current product candidates, and to identify new product candidates suitable for this development strategy that would add significant commercial value to us.

An important part of our strategy is the utilization of FDA's 505(b)(2) NDA process for approval. Under the 505(b)(2) process, we are able to seek FDA approval of a new dosage form, dosage regimen or new indication of an FDA approved drug. This regulation enables us to partially rely on the FDA's previous findings of safety and effectiveness for the drug, including clinical and nonclinical testing, and thereby reduce, although not eliminate, the need to engage in these costly and time consuming activities. A typical development program for a 505(b)(2) submission will include:

- single and multiple dose toxicity studies in a single species of animals,
- pharmacokinetic evaluation of the new dosage form in humans,
- stability data on the drug substance,
- description of drug product components and formulation,
- description and validation of manufacturing process,
- one year stability data on three commercial scale batches of drug product, and
- depending on the drug product, may include:
  - (i) one or more placebo controlled clinical studies in humans to establish the efficacy of the product, and/or
  - (ii) a long term clinical study to establish the safety of the product in the intended patient population.

This drug development and regulatory approval process is less extensive and lengthy than for a NCE and, as a result, we believe, is a more cost effective way to bring new product candidates to market.

We have and intend to continue to target markets with unmet needs and new dosage forms of known drugs. As a result of employing well known drugs in novel technologies or new dosage forms/indications, we believe health care providers will be familiar with the drugs and accustomed to prescribing them. As with ONSOLIS®, BELBUCA™, and BUNAVAIL® our drug candidates have been through the regulatory process with safety and efficacy established for an indication, a formulation and a dose range. Consequently, our clinical trials need to demonstrate the safety and efficacy of our products in the chosen patient population

Endo Licensing Agreement for BELBUCA™

On January 6, 2012, we announced the signing of a world-wide licensing and development agreement for BELBUCA™ with Endo. Under terms of the agreement, Endo is responsible for the manufacturing, distribution, marketing and sales of BELBUCA™ on a worldwide basis. Endo will commercialize BELBUCA™ outside the U.S. through its own efforts or through regional partnerships. In the U.S., both companies collaborated on the planning and finalization of the Phase 3 clinical development program and regulatory strategy for BELBUCA™ for chronic pain. On October 23, 2015 the FDA approved BELBUCA™ for licensing in the United States.

In aggregate, the agreement is worth up to $180 million to us if all milestones or thresholds are met, which includes an upfront non-refundable license fee of $30 million (received January 2012), as well as intellectual property, development, regulatory and commercial milestone and sales threshold payments. Additionally, we will receive a tiered mid to upper teen royalty on U.S. net sales of BELBUCA™ and a tiered mid to upper single-digit royalty on sales outside the U.S. One of the key intellectual property milestones under our Endo Agreement was achieved when, in April 2012, the USPTO granted US Patent No. 8,147,866 (issued from US Patent Application No. 13/184,306), which will extend the exclusivity of the BEMA® drug delivery technology for BELBUCA™ (as well as BUNAVAIL® discussed below) from 2020 to 2027. As a result (and included in the aforementioned $180 million if all milestones or thresholds are met), we received a milestone payment in the amount of $15 million in May 2012, and also received an additional milestone payment of $20 million which was paid at the time of approval of a NDA by the FDA for BELBUCA™. The aforementioned $20 million patent-related payment will be earned over the extended patent period from 2020 to 2027. Additionally, we achieved another milestone with the locking of the database for our Phase 3 opioid naive clinical study on January 17, 2014. For the achievement of this milestone, per the terms of the agreement, we were due a milestone payment in the amount of $10 million, which was received February 2014 (which is included in the aforementioned $180 million if all milestones or thresholds are met) within thirty (30) days of the database lock. On June 25, 2014, the database for the pivotal Phase 3 efficacy study of BELBUCA™ in opioid-experienced patients was locked. The locking of the database triggered a $10 million milestone payment from Endo, which was received July 2014. On December 23, 2014, we and Endo announced the submission of a NDA for BELBUCA™ to the FDA, which was accepted February 23, 2015, which triggered a $10 million milestone payment due from Endo to us. As stated above, on October 23, 2015 the FDA approved BELBUCA™ for licensing in the United States, which we announced on October 26, 2015. The FDA's approval of BELBUCA™ triggered a milestone payment to us from Endo of $50 million, of which $20 million has been deferred for future revenue recognition as the payment is contingently refundable in the event a generic product is commercially launched during the patent extension period.

Meda Licensing Agreements for ONSOLIS®

North American Agreement. On September 5, 2007, we entered into a definitive License and Development Agreement with Meda and our subsidiary Arius pursuant to which we and Arius agreed to grant to Meda an exclusive commercial license to market, sell, and, following regulatory approval, continue development of ONSOLIS® in the United States, Mexico and Canada (which we refer to as the Meda North American License).

Pursuant to such license agreement, we have received or will receive:

- a $30.0 million milestone payment (received in 2007).
- a $29.8 million milestone payment for the approval of ONSOLIS® by the FDA and provision of commercial supplies of ONSOLIS® in the U.S. (received in 2009).
- a double digit royalty on net sales of ONSOLIS® in the covered territories, subject to certain third party royalty payment costs and adjustments, as well as other adjustments in the event of certain specific supply disruptions. The license agreement provides for certain guaranteed minimum annual royalties to us during the second through seventh years following the product's first commercial sale, which occurred in the fourth quarter of 2009.
- sales milestones equaling an aggregate of $30 million will be payable at:
    - $10.0 million when and if annual sales meet or exceed $75.0 million;
    - $10.0 million when and if annual sales meet or exceed $125.0 million; and
    - $10.0 million when and if annual sales meet or exceed $175.0 million.

European Agreement. In 2006, we announced collaboration with Meda to develop and commercialize BEMA® Fentanyl (marketed as BREAKYL™ in Europe). Under terms of the agreement, we granted Meda rights to the European development and commercialization of BREAKYL™, in exchange for an upfront fee of $2.5 million and a $2.5 million milestone payment (received in 2008) for completion of Phase 3 clinical trials. We have also received a double digit royalty on net sales and additional milestone payments of $2.5 million upon approval and $2.5 million upon launch in the first country in the European territory (received in 2012). Meda has managed the regulatory submission in Europe that led to approval in October 2010. Meda will exclusively commercialize BREAKYL™ in Europe.

In 2009, we received a $3 million payment in exchange for amending the European agreement to provide Meda the worldwide rights to ONSOLIS®, with the exception of South Korea and Taiwan. The sales royalties to be received by us will be the same for all territories as agreed to for Europe. In addition, various terms of the European agreements have been modified to reflect the rights and obligations of both us and Meda in recognition of the expansion of the scope of the European agreements.

Assignment and Revenue Sharing Agreement. On January 23, 2015, we entered into an assignment and revenue sharing agreement with Meda (which we refer to as the Assignment Agreement), under which Meda will transfer back to us the marketing authorizations for ONSOLIS® for the United States and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. On February 27, 2016 we entered into an Extension of Assignment and Revenue Sharing Agreement to extend the period of time as described below (which we refer to as the Extension Agreement).

Under the Assignment Agreement, for a period of up to December 31, 2016, we shall have the right and shall use commercially reasonable efforts to work directly with the FDA to attempt to resolve certain previously disclosed issues relating to ONSOLIS® in the United States and seek, and attempt to negotiate a definitive license agreement with, one or more new commercial partners for ONSOLIS® in the United States, Canada and Mexico (we refer to each of these in this discussion as a Subject Country and collectively as the Subject Countries) (such an agreement, a Replacement License and such a partner, a Replacement Licensee).

Following the effective date of the Assignment Agreement, Meda's rights and obligations related to the development and commercialization of ONSOLIS® in the Subject Countries shall be suspended. Prior to the entry by us into a Replacement License, we and Meda will negotiate in good faith a form of definitive termination agreement addressing in further detail the termination of the Meda North American License and its effects (which we refer to as the Termination Agreement). Pursuant to the Assignment Agreement, any Termination Agreement is required to include provisions requiring us to share with Meda various percentages of revenue received by the Company under any Replacement License for ONSOLIS® after, subject to certain limitations, first deducting from such revenue payments required to be made by us under that certain Clinical Development and License Agreement, dated July 14, 2005, as amended, between the us, our subsidiary, Arius Two, Inc., and CDC V, LLC.

In the event that we have not identified a Replacement Licensee and entered into a Replacement License by a certain agreed upon date, Meda will have the right, but not the obligation, to demand that the marketing authorizations, and the rights to pursue marketing authorizations, for ONSOLIS® in the Subject Countries revert back to Meda, with the full reinstatement of all of Meda's rights and obligations under the Meda North American License. Notwithstanding the foregoing, Meda's rights to terminate the Meda North American License remain unaffected by the Assignment Agreement. Subject to any such reversion of rights back to Meda or earlier termination, under the terms of Extension Agreement entered into as of February 27, 2016, the Assignment Agreement shall terminate on the earlier of (i) the termination of the Meda North American License or (ii) on February 28, 2017 without Meda's exercising its right to cause reactivation or our execution of a Replacement License with a Replacement Licensee.

Key Collaborative and Supply Relationships

We are and have been a party to collaborative agreements with corporate partners, contractors, universities and government agencies. Research collaboration may result in new inventions which are generally considered joint intellectual property unless invented solely by individuals we employ, or by third party transfer to us by contract. Our collaboration arrangements are intended to provide us with access to greater resources and scientific expertise in addition to our in-house capabilities. We also have supply arrangements with several of the key component producers of our delivery technology. Our collaborative and supply relationships include:

- *Endo*. We believe that our agreement with Endo is currently one of our most important third party agreements. For a description of our agreements with Endo, please see "Endo Pharmaceutical Licensing Agreement for BELBUCA™" above.
- *Meda*. We believe that our agreements with Meda are currently one of our most important third party agreements. For a description of our agreements with Meda, please see "Meda Licensing Agreements for ONSOLIS®" above.
- *LTS Lohmann Therapie-Systeme AG*. Effective December 15, 2006, we entered into a Process Development Agreement with LTS Lohmann Therapie-Systeme AG (which we refer to herein as LTS), pursuant to which LTS will undertake process development, scale-up activities and supply BREAKYL™ to us for European clinical trials. Under the agreement, LTS has granted us a license under European Patent No. 0 949 925, in regard to BREAKYL™ in the E.U.
- *ARx*. Effective July 30, 2014, we entered into an agreement with ARx, LLC. Pursuant to which ARx acts as a supplier of BUNAVAIL® laminate or bulk product for the United States. Our supply agreement with ARx runs for a term from July 30, 2014 until December 31, 2019 and can be renewed for additional terms by mutual agreement.
- *Sharp*. Effective March 6, 2014, we entered into an agreement with Sharp Corporation to punch or cut the BUNAVAIL® laminate or bulk product into individual dosage units and package them to supply finished BUNAVAIL® film products. Our supply agreement with Sharp runs for an initial term from March 6, 2014 until December 31, 2016 and can be extended by mutual agreement for subsequent one year terms.
- *Quintiles*. In March 2014, we announced we had entered into an agreement with Quintiles to support the launch of BUNAVAIL®. Under terms of the agreement, Quintiles provides a range of services to support the commercialization of

BUNAVAIL® in the U.S., including recruiting and training a field sales force. Our agreement with Quintiles shall continue until terminated, and the agreement is terminable upon a ninety day advance written notice by either party and also in cases of breach of the agreement by either party.

We also have relationships with third party contract research organizations that assist us with the management of our clinical trials.

In pursuing potential commercial opportunities, we intend to seek and rely upon additional collaborative relationships with corporate partners. Such relationships may include initial funding, milestone payments, licensing payments, royalties, access to proprietary drugs or potential applications of our drug delivery technologies or other relationships. Our agreements with Endo and Meda are examples of these types of relationships, and we will continue to seek other similar arrangements.

Relationship with CDC IV, LLC

On July 14, 2005, we entered into a Clinical Development and License Agreement (which we refer to as the CDLA), with the predecessor of CDC IV, LLC (which we refer to herein as CDC), which provided funds to us for the development of ONSOLIS®. On February 16, 2006, we announced that, as a result of our achievement of certain milestones called for under the CDLA, CDC made its initial $2 million payment to us. On May 16, 2006, we issued CDC 2 million shares of our common stock in return for accelerating the funding of the $4.2 million balance of $7 million of aggregate commitment under the CDLA and for eliminating the then required $7 million milestone repayment to CDC upon the approval by the FDA of ONSOLIS®.

Under the CDLA, as amended, CDC is entitled to receive a low-double digit royalty based on net sales of ONSOLIS®. The CDLA includes minimum royalties of $375,000 per quarter beginning in the second full year following commercial launch. The minimum provision came into effect in 2011. The royalty term and minimum payments end upon the latter of expiration of the patent or generic entry into any particular country.

The term of the CDLA lasts until the CDLA is terminated. Either we or CDC may terminate the CDLA for uncured breach or upon bankruptcy-like events, in each case following written notice. CDC may terminate the CDLA, following applicable cure periods, if we: (i) default on indebtedness in excess of $1 million which was accelerated or for which payment has been demanded, or (ii) fail to satisfy a judgment greater than $500,000.

We and CDC entered into a Royalty Purchase and Amendment Agreement, dated September 5, 2007 (or the RPAA) pursuant to which we granted CDC a 1% royalty on sales of the next BEMA® product, which is BUNAVAIL®, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval. In connection with the 1% royalty grant as previously mentioned: (i) CDC shall have the option to exchange its royalty rights to BUNAVAIL® in favor of royalty rights to a substitute BEMA® product, (ii) we shall have the right, no earlier than six (6) months prior to the initial commercial launch of BUNAVAIL®, to propose in writing and negotiate the key terms pursuant to which it would repurchase the royalty from CDC, (iii) CDC's right to the royalty shall immediately terminate at any time if annual net sales of BUNAVAIL® equal less than $7.5 million in any calendar year following the third (3rd) anniversary of initial launch of the product and CDC receives $18,750 in three (3) consecutive quarters as payment for CDC's 1% royalty during such calendar year and (iv) CDC shall have certain information rights with respect to BUNAVAIL®. The amount of royalties which we may be required to pay (including estimates of the minimum royalties) is not presently determinable because product sales estimates cannot be reasonably determined and the regulatory approvals of the product for sale is not possible to predict. As such, we expect to record such royalties, if any, as cost of sales.

On May 12, 2011, we entered into an Amendment to the CDLA with CDC and NB Athyrium LLC (or Athyrium). Under the terms of the CDLA Amendment, among other matters, the parties agreed to increase the royalty rate to be received by CDC/Athyrium retroactively to the initial launch date of ONSOLIS® and, accordingly, we recorded $0.3 million as additional cost of product royalties for the year ended December 31, 2011. In addition, certain terms of the CLDA were amended and restated to clarify that royalty payments by us under the CDLA will be calculated based on Meda's sales of ONSOLIS®, whereas previous royalty payments by us to CDC were calculated based on sales of ONSOLIS® by us to Meda. The difference between these two calculations resulted in a $1.1 million overpayment by us which was recorded as a prepayment. As a result, we did not pay any of the quarterly royalty payments (including any 2011 payments) due to CDC/Athyrium until the December 31, 2011 royalty calculation, which we paid during the first quarter of 2012.

Research and Development

The significant majority of our research and development relating to our BEMA® and other technologies is conducted through our collaboration with third parties in collaboration with us.

Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct and third party development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to non-clinical studies, including toxicology studies, and clinical trials, and costs relating to

compliance with regulatory requirements applicable to the development of our product candidates. For the years ended December 31, 2015, 2014 and 2013, we spent approximately $20.6 million, $34.3 million and $53.3 million, respectively, on research and development, and such expenses represented approximately 27%, 47% and 81%, respectively, of our total operating expenses for such fiscal years.

Endo is responsible for reimbursing us for certain research and development clinical trial expenses that exceed $45 million, as detailed in our License and Development Agreement that was executed on January 5, 2012. For the years ended December 31, 2015, 2014 and 2013, we have incurred $0.9 million, $12.7 million and $2.8 million, respectively, in such research and development expenses that are reimbursable by Endo to us. These reimbursable expenses are the primary activity reported as Research and Development Reimbursements in the accompanying consolidated statement of operations as of December 31, 2015, 2014 and 2013.

Market Overview for BUNAVAIL®, BELBUCA™, ONSOLIS® and Our Product Candidates

The following table summarizes the status of our marketed product and our current product candidates and product concepts:

Product/Formulation	Indication	Development Status	Commercial Status
BUNAVAIL®	Treatment of opioid dependence	Approval: June 2014	In-house commercialization
BELBUCA™	Moderate to severe chronic pain	Approval: October 2015	Partnered worldwide with Endo
ONSOLIS®/BREAKYL™/ PAINKYL™ (U.S./E.U./Taiwan trade names, respectively)	Breakthrough cancer pain in opioid tolerant patients	Approval: U.S. in July 2009; Canada in May 2010; E.U. in October 2010 and Taiwan in July 2013	Partnered outside the U.S., Canada and Mexico
Clonidine Topical Gel	Treatment of painful diabetic neuropathy	Clinical development program in process	In-house commercialization for specialty indications possible; primary care rights expected to be partnered
Buprenorphine Depot Injection	Opioid dependence and chronic pain	IND submission anticipated in mid 2016	Not partnered

The pharmaceutical industry and the therapeutic areas in which we compete are highly competitive and subject to rapid and substantial regulatory and technological changes. Developments by others may render our BEMA® technology, our marketed products and any proposed drug products and formulations under development noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

Below are some examples of companies seeking to develop potentially competitive technologies, though the examples are not all-inclusive. Many of these entities have significantly greater research and development capabilities than do we, as well as substantially more sales and marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' research, financial, sales and marketing, manufacturing and other resources. Such potential competitive technologies may ultimately prove to be safer, more effective, or less costly than any product candidates that we are currently developing or may be able to develop. Additionally, our competitive position may be materially affected by our ability to develop or successfully commercialize our drugs and technologies before any such competitor. Other external factors may also impact the ability of our products to meet expectations or effectively compete, including pricing pressures, healthcare reform and other government interventions as well as limitations on access that may be placed upon us through managed care organizations or through competitive contracting with payers.

There have been a growing number of companies developing products utilizing various thin film drug delivery technologies. While numerous over-the-counter pharmaceutical products have been brought to market in thin film formulations, few containing prescription products have been introduced in the U.S. Among the products to receive FDA approval are BUNAVAIL® (BDSI), BELBUCA™ (BDSI/Endo), ONSOLIS® (BDSI/Meda), Suboxone® film (Indivior) and Zuplenz® (Midatech Pharma). Companies in the development and manufacture of thin film technologies include LTS, ARx LLC and MonoSol Rx LLC (or MonoSol). In addition, a number of companies are developing improved versions of existing products using oral dissolving, nasal spray, aerosol, sustained release injection and other drug delivery technologies. We believe that potential competitors are seeking to develop and commercialize

technologies for buccal, sublingual or mucosal delivery of various therapeutics or groups of therapeutics. While our information concerning these competitors and their development strategy is limited, we believe our technology can be differentiated because the BEMA® technology provides for a rapid and consistent delivery, high drug bioavailability and convenient use based on how the BEMA® technology adheres to the buccal membrane and dissolves. Our clinical trials across a number of BEMA® products have demonstrated that the technology is an effective means of drug delivery that is well tolerated and offers convenience to patients.

BUNAVAIL®

In June 2014, BUNAVAIL® was approved by the FDA for the maintenance treatment of opioid dependence. BUNAVAIL® contains the partial opioid agonist buprenorphine, which binds to the same receptors as opiate drugs but has a higher affinity, slower onset and is both less addictive and less lethal in overdose. Naloxone, an opioid antagonist, is included as an abuse deterrent. When used as directed, the naloxone is swallowed and minimally absorbed; however, if misused (ie, dissolved and injected), the naloxone rapidly precipitates withdrawal symptoms.

Maintenance treatment with buprenorphine reduces the typical cravings and withdrawal symptoms associated with coming off opioid prescription painkillers and heroin. This allows the individual suffering from an addiction to opioids –along with counseling and support – to work toward recovery. On average, treatment lasts a couple months, reflecting relatively high dropout rates, but a significant number of people remain on buprenorphine treatment chronically, with nearly one-quarter of patients still on therapy after nine months. BUNAVAIL® provides an alternative treatment utilizing the advanced BEMA® drug delivery technology. BUNAVAIL® provides the highest bioavailability of any buprenorphine-containing product for opioid dependence, allowing for effective treatment with half the dose compared to Suboxone film. Additionally, BUNAVAIL® offers convenient and discrete buccal administration and avoids the need for patients to avoid talking and swallowing during administration. Data has also demonstrated an excellent tolerability profile with a 68% reduction at the end of 12 weeks in the incidence of constipation in a Phase 3 trial in patients converted from Suboxone® sublingual tablets or film to BUNAVAIL®.

The total market for buprenorphine containing products for opioid dependence exceeded $2 billion in 2015, an increase of 11% over 2014. The market has grown significantly as a result of the rapidly escalating problem of prescription opioid misuse and abuse, a recent resurgence of heroin use, the growing number of physicians treating opioid dependence, and the inclusion of addiction treatment as an essential benefit in the Affordable Care Act. We estimate that BUNAVAIL® for the maintenance treatment of opioid dependence has the potential to achieve 10% to 15% of the market by the end of 2018.

The products currently marketed for this indication include Suboxone®, a sublingual film formulation of buprenorphine and naloxone, a sublingual tablet, Zubsolv®, and generic formulations of both buprenorphine and buprenorphine/naloxone tablets. Suboxone® film, the market leader, achieved sales of $1.4 billion in the U.S. in 2015. In December 2014, Reckitt Benckiser Group PLC, the manufacturer of Suboxone® sublingual tablets and films, announced that they completed the spin-off of that company's pharmaceutical business (including the Suboxone® brand) under the name Indivior PLC in order to allow the consumer goods group to focus on its consumer health and hygiene products. The Indivior business will focus on addiction treatment and closely related areas including opioid overdose, cocaine overdose and alcohol dependence. In September 2012, Reckitt Benckiser announced that it had notified the FDA that they would be voluntarily discontinuing the distribution of Suboxone® tablets in the U.S. and subsequently halted further shipments in March 2013. The decision made by Reckitt Benckiser was reportedly due to accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone® films compared with their tablet formulation due to the child-resistant, unit-dose packaging of the film versus a multi-dose bottle for the tablets. Additionally, Reckitt Benckiser filed a Citizens Petition to request that the FDA require all manufacturers of buprenorphine-containing products for the treatment of opioid dependence to implement public health safeguards including child-resistant, unit-dose packaging to reduce the risk of pediatric exposure. FDA subsequently rejected the Citizens Petition in February 2013, which allowed for the approval of the first generic formulations of Suboxone® tablets.

Generic buprenorphine/naloxone tablet formulations were launched in early 2013 by Actavis and Amneal Pharmaceuticals and were followed by additional entrants including a generic formulation from Teva. The remaining prescription volume for Suboxone® tablets was rapidly converted to generics; however, the impact of generic buprenorphine/naloxone tablets on Suboxone® film and overall branded sales has been somewhat limited to date. In 2015, generic buprenorphine/naloxone tablets accounted for 18% of total buprenorphine/naloxone prescriptions, which is unchanged compared to the prior year. Additional generics may enter the market, though the timing is unclear and the impact is anticipated to be limited.

In terms of additional competition, Phase 3 trials were completed for Probuphine, a subcutaneous depot delivery system containing buprenorphine from Titan Pharmaceuticals (OTCBB:TTNP). Results of clinical studies demonstrated efficacy and safety, and Probuphine was submitted for FDA review in October 2012. Probuphine was anticipated to address the needs of the subset of patients undergoing treatment for opioid dependence who are unable to maintain compliance with alternative formulations or those who may be at high risk for diversion. In December 2012, Titan announced the signing of a license agreement with Braeburn Pharmaceuticals Sprl. The license grants Braeburn exclusive commercialization rights in the United States and Canada. In April 2013, the FDA issued a Complete Response Letter for Probuphine and requested additional data regarding its efficacy. An additional Phase 3 study assessing the efficacy and safety of Probuphine was initiated in April 2014. In June 2015, Titan announced favorable results in

their Phase 3 study and subsequently submitted an NDA. In January 2016, an FDA Advisory Panel voted in favor of the approval of Probuphine though several panelists noted that the drug's label must be clear about patient selection for the medication, since the product is only intended for patients who have been stabilized on 8 mg daily buprenorphine or less. Given the need for surgical implantation and removal as well as dosing limitations. We do not expect Probuphine is not expected to be a significant competitive threat to BUNAVAIL®.

A sublingual tablet, referred to as Zubsolv® was approved by FDA in July 2013 and subsequently launched in September 2013. Zubsolv® is a sublingual formulation of buprenorphine/naloxone using Orexo's proprietary sublingual drug delivery technology. Orexo is a specialty pharmaceutical company with headquarters in Sweden. Orexo is developing treatments using their proprietary sublingual drug delivery technology, which includes the marketed product Abstral® that delivers fentanyl for the treatment of breakthrough cancer pain.

The sales efforts for Zubsolv® are supported by a contract sales organization (InVentiv Health) and the product is being marketed predominantly based on its claims of improved taste and faster dissolve time compared to Suboxone®. Sales for Zubsolv® in 2015 totaled approximately $108 million in the U.S and a prescription market share of 5%. Zubsolv has benefited from limited exclusive contracts such as United Healthcare, and a preferred status with CVS/Caremark, which ended in January 1, 2016, at which time the product was moved to excluded status.

While limited information is available, other formulations of buprenorphine may also be in early stages of development for the treatment of opioid dependence, including an oral capsule (NTC-510 or NanoBup) from Nanotherapeutics, Inc. Nanotherapeutics reports that Phase 1 studies have been completed to date (two Phase 1a single dose pharmacokinetic studies and one Phase 1b, multidose pharmacokinetic study) and a Phase 2 dose ranging study was completed in late 2014. It has been demonstrated that NTC-510 administered orally achieves appropriate serum buprenorphine concentrations for analgesia and could potentially be dosed once daily. Relmada Therapeutics Inc. is developing an oral, enteric-coated buprenorphine (REL-1028 or BuTab) for chronic pain and opioid dependence indications. In December 2015, Relmada announced topline results of a proof-of-concept pharmacokinetic study in healthy volunteers which showed that the product can be delivered at therapeutic levels through the gastrointestinal route. Also in development is a sublingual spray formulation of buprenorphine/naloxone from Insys which is expected to complete a bioavailability study in early 2016 and buprenorphine hemiadipate (RBP-6300) from Indivior, an oral formulation of buprenorphine using Capsugel drug delivery technology.

While we anticipate that the market for buprenorphine/naloxone products for the treatment of opioid dependence will get increasingly more competitive, we believe a BEMA® formulation of buprenorphine/naloxone has significant appeal given its buccal administration, enhanced delivery of buprenorphine, tolerability profile, convenience, and lack of taste issues. We also believe that the increased number of companies promoting the use of buprenorphine containing-products for opioid dependence has the potential to create greater awareness and help to further expand what is already a significant and growing market.

BELBUCA™ (buprenorphine) buccal film for chronic pain

Chronic pain is often defined as any pain lasting more than 12 weeks. Whereas acute pain is a normal sensation that alerts us to possible injury, chronic pain persists – often for months or even longer. Chronic pain may arise from an initial injury, such as back sprain, or there may be an ongoing cause, such as an illness. Sometimes there is no clear cause. According to the National Institutes of Health, approximately 100 million people in the U.S. are living with chronic pain.

BELBUCA™ is intended to meet the need for a new narcotic and would be used for chronic pain, including lower back, osteoarthritis and rheumatoid arthritis. Compared to currently marketed products and products under development, we believe that BELBUCA™ will be differentiated based on the following features:

- strong and durable efficacy in both opioid naïve and opioid experienced patients;
- Schedule III designation by DEA, which indicates it is less prone to abuse and addiction and more convenient for physicians to prescribe (with prescription refills possible), pharmacists to dispense, and patients to obtain;
- favorable tolerability with a low incidence of constipation and low discontinuation rate;
- flexible dosing options covering up to 160 mg morphine sulfate equivalents (MSE); and
- buccal administration to optimize buprenorphine delivery.

The BEMA® delivery system may enable us to provide this opioid in a form suitable for ambulatory care and, because of the safety advantage associated with this opioid, we believe that BELBUCA™ could be an ideal next step product for patients with incomplete pain relief on short acting opioids.

The pain market is well established, with many pharmaceutical companies marketing new formulations of existing products as well as generic versions of older, non-patent protected products. In 2015, according to data from Symphony Health, the U.S. opioid market exceeded $10 billion in annual sales. Due to the ability of BELBUCA™ to potentially participate in the chronic pain market, we

estimate that BELBUCA™ for chronic pain has the potential to exceed $500 million in annual peak sales. A number of products may be competitors to BELBUCA™. A potential focus will be to position BELBUCA™ in patients who are transitioning from short to long acting opioids. Indications for such use include pain associated with lower back and severe arthritis conditions. Marketed competitors for these indications include Butrans® (buprenorphine transdermal patch) from Purdue and Schedule II opioids such as OxyContin® from Purdue, Avinza® from Pfizer, Zohydro® ER from Pernix Therapeutics, and Nucynta® ER from DepoMed. Other competition includes multiple generic opioid formulations, particularly hydrocodone containing products, new chemical entities in clinical development with different mechanisms of action and various combination formulations. We also believe that other companies may be exploring the use of buprenorphine in other delivery technologies, though we believe such products lag significantly behind BELBUCA™. This includes a sublingual spray formulation of buprenorphine from Insys which is being developed for the treatment of acute pain.

Additionally, “abuse deterrent” formulations of pain products are currently being marketed, in clinical development or under FDA review. These formulations, such as Embeda®, Exalgo®, Hysingla® ER and Zohydro® ER as well as new formulations of OxyContin® and Opana® ER use a variety of technologies to try and minimize the potential for abuse and misuse. Abuse deterrent products are likely to play an unclear but increasingly important role in prescribing, potentially even replacing the original product. An advantage of BELBUCA™ is that the compound, buprenorphine, may be inherently less likely to cause abuse and addiction given the lower propensity for the product to cause euphoria and is the current basis of its Schedule III classification.

The first buprenorphine formulation for the treatment of chronic pain was approved in 2010. Purdue Pharmaceuticals received FDA approval for Butrans® (buprenorphine transdermal system) in July 2010. Butrans® is indicated for the management of moderate to severe chronic pain and delivers buprenorphine transdermally (through the skin) over a period of seven days. The approval of Butrans® signaled the interest and approvability of new formulations of buprenorphine. It is our view that the flexibility of dosing with a BEMA® formulation, wider range of doses and ease of use will make it a preferred formulation for a significant number of patients with chronic pain conditions. Butrans® was launched in early 2011. Sales of Butrans® in 2015 totaled over $230 million and continue to steadily grow. Insys Therapeutics, Inc., is developing a sublingual spray formulation of buprenorphine for the treatment of pain. A Phase 3 study is expected to be conducted for the treatment of acute pain during the first half of 2016. Additionally, Insys plans to develop their sublingual spray formulation for the treatment of chronic pain, with trials anticipated to begin in the second half of 2016. However, development of a product for the treatment of chronic pain is more complex with lengthier trials and greater risk, thus Insys for chronic pain is not viewed as a threat to BELBUCA™ in the foreseeable future. While limited information is available, other formulations of buprenorphine may also be in early stages of development for the treatment of pain.

In August 2014, the U.S. Drug Enforcement Administration (DEA) published in the Federal Register their final ruling moving hydrocodone combination products (such as Vicodin, Lortab, Norco, etc.) from Schedule III to the more-restrictive Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) and as supported by the DEA’s own evaluation of relevant data. As a result of the ruling, hydrocodone containing products are now classified in the same category (Schedule II) as morphine and oxycodone. As a result of the change to Schedule II, access to these products will be more restricted. Among other changes, written prescriptions will be required and refills will not be permitted. The ruling also conveyed findings that hydrocodone combination products have a higher risk of abuse and addiction compared to Schedule III products. The ruling went into full effect in October 2014.

We recognized early the value of buprenorphine in the treatment of pain. Buprenorphine is one of the few remaining Schedule III opioids and has a lower risk of abuse and addiction compared to Schedule II opioids and thus will have fewer restrictions on dispensing. BELBUCA™ has the opportunity to provide a Schedule III option for the treatment of chronic pain thus help to replace the void left from the recent reclassification of hydrocodone combination products. We believe the actions taken to restrict the use of hydrocodone combination products may markedly increase the utility and appeal of BELBUCA™ as it now addresses an important unmet medical need for Schedule III options.

In addition to direct competitors, there are other factors that impact the market for pain products in general. The significant pricing pressures and availability of generic products in the U.S. and other regions are likely to have increasing influence on the pharmaceutical market, including pain products. Additionally, opioids continue to garner increased scrutiny based on the growing problem of prescription drug abuse and addiction. It remains unclear what steps, if any beyond the reclassification of hydrocodone, the FDA or other government agencies may take to address the problem of opioid abuse and addiction. However, in July 2012 the FDA approved a class-wide REMS program for the extended release and long-acting opioids. The class-wide REMS program consists of a REMS-compliant educational program offered by an accredited provider of continuing medical education, patient counseling materials and a medication guide. BELBUCA™ falls within the existing class-wide REMS program.

ONSOLIS®

According to the National Cancer Institute, there are approximately 14.5 million people in the United States diagnosed with or living with cancer. Cancer patients often suffer from a variety of symptoms including pain as a result of their cancer or cancer treatment. Pain is a widely prevalent symptom in cancer patients, and an estimated 50% to 90% of those with cancer also suffer from what is referred to as breakthrough cancer pain (or BTCP). Following rapid onset that peaks in three to five minutes, BTCP episodes

can last several minutes to an hour, and usually occur several times per day. BTCP can be difficult to treat due to its severity, rapid onset and the often unpredictable nature. Physicians typically treat BTCP with a variety of short-acting opioid medications, including morphine and fentanyl. A number of formulations of fentanyl are available employing a variety of drug delivery technologies, all which provide rapid onset and relatively short duration of action to address the fast onset and short duration of BTCP.

For ONSOLIS®, in the breakthrough cancer pain area, the market has become increasingly crowded and more competitive in recent years. The principal competitor has traditionally been Teva Pharmaceutical Industries Ltd., which completed its acquisition of Cephalon, Inc. in October 2011. Teva markets both lozenge (Actiq®) and effervescent buccal tablet (Fentora®) formulations of fentanyl. Over the last couple years, newer products entries, particularly Subsys® (fentanyl sublingual spray) from Insys, have gained significant market share. Additional competitors include Sentynl Therapeutics which licensed from Galena Biopharma the sublingual tablet formulation of fentanyl (Abstral®) and DepoMed, which licensed a nasal spray formulation of fentanyl (Lazanda®) from Archimedes. In addition, multiple generic formulations of Actiq® are currently available.

The transmucosal fentanyl class has faced significant challenges following safety issues stemming from inappropriate use of Fentora® and the subsequent "Dear Doctor" letter (Cephalon Press Release, September 2007).

On December 29, 2011, the FDA approved a REMS program covering all transmucosal fentanyl products. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all marketed transmucosal fentanyl products, including ONSOLIS®, under a single program which is meant to enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program ended the disparity in prescribing requirements for ONSOLIS® compared to similar products.

In 2015, the overall market for transmucosal fentanyl products for breakthrough pain according to Symphony Health, totaled $703 million in the U.S., an increase of 41% over 2014. The first approved product for the management of breakthrough cancer pain was Actiq® (oral transmucosal fentanyl citrate) which, according to Symphony Health, generated $14 million in sales in 2015. Total sales for generic versions of Actiq®, available from multiple manufacturers including Covidien, Teva and Actavis, totaled $54 million over the same period. Fentora® utilizes an effervescent tablet which is administered buccally. Fentora® was approved and launched in late 2006 and according to Symphony Health, generated $158 million in sales in 2015.

In December 2008, ProStrakan announced receipt of marketing authorization from the German regulatory authorities for their fentanyl sublingual tablet (under the brand name Abstral®; licensed from Orexo AB) which was subsequently launched in a number of countries. In January 2010, Abstral® was approved in the U.S. by the FDA, and Prostrakan launched Abstral® in the second quarter of 2011. In June 2012, Orexo announced that they would re-acquire the rights to Abstral® in the U.S. and subsequently licensed U.S. rights to Galena Biopharma. Galena relaunched Abstral® in 2014 and cumulative sales totaled $20 million at year end. In November 2015, Galena Biopharma divested its marketed products, including Abstral® which was sold to Sentynl Therapeutics.

In the U.S., additional products have been approved by the FDA utilizing other delivery technologies to administer fentanyl. These products include intranasal Lazanda®, which was approved in June 2011, and a fentanyl sublingual spray formulation from Insys known as Subsys®, which received FDA approval in January 2012. Subsys®, which was launched in early 2012, was the first sublingual spray formulation of fentanyl, and the first product shown to relieve pain within five minutes. The rapid onset of action, coupled with aggressive promotion and a significant co-pay support program, led to rapid growth. In 2015, Subsys® achieved a prescription market share in excess of 46%, or $430 million in sales.

Other potent pain products are also in development, including ARX-02 from AcelRx Pharmaceuticals, Inc. (NASDAQ:ACRX) which has a nano-tab drug/device delivery system containing sufentanil for the treatment of breakthrough pain. While we have limited information regarding this and potential other competitors and their development status and strategy, we believe that our technology may be differentiated because unlike these potential competitors, ONSOLIS® has a predefined residence time on the buccal membrane providing for consistent drug delivery from dose to dose. We believe that all of the competitive formulations of fentanyl will have intra-dose variability, meaning the patient may not get the same response each time the product is administered. In addition, it is our belief that the other competitive products may have tolerability issues and a higher level of potential abuse based on how they are delivered.

The chart below lists products that we believe may compete directly with ONSOLIS®.

Product	Company	Description	Status
Actiq® (oral transmucosal fentanyl citrate)	Teva/Generics	Fentanyl lozenge	Marketed (generics available)
Fentora® (fentanyl buccal tablet)	Teva	Effervescent buccal tablet	Marketed
Abstral® (fentanyl sublingual tablet)	Sentynl Therapeutics	Sublingual tablet	Marketed

Product	Company	Description	Status
Lazanda® (fentanyl nasal spray)	DepoMed	Nasal spray	Marketed
Subsys® (fentanyl sublingual spray)	INSYS Therapeutics	Sublingual spray	Marketed
NAL 1239	NAL Pharmaceuticals	Orally dissolving film	Proposed ANDA
ARX-02	AcelRx Pharmaceuticals	Nanotab containing sufentanil	Phase 2 (U.S.)

In Europe, the total market for transmucosal fentanyl products continues to grow with the availability of new formulations, including ONSOLIS® (marketed as BREAKYL™ in Europe by Meda). Multiple formulations of fentanyl have recently been approved and launched in Europe for the treatment of breakthrough cancer pain, including Abstral®, Effentora®, and Instanyl® (intranasal fentanyl spray).

Clonidine Topical Gel

In March 2013, we announced that we had entered into a worldwide licensing agreement with privately held Arcion, where we will develop and commercialize Clonidine Topical Gel (formerly ARC4558) for the treatment of PDN and potentially other indications. The PDN market is highly under-served by existing products and there is a strong scientific rationale for developing a topical treatment for PDN that delivers analgesia in a way that avoids systemic side effects.

Evidence has shown that clonidine stimulates an inhibitory receptor in the skin associated with pain fibers. Arcion has developed a patented topical gel formulation of clonidine and has assessed its effectiveness in reducing pain in PDN in a double-blind, placebo-controlled, Phase 2 study where the primary study endpoint was the change in pain intensity over a 3 month treatment period in diabetic foot pain. A significant treatment difference was seen in the planned subset analysis of diabetic patients who had documented evidence of "functioning pain receptors" in the skin of the lower leg (p=0.01, n=63) thus, at a minimum, supporting the effectiveness of topical clonidine in diabetic patients with functioning pain receptors of the skin. In the overall population that included patients without "functioning nerve receptors", there was a trend favoring Clonidine Topical Gel (p=0.07, n= 182), though the overall results did not reach statistical significance.

Nearly 26 million people in the U.S. have diabetes according to the American Diabetes Association. A substantial number of these people have neuropathy as manifest by impaired sensation and pain in the extremities, most commonly the feet. Patients with PDN often experience debilitating pain symptoms that affect day-to-day functioning and quality of life. How diabetes causes a length-dependent neuropathy is unknown. In the prior double-blind, randomized, controlled trial approximately 50% of the patients with PDN demonstrated functional nociceptors in the skin in the painful region as revealed by a response to topical capsaicin. Clonidine is thought to relieve pain by decreasing the abnormal excitability of these functional nociceptors. Currently available oral treatments are modestly effective in relieving symptoms and are limited by systemic side effects and drug interactions. There are no topical products approved for the treatment of this painful condition.

Along with antidepressants, antiepileptic drugs (AEDs) are often used as a first-line therapy for PDN. The most commonly prescribed AEDs for PDN are gabapentin and pregabalin (Lyrica). The choice between them is mostly influenced by physicians' preference for the more-favorable dosing attributes (less-frequent daily dosing, faster titration) of pregabalin in balance with price and accessibility. AEDs are commonly associated with side effects including somnolence, dizziness, and weight gain. If first-line AED or antidepressant monotherapy fails to provide acceptable pain relief, physicians initiate combination therapy. If AED/antidepressant combination therapy is not effective, physicians typically add a dual-acting opioid such as tramadol. For more-severe pain, physicians may add or switch to tapentadol ER (Nucynta ER), which is the first and only dual-acting opioid analgesic to gain approval for PDN in the U.S. If pain persists with the addition of tramadol or tapentadol, physicians often switch to a more potent opioid analgesic (e.g., oxycodone) while maintaining AED and/or antidepressant therapy. Although some experts acknowledge that strong opioids can be quite effective for PDN, they generally reserve this drug class for refractory cases and/or those with high pain intensity. For some PDN patients, particularly those experiencing highly localized pain, physicians may prescribe the lidocaine 5% patch (Lidoderm). Pain specialists generally consider that lidocaine is particularly beneficial for localized pain, and many physicians prefer it to oral agents because it does not cause systemic side effects and is easy to administer. In many cases, the patch is used in combination with an oral first-line AED and/or antidepressant therapy.

Oral medications that are approved for the treatment of PDN include anticonvulsants such as Lyrica (pregabalin), the antidepressant Cymbalta® (duloxetine) and the opioid Nucynta® ER (tapentadol ER), with sales for the treatment of neuropathic pain totaling over $3 billion in the U.S. according to Datamonitor. These treatments are modestly effective in relieving symptoms and their use can be limited by adverse effects and drug interactions. Additional oral formulations in development include an extended release formulation of pregabalin from Pfizer.

To our knowledge, there are a limited number of products in development specifically for the treatment of painful diabetic neuropathy. Teva and Xenon Pharmaceuticals are developing TV-45070 (formerly XEN402), a subtype selective ion channel inhibitor. TV-45070 is partnered with Teva in a milestone, royalty and co-promotion partnership. Using a topical (ointment)

formulation of TV-45070, Teva conducted a Phase 2b clinical trial in osteoarthritis, or OA, of the knee. In July 2015, it was reported that TV-45070 failed to demonstrate a statistically significant difference from placebo in efficacy endpoints. A Phase 2b study is currently ongoing for the treatment of post-herpetic neuralgia.

Buprenorphine Depot Injection

Despite the availability of effective treatments, including BUNAVAIL® buccal film, challenges remain regarding patient adherence to long-term buprenorphine treatment, which is critical to successfully managing opioid dependence. This has led to interest in alternative delivery systems for buprenorphine. One such opportunity is the development of an injectable, long-acting, depot formulation. Microsphere-based, long acting, buprenorphine injectable depot has the ability to change the treatment paradigm in opioid dependence and pain management. Such a dosage form provides improved therapy compliance through continuous delivery of drug for up to 30 days. In 2014, we entered into an exclusive agreement with Evonik to develop and commercialize a proprietary, injectable microparticle formulation of buprenorphine potentially capable of providing 30 days of continuous therapy following a single subcutaneous injection. While we plan to pursue an indication for the maintenance treatment of opioid dependence, we have also secured the rights and are developing a product for the treatment of chronic pain in patients requiring continuous opioid therapy. As part of the agreement, we will have the right to license the product(s) following the attainment of Phase 1 ready formulations. At that point, Evonik could receive downstream payments for milestones related to regulatory filings and subsequent NDA approvals as well as product royalties. Evonik has the exclusive rights to develop the formulation and manufacture the product(s). In 2015, significant progress was made in the development of a formulation we believe will allow for delivery once per month as well as provide advantages over other injectable buprenorphine products.

Additional long-acting depot formulations of buprenorphine are also in develop including one from Indivior, RBP-6000, which uses Atrigel technology and is currently in Phase 3 development for opioid dependence and a product licensed by Braeburn Pharmaceuticals utilizing a technology licensed from Camurus. The product referred to as CAM2038 from Camurus is being developed as both a 1-week and 1-month subcutaneous injection for opioid dependence and pain.

Licenses, Intellectual Property and Proprietary Information

Our intellectual property strategy is intended to maximize protection of our proprietary technologies and know-how and to further expand targeted opportunities by extension of our patents, trademarks, license agreements and trade secrets portfolio. In addition, an element of our strategic focus provides for varying specific royalty or other payment obligations by our commercial partners as our applicable intellectual property portfolio changes or business activity reaches certain thresholds.

However, patent positions of biotechnology and pharmaceutical organizations are considered to be uncertain and involve complex legal and technical issues. There is considerable uncertainty regarding the breadth of claims in patent cases which results in varied degrees of protection. While we believe that our intellectual property position is sound, it may be that our pending patent applications will not be granted or that our awarded claims may be too narrow to protect the products against competitors. It is also possible that our intellectual property positions will be challenged or that patents issued to others prior to our patent issuance may preclude us from commercializing our products. It is also possible that other parties could have or could obtain patent rights which may cover or block our products or otherwise dominate our patent position.

BEMA® Technology

The drug delivery technology space is congested, although we do not believe that our BEMA® products are in conflict with, dominated by, or infringing any external patents and we do not believe that we require licenses under external patents for our BEMA® based products in the United States, it is possible, however, that a court of law in the United States or elsewhere might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our products or technologies. We may be unable to obtain such licenses from the patent holders. If we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

This potential exists in our present litigation with MonoSol. MonoSol claimed in a litigation initiated in late 2010 that our confidential and trade secret manufacturing process for ONSOLIS® infringes their patented manufacturing process for thin films. We do not believe that we have infringed these claims. Moreover, we believe that the original claims in MonoSol patents ‘588, ‘292 and ‘891 are invalid or overbroad, and, in connection with inter partes and ex parte reexamination proceedings we have brought before the USPTO, the USPTO has either rejected and cancelled all claims, amended the original claims to make them narrower, or issued narrower, new claims replacing the broader original claims for each of the ‘588, ‘292 and ‘891 patents respectively. We also believe that the manufacturing processes for our product candidates, including BELBUCA™ and BUNAVAIL® do not infringe MonoSol’s patents, at least because they do not meet the limitations of the original, amended or new claims of MonoSol’s patents. We maintain our manufacturing processes for our BEMA® products and product candidates as trade secrets. Based on our examination of these patents, we do not believe our manufacturing processes infringe MonoSol’s patents. On March 7, 2012, the court granted our motion to stay the case pending outcome of the reexamination proceedings in the USPTO. On July 3, 2012, the USPTO issued an ex parte

reexamination certificate on the '891 patent, in which all original claims were amended to make them narrower. On August 26, 2012, the USPTO issued an ex parte reexamination certificate on the '292 patent, in which all the original broader claims were replaced with narrower, new claims. As for the '588 patent, at the conclusion of the reexamination proceedings (and its appeals process), on April 17, 2014, the Patent Trial and Appeal Board (or PTAB) of the USPTO issued a Decision on Appeal affirming the Examiner's rejection (and confirming the invalidity) of all the claims of the '588 Patent. MonoSol did not request a rehearing by the May 17, 2014 due date for making such a request and did not further appeal the Decision to the Federal Court of Appeals by the June 17, 2014 due date for making such an appeal. Subsequently, on August 5, 2014, the USPTO issued a Certificate of Reexamination cancelling the '588 Patent claims. The litigation resumed and on September 25, 2015 the court granted our motion of Summary Judgement of Intervening Rights and dismissed the case. MonoSol subsequently filed an appeal with the Federal Circuit. We have no reason to believe that the outcome will be different, but we are vigorously defending the appeal. MonoSol filed an appeal with the Federal Circuit and has subsequently decided to withdraw the appeal. On February 25, 2016, MonoSol filed an Unopposed Motion For Voluntary Dismissal Of Appeal, which was granted by the court on February 26, 2016 and the case dismissed. Thus, the district court's grant of the Summary Judgement of Intervening Rights will stand.

On March 1, 2011, we were granted a patent extending the exclusivity of the BEMA® drug delivery technology in Canada to 2027. The Canadian Patent No. 2,658,585 provides additional patent protection for ONSOLIS® and BELBUCA™. In April 2012, the USPTO granted US Patent No. 8,147,866, which will extend the exclusivity of the BEMA® drug delivery technology for BELBUCA™ and BUNAVAIL® in the United States from 2020 to 2027. In April 2014, the USPTO granted US Patent No. 8,703,177 (issued from US Patent Application No. 13/590,094), which will extend the exclusivity of the BEMA® drug delivery technology for BUNAVAIL® in the United States to at least 2032.

We own various patents and patent applications relating to the BEMA® technology. US Patent No. 6,159,498 (expiration date October 2016), US Patent No. 7,579,019 (expiration date January 22, 2020), US Patent No. 8,147,866 (expiration date July 23, 2027), Canadian Patent No. 2,658,585 (expiration date July 2027), EP2054031 (expiration date July 2027) and EP 0 973 497 (expiration date October 2017) are of particular value to our business and technology platform relating to the BEMA® delivery technology. On February 16, 2010, we filed a complaint with the United States Federal District Court for the District of Columbia, requesting the USPTO be required to further extend the patent term for US 7,579,019 from 835 days to 1,191 days. In March 2011, we prevailed in this case, and the patent expiration date of US Patent No. 7,579,019 is now extended from January 31, 2019 to January 22, 2020.

On January 22, 2014, MonoSol filed a Petition for Inter Partes Review (or IPR) on US Patent No. 7,579,019 with the USPTO. In the Petition, MonoSol is requesting an inter partes review because it is asserting that the claims of US Patent No. 7,579,019 are alleged to be unpatentable over certain prior art references. The USPTO instituted the IPR on the '019 Patent. The USPTO found all claims patentable and MonoSol filed a Request for Rehearing. A decision on MonoSol's request is expected in the first half of 2016. The IPR could invalidate or validate in whole or in part, this patent. Accordingly, we are continuing to defend our US Patent No. 7,579,019 vigorously in the IPR proceedings.

With respect to trademarks, "BDSI®," "BEMA®" and "BUNAVAIL®" are registered trademarks of BioDelivery Sciences International, Inc. ONSOLIS® and BREAKYL™ are trademarks owned by Meda Pharmaceuticals, Inc. PAINKYL™ is a trademark owned by TTY Biopharm. BELBUCA™ is a trademark of Endo Pharmaceuticals Inc.

Clonidine Topical Gel

On March 26, 2013, we entered into the Arcion Agreement with Arcion pursuant to which Arcion agreed to grant to us an exclusive commercial world-wide license, with rights of sublicense, under certain patent and other intellectual property rights of Arcion to develop, manufacture, market, and sell gel products containing clonidine (or a derivative thereof), alone or in combination with other active ingredients, for topical administration for the treatment of painful diabetic neuropathy and other indications (the Clonidine Gel Products).

Per the Arcion Agreement, we have exclusive rights to various patents pertaining to the Clonidine Gel Products. US Patent No. 6,147,102 (expiration date October 26, 2019), US Patent No. 6,534,048 (expiration date October 26, 2019), US Patent No. 8,026,266 (expiration date September 30, 2029) and their corresponding patents in other countries (*e.g.*, Australia, Canada, Germany, *etc.*) are of particular value to our business and technology platform relating to the Clonidine Gel Products.

Although we do not believe that our Clonidine Gel Products are in conflict with, dominated by, or infringing any external patents and we do not believe that we require licenses under external patents for Clonidine Gel Products, it is possible, however, that a court of law in the United States or elsewhere might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our products or technologies. We may be unable to obtain such licenses from the patent holders. If we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

Buprenorphine Depot Injection Product

On October 27, 2014, we entered into a definitive Development and Exclusive License Option Agreement (which we refer to as the Evonik Development Agreement) with Evonik pursuant to which Evonik agreed to grant two exclusive options to acquire exclusive worldwide licenses, with rights of sublicense, to certain patents and other intellectual property rights of Evonik to develop and commercialize certain injectable, extended release products containing buprenorphine (which we refer to as Buprenorphine Depot Injection Products). If such options are exercised, such licenses would be memorialized in a definitive license agreement.

Although we do not believe that any Buprenorphine Depot Injection Products would be in conflict with, dominated by, or infringing any external patents and we do not believe that we require licenses under external patents for Buprenorphine Depot Injection Products, it is possible, however, that a court of law in the United States or elsewhere might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our products or technologies. We may be unable to obtain such licenses from the patent holders. If we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

Manufacturing

We rely on third-party manufacturers, packagers, and analytical testing laboratories to produce commercial product and developmental products for research, product development, and clinical supplies. We are currently party to the following manufacturing arrangements for different companies:

BUNAVAIL®

Effective July 30, 2014, we entered a Supply Agreement with ARx LLC for manufacturing, and effective March 6, 2014, we entered a Supply Agreement with Sharp for packaging for BUNAVAIL® commercial supplies, respectively. Both companies underwent successful FDA preapproval inspections and will be subject to annual quality audits. Both our contracts are also supported by a quality assurance agreement requiring our counterparties to adhere to product quality standards and cGMP manufacturing and packaging requirements. BUNAVAIL® is currently manufactured by ARx LLC.

BELBUCA™

Effective January 5, 2012, we entered a license and development agreement with Endo for BELBUCA™. Over the past two years, the technical operations and supply activities have been gradually transitioned from our company to Endo. As a result of the licensing and developmental agreement, all of the commercial supply agreements will be negotiated by and the responsibility of Endo.

ONSOLIS®

Effective October 17, 2005, we entered into an agreement with Aveva pursuant to supply ONSOLIS® for clinical trials and commercial sale. Under the terms of this agreement, Aveva is the sole supplier of ONSOLIS® for the United States and Canada. The current agreement expires on October 15, 2015. On October 9, 2014, Aveva sent us written notice of their intent not to renew our supply agreement. Therefore, our supply agreement with Aveva will expire on October 15, 2015.

On March 12, 2012, we announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide REMS with two appearance issues raised by FDA during an inspection of Aveva's manufacturing facility. Specifically, the FDA identified the formation of microscopic crystals and a fading of the color in the mucoadhesive layer during the 24-month shelf life of the product. ONSOLIS® has been subsequently reformulated with 24 months of available stability data on the reformulated product.

In February 2015, we re-acquired the rights to the ONSOLIS® NDA from Meda, and we submitted the reformulated product on March 27, 2015 as a prior approval supplement. The reformulated product was approved on August 11, 2015. Since the contract with the approved supplier expired on October 15, 2015, we are currently initiating activities on the qualification of a new supplier. Our anticipated prior approval supplement with requisite stability data for a new manufacturing site is targeted for 3Q 2016 in the event we are able to secure a new commercial partner for the product.

BREAKYL™

Effective December 15, 2006, we entered into a process development agreement and a commercial Supply Agreement on April 26, 2012, both with LTS. Under the terms of this supply agreement, LTS is the exclusive manufacturer of BEMA® Fentanyl for all countries with exception of the United States and Canada. LTS continues to manufacture BREAKYL™ for MEDA since it was first launched in the E.U. in September 2012.

PAINKYL™

We entered a license and commercial supply agreement with TTY in Taiwan on October 4, 2010. In July 2013, Taiwan FDA (TFDA) approved PAINKYL™ for market authorization. LTS manufacture PAINKYL™ for *TTY* since it was first launched on January 28, 2015

Clonidine Topical Gel

Effective October 22, 2014, we entered into a master service agreement with Ei LLC for formulation, analytical and manufacturing services, clinical supplies, packaging and product release for the Clonidine Topical Gel. We have also made similar arrangements with Frontage and Tapemark for bulk manufacture for initial clinical trial supplies and individual dose units packaging, respectively.

Buprenorphine Depot Injection

Effective October 27, 2014, we entered into an exclusive agreement with Evonik to develop and commercialize a proprietary long acting, sustained release, biodegradable microparticle buprenorphine formulation capable of providing 30 days of continuous therapy following a subcutaneous injection. Through the agreement, we also secured the license to Evonik-owned intellectual property related to products for the maintenance treatment of opioid dependence and for the treatment of chronic pain.

Sales and Marketing

Following, and assuming, completion of clinical development and regulatory approval for each candidate product, we will pursue one of several approaches (or a combination thereof) for marketing and selling our products. These include licensing the products to appropriate partners so that they can market and distribute the products for us, co-promotions where we would share in the sales promotion, or use of our own recently established contract sales organization. We have already utilized this strategy with regard to our worldwide license and development agreement with Endo for BELBUCA™ for chronic pain and to our approved product ONSOLIS®/ BREAKYL™ with our licensing agreements with Meda world-wide except Taiwan (TTY) and South Korea.

This strategy was further implemented in 2014 with the creation of our own exclusive contract sales force through Quintiles for the launch of BUNAVAIL®. This existing sales force (the leadership of which we have made our permanent employees) provides us with the means to sell BUNAVAIL® but also affords us the opportunity to consider selling other products in our own portfolio or those that we acquire, in-license or for which we may have co-promote opportunities. Using our own sales force provides us with significantly more control over commercialization efforts and makes us capable of selling our own products in specialty pharmaceutical markets while leaving with partners promotional responsibilities for the large primary care audiences.

For BUNAVAIL®, we completed our plans to self-commercialize the product in early 2014 and successfully launched our contract sales force in September.

BUNAVAIL®

During 2013, we engaged in the process of assessing a variety of strategic options for the commercialization of BUNAVAIL® in the U.S. The options we explored included commercial partnerships, co-promotion arrangements, leading commercial efforts internally through the use of contract resources, or a combination of the aforementioned strategic options. Outside the U.S., we will likely pursue partnerships.

Following a thorough assessment of commercialization options for BUNAVAIL®, we identified BUNAVAIL® as an attractive product to build a commercial presence capable of supporting both BUNAVAIL® and our other future products. Additionally, the self-commercialization of BUNAVAIL® supports our longer term vision to become a fully integrated pharmaceutical company. The dynamics of the opioid dependence market made self-commercialization a feasible and attractive option. In total, approximately 90% of all prescriptions are written by approximately 5,000 physicians – which include primary care physicians, psychiatrists, addiction medicine specialists and pain specialists, with most concentrated in the eastern third of the U.S. and the west coast, allowing for coverage of a majority of the prescriber base with a modest sized sales force. Additionally, the relatively small prescriber base along with the limited number of competitors results in relatively modest marketing expenditures. And finally, the high awareness and physician acceptance of buprenorphine for the treatment of opioid dependence lessens the need for costly educational and promotional programs.

Plans to self-commercialize BUNAVAIL® were completed in early 2014. We chose to utilize internal resources to provide the strategic direction and oversight of specialized contractor resources. In March 2014, we entered into an agreement with Quintiles to support the launch of BUNAVAIL®. Under terms of the agreement, Quintiles provides a range of services to support the commercialization of BUNAVAIL® in the U.S., including recruiting and training a field sales force. Separately, we entered into an agreement with Ashfield Market Access to provide managed markets and trade support for BUNAVAIL®. Ashfield Market Access,

which is led by industry veterans including those who led GlaxoSmithKline's managed markets group for more than 20 years, took responsibility for executing a payer strategy aimed at maximizing patient access to BUNAVAIL®.

We began our efforts at the 2014 annual meeting of the American Society of Addiction Medicine (ASAM) with deployment of a contract Medical Science Liaison (MSL) team under the oversight of Medical Affairs. Following ASAM, the MSL team focused on introducing physicians to the BEMA® technology.

Under our full oversight, recruitment and hiring of our specialty addiction sales force was completed during the third quarter of 2014. A highly experienced sales force with experience in the areas of pain and addiction medicine was deployed. Approximately 60% of representatives held ten or more years of pharmaceutical sales experience and nearly 90% with five or more years of experience. Three-quarters of the field force previously had prior experience in the areas of pain management or addiction medicine.

On November 3, 2014, we announced the availability of BUNAVAIL® in the U.S. where it was supported by a 60-person field sales force and a full marketing effort targeting the nearly 5,000 physicians who are responsible for approximately ninety percent of prescriptions for buprenorphine products for the treatment of opioid dependence. The launch was also supported by a full marketing effort aimed at increasing product awareness including advertising and promotion, direct mail and email, a speakers program and a number of initiatives, including a copay support program, to minimize access issues.

In August 2015, we announced the appointment of Scott M. Plesha as Senior Vice President of Sales. Mr. Plesha joined us with more than 25 years of sales experience within the pharmaceutical and medical industries. Most recently, he held the position of Senior Vice President, GI Sales Force and Training, for Salix Pharmaceuticals, where since 2002 he led Salix's top rated gastroenterology (GI) specialty sales force. In addition, we hired the head of managed markets for Salix to assume responsibility for our managed markets efforts.

We recognize the competitive nature of the opioid dependence market and continuously evaluate the size and structure of our sales force relative to our competitors. In late 2015, we added additional territories in areas of high business potential (from 51 to 65). This gave us the ability to improve our overall reach and frequency among our target physicians and to improve the efficiency and productivity of our sales force. Additionally, we added 4 Regional Sales Managers, bringing the total to 8, allowing for greater customer interaction, more focus on performance management and an increased opportunity for field-based coaching and training. Combined, the four recently hired Regional Sales Managers have nearly 60 years of pharmaceutical sales and sales management experience and were top performers and recipients of multiple President's Club and other awards. All four Regional Sales Managers joined our company following successful careers at Salix Pharmaceuticals.

The sales force changes described were completed in early 2016. While we recognize that we may not be able to support a sales force the size of more established competitors, we believe we can maintain a competitive share of voice through both personal and non-personal selling efforts. We also believe that BUNAVAIL® offers distinct and important benefits over other products in the opioid dependence market which will allow it to successfully compete in the long term.

BELBUCA™ (buprenorphine) buccal film for Chronic Pain

We announced the signing of a world-wide licensing and development agreement for BELBUCA™ with Endo in January 2012. Under terms of the agreement, Endo is responsible for the manufacturing, distribution, marketing and sales of BELBUCA™ on a worldwide basis.

Endo is one of the premier companies in the area of pain management and has demonstrated significant success in the pain space particularly with the development, launch and commercialization of a portfolio of pain therapeutics including Opana® ER, Lidoderm®, Percocet® and Voltaren® Gel. Endo's long experience in pain includes a strong sales and marketing capability, with sales representatives that are established in the offices of many high value healthcare practitioners who are high prescribers of opioids and other pain products.

We believe that BELBUCA™ is an excellent fit to Endo's pain portfolio and will provide Endo with an additional pain product that can be aligned with other products in their portfolio based on factors such as pain severity and opioid scheduling. Endo is responsible for all sales and marketing and will focus their promotional and educational efforts on high volume prescribers of opioids and other analgesics, which includes predominantly pain management specialists and primary care physicians. Endo more than doubled the size of its pain sales force to support the launch of BELBUCA™. Endo will commercialize BELBUCA™ outside the U.S. through its own efforts or through regional partnerships. We believe that BELBUCA™ would potentially be aligned with the needs of pain specialists and primary care physicians who seek an alternative to Schedule II opioids for the treatment of moderate to severe chronic pain that is not adequately controlled with commonly prescribed first-line therapies (e.g. short acting opioids).

ONSOLIS®/BREAKYL™

European Union

In September 2006, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for BEMA® Fentanyl in the E.U., which is being marketed in Europe under the trade name BREAKYL™. The agreement between Meda and us specifies that Meda is responsible for all post-approval clinical studies and label expansion trials. BREAKYL™ received marketing authorization from the European regulatory authorities in October 2010 and has been launched in over thirteen European countries including Germany, France and the U.K. On January 2, 2009, we entered into amendments to our agreements with Meda to grant Meda worldwide commercialization rights for ONSOLIS®/BREAKYL™ with the exception of Taiwan and South Korea. The sales royalties to be received by us will be the same for all territories as agreed to for Europe.

North America

In September 2007, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for ONSOLIS®, under which Meda was responsible for the sales, marketing and distribution of ONSOLIS® in the U.S., Canada and Mexico. The agreement specified that ONSOLIS® was to be detailed in the primary position for a specified duration among target prescribers.

ONSOLIS® was commercially launched in the United States in mid-October 2009 following approval by the FDA in July 2009. Under the Meda agreement, ONSOLIS® commercial efforts were supported by a therapeutic specialty sales force assembled by Meda to target oncologists and pain management specialists treating breakthrough cancer pain.

ONSOLIS® was approved by the Canadian regulatory authorities in May 2010, and was the first product approved in Canada for the management of breakthrough cancer pain. Meda Valeant Pharma Canada Inc., a joint venture between Meda and Valeant Canada Limited was responsible for promotion of ONSOLIS® in Canada. ONSOLIS® was launched in Canada in the third quarter of 2011.

On March 12, 2012, we announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide REMS until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, raised by the FDA during an inspection of our North American manufacturing partner for ONSOLIS®, Aveva. While the appearance issues do not affect the product's underlying integrity, safety or performance, the FDA believed that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of ONSOLIS® was found to be specific to a buffer used in its formulation.

On January 27, 2015, we announced that we had entered into the Assignment Agreement with Meda to return to us the marketing authorizations for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. We made modifications to the formulation for ONSOLIS®, submitted a prior approval supplement and subsequently received FDA approval in August 2015. We continue to evaluate options to return ONSOLIS® to the market, including outlicensing ONSOLIS® to a company with a commercial presence in pain.

Additional Territories

In 2010, licensing agreements were secured in Taiwan and South Korea providing the opportunity for commercialization in all territories globally. In May 2010, we announced a commercial partnership with Kunwha for the exclusive rights to develop and commercialize ONSOLIS® in the Republic of Korea. Those rights were subsequently returned to us due to changes in the market dynamics and the Kunwha License Agreement was terminated on August 31, 2015. In October 2010, a commercial partnership with TTY was announced, providing commercialization rights for Taiwan. This agreement results in potential milestone payments of up to $1.3 million along with royalties based on sales and included an upfront payment of $0.3 million.

In November 2011, we announced that TTY had submitted a NDA for marketing authorization of BEMA® Fentanyl to the Taiwan Food and Drug Administration. This triggered a milestone payment to us of approximately $0.3 million, which was received November 2011. In July 2013, we announced the regulatory approval of BEMA® Fentanyl in Taiwan, where the product will be marketed under the brand name PAINKYL™. The approval in Taiwan resulted in a milestone payment of $0.3 million to us, which was received in the third quarter 2013. TTY launched PAINKYL™ in Taiwan in 2015.

We believe that utilizing commercial partners to market and sell ONSOLIS®/BREAKYL™/PAINKYL™ relieves us of the burden associated with a significant increase in expenditures or headcount otherwise associated with a commercial launch of a first product. Additionally, we believe our commercial partnerships for ONSOLIS®/BREAKYL™ allows internal efforts to be focused on the development of our pipeline of products. Our partnership with Endo allows for access to a large and heavily primary care based target audience which could be associated with significant expenditures and commercial risk.

Government Regulation

The nonclinical and clinical development, manufacturing and marketing of any drug product, is subject to significant regulation by governmental authorities in the United States and other countries. Complying with these regulations involves considerable time, expense and uncertainty.

In the United States, drugs are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our drugs. Drug development and approval within this regulatory framework is difficult to predict, requires a number of years and involves the expenditure of substantial resources. Moreover, ongoing legislation by Congress and rule making by the FDA presents an ever-changing landscape where we could be required to undertake additional activities before any governmental approval to market our products is granted.

The steps required before a pharmaceutical product may be marketed in the United States include:

1. small scale manufacturing of the product;
2. laboratory and nonclinical tests for safety of the product;
3. submission of an IND to the FDA for the product which must become effective before human clinical trials can commence;
4. larger scale manufacturing of the product;
5. clinical trials to characterize the efficacy and safety of the product in the intended patient population;
6. submission of an NDA to the FDA; and
7. approval of the NDA by the FDA.

In addition to obtaining FDA approval for each product, each product-manufacturing establishment must be registered with, and approved by, the FDA. Manufacturing establishments are subject to biennial inspections by the FDA and must comply with the FDA's Good Manufacturing Practices and with other federal and local regulations.

Nonclinical Testing

Nonclinical testing includes laboratory evaluations of the active drug substance and formulation, as well as tissue culture and animal studies to assess the safety and potential efficacy of the investigational product. Nonclinical tests must be conducted by laboratories that comply with FDA Good Laboratory Practices regulations. Nonclinical testing is inherently risky and the results can be unpredictable or difficult to interpret. The results of nonclinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of clinical trials. Unless the FDA places a clinical hold on an IND, clinical studies may begin thirty (30) days after the IND is submitted.

We have relied and intend to continue to rely on third party contractors to perform nonclinical trials.

Clinical Research

Clinical research involves administration of the investigational product to healthy volunteers and/or to patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with Good Clinical Practices following protocols acceptable to FDA that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy and the planned evaluation of results. Each protocol must be submitted to the FDA prior to its conduct. Further, each clinical study must be conducted under the auspices of an independent institutional review board that protects the rights and welfare of the study subjects. The drug product used in clinical trials must be manufactured according to Good Manufacturing Practices.

Clinical research is typically conducted in three sequential phases, but the phases may overlap and not all phases may be necessary when developing investigational products that will utilize the FDA's 505(b)(2) approval process. Phase 1 studies are typically performed in normal healthy volunteers to assess the safety (adverse side effects), absorption, metabolism, bio-distribution, excretion, and food and drug interactions of the investigational drug product. Additional studies may be performed to assess abuse potential as well as limited measures of pharmacologic effect. Phase 2 is the proof of principle stage and involves studies in a limited number of patients in order to:

- assess the potential efficacy of the product for specific, targeted indications;
- identify the range of doses and dose regimens likely to be effective for the indication; and
- identify possible adverse events and safety risks.

When there is evidence that the product may be effective and has an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to establish the clinical efficacy and safety profile of the product within a larger population at geographically dispersed clinical study sites. Phase 3 frequently involves randomized controlled trials and, whenever possible, studies are conducted in a manner so that neither the patient nor the investigator knows what treatment is being administered. We, or the FDA, may suspend clinical trials at any time if it is believed that the individuals participating in such trials are being exposed to unacceptable health risks.

New Drug Application and FDA Approval Process

The results of the pharmaceutical and manufacturing development work, nonclinical studies and clinical studies are submitted to the FDA in the form of an NDA for approval to market and sell the product. The testing and approval process is likely to require substantial time and effort. In addition to the results of nonclinical and clinical testing, the NDA applicant must submit detailed information about chemistry, manufacturing and controls that will describe how the product is made, packaged, labeled, and tested through the manufacturing process. The manufacturing process continues to develop throughout the period of clinical trials such that at the time of the NDA, it has been demonstrated that there is control of the process and the product can be made consistently at commercial scale.

The NDA review process involves FDA investigation into the details of the manufacturing process, as well as the design and analysis of each of the nonclinical and clinical studies. This review includes inspection of the manufacturing facility, the data recording process for the clinical studies, the record keeping at a sample of clinical trial sites and a thorough review of the results for each nonclinical and clinical study. Through this review, the FDA reaches a decision about the risk-benefit profile of a product candidate. If the benefit outweighs the risk, the FDA begins negotiation with the company on the content of an acceptable package insert and an associated REMS plan if required.

The NDA review process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Consequently, there is a risk that approval may not be granted on a timely basis, if at all. The FDA may deny approval of an NDA if applicable regulatory criteria are not satisfied. Moreover, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which it may be marketed, require additional testing or information, or require post-marketing testing (Phase 4) and surveillance to monitor the safety of a company's product if it does not believe the NDA contains adequate evidence of its safety. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or health problems are identified that would alter the risk-benefit analysis for the product. Post-approval studies may be conducted to explore the use of the product for new indications or populations such as pediatrics.

Among the conditions for NDA approval is the requirement that any prospective manufacturer's quality control and manufacturing procedures conform to Good Manufacturing Practices and the specifications approved in the NDA. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of quality control and quality assurance to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by other federal, state or local agencies. Additionally, in the event of non-compliance, the FDA may issue warning letters and/or seek criminal and civil penalties, enjoin manufacture, seize product or revoke approval.

Risk Evaluation and Mitigation Strategy

In March 2008, new legislation designated as the Food and Drug Administration Amendments Act of 2007 (the FDAAA) took effect. This legislation strengthened the FDA's authority over drug safety and directs the FDA to develop systems aimed at managing the risk-benefit ratio of a drug, with a particular focus on post-approval safety. FDAAA authorized the FDA to require and enforce a Risk Evaluation and Mitigation Strategy, or REMS, if the FDA determines that it is necessary to ensure that the benefits of a drug outweigh the potential risks. The legislation also provides the FDA with increased authority to require REMS at any point in a drug product's lifecycle based on new safety information.

A REMS is defined by the FDA as a strategy to manage a known or potential serious risk associated with a drug or biological product. The FDA's assessment of whether to require a REMS as a condition for approval considers factors such as the size of the population likely to use the drug, the seriousness of the disease or condition that is to be treated by the drug, the expected benefit, and the seriousness of any known or potential adverse events that may be related to the drug. A REMS may be conveyed through the use of a number of tools including a Medication Guide for distribution when the drug is dispensed, a communication plan to physicians to convey potential risks, and elements to ensure safe use. These elements may include provisions that healthcare providers who prescribe the drug and pharmacists who dispense the drug have particular training, experience or special certifications; that the drug be dispensed only in certain healthcare settings; that the drug be dispensed to patients with evidence of safe-use conditions; and/or that patients must be enrolled in a registry. Under the FDAAA, the FDA has also been granted enforcement authority over violations of the REMS provisions. The FDA may impose civil monetary penalties, the drug or biological product can be deemed misbranded, and/or the FDA may obtain injunctive relief against further distribution of the product.

On December 29, 2011, the FDA approved a "class-wide" REMS program covering all transmucosal fentanyl products under a single risk management program. ONSOLIS® is subject to this REMS.

Additionally, FDA has implemented a class-wide REMS covering the extended release and long acting opioid class. The class-wide REMS program consists of a REMS-compliant educational program offered by an accredited provider of continuing medical education, patient counseling materials and a medication guide. BELBUCA™ is anticipated to fall within the existing class-wide REMS program. The cost and implementation of the extended release and long-acting opioid REMS is shared among multiple companies in the category.

There also continues to be a REMS in place for buprenorphine for the treatment of opioid dependence. BUNAVAIL® is included in this existing REMS that is far less cumbersome than the ONSOLIS® REMS and includes a medication guide and healthcare professional and patient education.

International Approval

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country at this time has its own procedures and requirements.

Other Regulation

In addition to regulations enforced by the FDA, we are also subject to United States regulation under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state, local or similar foreign regulations. Our research and development may involve the controlled use of hazardous materials, chemicals and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of any accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Employees

As of March 7, 2016, we have 40 full-time employees. Fourteen are involved in our clinical development program and operations, ten handle our administration, accounting, legal and supply chain management and sixteen handle our internal sales, marketing and managed markets. Advanced degrees and certifications of our staff include four Ph.Ds, two Pharm.Ds, two M.Ds, one CPA, seven MBAs, two MSs and one JD. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our engineering and administrative functions. We consider relations with all of our employees to be good. Each of our employees has entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (which we refer to herein as the Exchange Act), are filed with the SEC. Such reports and other information that we file with the SEC are available free of charge on our website at http://bdsi.investorroom.com/sec_filings when such reports are available on the SEC website. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. The contents of these websites are not incorporated into this filing. Further, the foregoing references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before purchasing our common stock, you should carefully consider the following risk factors as well as all other information contained in this Report, including our consolidated financial statements and the related notes. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Relating to Our Business

We have incurred significant losses since inception, have relatively limited working capital and have only generated minimal revenues from actual products sales. As such, you cannot rely upon our historical operating performance to make an investment decision regarding our company.

From our inception in January 1997 and through December 31, 2015, we have recorded significant losses. Our accumulated deficit at December 31, 2015 was approximately $243.2 million. As of December 31, 2015, we had working capital of approximately $64 million, but we do not generate meaningful recurring revenue or cash flow and thus use our working capital to maintain our operations. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates and product concepts, obtain the required regulatory approvals and manufacture, market and sell our products if approved. We may be unable to achieve any or all of these goals.

Although we have generated licensing-related and other revenue to date, we have only recently begun to generate revenue from the commercial sales of our approved products —BUNAVAIL®, BELBUCA™ and ONSOLIS® — and such revenue has been minimal to date. In the case of BUNAVAIL®, sales have been minimal as we have only recently commenced the commercial launch of the product in November 2014 and are subject to the risks of launching a new product. There is a risk that we will be unable to generate sustained and predictable revenues from product sales. In the case of BELBUCA™, our recent approval has only recently generated milestone revenue from our commercial partner. In the case of ONSOLIS®, sales have been adversely affected by: (i) the lack of a uniform REMS program at the time of the launch of ONSOLIS®, and (ii) certain post-FDA approval appearance issues associated with ONSOLIS® which have led to the temporary suspension of manufacturing and marketing of ONSOLIS® in the US and Canada.

Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel. Since 2005, we have also focused on clinical and commercialization activities, originally relating to ONSOLIS® and more recently with BUNAVAIL®, BELBUCA™, Clonidine Topical Gel, and Buprenorphine Depot injection. This relatively limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize our technologies and proposed formulations or products, obtain FDA approval and achieve market acceptance of our proposed formulations or products and respond to competition. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive material revenues from our product candidates or product concepts in the timeframes we project, if at all, and our inability to do so would materially and adversely impact our viability as a company.

There are risks and we have experienced challenges associated with the November 2014 launch of our BUNAVAIL® product. We thus cannot accurately predict the volume or timing of any future sales of our recently launched BUNAVAIL® product, making the timing of any revenues therefrom difficult to predict.

In 2014, we commenced the commercial launch of BUNAVAIL®, which represented the commencement of the first self-commercialization effort for our company. As such, our ability to establish and increase sales of BUNAVAIL® is important to us, both for the revenue it may generate as well as to demonstrate our capabilities as an integrated specialty pharmaceutical company as opposed to a research and development organization. The commercial launch of any product is subject to significant risks, and particularly so for us given the size and relative in experience of our company with commercial operations. In addition, we face lengthy customer evaluation and formulary and managed care approval processes associated with the launch of BUNAVAIL®. Consequently, we have and may continue to incur substantial expenses and devote significant management effort and expense in developing customer trial and adoption of BUNAVAIL® which may or have an adverse impact on our ability to generate revenue from sales of this product. We must obtain as approval for commercial insurance and government reimbursement in order to initiate high volume sales of BUNAVAIL®, which approval is subject to risk, potential delays and contract terms, and which may not actually occur or may occur with less favorable terms. The sales of BUNAVAIL® are also dependent on the effectiveness of our selling and promotional efforts as well as influenced by competitive activity, new product approvals, pricing pressure, litigation, regulatory influences, and generic entrants. We have to some extent experienced all of the foregoing in connection with our launch of BUNAVAIL®As such, we cannot accurately predict the volume or timing of any future sales of BUNAVAIL®, and our inability to commercialize this product would likely have an adverse effect on our results of operations and public stock price.

We have limited experience as a company in self-commercializing pharmaceutical products, which heightens the risks related to our self-commercialization of BUNAVAIL®.

Prior to the launch of BUNAVAIL®, we had only partnered our products with larger pharmaceutical companies, who have taken primary responsibility for development and commercialization activities for such products. We are presently self-commercializing BUNAVAIL®. As a company, prior to our commercialization of BUNAVAIL®, we had never been primarily responsible for manufacturing, supply chain, sales and marketing efforts for one of our products, and therefore our efforts with BUNAVAIL® are our initial efforts in this regard. Given this lack of experience, there is a risk that we may be unable to adequately execute one or more elements of our commercial plans for BUNAVAIL®. If this were to occur, we may not achieve anticipated revenues from BUNAVAIL®, which would have a material adverse effect on our results of operations, cash flow, reputation and stock price.

BUNAVAIL® is the first product that we have elected to commercialize. If we are unable to adequately develop, implement, or manage our sales, marketing and distribution capabilities, either on our own or through third parties who perform these functions, our commercialization efforts for BUNAVAIL® or any future product we may commercialize would not produce the desired results, which would hurt our revenues and results of operations.

Prior to our decision to commercialize BUNAVAIL®, we have relied on third parties to manage sales and marketing efforts for us, including Meda for ONSOLIS® and Endo for BELBUCA™. We therefore have little experience as a company in commercializing a product, and our sales, marketing and distribution capabilities are new. As such, we may not achieve success in marketing and promoting BUNAVAIL®, or any other products we develop or acquire in the future or products we may commercialize through the exercise of co-promotion rights. Specifically, in order to optimize the commercial potential of BUNAVAIL®, we must execute upon our commercialization plan effectively and efficiently. In addition, we must continually assess and modify our commercialization plan in order to adapt to the promotional response. Further, we must continue to focus and refine our marketing campaign to ensure a clear and understandable physician-patient dialogue around BUNAVAIL® as an appropriate therapy. In addition, we must provide our sales force with the highest quality training, support, guidance and oversight in order for them to effectively promote BUNAVAIL®. If we fail to perform these commercial functions in the highest quality manner, BUNAVAIL® will not achieve its maximum commercial potential or any level of success at all. With respect to BUNAVAIL®, we rely on our agreement with Quintiles, who is responsible for providing our sales force on an outsourced basis. Should our relationship with Quintiles deteriorate or if our agreement with Quintiles is terminated, our sales efforts with BUNAVAIL® would likely suffer materially and we may not be able to keep or reconstitute our sales force. In addition, sales and marketing efforts could be negatively impacted by the delay or failure to obtain additional supportive clinical trial data for our products, as is the requirement for BUNAVAIL®. The deterioration or loss of our sales force would materially and adversely impact our ability to generate sales revenue, which would hurt our results of operations. Finally, we are competing and expect to compete with other companies that currently have extensive and well-funded marketing and sales operations, and our marketing and sales efforts may be unable to compete against these other companies, which would also hurt our results of operations.

If our competitors are successful in obtaining approval for Abbreviated New Drug Applications for products that have the same active ingredients as our BUNAVAIL® product, sales of our BUNAVAIL® product may be adversely affected.

Our competitors may submit for approval certain Abbreviated New Drug Applications (or ANDAs) which provide for the marketing of a drug product that has the same active ingredients in the same strengths and dosage form as a drug product already listed with the FDA, and which has been shown to be bioequivalent to such FDA-listed drug. Drugs approved in this way are commonly referred to as generic versions of a listed drug, and can often be substituted by pharmacists under prescriptions written for an original listed drug. Any applicant filing an ANDA is required to certify to the FDA that the new product subject to the ANDA will not infringe an already approved product's listed patents or that such patents are invalid (otherwise known as a Paragraph IV Certification).

In February 2016, we announced that a generic competitor (Actavis Laboratories UT, Inc.) had filed a Paragraph IV Certification challenging certain of our BUNAVAIL-related patents. The filing of this certification will require us to initiate costly litigation against Actavis. In addition, a number of our competitor companies have filed Paragraph IV Certifications challenging the patent for Suboxone® film, the market leader in the field in which we are seeking to generate sales of BUNAVAIL®. To the extent that any company is successful in challenging the validity of certain patents covering BUNAVAIL® or Suboxone® film under a Paragraph IV Certification, it could result in FDA approval of a drug that is lower in price to BUNAVAIL® or Suboxone® film. Such a new drug could make it more difficult for BUNAVAIL® to gain any significant market share in an increasingly generic marketplace, which would have a material adverse effect on our results of operations, cash flow, reputation and stock price.

Until we are able to generate recurring and predictable revenues for commercial operations, we will likely need to raise additional capital from time to time to continue our operations or expand our business, and our failure to do so would significantly impair our ability to fund our operations, develop our technologies and product candidates, attract commercial partners, retain key personnel or promote our products.

Our operations have been funded almost entirely by external financing and not from commercial revenues. Such financing has historically come primarily from license and royalty fees, the sale of common and preferred stock and convertible debt to third parties, related party loans and, to a lesser degree, from grants and bank loans. At December 31, 2015, we had cash of approximately $83.6 million. Depending on BUNAVAIL® sales, receipt of future Endo milestone and royalty payments on sales for BELBUCA™, and royalty payments from both MEDA and TTY, we may not need to raise capital to fund our foreseeable business activities. However, even without any business adjustments, we have sufficient cash into the middle of 2017, although this assumes that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements. Moreover, all or a portion of a $20 million patent-related milestone payment we received from Endo could be refundable to Endo if a generic form of BELBUCA™ is sold in the United States in the future, with the amount of the refund (if any) being dependent on the timing of the generic sales. If this were to occur our cash position would be adverse affected.

Depending on the timing and receipt or potential refund of milestone payments from our commercial partnership with Endo and given our anticipated cash usage and lack of significant revenues, there is a risk that we will need to raise additional capital in the future to fund our anticipated operating expenses and progress our business plans. This will include in large part the need to fund our current and potential new development activities. As a result, we may require significant additional capital to further our planned activities. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make raising additional capital more difficult or impossible and may also result in a lower price for our shares.

We may have difficulty raising any needed additional capital.

We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of material revenues from sales, as well as the inherent business risks associated with our company and present and future market conditions. Our business currently only generates a small amount of revenue from product sales and milestone revenues, and such current sources of revenue

will likely not be sufficient to meet our present and future capital requirements. Therefore, given that we plan to continue to expend substantial funds on commercialization activities (including those relating to BUNAVAIL®) as well as potentially on other strategic initiatives, there is a risk that we will require additional capital to fund these activities. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs, product launches or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are subject to numerous risks.

Our long term capital requirements are expected to depend on many factors, including, among others:

- the number of potential products we have in development;
- progress and cost of our research and development programs;
- progress with non-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) clearance and addressing regulatory and other issues that may arise post-approval (such as we have experienced with ONSOLIS® and, to a lesser extent, with BUNAVAIL®);
- costs involved in preparing, filing, prosecuting, maintaining and enforcing (through litigation or other means) our patents, trademarks and other intellectual property;
- costs of developing sales, marketing and distribution channels and our ability to sell our products;
- costs involved in establishing manufacturing capabilities for commercial quantities of our products;
- costs we may incur in acquiring new technologies or products;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining employees and consultants;
- costs for training physicians; and
- legal, accounting, insurance and other professional and business related costs.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources, which may have a material effect on our current or future business prospects.

Our additional financing requirements could result in dilution to existing stockholders.

The additional financings which we have undertaken and which we will likely in the future require, have and may be obtained through one or more transactions that have diluted or will dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 75 million shares of common stock and 5 million shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

Our amended and restated credit and security Agreement with MidCap Financial Trust (or MidCap) contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect under our Credit Agreement if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

In May 2015, we entered into a $30 million amended and restated credit and secured loan facility with MidCap. The credit agreement is a restatement, amendment and modification of a prior credit and security agreement, dated as of July 5, 2013 between us and MidCap, and certain lenders thereto. The credit agreement restructures, renews, extends and modifies the obligations under the prior agreement and the other financing documents executed in connection with the prior agreement. The amount of principal under the prior loan, which was included as part of the Loan, was approximately $9.3 million. We received net loan proceeds in the aggregate amount of approximately $20.1 million. The agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur additional indebtedness;
- enter into a merger, consolidation or certain changing of control events without complying with the terms of the credit agreement;
- change the nature of our business;

- change our organizational structure or type;
- amend, modify or waive any of our material agreements or organizational documents;
- grant certain types of liens on our assets;
- make certain investments;
- pay cash dividends;
- enter into material transactions with affiliates; and

The restrictive covenants of the Credit Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. A breach of any of these covenants could result in an event of default under the Credit Agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the Credit Agreement occurs. In the case of a continuing event of default under the agreement, MidCap could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, proceed against the collateral in which we granted MidCap a security interest under the Credit Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Credit Agreement are secured by all of our existing and future assets (excluding certain intellectual property).

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to make any required prepayment or repay such indebtedness at the time any such prepayment event or event of default occurs. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

Until we enter into a replacement license agreement for the marketing of ONSOLIS® in North America, we will not receive revenues from our ONSOLIS® product.

In January 2015, we entered into a definitive assignment agreement (which was extended in February 2016) under which Meda transferred back to us the rights to marketing authorizations in the United States for ONSOLIS®. As a result, we must find a new strategic partner to enter into a potential replacement license. To date, we have been unable to secure a replacement partner, and there is a risk that we will be unable to find a replacement licensee for ONSOLIS® in a timely manner, or at all. If we fail to find a replacement licensee, we will not receive any royalty from revenues associated with the sale of ONSOLIS®, as contemplated by the original Meda license. In addition, we may be required to market the product without any assistance from a third party that specializes in the marketing within the product category and may be better equipped to effect a higher volume of sales. We may expend significant resources to these efforts without any assurance that such marketing efforts will yield any substantial revenue stream.

Moreover, in the event that we cannot identify a replacement licensee by a certain agreed upon date, Meda will have the right, but not the obligation, to demand that the marketing authorizations, and the rights to pursue marketing authorizations, for ONSOLIS® in North America revert back to Meda, with the full reinstatement of all of Meda's rights and obligations under the Meda license. Such reinstatement would be in the full discretion of Meda and we cannot provide any assurance that Meda will exercise its option to reinstate the license. If we cannot find a replacement licensee, and Meda does not choose to reinstate its license, our revenue and results of operations may be adversely affected.

Acceptance of our technologies, product candidates or products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate material revenues.

Our future financial performance will depend, to a large extent, upon the introduction and physician and patient acceptance of our technologies, product candidates and products. Even if approved for marketing by the necessary regulatory authorities, our technologies, product candidates and products may not achieve market acceptance.

The degree of market acceptance for our products and product candidates will depend upon a number of factors, including:

- regulatory clearance of marketing claims for the uses that we are developing;
- demonstration of the advantages, safety and efficacy of our products and technologies;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our products;
- regulatory programs such as the class-wide REMS for ONSOLIS® or market (including competitive) forces that may make it more difficult for us to penetrate a particular market segment; and
- ability to timely and effectively manufacture and market our products.

Physicians, various other health care providers, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our approved products or product candidates. If we are unable to obtain regulatory approval, or are unable (either on our own or through third parties) to manufacture, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

All of these risks are particularly true for BUNAVAIL®, which is our first product that we have commercialized ourselves.

If we are unable to convince physicians as to the benefits of our products or product candidates, we may incur delays or additional expense in our attempt to establish market acceptance.

Use of our products and, if approved, our product candidates will require physicians to be informed regarding the intended benefits of our products and product candidates. The time and cost of such an educational process may be substantial. Inability to carry out this physician education process may adversely affect market acceptance of our proposed formulations or products. We may be unable to timely educate physicians regarding our intended pharmaceutical formulations or products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our formulations or products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our products or product candidates are created, if at all. Nonetheless, even with our best efforts, certain physicians may never prescribe our product.

We have been and expect to be significantly dependent on our collaborative agreements for the development, manufacturing and sales of our products and product candidates, which expose us to the risk of reliance on the performance of third parties.

In conducting our research and development activities, we currently rely, and expect to continue to rely, on numerous collaborative agreements with third parties such as manufacturers, contract research organizations, contract sales organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements are our commercialization agreement with Endo, our agreements relating to Clonidine Topical Gel and Buprenorphine Depot Injection, and our manufacturing agreements with LTS relating to BREAKYL™. For BUNAVAIL®, we have manufacturing and supply arrangements in place.

The termination of these relationships, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under their applicable agreements or arrangements with us, or our failure to secure additional agreements for our product candidates, including a new licensing agreement for marketing rights in North America with respect to ONSOLIS®, would substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials and commercial sales. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

The risks associated with reliance on key third parties was demonstrated in 2010 when Aveva experienced certain adverse equipment and regulatory issues leading to the temporary stoppage of manufacturing of all products at that site, which left us exposed to delays in our and our partners' commercial plans. In addition, in March 2012 Meda temporarily suspended distribution of ONSOLIS® following discussions with the FDA regarding issues with the product's appearance. Specifically, the FDA raised concerns about two cosmetic issues that may have originated from the formulation used in the manufacturing of ONSOLIS® following an inspection of Aveva, which manufactures ONSOLIS® on our behalf. On March 12, 2012, we announced the postponement of the U.S. and Canadian re-launch of ONSOLIS® until the product formulation can be modified to address these issues. Therefore, ONSOLIS® is not currently being marketed in the U.S. and Canada and the relaunch and additional manufacturing of ONSOLIS® has been postponed until such product issues have been resolved. Any future manufacturing interruptions or related supply issues could have a material adverse effect on our company.

Under our license option agreement with Evonik, we are responsible for paying certain costs relating to the development, formulation and commercialization of buprenorphine for the treatment of opioid dependence. In addition, under our licensing and development agreement with Endo, we are responsible for supporting the clinical development of BELBUCA™ for pain by conducting certain specified clinical trials in the United States. Our inability to adequately project or control our costs under these agreements could have a material adverse effect on our potential profits from such agreements.

We depend upon key personnel who may terminate their employment with us at any time, and we will need to hire additional qualified personnel.

Our ability to achieve our corporate objectives will depend to a significant degree upon the continued services of key management, technical and scientific personnel, particularly our senior executive officers such as our President and Chief Executive Officer Mark Sirgo. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the

process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We may be unable to manage our growth effectively.

After focusing our efforts for many years on clinical development of products, our business strategy now contemplates growth and expansion as we continue our evolution into a fully integrated specialty pharmaceutical company. For example, as we in-license or acquire additional product candidates, we will likely have to expand existing operations in order to conduct additional clinical trials, increase our contract manufacturing capabilities, hire and train new personnel to handle the marketing and sales of our products and assist patients in obtaining reimbursement for the use of our products. We may also need to grow to support our commercial activities for BUNAVAIL® or other approved products. This growth may place significant strain on our management and financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems and procedures. Our ability to effectively manage growth depends on our success in attracting and retaining highly qualified personnel, for which the competition may be intense. If we fail to manage these challenges effectively, our business could be harmed.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims are likely to be asserted against us at some point. In addition, the use in our clinical trials of pharmaceutical formulations and products and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We currently have a general liability/product liability policy which includes coverage for our clinical trials and our commercially marketed products. Annual aggregate limits include $2 million for general liability, with $1 million for each occurrence; product liability is $15 million for aggregate and $15 million per occurrence with excess liability in the amount of an additional $5 million; umbrella liability is $5 million aggregate and $5 million per occurrence. It is possible that this coverage will be insufficient to protect us from future claims. Under our agreements, our partners are required to carry comprehensive general product liability and tort liability insurance, each in amounts not less than $2 million per incident and US $10 million annual aggregate and to name us as an additional insured thereon. However, we or our commercial partners may be unable to obtain or maintain adequate product liability insurance on acceptable terms, if at all, and there is a risk that our insurance will not provide adequate coverage against our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us or our partners could have a material adverse effect on our business, financial condition and results of operations.

Moreover, product liability insurance is costly, and due to the nature of the pharmaceutical products underlying ONSOLIS®, BUNAVAIL®, BELBUCA™ and our product candidates, we or our partners may not be able to obtain such insurance, or, if obtained, we or our partners may not be able to maintain such insurance on economically feasible terms. If a product or product candidate related action is brought against us, or liability is found against us prior to our obtaining product liability insurance for any product or product candidate, or should we have liability found against us for any other matter in excess of any insurance coverage we may carry, we could face significant difficulty continuing operations.

We are presently a party to lawsuits by third parties who claim that our products, methods of manufacture or methods of use infringe on their intellectual property rights, and we may be exposed to these types of claims in the future.

We are presently, and may continue to be, exposed to litigation by third parties based on claims that our technologies, processes, formulations, methods, or products infringe the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in pharmaceutical patents is, in most instances, uncertain and highly complex. Any litigation or claims against us, whether or not valid, would result in substantial costs, could place a significant strain on our financial and human resources and could harm our reputation. Such a situation may force us to do one or more of the following:

- incur significant costs in legal expenses for defending against an intellectual property infringement suit;
- delay the launch of, or cease selling, making, importing, incorporating or using one or more or all of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;

- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our formulations or products, which would be costly and time-consuming.

With respect to our BEMA® delivery technology, the thin film drug delivery technology space is highly competitive. There is a risk that a court of law in the United States' or elsewhere could determine that one or more of our BEMA® based products is in conflict with or covered by external patents. This risk presently exists in our litigation with MonoSol which was filed by MonoSol in November 2010, wherein MonoSol claims that our and our partner's trade secret manufacturing process for ONSOLIS® is infringing upon MonoSol's patented manufacturing process, as well as a similar litigation with Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol relating to our BUNAVAIL® product which was filed in October 2013. If the courts in these cases were to rule against us and our partner in that case, we could be forced to license technology from MonoSol or otherwise incur liability for damages, which could have a material adverse effect on our ability for us or our partners to market and sell BUNAVAIL® or ONSOLIS®. In addition, we expect to initiate patent litigation against Actavis in connection that firm's Paragraph IV Certification filed against certain of our patents.

We have been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market BELBUCA™ and ONSOLIS® within the countries of the European Union. We are required to pay a low single digit royalty on sales of products that are covered by this patent in the European Union. We have not conducted freedom to operate searches and analyses for our other proposed products. Moreover, the possibility exists that a patent could issue that would cover one or more of our products, requiring us to defend a patent infringement suit or necessitating a patent validity challenge that would be costly, time consuming and possibly unsuccessful.

Our lawsuits with MonoSol and RB Pharmaceuticals have caused us to incur significant legal costs to defend ourselves, and we would be subject to similar costs if we are a party to similar lawsuits in the future (such as our pending litigation with Actavis). Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our BEMA® products. We may be unable to obtain such licenses from the patent holders, which could materially and adversely impact our business.

If we are unable to adequately protect or enforce our rights to intellectual property or secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming there is any market share, or incur costly litigation to, enforce, maintain or protect such rights.

Our ability to license, enforce and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others will be important to our commercializing any formulations or products under development. The current and future development of our drug delivery technologies is contingent upon whether we are able to maintain licenses and access patented technologies. Without these licenses, the use of technologies would be limited and the sales of our products could be prohibited. Therefore, any disruption in access to the technologies could substantially delay the development and sale of our products.

The patent positions of biotechnology and pharmaceutical companies, including ours, which involve licensing agreements, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patents, patent applications and licensed rights may not provide protection against competitive technologies or may be held invalid if challenged or could be circumvented. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements provide that materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances and assign the ownership of relevant inventions created during the course of employment to us. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology.

In addition, we may have to resort to costly and time consuming litigation to protect or enforce our rights under certain intellectual property, or to determine their scope, validity or enforceability. For example, we expect to commence litigation against Actavis Laboratories UT, Inc. in connection with a Paragraph IV Certification filed by such company challenging certain of our BUNAVAIL®-related patents. The filing of this certification will require us to initiate costly litigation against Actavis, and there is a risk that we may not prevail and some or all of the claims in the subject patents will be invalidated, which would have a material adverse effect on our company. Enforcing or defending our rights will be expensive, could cause significant diversion of our

resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technologies to develop or sell competing products.

We are dependent on third party suppliers for key components of our delivery technologies, products and product candidates.

Key components of our drug delivery technologies, products and product candidates may be provided by sole or limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs. Certain components used in our research and development activities, such as the active pharmaceutical component of our products, are currently purchased from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

- delays associated with research and development and non-clinical and clinical trials due to an inability to timely obtain a single or limited source component;
- inability to timely obtain an adequate supply of required components; and
- reduced control over pricing, quality and timely delivery.

Our relationships with our manufacturers and suppliers are particularly important to us and any loss of or material diminution of their capabilities due to factors such as regulatory issues, accidents, acts of God or any other factor would have a material adverse effect on our company. Such risks were demonstrated when certain manufacturing issues were experienced at Aveva in 2010-2011 and when, subsequently and separately, the FDA identified certain product appearance issues with ONSOLIS®, which resulted in the March 2012 postponement of the U.S. and Canadian relaunch of the product until such issues are resolved. Any loss of or interruption in the supply of components from our suppliers or other third party suppliers would require us to seek alternative sources of supply or require us to manufacture these components internally, which we are currently not able to do.

If the supply of any components is lost or interrupted, product or components from alternative suppliers may not be available in sufficient quality or in volumes within required time frames, if at all, to meet our or our partners' needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing or cause us to lose sales, force us into breach of other agreements, incur additional costs, delay new product introductions or harm our reputation. Furthermore, product or components from a new supplier may not be identical to those provided by the original supplier. Such differences could have material effects on our overall business plan and timing, could fall outside of regulatory requirements, affect product formulations or the safety and effectiveness of our products that are being developed.

We have limited manufacturing experience and therefore depend on third parties to formulate and manufacture our products. We may not be able to secure or maintain the manufacture of sufficient quantities or at an acceptable cost necessary to successfully commercialize or continue to sell our products.

Our management's expertise has primarily been in the areas of research and development, formulation development and clinical trial phases of pharmaceutical product development. Our management's experience in the manufacturing of pharmaceutical products is more limited and we have limited equipment and no facilities of our own from which these activities could be performed. Therefore, we are fully dependent on third parties for our formulation development, manufacturing and the packaging of our products. This is particularly true with respect to ARx and Sharp, the primary manufacturers of our approved and commercialized product, BUNAVAIL®. We also rely on LTS, the manufacturer for BREAKYL™ in the E.U. This reliance exposes us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to formulate sufficient product to conduct clinical trials and maintain adequate supplies to meet market demand for our products.

Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production, which could leave our commercial partners with inadequate supplies of product to sell, especially when regulatory requirements or customer demand necessitate the need for additional product supplies. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes, and the inability of third party manufacturers like ARx, Sharp and LTS to consistently supply quality product when required would have a material adverse effect on our ability to commercialize and sell our products.

These risks associated with reliance on key third party manufacturers was demonstrated in March 2012, when Meda temporarily suspended distribution of ONSOLIS® following discussions with the FDA regarding certain appearance issues with the product. Specifically, the FDA raised concerns about two appearance issues with ONSOLIS® following an inspection of Aveva's manufacturing facility. On March 12, 2012, we announced the postponement of the U.S. and Canadian relaunch of ONSOLIS® until the product formulation can be modified to address these issues. Therefore, ONSOLIS® is not currently being marketed in the US and Canada and the relaunch and additional manufacturing of ONSOLIS® for those jurisdictions has been postponed until such product issues have been resolved. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including loss of sales and royalty revenue and claims by or against us or our partners for breach of contract.

There are risks associated with our reliance on third parties for marketing, sales, managed care and distribution infrastructure and channels.

We expect that we will be required to enter into agreements with commercial partners (such as our agreement with Endo) to engage in sales, marketing and distribution efforts around our products and product candidates. This is the case with our current self-commercialization activities with BUNAVAIL®, for which we have contracted with Quintiles to provide our sales force. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors. If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, we will need to develop our own sales and marketing capabilities.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our formulations or products;
- cease operations with little or no notice to us; or
- offer, design, manufacture or promote competing formulations or products.

If we fail to develop sales, managed care, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

The class-wide Risk Evaluation and Mitigation Strategy (REMS) for all transmucosal fentanyl products, and similar programs for other narcotic products, may continue to slow sales and marketing efforts for ONSOLIS® and our future sales and marketing efforts for future products that contain narcotics, which could impact our royalty and sales revenue from such products.

Our approved product ONSOLIS® is formulated with the potent narcotic fentanyl. On December 29, 2011, FDA approved a REMS program covering all transmucosal fentanyl products. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all approved transmucosal fentanyl products under a single program and was implemented in March 2012. Additionally, the FDA has implemented a class-wide REMS covering the extended release and long acting opioid class. The class-wide REMS program consists of a REMS-compliant educational program offered by an accredited provider of continuing medical education, patient counseling materials and a medication guide. BELBUCA™ is anticipated to fall within the existing class-wide REMS program. The cost and implementation of the extended release and long-acting opioid REMS is shared among multiple companies in the category.

There also continues to be a REMS in place for buprenorphine for the treatment of opioid dependence referred to as the BTOD (Buprenorphine-containing Transmucosal products for Opioid Dependence) REMS. BUNAVAIL® falls within the existing REMS, which is far less cumbersome and includes a medication guide and healthcare professional and patient education. Given the existence of a REMS in both the extended release and long-acting opioid and opioid dependence markets, we anticipate our products will fit within the existing REMS and will avoid the issues encountered with ONSOLIS®, where a REMS program was yet to be developed.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors, and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. System failures, accidents, or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercialization activities, development programs and our business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 the commercialization of any potential product candidate could be delayed.

Risks Related to Our Products in Development and Regulation

We depend in large part on our BEMA® drug delivery technology, and the loss of access to this technology would terminate or delay the further development of our products, injure our reputation or force us to pay higher fees.

We depend, in large part, on our BEMA® drug delivery technology. The loss of this key technology would seriously impair our business and future viability, and could result in delays in developing, introducing or maintaining our products and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the BEMA® technology or other technologies we gain access to in the future could prevent the implementation or impair the functionality of our products or formulations, delay new product or formulation introductions or injure our reputation. If we are required to acquire or enter into license agreements with third parties for replacement technologies, we could be subject to higher fees, milestone or royalty payments, assuming we could access such technologies at all.

Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our technologies and proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.

Our research and development activities and the manufacture and marketing of our products and product candidates are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA or foreign regulatory clearance to market our proposed formulations and products, we will have to demonstrate that our formulations and products are safe and effective in the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, regulatory approvals can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources.

Moreover, although we received FDA approval for BUNAVAIL®, BELBUCA™ and ONSOLIS®, ONSOLIS® is not currently being marketed in the U.S. and Canada pending resolution of certain appearance and related formulation issues, and we may not receive regulatory approval for any required changes to the ONSOLIS® formulation or of our other product candidates. We may be unable to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and viability.

Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair the viability of our company.

In order to be commercially viable, we must research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute formulations or products incorporating our technologies. For each drug that we formulate with our drug delivery technologies, we must meet a number of critical developmental milestones, including:

- demonstration of the benefit from delivery of each specific drug through our drug delivery technologies;
- demonstration, through non-clinical and clinical trials, that our drug delivery technologies are safe and effective; and
- establishment of a viable Good Manufacturing Process capable of potential scale-up.

The estimated required capital and time-frames necessary to achieve these developmental milestones is subject to inherent risks, many of which may be beyond our control. As such, we may not be able to achieve these or similar milestones for any of our proposed product candidates or other product candidates in the future. Our failure to meet these or other critical milestones would adversely affect the viability of our company.

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny as well as the risk of failing to meet the primary endpoint of such trials. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a drug product, the FDA requires the submission of an IND. The FDA has 30 days to review the IND and, unless the FDA raises an issue or concern about the clinical trial plan during that time period, the IND becomes effective at the end of that 30 days and sponsors may proceed with their clinical trial plans. The FDA can suspend or terminate clinical trials at any time due to a number of factors, including for safety or efficacy reasons, because we or our clinical investigators did not comply with the FDA's requirements for conducting clinical trials, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If the FDA does not permit us to proceed with our planned clinical trials or the trials are suspended or permanently terminated by us, the FDA or any institutional review boards overseeing the trials, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, it is our stated intention to seek to avail ourselves of the FDA's 505(b)(2) approval procedure where it is appropriate to do so. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file a NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected. For example, in September 2012, the FDA received a Citizen Petition requesting that it refuse to file any Section 505(b)(2) NDA or abbreviated new drug application, or ANDA, for buprenorphine/naloxone drugs intended to be applied to the oral mucosal membranes unless such application refers to the sublingual film formulation of Suboxone®, rather than the tablet formulation, as the reference listed drug, or RLD. Our proposed Section 505(b)(2) marketing application for BUNAVAIL® is expected to reference the tablet formulation of Suboxone® rather than the film formulation as the reference listed drug, and the data we have generated has been based off of the tablet formulation of Suboxone®. While the FDA, on February 22, 2013, rejected the Citizen Petition referred to above, we may be faced with similar issues in the future which might require us to conduct additional studies of our product candidates or otherwise face delays and additional costs.

Moreover, we may be required to conduct additional costly and time-consuming clinical studies beyond those that we originally anticipate in the event that our clinical trials fail to meet their primary endpoints or for other reasons, which would render them inadequate to support approval by the FDA. For example, in September 2011, we announced that our Phase 3 clinical trial for BELBUCA™ did not meet its primary endpoint and therefore we were required to conduct new and costly trials under our license and development agreement with Endo. If our trials fail to meet their endpoints and we elect to move forward with clinical development, conducting new clinical trials in accordance with the FDA requirements and with designs that seek to remedy any prior trial deficiencies will require significant additional capital with no assurances of positive outcomes, and will not able to commercialize and sell our any applicable product until we were able to meet our primary endpoints, of which no assurances can be given.

Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approvals.

Data already obtained, or data we may obtain in the future, from non-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later non-clinical studies and clinical trials. Moreover, non-clinical and clinical data are susceptible to multiple and varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including those involved in competing drug delivery technologies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the product candidate, resulting in delays to commercialization, and could materially harm our business. In addition, our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing. Finally, if any of our clinical trials do not meet their primary endpoints, or for a variety of other reasons, we may be required to conduct additional clinical trials in order to progress development of the subject product. These additional trials would be costly and time-consuming, and would divert resources from other projects.

The foregoing risks were evidenced by the failure of our Phase 3 trial for BELBUCA™ for the treatment of moderate to severe chronic pain to meet its primary endpoint, which we announced September 2011. These risks were further evidenced in that, on March 30, 2015, we announced that the primary efficacy endpoint in the Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement (n=158; p<0.02) in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, we initiated a second study. The study incorporates significant learnings from previously conducted studies and involves tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. The final study subject is expected to complete treatment by the end of 2016.

We compete with larger and better capitalized companies, and competitors in the drug development or specialty pharmaceutical industries may develop competing technologies or products which outperform or supplant our technologies or products.

Drug companies and/or other technology companies have developed (and are currently marketing in competition with us), have sought to develop and may in the future seek to develop and market mucosal adhesive, encapsulation or other drug delivery technologies and related pharmaceutical products which do and may compete with our technologies and products. Competitors have developed and may in the future develop similar or different technologies or products which may become more accepted by the marketplace or which may supplant our technology entirely. In addition, many of our current competitors are, and future competitors may be, significantly larger and better financed than we are, thus giving them a significant advantage over us.

We and our partners may be unable to respond to competitive forces presently in the marketplace (including competition from larger companies), which would severely impact our business. Moreover, should competing or dominating technologies or products come into existence and the owners thereof patent the applicable technological advances, we could also be required to license such technologies in order to continue to manufacture, market and sell our products. We may be unable to secure such licenses on commercially acceptable terms, or at all, and our resulting inability to manufacture, market and sell the affected products could have a material adverse effect on us.

Our approved product and other product candidates contain narcotic ingredients which are tightly regulated by federal authorities. The development, manufacturing and sale of such products are subject to strict regulation, including the necessity of risk management programs, which may prove difficult or expensive to comply with.

Our FDA approved products BUNAVAIL®, BELBUCA™ and ONSOLIS®, contain tightly controlled and highly regulated narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. The FDA or the U.S. Drug Enforcement Administration, or DEA, currently impose and may impose additional regulations concerning the development, manufacture, transportation and sale of prescription narcotics. Such regulations include labeling requirements, the development and implementation of risk management programs, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. This is particularly true with respect to the REMS that the FDA required for ONSOLIS®. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. Any such current or new regulations may be difficult and expensive for us and our manufacturing and commercial partners to comply with, may delay the introduction of our products, may adversely affect our net sales, if any, and may have a material adverse effect on our results of operations.

The DEA limits the availability of the active ingredients used in BUNAVAIL®, BELBUCA™, ONSOLIS® and certain of our product candidates and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in our approved product BUNAVAIL® (buprenorphine), BELBUCA™ (BEMA® Buprenorphine) and ONSOLIS® (fentanyl) are listed by the DEA as Schedule II (ONSOLIS®) and III (BUNAVAIL® and BELBUCA™) substances, respectively, under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled.

The DEA limits the availability of the active ingredients used in BUNAVAIL®, BELBUCA™ and ONSOLIS® and, as a result, our procurement quota of these active ingredients may not be sufficient to complete clinical trials or meet commercial demand. We must annually apply to the DEA for a procurement quota in order to obtain these substances. The DEA may not establish a procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides for public comment on the labeling, promotion, risk management plan and other documents associated with such product. A DEA review of such materials may result in potentially significant delays in obtaining procurement quota for controlled substances, a reduction in the quota issued to us or an elimination of our quota entirely. Any delay or refusal by the DEA in establishing our procurement quota for

controlled substances could delay or stop our clinical trials, product launches or sales of products, which could have a material adverse effect on our business and results of operations.

Risks Related to Our Industry

The market for our products and product candidates is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies, our approved products and our product candidates noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others now existing or diversifying into the field is intense and is expected to increase. Many of these entities (including our competitors with respect to our three approved products, ONSOLIS®, BUNAVAIL® and BELBUCA™) have significantly greater research and development capabilities, human resources and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

With respect to our drug delivery technologies, we may experience technical or intellectual property related challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our technologies. Our competitors may develop drug delivery technologies and drugs that are safer, more effective or less costly than our proposed formulations or products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or products, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies, formulations and products to receive widespread acceptance if commercialized.

If users of our products and product candidates are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed formulations or products may be limited and we may not achieve material revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals and related laws, rules and regulations could materially harm our business, financial conditions, results of operations or stock price. Moreover, the passage of the Patient Protection and Affordable Care Act in 2010, and efforts to amend or repeal such law, has created significant uncertainty relating to the scope of government regulation of healthcare and related legal and regulatory requirements, which could have an adverse impact on sales of our products.

The ability of our company to commercialize BUNAVAIL®, or any partners with which we have a licensing arrangement to sell BELBUCA™ or enter into a new licensing arrangement to sell ONSOLIS® will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Consumers and third-party payers are increasingly challenging the prices charged for drugs and medical services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

We could be exposed to significant drug product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. All of our clinical trials have been, and all of our proposed clinical trials are anticipated to be

conducted by collaborators and third party contractors. We currently have a general liability/product liability policy which includes coverage for our clinical trials and our commercially marketed products. Annual aggregate limits include $2 million for general liability, with $1 million for each occurrence; product liability is $15 million for aggregate and $15 million per occurrence with excess liability in the amount of an additional $5 million; umbrella liability is $5 million aggregate and $5 million per occurrence. It is possible that this coverage will be insufficient to protect us from future claims. Under our agreements, Meda is required to carry comprehensive general product liability and tort liability insurance, each in amounts not less than $2 million per incident and US $10 million annual aggregate and to name us as an additional insured thereon.

Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products and product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products. In addition, although third party partners are required to provide insurance in connection with specific products such partners may face similar insurance related risks.

Our business involves environmental risks related to handling regulated substances which could severely affect our ability to conduct research and development of our drug delivery technology and product candidates.

In connection with our or our partners' research and clinical development activities, as well as the manufacture of materials and products, we and our partners are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We and our partners may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and clinical development, as well as the activities of our manufacturing and commercial partners, both now and in the future, may involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Government and other efforts to reform the healthcare industry could have adverse effects on our company, including the inability of users of our current and future approved products to obtain adequate reimbursement from third-party payers, which could lead to diminished market acceptance of, and revenues from, such products.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (or the PPACA). The Healthcare and Education Reconciliation Act of 2010 (or the Reconciliation Act), which contains a number of amendments to the PPACA, was signed into law on March 30, 2010. Two primary goals of the PPACA, combined with the Reconciliation Act (which we collectively refer to as the Health Reform Legislation), are to provide for increased access to coverage for healthcare and to reduce healthcare-related expenses. On June 28, 2012, the United States Supreme Court upheld the constitutionality of the requirement in PPACA that individuals maintain health insurance or pay a penalty.

The Healthcare Reform Legislation contains a number of provisions that are expected to impact our business and operations or those of our commercial partners, including provisions governing enrollment in federal healthcare programs, reimbursement and discount programs and fraud and abuse prevention and control. The impact of these programs on our business is presently uncertain and may have unexpected consequences for our company. For example, expansion of health insurance coverage under the Health Reform Legislation may result in a reduction in uninsured patients and increase in the number of patients with access to healthcare that have either private or public program coverage, and subsequently prescription drug coverage, including coverage for those products currently approved or in development by us or our partners. However, this outcome, along with any other potential benefits of the Health Reform Legislation which could prove a benefit for us or our commercial partners, is uncertain and may not occur.

In addition to the Health Reform Legislation, we expect that there will continue to be proposals by legislators or new laws, rules and regulations at both the federal and state levels, as well as actions by healthcare and insurance regulators, insurance companies, health maintenance organizations and other payers of healthcare costs aimed at keeping healthcare costs down while expanding individual healthcare benefits. Certain of these changes (including, without limitation, those enacted in connection with the federal or state implementation of the Health Reform Legislation) could impose limitations on the prices we or our commercial partners will be able to charge for any of our approved products or the amounts of reimbursement available for these products from governmental agencies or third-party payors, or may increase the tax obligations on life sciences companies such as ours. Any or all of these changes (which are presently unclear and subject to potential modification on an ongoing basis) could impact the ability of users of our approved products to obtain insurance reimbursement for the use of such products or the ability of healthcare professionals to prescribe such products, any of which could have a material adverse effect on our revenues (royalty or otherwise), potential profitability and results of operations.

Furthermore, the ability of our company to commercialize BUNAVAIL® and our BELBUCA™ product with our partner Endo or of future partners of our company with whom we may enter into licensing arrangements to sell ONSOLIS® (once it is reformulated and placed back on the market in the U.S. and Canada) will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers, managed care, and other organizations and may all result in lower prices for or rejection of our products, which could further have a material adverse effect on our revenues (royalty or otherwise) and results of operations.

We may also be subject to healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Although we currently do not directly market or promote any of our products, we may also be subject to several healthcare regulations and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Risks Related to Our Common Stock and Series A Non-Voting Convertible Preferred Stock

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the Securities and Exchange Commission (or the SEC) and the Nasdaq Capital Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act.

There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as shareholder approval of executive compensation ("say on pay") and proxy access. Our efforts to comply with these requirements are likely to result in an increase in expenses which is difficult to quantify at this time.

In addition, we are subject to often complex accounting rules and interpretations promulgated by the Financial Accounting Standards Board (including its Emerging Issues Task Force). In 2012, we became engaged in an SEC review process over our accounting (under applicable revenue recognition literature) for payments we received under our license and commercialization with Endo. On February 28, 2013, we announced the conclusion of that review, which led to our adoption of an alternative revenue recognition interpretation and a resulting restatement of our unaudited financial statements for the first three fiscal quarters of 2012. We may be faced with similar issues in the future, and adjustments to or restatements of our financial statements or accounting policies could have a material adverse effect on our public stock price and our reputation.

Our stock price is subject to market factors and market volatility, both generally and with respect to our industry and our company specifically. As such, there is a risk that your investment in our common stock could fluctuate in value.

The overall market for securities in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies. In particular, the market prices of securities of biotechnology and pharmaceutical companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to operating performance of these companies. These broad market fluctuations (as well as market reactions to particular developments with our company) have and could continue to result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of your common stock. These fluctuations, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

If we cannot meet the NASDAQ Capital Market's continuing listing requirements and NASDAQ rules, NASDAQ may delist our securities, which could negatively affect our company, the price of our securities and your ability to sell our securities.

As of the date of this Report, our shares are listed on the NASDAQ Capital Market. In the future, however, we may not be able to meet the continued listing requirements of the NASDAQ Capital Market and NASDAQ rules, which require, among other things, maintaining a minimum bid price per share of $1.00, minimum stockholders equity of $2.5 million or a minimum market capitalization of $35 million and a majority of "independent" directors on our board of directors. We have been subject to delisting proceedings and comments by NASDAQ in the past, and during 2011 our stock price declined to levels that put us at risk of not being able to maintain the required minimum bid price or market capitalization levels or both. If we are unable to satisfy the NASDAQ criteria for continued listing, especially at our current stock price levels, our securities could again be subject to delisting. Trading, if any, of our securities would thereafter be conducted in the over-the-counter market, in the so-called "pink sheets" or on the OTC Bulletin Board. As a consequence of any such delisting, our stockholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the prices of our securities.

Our Series A Non-Voting Convertible Preferred Stock ranks senior to our common stock in the event of a bankruptcy, liquidation or winding up of our assets.

As of the date of this Report, we currently have 2,139,000 issued and 2,093,155 outstanding shares of Series A Non-Voting Convertible Preferred Stock, which we issued in connection with our $40 million financing which closed on December 2012. In the event of our bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Series A Non-Voting Convertible Preferred Stock in preference to the holders of our common stock.

Executive officers, directors and entities affiliated with them could, due to their collective ownership interests in our company, have a material level of control over us, which could delay or prevent a change in our corporate control favored by our other stockholders.

As of the date of this Report, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 8.95% of our outstanding common stock. These figures do not reflect any future potential exercise of outstanding common stock purchase warrants into shares of common stock. The interests of our current officers, directors and affiliated stockholders may differ from the interests of other stockholders. As a result, these current officers, directors and affiliated stockholders could have the ability to exercise substantial influence over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

- approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets and material financing transactions;
- election of directors;
- adoption of or amendments to stock option plans;
- amendment of charter documents; or
- issuance of "blank check" preferred stock.

Additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market for our common stock.

As of March 7, 2016, there are 53,482,697 shares of common stock issued and 53,467,206 shares of common stock outstanding and there were 2,139,000 shares issued and 2,093,155 outstanding of Series A Non-Voting Convertible Preferred Stock issued and outstanding. On July 21, 2011, our stockholders approved an amendment to our certificate of incorporation to increase the number of authorized shares of common stock, par value $.001, of our common stock from 45,000,000 to 75,000,000 shares. This increase in our authorized shares of common stock provides us with the flexibility to issue more shares in the future, which might cause dilution to our stockholders. In addition, the total number of shares of our common stock issued and outstanding does not include shares reserved

in anticipation of the exercise of outstanding options or warrants. To the extent such options (including options under our stock incentive plan) or warrants are exercised, the holders of our common stock may experience further dilution.

Moreover, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors would experience additional dilution. Finally, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5 million shares of authorized preferred stock, of which 2,139,000 shares have been designated as Series A Non-Voting Convertible Preferred Stock. The remaining 2,290,700 shares of preferred stock remain undesignated shares of preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

Shares eligible for future sale may adversely affect the market for our common stock.

We have a material number of shares of common stock underlying securities of our company, the future sale of which could depress the price of our publicly-traded stock. As of March 7, 2016: (i) 3,506,155 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $5.39 per share, (ii) 4,566,886 restricted stock units eligible to be converted shares of our common stock and (iii) 2,093,155 shares of Series A preferred eligible to be converted into shares of our common stock. If and when these securities are exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

In addition, from time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, which we refer to herein as the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated stockholder (or stockholders whose shares are aggregated) may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated stockholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one year holding period without any limitation or restriction. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale report may have a material adverse effect on the market price of our securities.

Furthermore, sales of our common stock by our directors, officers, or employees may occur as a result of sales effected pursuant to predetermined trading plans adopted under the safe-harbor afforded by SEC Rule 10b5-1.

Our certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, as amended, our amended and restated bylaws (which were adopted in 2010) and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- providing for a staggered board of directors, which impairs the ability of our stockholders to remove our directors at annual or special meetings of stockholders;
- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- limiting the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;
- requiring a super-majority vote of our stockholders to remove directors of our company; and
- providing that our stockholders may only remove our directors for "cause" (as defined in our bylaws).

These provisions affect your rights as a stockholder since they permit our board of directors to make it more difficult for common stockholders to replace members of the board or undertake other significant corporate actions. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this Report should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

We do not intend to pay dividends on our common stock.

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

Our additional financing requirements could result in dilution to existing stockholders.

The additional financings which we have undertaken and which we may in the future require, have and may be obtained through one or more transactions which have diluted or will dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 75 million shares of common stock and 2,290,700 shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Description of Property.

Our corporate headquarters is located in Raleigh, North Carolina. We moved into our current headquarters in February 2015. The lease for this office, which commenced November 14, 2014 for 89 months, is approximately 12,000 square foot space and has remaining base rent of $2.3 million payable through July, 2022. Rent is payable in monthly installments, and is subject to yearly price increases and increases for our share of common area maintenance costs. The landlord for this space is HRLP Raleigh, L.P. We believe this space is adequate as our principal executive office location.

Item 3. Legal Proceedings.

Readers are advised that the following disclosure regarding our ongoing litigations with MonoSol and Reckitt Benckiser is intended to provide some background and an update on the matter as required by the rules of the SEC. Additional details regarding the past procedural history of the matter can be found in our previously filed periodic filings with the SEC.

Litigation Related To ONSOLIS®

On November 2, 2010, MonoSol filed an action against us and our commercial partners for ONSOLIS® in the Federal District Court of New Jersey (the DNJ) for alleged patent infringement and false marking. We were formally served in this matter on January 19, 2011. MonoSol claims that our manufacturing process for ONSOLIS®, which has never been disclosed publicly and which we and our partners maintain as a trade secret, infringes its patent (United States Patent No. 7,824,588) (the ’588 Patent). Of note, the BEMA® technology itself is not at issue in the case, nor is BELBUCA™ or BUNAVAIL®, but rather only the manner in which ONSOLIS®, which incorporates the BEMA® technology, is manufactured. Pursuant to its complaint, MonoSol is seeking an unspecified amount of damages, attorney’s fees and an injunction preventing future infringement of MonoSol’s patents.

We strongly refute as without merit MonoSol’s assertion of patent infringement, which relates to our confidential, proprietary manufacturing process for ONSOLIS®. On September 12, 2011, we filed a request for inter partes reexamination in the United States Patent and Trademark Office (USPTO) of MonoSol’s ’588 Patent demonstrating that all claims of such patent were anticipated by or obvious in the light of prior art references, including several prior art references not previously considered by the USPTO, and thus

invalid. On September 16, 2011, we filed a motion for stay pending the outcome of the reexamination proceedings, which subsequently was granted.

In November 2011, the USPTO rejected all 191 claims of MonoSol's '588 Patent. On January 20, 2012, we filed requests for reexamination before the USPTO of MonoSol's US patent No 7,357,891 (the '891 Patent), and No 7,425,292 (the '292 Patent), the two additional patents asserted by MonoSol, demonstrating that all claims of those two patents were anticipated by or obvious in the light of prior art references, including prior art references not previously considered by the USPTO, and thus invalid. The USPTO granted the requests for reexamination with respect to MonoSol's '292 and '891 Patents. In its initial office action in each, the USPTO rejected every claim in each patent.

As expected, in the '891 Patent and '292 Patent Ex Parte Reexamination proceedings, MonoSol amended the claims several times and made multiple declarations and arguments in an attempt to overcome the rejections made by the USPTO. These amendments, declarations and other statements regarding the claim language significantly narrowed the scope of their claims in these two patents. In the case of the '891 Patent, not one of the original claims survived reexamination and five separate amendments were filed confirming our position that the patent was invalid. Additionally, we believe that arguments and admissions made by MonoSol prevent it from seeking a broader construction during any subsequent litigation by employing arguments or taking positions that contradict those made during prosecution.

A Reexamination Certificate for MonoSol's '891 Patent in its amended form was issued August 21, 2012 (Reexamined Patent No. 7,357,891C1 or the '891C1 Patent). A Reexamination Certificate for MonoSol's '292 Patent in its amended form was issued on July 3, 2012 (Reexamined Patent No. 7,425,292C1 or the '292C1 Patent). These actions by the USPTO confirm the invalidity of the original patents and through the narrowing of the claims in the reissued patents strengthens our original assertion that our products and technologies do not infringe on MonoSol's original patents.

On June 12, 2013, despite our previously noted success in the prior ex parte reexaminations for the '292 and '891 Patents, we filed requests for *inter partes* reviews (or IPR) on the narrowed yet reexamined patents, the '292 C1 and '891 C1 Patents, to challenge their validity and continue to strengthen our position. On November 13, 2013, the USPTO decided not to institute the two inter partes reviews for the '891 C1 and '292 C1 Patents. The USPTO's decision was purely on statutory grounds and based on a technicality (in that the IPRs were not filed within what the UPSTO determined to be the statutory period) rather than substantive grounds. Thus, even though the inter partes reviews were not instituted, the USPTO decision preserves our right to raise the same arguments at a later time (e.g., during litigation). Regardless, our assertion that our products and technologies do not infringe the original '292 and '891 Patents and, now, the reexamined '891 C1 and '292 C1 Patents remains the same.

Importantly, in the case of MonoSol's '588 Patent, at the conclusion of the reexamination proceedings (and its appeals process), on April 17, 2014, the Patent Trial and Appeal Board (PTAB) issued a Decision on Appeal affirming the Examiner's rejection (and confirming the invalidity) of all the claims of the '588 Patent. MonoSol did not request a rehearing by the May 17, 2014 due date for making such a request and did not further appeal the Decision to the Federal Court of Appeals by the June 17, 2014 due date for making such an appeal. Subsequently, on August 5, 2014, the USPTO issued a Certificate of Reexamination cancelling the '588 Patent claims.

Based on our original assertion that our proprietary manufacturing process for ONSOLIS® does not infringe on patents held by MonoSol, and the denial and subsequent narrowing of the claims on the two reissued patents MonoSol has asserted against us while the third has had all claims rejected by the USPTO, we remain very confident in our original stated position regarding this matter. Thus far, we have proven that the "original" '292 and '891 patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, the '588 patent, was invalid as well with all its claims cancelled. Given the outcomes of the '292, '891 and '588 reexamination proceedings, at a January 22, 2015 status meeting, the Court decided to lift the stay and grant our request for the case to proceed on an expedited basis with a Motion for Summary Judgment to dismiss the action. On September 25, 2015, the Honorable Freda L. Wolfson granted our motion for summary judgment and ordered the case closed. We were found to be entitled to absolute intervening rights as to both patents in suit, the '292 and '891 patents and our ONSOLIS® product is not liable for infringing the patents prior to July 3, 2012 and August 21, 2012, respectively. In October 2015, MonoSol appealed the decision of the court to the Federal Circuit. We have no reason to believe the outcome will be different and will vigorously defend the appeal. MonoSol filed an appeal with the Federal Circuit and has subsequently decided to withdraw the appeal. On February 25, 2016, MonoSol filed an Unopposed Motion For Voluntary Dismissal Of Appeal, which was granted by the court on February 26, 2016 and the case dismissed. Thus, the district court's grant of the Summary Judgement of Intervening Rights will stand. In addition, the possibility exists, however, that MonoSol could file another suit alleging infringement of the '292 and '891 patents. We believe ONSOLIS® and our other products relying on the BEMA® technology, including BUNAVAIL® and BELBUCA™, do not infringe any amended, reexamined claim from either patent after those dates.

Litigation Related To BUNAVAIL®

RB and MonoSol

On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol (collectively, the RB Plaintiffs) filed an action against us relating to our BUNAVAIL® product in the United States District Court for the Eastern District of North Carolina for alleged patent infringement. BUNAVAIL® is a drug approved for the maintenance treatment of opioid dependence. The RB Plaintiffs claim that the formulation for BUNAVAIL®, which has never been disclosed publicly, infringes its patent (United States Patent No. 8,475,832) (the '832 Patent).

On May 21, 2014, the Court granted our motion to dismiss. In doing so, the Court dismissed the case in its entirety. The RB Plaintiffs did not appeal the Court Decision by the June 21, 2014 due date and therefore, the dismissal will stand and the RB Plaintiffs lose the ability to challenge the Court Decision in the future. The possibility exists, however, that the RB Plaintiffs could file another suit alleging infringement of the '832 Patent. If this occurs, based on our original position that our BUNAVAIL® product does not infringe the '832 Patent, we would defend the case vigorously (as we have done so previously), and we anticipate that such claims against us ultimately would be rejected.

On September 20, 2014, based upon our position and belief that our BUNAVAIL® product does not infringe any patents owned by the RB Plaintiffs, we proactively filed a declaratory judgment action in the United States District Court for the Eastern District of North (EDNC) Carolina, requesting the Court to make a determination that our BUNAVAIL® product does not infringe the RB Plaintiffs' '832 Patent, US Patent No. 7,897,080 ('080 Patent) and US Patent No. 8,652,378 ('378 Patent). With the declaratory judgment, there is an automatic stay in proceedings. The RB Plaintiffs may request that the stay be lifted, but they have the burden of showing that the stay should be lifted. For the '832 Patent, the January 15, 2014 IPR was instituted and in June 2015, all challenged claims were rejected for both anticipation and obviousness. In August 2015, the RB Plaintiffs filed an appeal to the Federal Circuit. We will vigorously defend this appeal at the Federal Circuit. For the '080 Patent, all claims have been rejected in an inter partes reexamination and the rejection of all claims as invalid over the prior art has been affirmed on appeal by the PTAB in a decision dated March 27, 2015. In May 2015, the RB Plaintiffs filed a response after the decision to which we filed comments. In December 2015 the Board denied MonoSol's request to reopen prosecution, but provided MonoSol an opportunity to file a corrected response. MonoSol filed the request in December 2015 and we subsequently filed comments on December 23, 2015. We are awaiting a further decision from the Board, which we have no reason to believe will be inconsistent with the original decision rendered in March 2015. For the '378 Patent, an IPR was filed on June 1, 2014, but an IPR was not instituted. However, in issuing its November 5, 2014 decision not to institute the IPR, the PTAB construed the claims of the '378 Patent narrowly. As in prior litigation proceedings, we believe these IPR and the reexamination filings will provide support for maintaining the stay until the IPR and reexamination proceedings conclude. Indeed, given the PTAB's narrow construction of the claims of the '378 Patent, we filed a motion to withdraw the '378 Patent from the case on December 12, 2014. In addition, we also filed a joint motion to continue the stay (with RB Plaintiffs) in the proceedings on the same day. Both the motion to withdraw the '378 Patent from the proceedings and motion to continue the stay were granted.

On September 22, 2014, the RB Plaintiffs filed an action against us (and our commercial partner) relating to our BUNAVAIL® product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL®, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent No. 8,765,167 ('167 Patent). As with prior actions by the RB Plaintiffs, we believe this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL®. We strongly refute as without merit the RB Plaintiffs' assertion of patent infringement and will vigorously defend the lawsuit. On December 12, 2014, we filed a motion to transfer the case from New Jersey to North Carolina and a motion to dismiss the case against our commercial partner. The Court issued an opinion on July 21, 2015 granting our motion to transfer the venue to the EDNC, but denying our motion to dismiss in its entirety as moot. We will continue to vigorously defend this case in the EDNC.

In a related matter, on October 28, 2014, we filed multiple IPR requests on the '167 Patent demonstrating that certain claims of such patent were anticipated by or obvious in light of prior art references, including prior art references not previously considered by the USPTO, and thus, invalid. The USPTO instituted three of the four IPR requests and we filed a request for rehearing for the non-instituted IPR. A final decision on the instituted '167 IPRs is expected in May 2016.

On January 22, 2014, MonoSol filed a Petition for IPR on US Patent No. 7,579,019 (the '019 Patent). The Petition asserted that the claims of the '019 Patent are alleged to be unpatentable over certain prior art references. The IPR was instituted on August 6, 2014. An oral hearing was held in April 2015 and a decision upholding all seven claims was issued August 5, 2015. In September 2015, MonoSol requested that the USPTO rehear the IPR. We will continue to vigorously defend our '019 patent. We expect the USPTO to issue a decision in the first half of 2016.

Actavis

On February 8, 2016, we received a purported notice relating to a Paragraph IV certification from Actavis Laboratories UT, Inc. ("Actavis") seeking to find invalid three Orange Book listed patents (the "Patents") relating specifically to BUNAVAIL®. The

Paragraph IV certification relates to an Abbreviated New Drug Application (the "ANDA") filed by Actavis with the U.S Food and Drug Administration ("FDA") for a generic formulation of BUNAVAIL®. The Patents subject to Acatvis' certification are U.S. Patent Nos. 7,579,019 ("the '019 Patent"), 8,147,866 and 8,703,177.

We believe that Actavis' claims of invalidity of the Patents are wholly without merit and, as we have done in the past, we intend to vigorously defend our intellectual property. We are highly confident that the Patents are valid, as evidenced in part by the fact that the '019 Patent has already been the subject of an unrelated IPR before the U.S. Patent and Trademark Office (the "USPTO") under which we prevailed and all claims of the '019 Patent survived. Although there is a pending request for rehearing of the final IPR decision regarding the '019 Patent pending at the USPTO, we believe the USPTO's decision will be upheld. Under the Food Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the "Hatch-Waxman Amendments"), after receipt of a valid Paragraph IV notice, we may, and in this case plan to, bring a patent infringement suit in federal district court against Actavis within 45 days from the date of receipt of the certification notice. If such a suit is commenced within this 45 day period, we are entitled to receive a 30 month stay on FDA's ability to give final approval to any proposed products that reference BUNAVAIL®. The 30 month stay is expected to preempt any final approval by FDA on Actavis' ANDA until at least August of 2018. In addition, given the FDA approval of BUNAVAIL®, we are entitled to three years of market exclusivity for BUNAVAIL® ending in June 2017. Given this timeframe, Actavis' action is not unexpected. In addition, we have additional pending intellectual property which, if issued, would be capable of extending the patent life of all three of our BEMA®-related products, including BUNAVAIL®, and potentially be listed in the Orange Book.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock is listed for quotation on the NASDAQ Capital Market under the symbol "BDSI". The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2015 and 2014, as reported by the NASDAQ Capital Market, is set forth below.

Quarterly Common Stock Price Ranges

Fiscal Year 2015, Quarter Ended:	High	Low
March 31, 2015	$15.50	$ 9.32
June 30, 2015	$10.58	$ 7.17
September 30, 2015	$ 9.91	$ 4.66
December 31, 2015	$ 7.04	$ 4.64

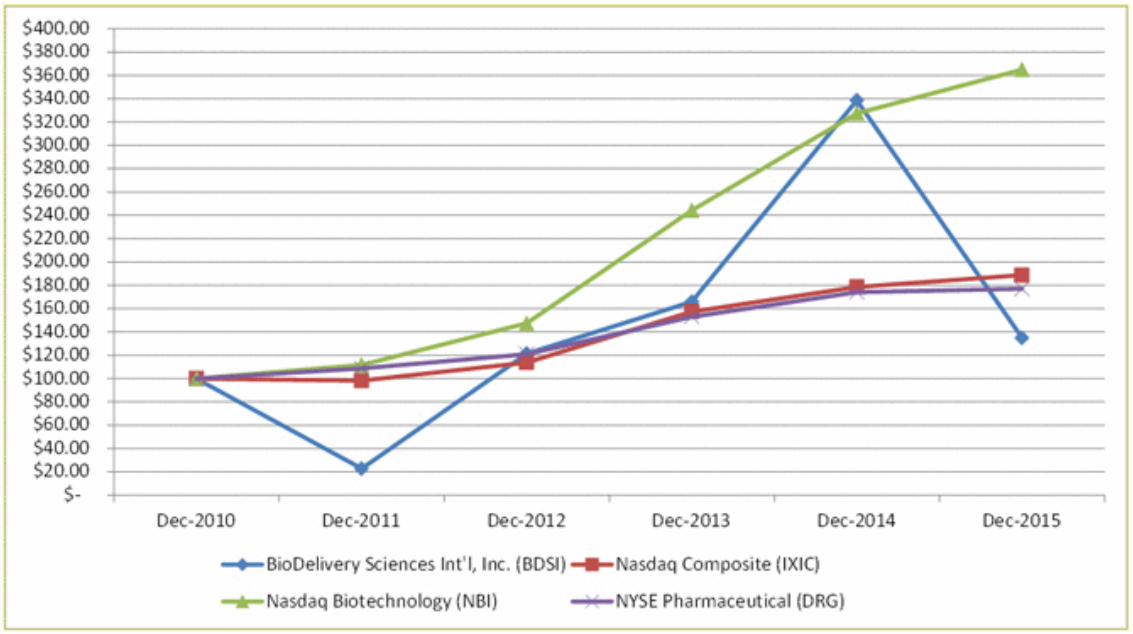
Fiscal Year 2014, Quarter Ended:	High	Low
March 31, 2014	$10.20	$ 5.65
June 30, 2014	$12.81	$ 6.71
September 30, 2014	$18.48	$11.76
December 31, 2014	$18.33	$11.48

As of March 7, 2016, we had approximately 113 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain earnings for further business development and do not expect to pay cash dividends in the foreseeable future.

Performance Graph

The following graph shows a comparison of the five year total cumulative returns of an investment of $100 in cash on December 31, 2010 in (i) our common stock (ii) the Nasdaq Composite Index (iii) the Nasdaq Biotechnology Index and (iv) the NYSE Pharmaceutical Index. All values assume reinvestment of the full amount of all dividends (to date, we have not declared any dividends).

This stock performance graph shall not be deemed "filed" with the SEC or subject to Section 18 of the Securities Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended (the "Securities Act"). Comparison of cumulative total return on investment since December 31, 2010:



	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
BioDelivery Sciences Int'l, Inc.	$ 100.00	$ 22.82	$ 121.41	$ 165.92	$ 338.59	$ 134.93
Nasdaq Composite (U.S. Companies)	100.00	98.20	113.82	157.44	178.53	188.75
Nasdaq Biotechnology	100.00	111.81	147.48	244.24	327.52	364.93
NYSE Pharmaceutical	100.00	108.85	120.82	153.02	174.18	177.01

Item 6. Selected Financial Data.

The statements of operations data and statements of cash flows data for the years ended December 31, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2015 and 2014 have been derived from our audited consolidated financial statements included elsewhere in this annual report. The statements of operations data and statements of cash flows data for the years ended December 31, 2012 and 2011 and the balance sheet data as of December 31, 2013, 2012 and 2011 have been derived from our audited consolidated financial statements not included in this annual report. The following selected financial data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and consolidated financial statements and related notes beginning on page F-1 and other financial information included in this Report.

	2015	2014	2013	2012	2011
Statements of Operations Data:					
Total revenue	$ 48,231	$ 38,944	$ 11,356	$ 54,542	$ 3,263
Operating (loss) income	(35,179)	(38,740)	(56,402)	7,062	(26,988)
Net (loss) income	(37,672)	(54,218)	(57,394)	1,652	(23,325)
Diluted net (loss) income per share	(0.72)	(1.12)	(1.51)	0.05	(0.82)
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 83,560	$ 70,472	$ 23,176	$ 63,189	$ 10,750
Total assets	102,772	88,840	38,005	75,739	23,645
Long-term liabilities	42,993	4,402	12,545	—	—
Accumulated deficit	(243,203)	(205,531)	(151,313)	(93,919)	(95,572)
Total stockholders' equity (deficit)	31,696	54,396	(812)	49,777	4,120
Statements of Cash Flows Data:					
Net cash flows from operating activities	$ (3,732)	$ (28,833)	$ (60,102)	$ 12,187	$(23,275)

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those which are not within our control.

Overview

Strategy

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of approved therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. We have developed and are continuing to develop pharmaceutical products oriented principally in the areas of pain management and addiction.

Our strategy is to:

- Focus our commercial and development efforts in the areas of pain management and addiction within the U.S. pharmaceutical marketplace;
- Identify and acquire rights to products that we believe have potential for near-term regulatory approval through the FDA's 505(b)(2) approval process or are already approved;
- Market our products through specialty sales teams by primarily focusing on high-prescribing U.S. physicians in pain and addiction.

We believe this strategy will allow us to increase our revenues, improve our margins and profitability and enhance stockholder value.

Background of Our Company

We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation and conducted our initial public offering in 2002. In August 2004, we acquired Arius Pharmaceuticals, the then licensee (and now owner) of our BEMA® drug delivery technology, and July 2006, we licensed commercialization rights in Europe for our lead product; BEMA® based ONSOLIS®, to Meda. In September 2007, we entered into a definitive License and Development Agreement with Meda for ONSOLIS® in the U.S., Canada and Mexico. In January 2012, we entered into a definitive License and Development Agreement with Endo for BELBUCA™ for chronic pain and in December 2014, we and Endo filed the NDA submission for FDA approval for BELBUCA™, which was accepted February 2015 and later approved by the FDA on October 23, 2015 and commercially launched by Endo in February 2016. In March 2013, we entered into a definitive Exclusive License Agreement with Arcion pursuant to which Arcion agreed to grant to us an exclusive commercial world-wide license, with rights of sublicense, under certain patent and other intellectual property rights related to in-process research and development to develop, manufacture, market, and sell gel products containing clonidine (or a derivative thereof), alone or in combination with other active ingredients, for topical administration for the treatment of PDN and other indications. On July 31, 2013, we submitted the NDA for BUNAVAIL® to the FDA for review, and on June 6, 2014, we announced the FDA approval of BUNAVAIL®, which we commercially launched November 3, 2014.

2015 and Beyond Highlights

- On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Meda to return to us the marketing authorizations for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. We modified the formulation and submitted a prior approval supplement that responded to FDA questions and led to approval of the new formulation of ONSOLIS® in August 2015. We plan to relaunch ONSOLIS® upon completing transfer of manufacturing to a new supplier and securing a U.S. commercial partner, both of which are progressing.
- On February 23, 2015, the NDA for our BELBUCA™ (buprenorphine buccal film) product (which is partnered with Endo) was accepted by the FDA.
- In March, 2015, we received a $10 million milestone from Endo upon FDA acceptance of the NDA filed for BELBUCA™.
- On May 14, 2015, we and Endo presented pivotal data from two Phase 3 studies for investigational study drug BELBUCA™. The findings, presented at the American Pain Society's 34th Annual Scientific Meeting in Palm Springs, CA, showed BELBUCA™ consistently decreased pain scores compared to the placebo.

- On May 29, 2015, we entered into a $30 million secured loan facility with MidCap Financial Trust, (or MidCap). The Credit Agreement is a restatement, amendment and modification of a prior credit and security agreement, dated as of July 5, 2013 among us and MidCap Financial SBIC, LLP, a predecessor to MidCap, and certain lenders thereto. We received net loan proceeds in the aggregate amount of approximately $20.1 million and will use the loan proceeds for general corporate purposes or other activities permitted under the credit agreement.
- On July 2, 2015, we filed a shelf registration statement which registered up to $150 million of our securities for potential future issuance, and such registration statement was declared effective on July 13, 2015. Concurrent with the filing of such registration statement, we established an "at-the-market" offering program utilizing the universal shelf registration for up to $40 million of Common Stock.
- On August 13, 2015, we announced the approval by the FDA of a Supplemental New Drug Application (sNDA) for a new formulation of ONSOLIS® Schedule II for the management of breakthrough pain in patients with cancer who are opioid tolerant. The new formulation was submitted to address previously announced appearance-related changes. Approval of this new formulation is expected to allow ONSOLIS® to return to the U.S. market sometime in 2016.
- On September 8, 2015, we secured a two-year contract with Tennessee Medicaid, also referred to as TennCare, making BUNAVAIL® the only buprenorphine/naloxone treatment for opioid dependence with preferred coverage status on TennCare's preferred drug list (PDL). Preferred coverage status for BUNAVAIL® means that all covered patients will receive BUNAVAIL®, with the exception that non-preferred products can be used only following trial and failure, contraindication or intolerance to the preferred product, BUNAVAIL®. The TennCare contract began October 1, 2015.
- On October 26, 2015, BDSI and Endo announced that the FDA approved BELBUCA™ for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate. FDA approval of BELBUCA™ has triggered a milestone payment to us from Endo of $50 million pursuant to the Endo Agreement, less approximately $6 million of cumulative pre-payments received. The aforementioned $20 million is contingently refundable to Endo based on a third party generic introduction in the U.S. during the patent extension period from 2020 to 2027. Should such introduction occur any time during the 2020 to 2027 period, a refund would be due to Endo based on the number of complete calendar months beyond December 31, 2019 where the first generic was sold over the denominator of 84 months times $20 million. For example, if a generic product were to be introduced in the U.S. in January of 2026, that would mean that 72 of the 84 months of patent exclusivity would have been earned and 12 months would have to be refunded. The calculation would be 12/84, multiplied by $20 million, or a refund of $2.9 million. The method of the refund payment to Endo would be accomplished first by crediting against milestone payments, second by reducing the royalty by 50% until the $2.9 million is paid back, and third by BDSI making a payment in the amount due to Endo. Otherwise, the $20 million will be earned as revenue each month over the patent extension period from 2020 to 2027.
- On February 22, 2016, the Company and Endo announced the commercial availability of BELBUCA™ buccal film. BELBUCA™, distributed and promoted by Endo, is now available nationwide.

Our Products and Related Trends

Our product portfolio currently consists of five products. As of the date of this report, three products are approved by the FDA and two are in development. Three of these five products utilize our patented BEMA® thin film drug delivery technology.

- **BUNAVAIL®** was approved by the FDA in June 2014 for the maintenance treatment of opioid dependence. BUNAVAIL® also uses our BEMA® technology. We are commercializing BUNAVAIL® ourselves and launched the product during the fourth quarter of 2014. We undertook significant steps in 2015 to augment our sales, marketing and managed care capabilities for BUNAVAIL®. As with all other buprenorphine containing products for opioid dependence, the approval of BUNAVAIL® carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BUNAVAIL® on QT prolongation (i.e., an abnormal lengthening of the heartbeat). The clinical study results must be reported to the FDA by the end of 2016.
- **BELBUCA™** (which also uses our BEMA® technology) is for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. This product is licensed on a worldwide basis to Endo. On October 26, 2015, we announced with Endo that the FDA approved BELBUCA™. BELBUCA™ was launched by Endo in February 2016, and the commercialization of this product may trigger additional milestone payments from Endo in the future if certain sales milestones are met. We may also be entitled to receive tiered royalties that start in the mid-teens on net sales of BELBUCA™.
- **ONSOLIS®** is approved in the U.S., Canada, EU (where it is marketed as BREAKYL™) and Taiwan (where it is marketed as PAINKYL™), for the management of breakthrough pain in opioid tolerant adult patients with cancer. The commercial rights to ONSOLIS® are licensed to Meda for all territories worldwide except for Taiwan (licensed to TTY). ONSOLIS® utilizes our BEMA® thin film drug delivery technology.

- **Clonidine Topical Gel** is a non- BEMA® product which is currently in Phase 3 development for the treatment of painful diabetic neuropathy (or PDN). We licensed this product from Arcion in March 2013. In June 2014, we announced the completion of patient enrollment for our Phase 3 study of Clonidine Topical Gel. In August 2014, we announced our completion of a pre-specified interim analysis of the ongoing initial pivotal Phase 3 trial for Clonidine Topical Gel, at which point we re-opened enrollment to complete recruitment. On March 30, 2015, we announced that the primary efficacy endpoint in our initial Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement ($n=158$; $p<0.02$) in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, we initiated a second study. The study incorporates significant learnings from previously conducted studies and involves tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. The final study subject is expected to complete treatment by the end of 2016.
- **Buprenorphine Depot Injection** is in development as an injectable, extended release, microparticle formulation of buprenorphine for the treatment of opioid dependence and chronic pain, the rights to which we secured when we entered into a definitive development and exclusive license option agreement from Evonik in October 2014. This product candidate is currently in the pre-clinical stage of development.

As we focus on the growth of our existing products and other product candidates, we also continue to position ourselves to execute upon the licensing and acquisition opportunities that will facilitate future growth. Our organization is fully committed to this effort, and we believe we will be successful in executing upon our corporate strategy in ways that will provide this future growth. In order to do so, we will need to continue to maintain our strategic direction, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships. We believe these actions, combined with the experience and expertise of our management team, position us well to deliver future growth of our revenue and income.

We expect to continue our research and development of pharmaceutical products and related drug delivery technologies, some of which will be funded by our commercialization agreements. We will continue to seek additional license agreements, which may include upfront payments. We anticipate that funding for the next several years will come primarily from milestone payments and royalties from Meda, Endo and TTY, earnings from sales of BUNAVAIL®, potential sales of securities and collaborative research agreements, including those with pharmaceutical companies.

We have a very limited history of commercial operations, having focused the vast majority of our corporate effort on research and development activities. We have, since our founding, received revenue in the form of: (i) contract revenue from Endo related to an upfront, non-refundable payment for a license of our BELBUCA™ product in 2012 (a portion of which was recorded as deferred revenue that is being recognized as revenue under prevailing revenue recognition rules), (ii) payment from Endo for a certain patent-related milestones (a portion of which might be refundable based on the entry of generic competition into the marketplace), (iii) royalty revenue from Meda for sales of BREAKYL™ and ONSOLIS®, (iv) upfront non-refundable license and milestone payments from Meda in 2007, 2008, 2009 and 2012 (which were initially classified as deferred revenue and subsequently, a substantial amount was reclassified as recognized revenue under prevailing revenue recognition rules), (v) product sales revenue related to BUNAVAIL® sales (vi) contract revenue from Endo related to two full database locks in 2014, (vii) contract revenue from Endo upon FDA acceptance of the filed NDA of our BELBUCA™ product in 2015 and subsequent regulatory approval, (viii) and sponsored research revenue from both Endo and Meda. Only the BUNAVAIL® product sales and BREAKYL™ royalty revenues have the potential to be repeating or predictable. Until recurring revenue from product sales (BUNAVAIL® is the foremost opportunity) becomes a larger portion of our total revenue, we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future.

Readers are cautioned that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties normally encountered by companies that are involved in the development and commercialization of their products and related technologies, particularly companies in new and rapidly changing markets such as pharmaceuticals, drug delivery and biotechnology. For the foreseeable future, we must, among other things, invest in non-clinical and clinical trials of, and seek regulatory approval for and commercialization of, our product candidates, the outcomes of which are subject to numerous risks, many of which are beyond our control. We must also maintain our relationships with our key commercial partners and address regulatory, legal and/or commercial issues and risks that relate to our business from time to time, many of which could impact, perhaps negatively, our planned operations. We may not be able to appropriately address these risks and difficulties.

Update on Relaunch Activities in the U.S. for ONSOLIS®

On March 12, 2012, we announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide Risk Evaluation and Mitigation Strategy ("REMS") and until the product formulation could be modified to address two

appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, raised by the FDA during an inspection of our North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. ("Aveva"). While the appearance issues do not affect the product's underlying integrity, safety or performance, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of the color in the mucoadhesive layer of ONSOLIS® was found to be specific to a buffer used in its formulation. We modified the formulation and submitted a prior approval supplement that responded to FDA questions and led to approval of the new formulation of ONSOLIS® in August 2015. As of the date of this report we have more than 12 months of stability data on the reformulated product that shows no signs of microcrystal formation or color changes.

On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Meda to return to us the marketing authorizations for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. We plan to relaunch ONSOLIS® upon completing transfer of manufacturing to a new supplier and the securing of a U.S. commercialization partner, both of which are progressing. On February 27, 2016 we entered into an Extension of Assignment and Revenue Sharing Agreement to extend the period of time as described below.

Under the Assignment Agreement, for a period of up to December 31, 2016, we shall have the right and shall use commercially reasonable efforts to work directly with the FDA to attempt to resolve certain previously disclosed issues relating to ONSOLIS® in the United States and seek, and attempt to negotiate a Replacement License with, one or more new commercial partners for ONSOLIS® in the Subject Countries.

Recent efforts to extend our supply agreement with our ONSOLIS® manufacturer, Aveva, which is now a subsidiary of Apotex, Inc. (or Apotex), have been unsuccessful and the agreement expired. However, we have identified an alternate supplier and requested guidance from the FDA on the specifics required for obtaining approval to supply product from this new vendor. This will in part help us to better determine when ONSOLIS® may be available to the marketplace and help assist us as we seek a new commercial partnership arrangement. Based on our current estimates, we believe that we will submit the necessary documentation to FDA for qualification of the new manufacturer by the fourth quarter of 2016 and have approval by the first half of 2017.

Critical Accounting Policies and Estimates

Impairment Testing

In accordance with Generally Accepted Accounting Principles (referred to herein as GAAP), goodwill impairment testing is performed at the reporting unit level annually, or more frequently if indicated by events or conditions. We performed an evaluation and determined that there is only one reporting unit. In the course of the evaluation of the potential impairment of goodwill, either a qualitative or a quantitative assessment may be performed. If a qualitative evaluation determines that no impairment exists, then no further analysis is performed. If a qualitative evaluation is unable to determine whether impairment has occurred, a quantitative evaluation is performed. The quantitative impairment test first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired. If the carrying value exceeds the fair value, the implied fair value of goodwill is calculated and an impairment is recorded if the implied fair value is less than the carrying amount. The determination of goodwill impairment is highly subjective. It considers many factors both internal and external and is subject to significant changes from period to period. No goodwill impairment charges have resulted from this analysis for 2015, 2014 or 2013.

An impairment of a long-lived asset other than goodwill is recognized under GAAP if the carrying value of the asset (or the group of assets of which it is a part) exceeds (i) the future estimated undiscounted cash flow from the use of the asset (or group of assets) and (ii) the fair value of the asset (or asset group). In making this impairment assessment, we predominately use an undiscounted cash flow model derived from internal forecasts. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In the event that our management determines that the value of intangible assets have become impaired using this approach, we will record an accounting charge for the amount of the impairment. No impairment charges have been recorded for other amortizing intangibles in 2015, 2014 or 2013.

Fair market value accounting (derivative liability)

The most significant estimate that could have had a material effect on net (loss) gain is the fair market value accounting for our derivative liability. Our derivative liability previously consisted of free standing warrants that were recorded as liabilities due to the registration rights agreements and the requirement for continued effectiveness of the warrants. As a result, the warrants must be recorded as a liability at fair value. The changes in fair value were posted to the derivative (loss) gain in other (loss) income. We utilized the Black-Scholes method to estimate the fair value of our warrants. The three most significant factors in the Black-Scholes calculation are (i) our stock price, (ii) the volatility of our stock price and (iii) the remaining term of the warrants. During the year

ended December 31, 2013, we had a lower average remaining term of the warrants, and the Black-Scholes volatility of our stock over this remaining term was relatively low compared to 2012. These two factors lowered the Black-Scholes value of the warrants, even though our stock price increased in 2013 by $1.58. The result was a $0.1 million derivative gain. During the year ended December 31, 2014, a $6.13 increase in the value of our stock was the primary cause of the $13.2 million derivative loss, which completed the remaining term of our warrants. There was no derivative (loss) or gain during the year ended December 31, 2015.

Stock-Based Compensation and other stock-based valuation issues (derivative accounting)

We account for stock-based awards to employees and non-employees using Financial Accounting Standards Board Accounting Standards Codification (FASB)(ASC) FASB ASC Topic 718 — Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our common stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

We use the Black-Scholes option pricing model to determine the fair value of stock option and warrant grants. In applying the Black-Scholes option pricing model, assumptions are as follows:

	2015	2014	2013
Expected price volatility	73.00%-76.78%	73.00%-78.05%	77.59%-81.65%
Risk-free interest rate	1.25%-1.68%	1.58%-1.70%	0.70%-1.60%
Weighted average expected life in years	6 years	6 years	5-6 years
Dividend yield	—	—	—

Revenue Recognition

Meda License, Development and Supply Agreements

In August 2006 and September 2007, we entered into certain agreements with Meda AB (“Meda”), a Swedish company to develop and commercialize our ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered utilizing our BEMA® technology. The agreements relate to the United States, Mexico and Canada (“Meda U.S. Agreements”) and to certain countries in Europe (“Meda EU Agreements”). They carry license terms that commenced on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of the patents, which begin to expire in 2020.

We determined that, upon inception of both the U.S. and EU Meda arrangements, all deliverables were considered one combined unit of accounting. As such, all cash payments from Meda that were related to these deliverables were initially recorded as deferred revenue. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain deliverables associated with research and development services were delivered to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, $59.7 million of the aggregate milestones and services revenue was recognized as revenue in fiscal year 2009. In connection with the return of the U.S. marketing authorization by Meda to us in January 2015, the remaining U.S.-related deferred revenue of $1.0 million was recorded as contract revenue during the year ended December 31, 2015. U.S. related deferred revenue of $0.2 million was recorded as contract revenue during the year ended December 31, 2014.

Upon delivery of the license to Meda, we have determined that each of the undelivered obligations have stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. We have also obtained third-party evidence of fair value for the other research and development services and other service obligations, based on hourly rates billed by unrelated third-party providers for similar services contracted by us. We have obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged to us from the third-party supplier of the product. The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the ONSOLIS® product and (3) the combined requirements related to the remaining other service-related obligations due Meda to include participation in committees and certain other specified services.

We have determined that we are acting as a principal under the Meda Agreements and, as such, we will record product supply revenue, research and development services revenue and other services revenue amounts on a gross basis in our consolidated financial statements.

Endo License, Development and Supply Agreements

In January 2012, we entered into a License and Development Agreement with Endo pursuant to which we granted Endo an exclusive commercial world-wide license to develop, manufacture, market and sell our BELBUCA™ product and to complete U.S. development of such product for purposes of seeking FDA approval (the "Endo Agreement"). BELBUCA™ is for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BELBUCA™ and to sell the product worldwide. Although Endo has obtained all such necessary rights, we have agreed under the Endo Agreement to be responsible for the completion of certain clinical trials regarding BELBUCA™ (and providing clinical trial materials for such trials) necessary to submit a NDA to the FDA in order to obtain approval of BELBUCA™ in the U.S. We are responsible for development activities through the filing of the NDA in the U.S., while Endo is responsible for the development following the NDA submission as well as the manufacturing, distribution, marketing and sales of BELBUCA™ on a worldwide basis. In addition, Endo is responsible for all filings required in order to obtain regulatory approval of BELBUCA™.

Pursuant to the Endo Agreement, we have received (or are expected to receive upon satisfaction of applicable conditions) the following payments (some portion(s) of which will be utilized by us to support our development obligations under the Endo Agreement with respect to BELBUCA™):

- $30 million non-refundable upfront license fee (earned in January 2012);
- $15 million for enhancement of intellectual property rights (earned in May 2012);
- $20 million for full enrollment in two clinical trials ($10 million earned in January 2014 and $10 million earned in June 2014);
- $10 million upon FDA acceptance of filing NDA (earned in February 2015);
- $50 million upon regulatory approval, earned in October 2015 and received in November 2015, with the revenue recognition treatment for $20 million of such $50 million payment deferred due to the fact that all or a portion of such $20 million is contingently refundable to Endo based on a third party generic introduction in the U.S. during the patent extension period from 2020 to 2027. Should such introduction occur any time during the 2020 to 2027 period, a refund would be due to Endo based on the number of complete calendar months beyond December 31, 2019 where the first generic was sold over the denominator of 84 months times $20 million. For example, if a generic product were to be introduced in the U.S. in January of 2026, that would mean that 72 of the 84 months of patent exclusivity would have been earned and 12 months would have to be refunded. The calculation would be 12/84, times the $20 million, or a refund of $2.9 million. The method of the refund payment to Endo would be first by crediting against milestone payments, second by reducing the royalty by 50% until the $2.9 million is paid back, and third by BDSI making a payment in the amount due to Endo. Otherwise, the $20 million will be earned as revenue each month over the patent extension period from 2020 to 2027.
- up to an aggregate of $55 million based on the achievement of four separate post-approval sales thresholds; and
- sales-based royalties in a particular percentage range on U.S. sales of BELBUCA™, and royalties in a lesser range on sales outside the United States, subject to certain restrictions and adjustments.

We have assessed our arrangement with Endo and our deliverables thereunder at inception to determine: (i) the separate units of accounting for revenue recognition purposes, (ii) which payments should be allocated to which of those units of accounting and (iii) the appropriate revenue recognition pattern or trigger for each of those payments. The assessment requires subjective analysis and requires management to make judgments, estimates and assumptions about whether deliverables within multiple-element arrangements are separable and, if so, to determine the amount of arrangement consideration to be allocated to each unit of accounting.

At the inception of the Endo arrangement, we determined that the Endo Agreement was a multi-deliverable arrangement with three deliverables: (1) the license rights related to BELBUCA™, (2) services related to obtaining enhanced intellectual property rights through the issuance of a particular patent and (3) clinical development services. We concluded that the license delivered to Endo at the inception of the Endo Agreement has stand-alone value. It was also determined that there was a fourth deliverable, the provision of clinical trial material ("CTM"). The amounts involved are, however, immaterial and delivered in essentially the same time frame as the clinical development services. Accordingly, we did not separately account for the CTM deliverable, but consider it part of the clinical development services deliverable.

The initial non-refundable $30 million license fee was allocated to each of the three deliverables based upon their relative selling prices using best estimates. The analysis of the best estimate of the selling price of the deliverables was based on the income

approach, our negotiations with Endo and other factors, and was further based on management's estimates and assumptions which included consideration of how a market participant would use the license, estimated market opportunity and market share, our estimates of what contract research organizations would charge for clinical development services, the costs of clinical trial materials and other factors. Also considered were entity specific assumptions regarding the results of clinical trials, the likelihood of FDA approval of the subject product and the likelihood of commercialization based in part on our prior agreements with the BEMA® technology.

We concluded that each of the performance based milestones are substantive and, therefore, revenue has and will be recognized when milestones are earned.

Based on this analysis, $15.6 million of the up-front license fee was allocated to the license (which was estimated to have a value significantly in excess of $30 million), and $14.4 million to clinical development services (which is inclusive of the cost of CTM). Although the intellectual property component was considered a separate deliverable, no distinct amount of the up-front payment was assigned to this deliverable because we determined the deliverable to be perfunctory. The amount allocated to the license was recognized as revenue in fiscal year 2012. The portion of the upfront license fee allocated to the clinical development services deliverable of $14.4 million is being recognized as those services are performed. We estimated that such clinical development services would extend into the first half of 2015. Such services were completed by March 2015 and resulted in the recognition of $0.4 million, $2.5 million and $6.3 million as contract revenue in fiscal years, 2015, 2014 and 2013, respectively.

The term of the Endo Agreement shall last, on a country-by-country basis, until the later of: (i) 10 years from the date of the first commercial sale of BELBUCA™ in a particular country or (ii) the date on which the last valid claim of our patents covering BELBUCA™ in a particular country has expired or been invalidated. The Endo Agreement shall be subject to termination by Endo, at any time, upon a specific timeframe of prior written notice to us and under certain other conditions by either party as specified in the Endo Agreement.

The remaining milestone payments are expected to be recognized as revenue as they are achieved, except that one milestone is contingently refundable for a period of time. Revenue related to such contingently refundable milestone is expected to be recognized as refund provisions, as described in the Endo Agreement, expire. Sale threshold payments and sales-based royalties will be recognized as they accrue under the terms of the Endo Agreement.

We were reimbursed by Endo for certain contractor costs when these costs went beyond set thresholds as outlined in the Endo Agreement. Endo reimbursed us for this spending at cost and we received no mark-up or profit. The gross amount of these reimbursed research and development costs were reported as research and development reimbursement revenue. We acted as a principal, had discretion to choose suppliers, bear credit risk and may perform part of the services required in the transactions. Therefore, these reimbursements were treated as revenue to us. The actual expenses creating the reimbursements are reflected as research and development expense.

Beginning in March 2014, total reimbursable contractor costs exceeded a set threshold, at which point all such expenses are to be borne at a rate of 50% by Endo and 50% by us. Endo has continued to reimburse us for 100% of such costs, with 50% thereof to be taken by Endo as a credit against potential future milestones associated with achievement of certain regulatory events. As of December 31, 2014, we have recorded approximately $6 million of such cumulative payment in deferred revenue current. This credit amount was deducted from the $50 million regulatory approval milestone earned by us in October 2015. During the year ended December 31, 2015 and 2014, the Company recognized $0.9 million and $12.7 million, respectively, of reimbursable expenses related to the Endo Agreement, which is recorded as research and development reimbursement revenue.

On December 23, 2014, BDSI and Endo announced the submission of a NDA for BELBUCA™ to the FDA, which was accepted February 23, 2015. On October 26, 2015, BDSI and Endo announced that the FDA approved BELBUCA™ (on October 23, 2015). FDA approval of BELBUCA™ triggered a milestone payment to us from Endo of $50 million pursuant to the Endo Agreement, less approximately $6 million of the aforementioned cumulative pre-payments received and recorded in deferred revenue, current. We received payment of such milestone in November 2015 with the revenue recognition treatment for $20 million of such $50 million payment having been deferred for future revenue recognition and will be earned over the extended patent period from 2020 to 2027 as the payment is contingently refundable pending a generic product commercially launched during the patent extension period.

Product Royalty Revenues

Product royalty revenue amounts are based on a percentage of net sales revenue of the ONSOLIS® product under our license agreement with Meda. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. This is shown as product royalty revenues on the accompanying consolidated statements of operations. Meda has the right to reject products that do not comply with product, packaging, or regulatory specifications. Defective product must be identified by Meda within 10 days after inspection at Meda's

distribution site. We bill Meda immediately upon receipt by Meda of product (FOB manufacturer). On a quarterly basis, a reconciliation is prepared that reflects the difference between actual net sales by Meda multiplied by the royalty percentage, and the actual royalty payments made during the quarter (which is based on a "transfer price" at the time we invoice Meda). The parties "true-up" the differences within 45 days of each quarter-end.

Product Sales

Product sales amounts relate to sales of BUNAVAIL® which was launched in November 2014. These sales are recognized as revenue when prescriptions are filled. This is shown as product sales on the accompanying consolidated statements of operations.

Contract Revenue

Contract revenue amounts are related to our license agreements when we receive and recognize revenue from Endo, Meda, TTY and Kunwha, which the Kunwha license agreement was terminated on August 31, 2015. We also recognize as revenue previously deferred revenue related to our agreement with Meda associated with ONSOLIS®.

Research and Development Reimbursements

Reimbursable revenue amounts are related to certain research and development expenses that are reimbursable from Endo related to the Buprenorphine chronic pain program. Our contract with Endo states that Endo will begin reimbursing us for certain research and development expenses once these expenses exceeded $45 million. During the years ended December 31, 2015, 2014 and 2013, we recognized $0.9 million, $12.7 million and $2.8 million, respectively of reimbursable expenses related to our Endo agreement. This is shown as reimbursable revenue on the accompanying consolidated statements of operations.

Cost of Sales

The cost of sales includes direct costs attributable to the production of BREAKYL™, PAINKYL™ and BUNAVAIL®. Cost of sales also includes royalty expenses owed to third parties.

For BREAKYL™ and PAINKYL™, we do not take ownership of the subject product as we do not have inventory, as such product is transferred to Meda, in the case of BREAKYL™ and TTY in the case of PAINKYL™, immediately in accordance with the terms of our contractual arrangements with Meda and TTY. LTS manufactures both products for us. Meda's and TTY's royalty payments to us include an amount related to cost of sales. Ownership and title to the product, including insurance risk, belong to LTS from raw material through completion and inventory of the subject product, and then to Meda and TTY upon shipment of such subject product. This is in accordance with our contracts with LTS and Meda and TTY, which identify the subject product as FOB manufacturer.

For BUNAVAIL®, cost of sales includes raw materials, production costs at our two contract manufacturing sites, quality testing directly related to the product, and depreciation on equipment that we have purchased to produce BUNAVAIL®. It also includes any batches not meeting specifications and raw material yield loss. At launch during the year ended December 31, 2014, $0.7 million of our BUNAVAIL® manufacturing costs had been deferred as deferred costs of sales and will be recognized as cost of sales when prescriptions are filled. Deferred cost of sales during the year ended December 31, 2015 was $1.7 million. Yield losses and batches not meeting specifications are expensed as incurred.

A significant majority of our gross to net accruals are the result of our voucher program and Medicaid rebates, with the majority of those programs having an accrual to payment cycle of anywhere from one to three months. In addition to this relatively short accrual to payment cycle, we receive daily information from the wholesalers regarding their sales of our products and actual on hand inventory levels of our products. During the year ended December 31, 2015, the three large wholesalers account for approximately 77% of our voucher and Medicaid accruals. This enables us to execute accurate provisioning procedures. Consistent with the pharmaceutical industry, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products. However, since we do not have sufficient experience with measuring returns, at the time of exfactory sales, we record revenue when the risk of product return has been substantially eliminated.

Once we have adequate experience with measuring returns, we can then record sales exfactory.

Research and Development Expenses

Overview

Our research and development expenses consist (and have historically consisted) primarily of expenses incurred in identifying, developing, testing, manufacturing and seeking regulatory approval of our product candidates, including:

- expenses associated with regulatory submissions, clinical trials and manufacturing, including additional expenses to prepare for commercial manufacture prior to FDA approval;

- fees paid to third-party contract research organizations, contract laboratories and independent contractors;
- payments made to consultants who perform research and development on our behalf and assist us in the preparation of regulatory filings;
- personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation for personnel directly involved in product development activities;
- payments made to third-party investigators who perform research and development on our behalf and clinical sites where such research and development is conducted; and
- other related expenses.

Clinical trial expenses for our product candidates are a significant component of our research and development expenses. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to the increased size and duration of the clinical trials. We coordinate clinical trials through a number of contracted investigational sites, and the associated expense is based on a number of factors, including actual subject enrollment and visits, direct pass-through costs and other clinical site fees.

Product development expenses are expensed as incurred and reflect costs directly attributable to product candidates in development during the applicable period. Additionally, product development expenses include the cost of qualifying new, current Good Manufacturing Practice (known as cGMP) third-party manufacturing for our product candidates, including expenses associated with any related technology transfer.

Results of Operations

For the Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

Product Sales. We recognized $4.2 million and $0.1 million in product sales during the years ended 2015 and 2014, respectively, from our product BUNAVAIL®. The increase in 2015 over 2014 is a result of the BUNAVAIL® launch in November 2014.

Product Royalty Revenues. We recognized $1.4 million and $3.4 million in product royalty revenue during the years ended 2015 and 2014, respectively, under our license agreement with Meda for BREAKYL™ in Europe. The decrease in product royalty revenues in 2015 can be attributed to lower sales in Europe during 2015 and timing of deliveries of product.

Research and Development Reimbursements. We recognized $0.9 million and $12.7 million of reimbursable revenue related to our agreement with Endo during the years ended 2015 and 2014, respectively. Our 2012 license agreement with Endo includes an obligation for Endo to reimburse us for certain trial expenses that exceed a maximum threshold. In the last quarter of 2013, these thresholds were exceeded. The decrease in 2015 over 2014 is principally a result of the clinical trial program ending during the first half of 2015.

Contract Revenues. We recognized $41.8 million and $22.7 million in contract revenue during the years ended 2015 and 2014, respectively, principally under our license agreement with Endo. Contract revenue in 2015 primarily consisted of recognizing as revenue $40.4 million in two milestone payments from Endo associated with submission and subsequent approval by the FDA of the NDA for BELBUCA™. Also included in 2015 was $1.1 million in contract revenue under our license agreement with Meda. Additionally, we received $0.3 million under our license agreement with Kunwha. Contract revenue in 2014 consisted of two $10 million milestone payments received from Endo as a result of finalizing clinical trials. The remaining $2.7 million of 2014 contract revenue is from recognition of a portion of the deferred revenue arising from the $30 million upfront payment received in 2012 from Endo. Of the $30 million initially received, $14.4 million was deferred and recognized over the life of our research and development spending on the Endo-related clinical trials.

Cost of Sales. We incurred $8.1 million and $4.9 million in cost of sales during the years ended 2015 and 2014, respectively. In 2015, we had a standard, minimum $1.5 million contractual royalty due to CDC related to our ONSOLIS® and BREAKYL™ product. Also in 2015, we incurred $5.9 million in cost of sales for BUNAVAIL®. The remaining $0.7 million in 2015 represents cost of sales for BREAKYL™ in Europe. In 2014, we incurred the same $1.5 million royalty to CDC and $1.3 million for our increased BREAKYL™ sales in Europe. In addition for 2014, we incurred $2.1 million in cost of sales for BUNAVAIL® which included immediate expensing of certain production that did not meet specifications during product validation and batch size scale up.

Expenditures for Research and Development Programs (2015 vs. 2014)

BUNAVAIL®

We incurred research and development expenses for BUNAVAIL® of approximately $6.2 million for the year ended December 31, 2015 and approximately $2.9 million for the year ended December 31, 2014. We have incurred approximately $33.5 million in the aggregate since inception of our development of this product. BUNAVAIL® was approved by the FDA in 2014. Therefore, BUNAVAIL® research and development expenses in 2015 primarily consist of supporting costs for additional indications of BUNAVAIL® and allocated wages and compensation.

BELBUCA™

We incurred research and development expenses for BELBUCA™ of approximately $2.8 million for the year ended December 31, 2015 and approximately $22.0 million for the year ended December 31, 2014. Aggregate expenses approximate $114.2 million since inception of our development of this product. Our expense obligations for this product were detailed in our license and development agreement with Endo. Since our license agreement with Endo in 2012, a portion of these expenses were reimbursed by Endo. Our expenses for this product over such periods consisted primarily of three large clinical trials addressing the efficacy and safety of the product, along with formulation and manufacturing development and allocated wages and compensation. BELBUCA™ was approved by the FDA in 2015.

Clonidine Topical Gel

We incurred research and development expenses for Clonidine Topical Gel of approximately $8.5 million for the year ended December 31, 2015 and approximately $9.0 million for the year ended December 31, 2014. We have incurred approximately $20.8 million in the aggregate since inception of our development of this product candidate. Our expenses for this product candidate over such periods consisted mainly of several clinical trials testing the efficacy of the product, a Long-Term Safety Study and allocated wages and compensation.

Buprenorphine Depot Injection

We incurred research and development expenses for Buprenorphine Depot Injection of approximately $2.8 million for the year ended December 31, 2015, about $0.4 million for the year ended December 31, 2014 and approximately $3.2 million in the aggregate since inception of our development of this product candidate. Our 2015 expenses for this product candidate consisted of pre-clinical formulation and manufacturing development in anticipation of filing an IND in 2016. Also included were allocated wages and compensation.

ONSOLIS®

We incurred research and development expenses for ONSOLIS® of approximately $0.3 million for the year ended December 31, 2015. There were no such expenses incurred during the year ended December 31, 2014. We have incurred approximately $0.3 million in the aggregate since inception of our development of this product. Our expenses for this product for 2015 consisted mainly of development work in support of the reformulation of ONSOLIS® that was approved by the FDA in August 2015 and allocated wages and compensation.

Selling, General and Administrative Expenses. During the years ended December 31, 2015 and 2014, selling, general and administrative expenses totaled $54.7 million and $38.5 million, respectively. Selling, general and administrative costs include BUNAVAIL® sales, marketing, and commercial expenses. These costs also include legal and professional fees, wages, and stock-based compensation expense. The increase in selling, general and administrative expenses can be attributed to a full year of commercial activities and related expenses for BUNAVAIL®. Such costs include the hiring of a sales force, marketing, market support studies, and wages. The remaining increase in selling, general and administrative costs is related primarily to stock compensation expense, patent defense and litigation expenses.

Interest Expense, Net. During the year ended December 31, 2015 we had net interest expense of $2.5 million, consisting of $2.0 million of scheduled interest payments and $0.5 million of related amortization of discount and loan costs associated with the July 2015 secured loan facility from MidCap. During the year ended December 31, 2014 we had net interest expense of $2.1 million, consisting of $1.4 million of scheduled interest payments and $0.7 million of related amortization of discount and loan costs associated with the July 2013 secured loan facility from MidCap. These 2014 costs were partially offset by interest income of $0.07 million.

Derivative Loss. Derivative loss in 2014 was related to the adjustment of derivative liabilities to fair value as of December 31, 2014. Our derivatives are free-standing warrants. The warrants are measured using Black-Scholes calculations. A major component of

the calculation is our stock price. As our stock price increases, the warrants are valued higher, which results in an increase in the derivative liability and a corresponding derivative loss. During the year ended December 31, 2014, our stock price increased dramatically, from $5.89 to $12.02, which resulted in a $13.2 million derivative loss. There were no remaining derivatives after December 31, 2014, therefore, there was no derivative loss or gain during the year ended December 31, 2015.

Income Tax Expense and Tax Net Operating Loss Carryforwards. We had federal and state net operating loss carryforwards (or NOLs) of approximately $168 million and $178 million, respectively at December 31, 2015 as compared to federal and state NOLs of $159 million and $143 million, respectively as of December 31, 2014. These loss carryforwards expire principally beginning in 2020 through 2035 for federal and 2030 for state purposes. In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, we recorded a valuation allowance with respect to all of our deferred tax assets. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation" (as defined in the Internal Revenue Code), there are annual limitations on the amount of the net operating loss and other deductions which are available to us.

For the Year Ended December 31, 2014 Compared to the Year Ended December 31, 2013

Product Sales. We recognized $0.1 million in product sales during the year ended 2014 from the launch of BUNAVAIL®. There were no product sales during the year ended 2013.

Product Royalty Revenues. We recognized $3.4 million and $1.8 million in product royalty revenue during the years ended 2014 and 2013, respectively, under our license agreement with Meda for BREAKYL™ in Europe. The increase in product royalty revenues in 2014 can be attributed to more orders from Meda for Spain, France, and the Netherlands as sales in those countries continue to increase over the initial launch year.

Research and Development Reimbursements. We recognized $12.7 million and $2.8 million of reimbursable revenue related to our agreement with Endo during the years ended 2014 and 2013, respectively. Our 2012 license agreement with Endo includes an obligation for Endo to reimburse us for certain trial expenses that exceed a maximum threshold. In the last quarter of 2013, these thresholds were exceeded. Therefore, near the end of 2013 Endo reimbursed us for two months of applicable research and development spending, whereas there was a full year of these reimbursable expenses in 2014.

Contract Revenues. We recognized $22.7 million and $6.8 million in contract revenue during the years ended 2014 and 2013, respectively, principally under our license agreement with Endo. Contract revenue in 2014 consisted of two $10 million milestone payments received from Endo as a result of finalizing two clinical trials. The remaining $2.7 million of 2014 contract revenue is from recognition of a portion of the deferred revenue arising from the $30 million upfront payment received in 2012 from Endo. Of the $30 million initially received, $14.4 million was deferred and recognized over the life of our research and development spending on the Endo-related clinical trials. In 2013, we recognized $6.5 million of Endo-related deferred revenue. The revenue recognition in 2013 was higher than 2014 because we had incurred higher research and development spending, as three large clinical trials were being conducted in 2013.

Cost of Sales. We incurred $4.9 million and $2.1 million in cost of sales during the years ended 2014 and 2013, respectively. In 2013, we had a standard, minimum $1.5 million contractual royalty due to CDC related to our ONSOLIS® and BREAKYL™ product. The remaining $0.6 million in 2013 represents cost of sales for our BREAKYL™ European sales. In 2014, we incurred the same $1.5 million royalty to CDC and $1.3 million for our increased BREAKYL™ sales in Europe. In addition for 2014, we incurred $2.1 million in cost of sales for BUNAVAIL® which included immediate expensing of certain production that did not meet specifications during product validation and batch size scale up.

Expenditures for Research and Development Programs (2014 vs. 2013)

BUNAVAIL®

We incurred research and development expenses for BUNAVAIL® of approximately $2.9 million for the year ended December 31, 2014 and approximately $7.1 million for the year ended December 31, 2013. We have incurred approximately $27.3 million in the aggregate since inception of our development of this product. BUNAVAIL® was approved by the FDA in 2014. Therefore, BUNAVAIL® research and development expenses in 2014 primarily consist of manufacturing process development and stability work prior to approval.

BELBUCA™ (BEMA® Buprenorphine)

We incurred research and development expenses for BELBUCA™ of approximately $22.0 million for the year ended December 31, 2014 and approximately $41.8 million for the year ended December 31, 2013. Aggregate expenses approximate $111.4

million since inception of our development of this product candidate. Our expense obligations for this product candidate were detailed in our license and development agreement with Endo. Since our license agreement with Endo in 2012, a portion of these expenses were reimbursed by Endo. Our expenses for this product over such periods consisted primarily of three large clinical trials addressing the efficacy and safety of the product, along with formulation and manufacturing development.

Clonidine Topical Gel

We incurred research and development expenses for Clonidine Topical Gel of approximately $9.0 million for the year ended December 31, 2014, approximately $3.3 million for the year ended December 31, 2013 and have incurred approximately $12.3 million in the aggregate since inception of our development of this product candidate. Our expenses for this product candidate over such periods consisted mainly of a Phase 2 trial testing the efficacy of the product candidate and expensing of $2.5 million of in-process research and development associated with licensing of the product from Arcion.

Buprenorphine Depot Injection

We incurred research and development expenses for Buprenorphine Depot Injection of approximately $0.4 million for the year ended December 31, 2014 and in the aggregate since inception of our development of this product candidate. No such expenses were incurred in 2013. Our 2014 expenses for this product candidate consisted mainly of one payment to Evonik for Buprenorphine data in accordance with our agreement.

Selling, General and Administrative Expenses. During the years ended December 31, 2014 and 2013, selling, general and administrative expenses totaled $38.5 million and $12.3 million, respectively. Selling, general and administrative costs include BUNAVAIL® sales, marketing, and commercial expenses. These costs also include legal and professional fees, wages, and stock-based compensation expense. The increase in general and administrative expenses can be attributed to the preparation for and launch of BUNAVAIL® during 2014, which represents $17.3 million of the increase. These BUNAVAIL® related costs include the hiring of a sales force, marketing, market support studies, and wages. The remaining increase in selling, general and administrative costs is due to higher stock compensation, patent defense and litigation expenses.

Interest Expense, Net. During the year ended December 31, 2014 we had net interest expense of $2.1 million, consisting of $1.4 million of scheduled interest payments and $0.7 million of related amortization of discount and loan costs associated with the July 2013 secured loan facility from MidCap. These 2014 costs were partially offset by interest income of $0.07 million. During the year ended December 31, 2013 we had net interest expense of $0.9 million, consisting of $0.9 million of scheduled interest payments and $0.3 million of related amortization of discount and loan costs associated with the July 2013 secured loan facility from MidCap. These 2013 costs were partially offset by interest income of $0.3 million.

Derivative (Loss) Gain. Derivative (loss) gain in 2014 and 2013 is related to the adjustment of derivative liabilities to fair value as of December 31, 2014 and 2013, respectively. Our derivatives are free-standing warrants. The warrants are measured using Black-Scholes calculations. A major component of the calculation is our stock price. As our stock price increases, the warrants are valued higher, which results in an increase in the derivative liability and a corresponding derivative loss. During the year ended December 31, 2014, our stock price increased from $5.89 to $12.02, which resulted in a $13.2 million derivative loss.

Income Tax Expense and Tax Net Operating Loss Carryforwards. We had federal and state net operating loss carryforwards (or NOL) of approximately $159 million and $143 million, respectively at December 31, 2014 as compared to federal and state NOLs of $109 million and $100 million, respectively as of December 31, 2013. These loss carryforwards expire principally beginning in 2020 through 2035 for federal and 2030 for state purposes. In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, we recorded a valuation allowance with respect to all of our deferred tax assets. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation" (as defined in the Internal Revenue Code), there are annual limitations on the amount of the net operating loss and other deductions which are available to us.

Major Research and Development Projects

In 2015, our research and development resources were focused on:

- Supporting Endo in the review and FDA approval of the BELBUCA™ NDA
- Continuing a Medical Affairs effort to support BUNAVAIL®
- Providing commercial supplies for BUNAVAIL®

- Completing a placebo controlled Phase 3 study to assess the efficacy of Clonidine Topical Gel for PDN as well as conduct a long-term safety study
- Formulation development work for Buprenorphine Depot Injection

The projected dates for IND and NDA submissions, and FDA approval of NDAs, our estimates of development costs and our projected sales associated with each of our product candidates discussed below and elsewhere in this Report are merely estimates and subject to multiple factors, many of which are, or may be beyond our control, including those detailed in the Risk Factors section of this Report. These factors and risks could cause delays, cost overruns or otherwise cause us to not achieve these estimates. Readers are also advised that our projected sales figures do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our market research and management's reasonable judgments, but readers are advised that such estimates may prove to be inaccurate.

The following is a summary of our current major research and development initiatives and the risks related to such initiatives:

BUNAVAIL®. The NDA for BUNAVAIL® was approved in June 2014 and BUNAVAIL® was launched in November 2014. Research and development work in 2015 included work to support a label expansion of BUNAVAIL® for the induction (conversion to buprenorphine) of opioid dependent subjects and improvements in commercial manufacturing and packaging.

The risks to our company associated with BUNAVAIL® include: (i) the inability to provide adequate clinical trial data to obtain expanded labeling for an induction claim or alternative dose strengths; and (ii) inability to continue to supply product in adequate quantities to meet the commercial demand.

BELBUCA™ (buprenorphine) buccal film. BELBUCA™ is our second analgesic product using the BEMA® technology. The Phase 3 studies to evaluate the efficacy and safety of BELBUCA™ in the treatment of opioid naïve and experienced patients with chronic pain were completed in 2014. The NDA was submitted on December 23, 2014, accepted February 23, 2015 and approved on October 23, 2015. We supported Endo in responding to FDA questions, scale-up of manufacturing and publishing the results of the clinical trials. Due to the ability of BELBUCA™ to participate in the $4.7 billion market for long acting opioids for the treatment of chronic pain, we believe that BELBUCA™ has the potential to achieve up to $500 million in peak annual sales. We expect to generate royalty revenue following the launch of BELBUCA™ beginning in early 2016. A license and development agreement was finalized with Endo for the worldwide rights to BELBUCA™ for chronic pain in January 2012.

The risks to our company associated with the BELBUCA™ project include: (i) inability to manufacture adequate supplies for commercial use; (ii) unexpected product safety issues; and (iii) failure of our commercial partner to effectively launch and sell the product. A technical or commercial failure of BELBUCA™ would have a material adverse effect on our future revenue potential and would negatively affect investor confidence in our company and our public stock price.

Clonidine Topical Gel. Prior to license of Clonidine Topical Gel to us, Arcion assessed its effectiveness in reducing pain associated with PDN in a double-blind, placebo-controlled, Phase 2 study where the primary study endpoint was the change in pain intensity over a 3 month treatment period in diabetic foot pain. A significant treatment difference was seen in the planned subset analysis of diabetic patients who had documented evidence of "functioning pain receptors" in the skin of the lower leg ($p=0.01$, $n=63$) thus, at a minimum, supporting the effectiveness of topical clonidine in diabetic patients with functioning pain receptors of the skin. In the overall population that included patients without "functioning nerve receptors", there was a trend favoring Clonidine Topical Gel ($p=0.07$, $n=182$), though the overall results did not reach statistical significance.

A Phase 3 clinical study assessing the efficacy and safety of Clonidine Topical Gel in the enriched population identified in the Phase 2 study performed by Arcion was started in 2014. An interim analysis in the summer indicated that a sample size increase was needed to maintain 90% power to demonstrate a statistical difference between clonidine and placebo. Randomization of the final subject at the revised sample size was completed in December. In March 2015, we announced that the primary efficacy endpoint in the Phase 3 study of Clonidine Topical Gel compared to placebo did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement ($n=158$; $p<0.02$) in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, we initiated a second study. The study incorporates significant learnings from previously conducted studies and involves tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. The final study subject is expected to complete treatment by the end of 2016. The risks to our company associated with the Clonidine Topical Gel clinical program include: (i) inability to develop and manufacture a stable formulation suitable for commercial use; (ii) failure of clinical trials; (iii) product safety issues; (iv) failure of or delay by the FDA to approve our NDA; (v) failure of a commercial partner or us to effectively launch and sell the product; and (vii) lack of funding to advance the program.

Buprenorphine Depot Injection. In 2014, we entered into an agreement with Evonik to develop and commercialize a long-acting buprenorphine depot injection capable of providing 30 days of continuous buprenorphine blood concentrations following a single monthly injection. In 2015, we completed initial development work and preclinical studies which has resulted in the identification of a formulation we believe is capable of providing 30 days of continuous buprenorphine treatment. During a pre-IND meeting with FDA in November 2015, FDA requested an additional study to assess the fate of the polymers used in the formulation. Upon completion of the study, we plan to submit an Investigational New Drug application (or IND) for this product candidate to FDA in the third quarter of 2016.

The risks to our company associated with the Buprenorphine Depot Injection program include: (i) inability to develop a formulation that provides suitable blood concentrations for the intended clinical use; (ii) inability to manufacture the formulation at adequate scale for clinical development and commercial purposes; (iii) failure of FDA to permit clinical development of the product under the IND; (iv) failure of the product to perform in the clinic; (v) slow patient enrollment in clinical trials; (vi) product safety issues; (vii) failure of or delay by the FDA to approve our NDA; (viii) failure of a commercial partner or us to effectively launch and sell the product; and (ix) lack of funding to advance the program.

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, funded research arrangements and revenue generated as a result of our worldwide license and development agreement with Meda regarding ONSOLIS® and revenue generated as a result of our January 2012 agreement with Endo regarding our BELBUCA™ product. We intend to finance our research and development, commercialization and working capital needs from existing cash, royalty revenue, earnings from the commercialization of BUNAVAIL®, new sources of debt and equity financing, existing and new licensing and commercial partnership agreements and, potentially, through the exercise of outstanding common stock options and warrants to purchase common stock.

During 2013, we entered into a $20 million secured loan facility with MidCap, from which we received net proceeds in the aggregate amount of $19.8 million.

In November 2013, we filed a shelf registration statement which registered up to $75 million of our securities for potential future issuance, and such registration statement was declared effective on December 18, 2013. Concurrently with the filing of such registration statement, we established an “at-the-market” offering program utilizing the universal shelf registration for up to $15 million of common stock. During 2014, we sold an aggregate of 1,304,410 shares of common stock under such offering program for approximate net proceeds of $14.5 million.

In January, 2014, we announced positive top-line results from our pivotal Phase 3 efficacy study of BELBUCA™ in opioid-“naive” subjects. The locking of the database for the opioid naive study triggered a $10 million milestone payment from Endo per our licensing agreement that was received February, 2014.

In February, 2014, we entered into a definitive Securities Purchase Agreement with certain institutional investors relating to our registered direct offering of 7,500,000 shares of our common stock. The shares were sold at a price of $8.00 per share, yielding net offering proceeds of $58.2 million. The offering price per share was determined based on an approximately 3.1% discount to the closing price of the common stock on February 7, 2014.

In March, 2015, we received a $10 million milestone from Endo upon FDA acceptance of filing our BELBUCA™ NDA.

On May 29, 2015, we entered into a $30 million secured loan facility with MidCap. The Credit Agreement is a restatement, amendment and modification of a prior credit and security agreement, dated as of July 5, 2013 among us and MidCap Financial SBIC, LLP, a predecessor to MidCap, and certain lenders thereto. We received net loan proceeds in the aggregate amount of approximately $20.1 million and will use the loan proceeds for general corporate purposes or other activities permitted under the credit agreement.

On July 2, 2015, we filed a shelf registration statement which registered up to $150 million of our securities for potential future issuance, and such registration statement was declared effective on July 13, 2015. Concurrent with the filing of such registration statement, we established an “at-the-market” offering program utilizing the universal shelf registration for up to $40 million of Common Stock.

On October 26, 2015, we and Endo announced that the FDA approved BELBUCA™ for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate. FDA approval of BELBUCA™ has triggered a milestone payment to us from Endo of $50 million pursuant to the Endo Agreement, less approximately $6 million of aforementioned cumulative pre-payments received. $20 million of such $50 million payment has been deferred for future revenue recognition and will be earned over the extended patent period from 2020 to 2027 as the payment is contingently refundable pending a generic product commercially launched during the patent extension period.

We anticipate that the cash used in operations and our investment in our facilities will continue beyond our BREAKYL™ agreements with Meda; pending reformulation of ONSOLIS® and our agreement with Endo regarding BELBUCA™ for chronic pain. We plan to research, develop and potentially, manufacture and commercialize additional drug formulations with our BEMA® technology such as our BUNAVAIL® product as well as other non-BEMA® related products and technologies that we are currently developing or that we may acquire from other companies. As it relates to the latter, we are exploring other new product opportunities in pain and dependency as well as drug delivery technologies that may allow us to become less dependent on our BEMA® technology and the products we are currently developing that utilize BEMA®.

At December 31, 2015, we had cash and cash equivalents of approximately $83.6 million. We used $3.7 million of cash from operations during the twelve months ended December 31, 2015 and had stockholders' equity of $31.7 million, versus $54.4 million at December 31, 2014. We have sufficient cash to manage the business into the middle of 2017, although this assumes that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements

Additional capital may be required to support our commercialization activities for BUNAVAIL®, our planned development of Clonidine Topical Gel, buprenorphine depot injection, the reformulation project for and anticipated commercial relaunch of ONSOLIS® and general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

Also, product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

Accordingly, we anticipate that we will be required to raise additional capital, which may be available to us through a variety of sources, including:

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- sale of product royalty;
- grants and new license revenues;
- bank loans;
- equipment financing;
- public or private debt; and
- exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations in 2016 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

Contractual Obligations and Commercial Commitments

Our non-cancellable contractual obligations as of December 31, 2015 are as follows (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 2,278	$ 320	$ 668	$ 1,073	$ 217
Secured loan facility	30,000	7,000	23,000	—	—
Purchase obligations*	270	171	99	—	—
Interest on secured loan facility	4,657	2,571	2,086	—	—
Minimum royalty expenses**	6,000	1,500	3,000	1,500	—
Total contractual cash obligations***	$43,205	$11,562	$28,853	$ 2,573	$ 217

* Purchase obligations are primarily related to long term contracts for minimum services from commercial vendors.
** Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC and Athyrium regardless of actual sales.
*** We signed a commercialization agreement with Endo in January 2012. Endo will have worldwide rights to market our BELBUCA™ product. In return for milestone payments and royalties, we are required to conduct and pay for certain clinical trials as outlined in a mutually agreed development plan. These costs will depend on the size and scope of the required trials. The Endo agreement does not specify minimums in terms of the cost of the trials.

Off Balance Sheet Arrangements

We are not a party to any off balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation covers $0.25 million for substantially all depository accounts. We may from time to time have amounts on deposit in excess of the insured limits. As of December 31, 2015, we had approximately $83.6 million, which exceeded these insured limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Market indexed security risk

We have issued warrants in the past to various holders underlying shares of our common stock. These warrant investments were re-measured to their fair value at each reporting period with changes in their fair value recorded as derivative gain (loss) in the accompanying consolidated statement of operations. We use the Black-Scholes model for valuation of the warrants.

Equity Price Risk.

We do not use derivative instruments for hedging of market risks or for trading or speculative purposes. Derivative instruments embedded in contracts, to the extent not already a free-standing contract, are bifurcated and accounted for separately. All derivatives are recorded on the consolidated balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. As of December 31, 2015, we did not have any derivative liabilities on our condensed consolidated balance sheet.

Item 8. Financial Statements and Supplementary Data.

Our Consolidated Financial Statements and Notes thereto and the report of Cherry Bekaert LLP, our independent registered public accounting firm, are set forth on pages F-1 through F-34 of this Report.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, at December 31, 2015, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Report that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations for the implementation of Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with GAAP. Our 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 our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. 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 or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2015. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (COSO). Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2015.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of March 7, 2016 are as follows:

Name	Age	Position(s) Held
Frank E. O'Donnell, Jr., M.D.	66	Executive Chairman and Director
Mark A. Sirgo, Pharm.D.	62	President, Chief Executive Officer and Director
Ernest R. De Paolantonio	62	Chief Financial Officer, Secretary and Treasurer
Niraj Vasisht, Ph.D.	52	Senior Vice President, Product Development & Chief Technology Officer
William B. Stone	72	Lead Director
Samuel P. Sears, Jr	72	Director
Thomas W. D'Alonzo	72	Director
Charles J. Bramlage	55	Director
Barry I. Feinberg	61	Director

There are no arrangements between our directors and any other person pursuant to which our directors were nominated or elected for their positions. There are no family relationships between any of our directors or executive officers.

Frank E. O'Donnell, Jr., M.D., age 66, has been our Chairman of the Board and a Director since March 29, 2002. He currently serves as Executive Chairman. Dr. O'Donnell has previously served as our President and Chief Executive Officer. In January 2005, he relinquished the title of President and in August 2005 he relinquished the title of Chief Executive Officer. For more than the last six years, Dr. O'Donnell has served as a Manager of The Hopkins Capital Group, an affiliation of limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare. Dr. O'Donnell is also Chairman of the Board of Directors of Hedgepath Pharmaceuticals, Inc., which is developing oncology drugs for an orphan indication. Dr. O'Donnell is qualified to serve on our board of directors because of his long history with our company and his extensive experience in managing and investing in biopharmaceutical companies. Dr. O'Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O'Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. He is a trustee of St. Louis University.

Mark A. Sirgo, Pharm.D., age 62, has been our President since January 2005 and Chief Executive Officer and Director since August 2005. He joined our company in August 2004 as Senior Vice President of Commercialization and Corporate Development upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder and Chief Executive Officer. He has also served as our Executive Vice President, Corporate and Commercial Development and our Chief Operating Officer. Dr. Sirgo has over 30 years of experience in the pharmaceutical industry, including 16 years in clinical drug development, 7 years in marketing, sales, and business development and 12 years in executive management positions. Prior to his involvement with Arius Pharmaceuticals from 2003 to 2004, he spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 while at Glaxo Wellcome, among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc., a leading contract service provider to the pharmaceutical industry. Dr. Sirgo served on the Board of Directors and as Chairman of the Compensation Committee of Salix Pharmaceuticals, Ltd. (NASDAQ:SLXP), a specialty pharmaceutical company specializing in gastrointestinal products from 2008 until its sale in 2015. Dr. Sirgo is qualified to serve on our board of directors because of his extensive experience in specialty biopharmaceutical companies. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

Ernest R. De Paolantonio, *CPA, MBA*, age 62, has been our Chief Financial Officer and Secretary since October of 2013 and has over 35 years of varied financial and business experience in the pharmaceutical industry. Mr. De Paolantonio also became our Treasurer in January 2015. Prior to joining the company, he served as the Chief Financial Officer of CorePharma LLC, a private specialty generic company, and was directly involved in the financial and commercial strategy to establish Core's proprietary labeled portfolio of products. In addition, he previously served in finance and controllers positions in roles of increasing responsibility at Colombia Laboratories, where he was also responsible for business development and logistics, including supply chain management for the company's first commercial product launch. Mr. De Paolantonio has served in various financial positions in senior management at Taro Pharmaceuticals where he was the Corporate Controller, Watson Pharmaceuticals where he was Executive Director of Finance, Group Controller and responsible for managing the Corporation's supply chain of Active Pharmaceutical Ingredients, and GlaxoSmithKline where he began his career in finance and spent over 17 years in areas of increasing responsibility including; Manufacturing, Corporate Finance, R&D and U.S. Pharmaceuticals where he was Group Controller. Mr. De Paolantonio received his Bachelor of Arts Degree from Lycoming College; his MBA in Finance at Saint Joseph's University and is a licensed CPA.

Niraj Vasisht, Ph.D., age 52, joined our company in February 2005 as the Vice President of Product Development. In October 2009, he was promoted to Senior Vice President of Product Development and Chief Technical Officer and later to Chief Technology Officer in January 2016. Dr. Vasisht heads the Chemistry, Manufacturing and Controls (CMC) for our pipeline products, and has led the efforts on formulation development, process development, and manufacturing of ONSOLIS®, BELBUCA™, and BUNAVAIL® based on BEMA® Technology. In his new role, Dr. Vasisht will focus on selecting suitable drug delivery platforms and product where delivery is the differentiating feature to continue growing our product development pipeline, while continuing to lead the CMC and Quality Operations. Dr. Vasisht will provide technical and strategic leadership to the business development function as he evaluates drug delivery platforms and candidate molecules. Dr. Vasisht is known as a key-opinion-leader (KOL) in the field of microencapsulation-based controlled/sustained release and drug delivery technologies. Prior to joining the company, Dr. Vasisht served as the Director of Microencapsulation, Pharmaceutical Development and Nanomaterials at Southwest Research Institute where he developed several commercial formulations and lead a team of prolific researchers in product conceptualization, product development, engineering scale up and commercial manufacturing across pharmaceutical, consumer health, and nutraceutical industry. Dr. Vasisht is the inventor for several patents that resulted in product commercialization. He received a Bachelor's degree in Chemical Engineering from the Indian Institute of Technology at Kanpur, a Master's of Science from the University of New Hampshire and a Doctorate in Chemical Engineering from Rensselaer Polytechnic Institute.

William B. Stone, age 72, has been a member of our board of directors since October 2001 and is our Lead Director and Chairman of the Audit Committee of our board of directors. For thirty years, until his retirement in October 2000, Mr. Stone was employed with Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and Chief Information Officer for 16 years and 4 years, respectively. During his tenure at Mallinckrodt, Mr. Stone was responsible for global accounting and reporting, financial organization, staffing and development, and systems of internal accounting control. In this capacity, he was responsible for Mallinckrodt's SEC and other financial filings, internal management performance reports, strategic and tactical financial planning and for evaluation of capital sources and investments. Mr. Stone presented financial analyses and special projects to Mallinckrodt's board of directors and audit committee, and reported to the audit committee regarding the conduct and effectiveness of the independent accountant's quarterly reviews and annual audit. In the capacity of Chief Information Officer, Mr. Stone was responsible for Mallinckrodt's worldwide computer information systems and organization, staffing and development. He assessed effectiveness and control for computer-assisted information systems and led a successful program for justification, selection and deployment of global standardized computer hardware and software. Further, Mr. Stone reported to the audit committee as leader of Mallinckrodt's successful global program to address Year 2000 implications associated with computer-assisted information, laboratory control and process control computer hardware and software. He also chaired Mallinckrodt's corporate employee benefits committee for over 8 years and has been a member of Financial Executives International since 1980. Mr. Stone is qualified to serve on our board of directors because of his extensive experience in accounting and with pharmaceutical companies. Mr. Stone is a graduate of the University of Missouri-Columbia where he earned BS and MA degrees in accounting, and is a Certified Public Accountant.

Samuel P. Sears, Jr., age 72, was appointed as a member of our board of directors in October, 2011 and since 2013 serves as Chairman of the Compensation Committee. Mr. Sears has extensive experience in the biopharmaceutical, nutraceutical and biotechnology industries. Since 2006, Mr. Sears has been a partner at the law firm of Cetrulo LLP, where he currently serves as managing partner, and from 2000 to 2006, he provided private consulting and legal advisory services to start-up and early stage development companies. Since 2013, Mr. Sears has served as Director of HedgePath Pharmaceuticals, Inc. (OTCBB: HPPI), a clinical stage biopharmaceutical company which is developing therapeutics for cancer patients. From 2000 to 2013, Mr. Sears served as Director, Chairman of the Audit Committee, Chairman of the Executive Committee, and Member of the Compensation Committee of Commonwealth Biotechnologies, Inc., a research and development support services company. From 1998 to 2000, Mr. Sears served as Vice Chairman and treasurer of American Prescription Providers, Inc., a specialty pharmacy network offering prescriptions and nutraceuticals to patients with chronic diseases. From 1994 through May 1998, Mr. Sears was Chief Executive Officer and Chairman of Star Scientific, Inc. (NASDAQ: CIGX). From 1968 to 1993, Mr. Sears was in private law practice. Mr. Sears is qualified to serve on our board of directors because of his extensive legal and business experience, including in the pharmaceutical industry. Mr. Sears is a graduate of Harvard College and Boston College Law School.

Thomas W. D'Alonzo, age 72, has served as a member of our board since April 23, 2013. Prior to joining our company, Mr. D'Alonzo served as a member of the board of directors of Salix Pharmaceuticals, Ltd. since May 2000 and has been the Chairman of the Board since June 2010. Mr. D'Alonzo also served as the Interim Chief Executive Officer of Salix from January 2015 to May 2015. From March 2007 to February 2009, Mr. D'Alonzo served as the Chief Executive Officer and a director of MiMedx Group, Inc. From May 2006 to April 2007, Mr. D'Alonzo was Chief Executive Officer of DARA BioSciences, Inc., now known as DARA Pharmaceuticals, Inc., and he served on its board of directors from September 2005 to December 2008. From 2006 to 2008, he also served on our board of directors. From 2000 to 2007, Mr. D'Alonzo acted as an independent consultant. Prior to that, from 1996 to 1999, Mr. D'Alonzo served as President and Chief Operating Officer of Pharmaceutical Product Development (PPD), a global provider of discovery and development services to pharmaceutical and biotechnology companies. Before joining PPD, from 1993 to 1996, he served as President and Chief Executive Officer of GenVec, Inc., a clinical-stage, biopharmaceutical company. From 1983 to 1993, Mr. D'Alonzo held positions of increasing responsibility within Glaxo, Inc., the U.S. division of GSK, including President. Mr. D'Alonzo is qualified to serve on our board of directors because of his extensive experience in working with and managing

biopharmaceutical companies. Mr. D'Alonzo received his B.S. in Business Administration from the University of Delaware, and his J.D. from the University of Denver College of Law.

Charles J. Bramlage, age 55, has served as a member of our board since July 17, 2014. Mr. Bramlage has also served as Chief Executive Officer of Pearl Therapeutics, Inc. since February 2011. He previously served as president of pharmaceutical products at Covidien plc (NYSE: COV) from 2008 to 2011. Mr. Bramlage served as the President of European Operations at Valeant Pharmaceuticals International, Inc. (NYSE: VRX) from 2004 to 2008 and President and Chief Executive Officer of BattellePharma, Inc., a specialty pharmaceutical company developing inhaled products from 2001 to 2004. From 1983 to 2001, Mr. Bramlage held positions of increasing responsibility at GlaxoSmithKline plc (LSE/NYSE: GSK) in product management, sales management, sales, and sales training, ultimately becoming Vice-President of Respiratory Global Commercial Development and Vice-President of U.S. Respiratory and Cardiovascular Marketing, where he led the team responsible for the global launch of Seretide®/Advair® and the U.S. launch of Flovent®. Mr. Bramlage is qualified to serve on our board of directors because of his extensive experience in working with and managing biopharmaceutical companies. Mr. Bramlage received a B.S. in Marketing from The Ohio State University-The Max M. Fisher College of Business and received an M.B.A in Finance from the University of Dayton.

Barry I. Feinberg, M.D., age 61, has served as a member of our board since July 17, 2014. Dr. Feinberg is an expert in the area of pain management and has served as adjunct faculty member of the Department of Anesthesia at Saint Louis University since November 2013. Since 2008, he has also served as a member of the Board of Directors and Medical Executive Committee of the Frontenac Surgery and Spine Care Center, where he maintains his private practice under the name Injury Specialists. From 2003 to 2011, Dr. Feinberg served as a member of the Board of Directors of Professional Imaging, LLC. He has served as a staff member of the Department of Anesthesia at the Missouri Baptist Medical Center in St. Louis, Missouri since August 2004 and as an associated staff member of the Department of Anesthesia at the DePaul Health Center in Bridgeton, Missouri, since June 1995. From 1988 to 1994, Dr. Feinberg served as Director of the Physicians' Pain Management Center in Bridgeton, Missouri, and the Chairman of the Department of Anesthesia at DePaul Heath Center in Bridgeton from 1986 to 1994. He has also served as Assistant Professor at the Department of Anesthesia at Mount Sinai Medical Center from 1984 to 1986 and staff member at the Intensive Care Unit of the Deborah Heart and Lung Center in Browns Mill, New Jersey, from 1983 to 1984. Dr. Feinberg is qualified to serve on our board of directors because of his medical degree and his specialty in the field of pain management. Dr. Feinberg received a Bachelor of Science in Biology from the State University of New York, Binghamton and a Doctor of Medicine from State University of New York Downstate Medical Center in Brooklyn, New York. Dr. Feinberg completed a residency in Anesthesiology at University of Pennsylvania School of Medicine. He also received a Juris Doctorate degree from the Washington University School of Law, St. Louis, Missouri.

Key Employees

Below are the biographies of certain key non-executive officer employees of our company:

Albert J. Medwar, M.B.A. joined our company in April 2007 and was our Vice President of Marketing and Corporate Development, with over 20 years of experience in marketing, sales, and marketing research, until promoted to Senior Vice President of Corporate and Business Development in 2015. Prior to joining our company, Mr. Medwar was the Head of Oncology Marketing at EMD Pharmaceuticals, the U.S. subsidiary of Merck KGaA, where he was responsible for developing the global market for a pipeline of oncology products. Mr. Medwar was also the Marketing Director for Triangle Pharmaceuticals, a start-up company focusing on the development and commercialization of compounds for HIV and hepatitis. Mr. Medwar's pharmaceutical career began in sales at Burroughs Wellcome, which later became Glaxo Wellcome. After six years of sales experience, he took on marketing research responsibilities, and then played an important role in the launch of a short acting opioid analgesic, remifentanil, and held increasing marketing responsibility for a number of products including a portfolio of anesthetic/analgesic agents, Zofran, and Wellbutrin SR. Mr. Medwar received a Bachelor of Science degree from Cornell University and a Masters of Business Administration from Bentley College.

Michael Bullock has been our National Director, Managed Markets since joining the company in June 2015, with more than 25 years of sales and 17 years of managed markets experience within the pharmaceutical and medical space. Mr. Bullock heads our Managed Markets department and is responsible for developing and implementing market access strategies and managing consultant relationships relating to managed markets, lobbying and government affairs. Prior to joining the company, Mr. Bullock was a Director, Managed Markets for Salix Pharmaceuticals, a GI pharmaceutical and medical device company, where he led a team of National and Regional Account Managers. While at Salix, Mr. Bullock was responsible for implementing market access strategies across various payer channels including commercial, Medicaid, Medicare, GPO, institutional, long term care and employer group customers, as well as developing medical policy for devices. Prior to joining Salix, Mr. Bullock held managed markets positions with UCB, Celltech Pharmaceuticals and Medeva Pharmaceuticals and was a sales representative with Adams Laboratories. Mr. Bullock received his Bachelor of Science in Agricultural Economics from The Ohio State University.

Stephana Patton, Ph.D., J.D. has been our Vice President & General Counsel since joining the company in June 2015, with over 15 years of combined experience in the pharmaceutical industry and the law. Dr. Patton heads our legal, compliance and intellectual property functions. Prior to joining the company, Dr. Patton held various senior management positions, including Head of Intellectual Property and Licensing at Salix Pharmaceuticals, a publicly-traded, global pharmaceutical company acquired by Valeant Pharmaceuticals. Prior to joining Salix, Dr. Patton was in private practice at a large international law firm known for its intellectual

property expertise. Her practice focused on counseling clients on intellectual property matters, including patent prosecution and litigation, as well as licensing transactions for biotechnology and pharmaceutical companies at varying stages of product development and company life cycle. Dr. Patton earned a Juris Doctor (J.D.) degree in law from the Boston University School of Law and a Ph.D. in Biochemistry, Cell and Developmental Biology from Emory University.

Scott Plesha joined the company in August 2015 as our Senior Vice President, Sales, with more than 26 years of sales experience and over 18 years of sales management experience within the pharmaceutical and medical industries. Mr. Plesha assumed the additional responsibility of leading our Marketing department in December 2015. Mr. Plesha leads our Specialty Sales Force, Marketing, and Training departments. Prior to joining the company, Mr. Plesha was Senior Vice President, GI Sales Force & Training at Salix Pharmaceuticals, where since 2002 he led Salix's top rated gastrointestinal (GI) sales forces, the sales training department as well as many other sales operations functions. During Mr. Plesha's tenure at Salix he was responsible for launching or growing product sales as well as optimizing and expanding the sales force to accommodate the multiple companies and products that Salix acquired. Prior to joining Salix, Mr. Plesha was a Regional Sales Manager for the O'Classen Dermatologics division of Watson Pharmaceuticals, Inc. Mr. Plesha began his pharmaceutical sales career with Solvay Pharmaceuticals where he was a field as well institutional sales representative. Mr. Plesha received a Bachelor of Arts in Pre-Medical Studies from DePauw University.

Joseph Lockhart has been our Vice President of Manufacturing and Supply Chain since joining the company in November 2015, with 29 years of experience in the pharmaceutical industry with specific focus in the areas of manufacturing, supply chain, product development, CMC (Chemistry, Manufacturing, and Controls) and quality. Mr. Lockhart heads our manufacturing and supply chain function, including both commercial production and scale-up/manufacturing support for products in the latter stages of development. Prior to joining the company, Mr. Lockhart was Vice President, Pharmaceutical Development and Manufacturing at Salix Pharmaceuticals, where since 2001 he established the Pharmaceutical Development and Manufacturing team and contributed to multiple NDA submissions, as well as multiple product acquisitions and launches. During Mr. Lockhart's tenure at Salix he held positions of increasing responsibility and was responsible for managing the functional areas of manufacturing, technical operations, formulation development, and clinical trial material operations, and contributed to the expansion and optimization of the overall supply chain operation which included over 40 contract vendors. Prior to joining Salix, Mr. Lockhart served in various CMC-related roles and responsibilities throughout the first 15 years of his pharmaceutical career including Manufacturing Manager (Blue Ridge Pharmaceuticals) and Associate Director of Quality (Mayrand Pharmaceuticals). Mr. Lockhart began his pharmaceutical career with Baxter Healthcare as an analytical chemist. Mr. Lockhart received a Master of Business Administration degree from the University of North Carolina at Charlotte as well as a Bachelor of Arts degree in Chemistry from the University of North Carolina at Chapel Hill.

Executive Chairman

On January 20, 2012, our board of directors, upon the recommendation of the Nominating and Corporate Governance Committee of the board, created the office of Executive Chairman of the Company and appointed Dr. Frank O'Donnell, then our Chairman of the Board, as Executive Chairman of our company. In taking such action, our board was intending to formally memorialize the role that Dr. O'Donnell has played with our company over the years.

As Executive Chairman of our company, Dr. O'Donnell acts as an officer and employee and, as such, performs his duties subject in all instances to the oversight of our board of directors and the power of our board of directors to approve all applicable corporation actions (which powers shall not be vested in the office of Executive Chairman). The Executive Chairman is not an "executive officer" (as defined in SEC Rule 3b-7) of our company as the role of the Executive Chairman by design is not an officer who performs a policy making function for our company. Rather, the Executive Chairman serves as a conduit between our board and our executive management team and is available to act as an advisor and consultant to our executive management team, with ultimate responsibility for development and implementation of our corporate policies being vested in our executive officers (Dr. Sirgo, Dr. Finn and Mr. De Paolantonio) under the supervision of our board of directors.

Subject to such other roles, duties and projects as may (consistent with the terms and provisions of our Amended and Restated Bylaws and the resolutions of our board that formed the office of Executive Chairman) be assigned by our board to the Executive Chairman, the primary responsibilities of the Executive Chairman are as follows:

1. Chair annual and special board meetings and annual stockholder meetings and, subject to availability, attend meetings of the committees of the board;

2. Provide overall board leadership and establish guiding principles for the board;

3. Manage the affairs of the board and facilitate board action in such a way that strategic and policy decisions are fully discussed, debated and decided by the board;

4. In cooperation with the President and Chief Executive Officer, ensure that our strategic orientation is defined and communicated to the board for its approval and that all material issues are dealt with by the board during the year;

5. Ensure that the board has efficient communication channels regarding all material issues concerning the business and see to it that directors are informed about these issues;

6. Act as a representative of the board and consult with board members outside the regularly scheduled meetings of the board and of board committees;

7. Meet and confer as often as required with our President and Chief Executive Officer to ensure that there is efficient communication between the Executive Chairman, the President and Chief Executive Officer and board members;

8. Offer advice and consultation to the President and Chief Executive Officer on the overall management of the business and affairs of our company as well as specific matters upon the request of the President and Chief Executive Officer;

9. In consultation and partnership with the President and Chief Executive Officer, the Executive Chairman may act as our representative with business partners of our company; and

10. At the request of the board or the President and Chief Executive Officer, and in consultation and partnership with the President and Chief Executive Officer, the Executive Chairman may be placed in charge of special corporate strategic initiatives or projects. The compensation of the Executive Chairman shall be determined from time to time by the Compensation Committee of the board in accordance with such committee's charter and practice. In March 2012, the Compensation Committee of our board (with input from our outside compensation consultant) determined and approved that Dr. O'Donnell would receive compensation at a level equal to 50% of the President/CEO's salary, cash bonus and options. The salary portion would begin on January 1, 2012 and the cash bonus and option portion would be determined in the first quarter of 2013, when, under normal circumstances, the company 2012 objectives would be evaluated. Because of the change in his compensation, Dr. O'Donnell will no longer receive cash retainers or option awards under the existing board of director remuneration program for his role as a member of our board of directors.

In 2015, Dr. O'Donnell received the following compensation for his service as Executive Chairman: $275,000 in cash compensation, $71,850 bonus, $5,885,538 in stock awards and $20,808 in benefits paid in 2015. We do not have a written employment or similar agreement with Dr. O'Donnell in connection with his service as our Executive Chairman.

Director Independence

We believe that William B. Stone, Samuel P. Sears, Jr. Thomas W. D'Alonzo, Charles J. Bramlage and Barry I. Feinberg qualify as independent directors for NASDAQ Stock Market purposes. This means that our board of directors is composed of a majority of independent directors as required by NASDAQ Stock Market rules.

Our former director, John J. Shea, served since March 2002 and retired in December 2015. His participation is excluded from calculations noted below.

Meetings of the Board of Directors and Stockholders

Our board of directors met in person and telephonically twelve times during 2015 and also acted by unanimous written consent. Each member of our board of directors was present at least 83% of the board of directors meetings held. It is our policy that all directors must attend all stockholder meetings, barring extenuating circumstances. All directors were present at the 2015 Annual Meeting of Stockholders, either in person or telephonically.

Board Committees

Our board of directors has established three standing committees: Audit, Compensation, and Nominating and Corporate Governance. Historically, all independent directors have been members of each board committee. In October 2013, our committees reorganized, and subsequently there were changes to the committee composition. All standing committees (as well as our Lead Director) operate under a charter that has been approved by the board. Our board of directors has also, from time to time, appointed non-standing committees to assist the board in its duties to our company. The charters for each of our board committees are available at http://www.bdsi.com/Corporate_Governance.aspx.

Audit Committee

Our board of directors has an Audit Committee, composed of William B. Stone, Samuel P. Sears, Jr., and Barry I. Feinberg, all of whom are independent directors as defined in accordance with section 3(a)(58)(A) of the Exchange Act and the rules of NASDAQ. Mr. Stone serves as chairman of the committee. The board of directors has determined that Mr. Stone is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee met four times during 2015. Each member of the Audit Committee was present at least 75% of the Audit Committee meetings held during such director's tenure as a member of the Audit Committee.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits and reviews of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually). As summarized below, the Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service and fees therefor to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;
- oversees all aspects of our systems of internal accounting and financial reporting control and corporate governance functions on behalf of the board; and
- provides oversight in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our board of directors has a Nominating and Corporate Governance Committee composed of William B. Stone, Thomas W. D'Alonzo and Charles J. Bramlage. Mr. D'Alonzo serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The Nominating and Corporate Governance Committee met four times in 2015 and has a charter which is reviewed annually. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the NASDAQ Stock Market. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders. To recommend a nominee please write to the Nominating and Corporate Governance Committee c/o Ernest R. De Paolantonio, BioDelivery Sciences International, Inc, 4131 ParkLake Avenue. Suite #225, Raleigh, NC. 27612. The Nominating and Corporate Governance Committee has established nomination criteria by which board candidates are to be evaluated. The Nominating and Corporate Governance Committee will assess all director nominees using the same criteria. During 2015, we did not pay any fees to any third parties to assist in the identification of nominees. During 2015, we did not receive any director nominee suggestions from stockholders.

In 2010, the Nominating and Corporate Governance Committee adopted a set of criteria by which it will seek to evaluate candidates to serve on our board of directors. The evaluation methodology includes a scored system based on criteria including items such as experience in the biotechnology sector, experience with public companies, executive managerial experience, operations and commercial experience, fundraising experience and contacts in the investment banking industry, personal and skill set compatibility with current board members, industry reputation, knowledge of our company generally, independence and ethnic and gender diversity. While diversity is considered as a board qualification criteria, it would not be weighted any more or less in an evaluation process than any other criteria. The established criteria do not distinguish board candidates based on whether the candidate is recommended by a stockholder of our company.

Compensation Committee

Our board of directors also has a Compensation Committee, which reviews or recommends the compensation arrangements for our management and employees and also assists the board of directors in reviewing and approving matters such as company benefit and insurance plans, including monitoring the performance thereof. The Compensation Committee has a charter (which is reviewed annually) and is composed of three members: Samuel P. Sears, Jr., William B. Stone and Charles J Bramlage. Mr. Sears serves as chairman of this committee. The compensation committee met five times during 2015.

The Compensation Committee has the authority to directly engage, at our expense, any compensation consultants or other advisers as it deems necessary to carry out its responsibilities in determining the amount and form of employee, executive and director compensation. In 2015, the Compensation Committee engaged Radford, an AON Consulting Company, to obtain market data against which it has measured the competitiveness of our compensation programs. In determining the amount and form of employee, executive and director compensation, the Compensation Committee has reviewed and discussed historical salary information as well as salaries for similar positions at comparable companies. We paid consultant fees to Radford of $0.06 million in 2015.

Lead Director

On July 26, 2007, our board of directors created the position of Lead Director. Our board of directors designated William B. Stone, an existing director, as our Lead Director. Pursuant to the charter of the Lead Director, the Lead Director shall be an independent, non-employee director designated by our board of directors who shall serve in a lead capacity to coordinate the activities of the other non-employee directors, interface with and advise management, and perform such other duties as are specified in the charter or as our board of directors may determine.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the "reporting persons") file with the SEC various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2015, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, with exception of Ernest De Paolantonio, Mark Sirgo and Francis O'Donnell, who filed Form 4s which were due on February 24, 2015 on February 27, 2015, to accommodate multiple connected transactions over several days all on one concise Form 4.

Code of Ethics

We have adopted a code of ethics that applies to all employees, as well as each member of our Board. Our code of ethics is posted on our website, and we intend to satisfy any disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of ethics by posting such information on our website, www.bdsi.com. A copy of our code of ethics is also available in print, without charge, upon written request to 4131 ParkLake Avenue, Suite #225, Raleigh, NC 27612. Attn: Ernest R. De Paolantonio.

Involvement in Certain Legal Proceedings

From September 2003 through December 2011, Dr. Frank O'Donnell, Jr., our Executive Chairman, served as chief executive officer of Accentia Biopharmaceuticals, Inc. (or Accentia). From February 2009 through December 2011, Dr. O'Donnell also served as chief executive officer of Biovest International, Inc., a majority-owned subsidiary of Accentia (or Biovest). In November 2008, Accentia and its subsidiaries, including Biovest, filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. In November 2010, both companies emerged from bankruptcy. In May 2013, Biovest again filed a voluntary petition to reorganize under Chapter 11 of the United States Bankruptcy Code. In July 2013, Biovest emerged from Chapter 11. We do not presently have any projects with Accentia or Biovest.

From 2000 to 2013, Mr. Samuel Sears, one of our independent directors, served as a director, Chairman of the Audit Committee, Chairman of the Executive Committee, and member of the Compensation Committee of Commonwealth Biotechnologies, Inc. (or CBI). On January 20, 2011, CBI filed a voluntary petition seeking relief under the provisions of Chapter 11 of Title 11 of the United States Bankruptcy Code. In August 2013, CBI emerged from bankruptcy under the name HedgePath Pharmaceuticals, Inc., of which Mr. Sears remains a director. We have not and do not presently have any projects with CBI or HedgePath Pharmaceuticals, Inc.

On July 24, 2013 and August 5, 2013, purported class actions were filed in the United States District Court for the Middle District of Florida (Tampa Division) against Accentia and several current and former directors and officers of Accentia and its former subsidiary Biovest (collectively the Class Action), including Dr. Frank O'Donnell, Jr., our Executive Chairman. The complaints alleged that the defendants violated federal securities laws by making or causing Accentia and/or Biovest to make false statements, and by failing to disclose or causing Accentia and/or Biovest to fail to disclose material information, concerning the results of the clinical trial of Biovest's cancer vaccine, BiovaxID, and status of its approval by the FDA. Plaintiffs sought damages in an unspecified amount on behalf of shareholders who purchased common stock of Accentia or Biovest during a defined time period. All defendants, including Dr. O'Donnell, believed this litigation to have been without merit, denied any wrongdoing or liability and had vigorously defended the alleged claims. A settlement of this matter, in which defendants made no admissions of wrongdoing or liability, had been agreed upon by all parties and approved by the applicable court on February 3, 2015.

Compensation Discussion and Analysis

The Compensation Committee of our board of directors has the responsibility to review, determine and approve the compensation for our executive officers. Further, the Compensation Committee oversees our overall compensation strategy, including compensation policies, plans and programs that cover all employees.

We employed three executive officers, each of whom served as a "Named Executive Officer" (or NEO) for purposes of SEC reporting as of December 31, 2015: (1) Mark A. Sirgo, Pharm.D., our President and Chief Executive Officer (who we refer to in this Compensation Discussion and Analysis as our CEO); (2) Ernest R. DePaolantonio, CPA, MBA, our Secretary, Treasurer and Chief Financial Officer; and (3) Andrew L. Finn, Pharm.D., our Executive Vice President of Product Development.

As of December 31, 2015, Dr. Finn retired from his positions with us in good standing, and as of January 1, 2016, Dr. Niraj Vasisht, our Senior Vice President—Product Development and Chief Technology Officer, was promoted to such position and assumed the status of a NEO of our company. As such, Dr. Vasisht's compensation for 2015 is not reflected in the accompanying executive compensation tables, but we have included a narrative discussion of his compensation in this Compensation Discussion and Analysis.

This Compensation Discussion and Analysis sets forth a discussion of the compensation for our NEOs as of December 31, 2015 as well as a discussion of our philosophies underlying the compensation for our NEOs and our employees generally.

Objectives of Our Compensation Program

The Compensation Committee's philosophy seeks to align the interests of our stockholders, officers and employees by tying compensation to individual and our performance, both directly in the form of salary and annual cash bonus payments, and indirectly in the form of incentive equity awards. The objectives of our compensation program enhance our ability to:

- attract and retain qualified and talented individuals; and
- provide reasonable and appropriate incentives and rewards to our team for building long-term value within our company, in each case in a manner comparable to companies similar to ours.

In addition, we strive to be competitive with other similarly situated companies in our industry. The process of developing pharmaceutical products and bringing those products to market is a long-term proposition and outcomes may not be measurable for several years. Therefore, in order to build long-term value for us and our stockholders, and in order to achieve our business objectives, we believe that we must compensate our officers and employees in a competitive and fair manner that reflects our current activities but also reflects contributions to building long-term value.

We utilize the services of the Radford Group, an AON consulting company (which we refer to herein as Radford), to review compensation programs of peer companies in order to assist the Compensation Committee in determining the compensation levels for our NEOs, as well as for other employees of ours. Radford is a recognized independent consulting company and services clients throughout the United States.

The companies that comprise our peer group are selected and reviewed no less frequently than biennially. The current peer group used to evaluate compensation for the fiscal year ended December 31, 2015 includes the following companies:

Company	Location
Aegerion Pharmaceuticals, Inc.	Cambridge, MA
Arena Pharmaceuticals, Inc.	San Diego, CA
BioCryst Pharmaceuticals, Inc.	Durham, NC
Corcept Therapeutics Incorporated	Menlo Park, CA
CTI BioPharma Corp.	Seattle, WA
Enanta Pharmaceuticals, Inc.	Watertown, MA
Galena BioPharma, Inc.	Lake Oswego, OR
Halozyme Therapeutics, Inc.	San Diego, CA
ImmunoGen, Inc.	Waltham, MA
Keryx Biophmaeuticals, Inc	New York, NY
Omeros Corporation	Seattle, WA
Orexigen Therapeutics, Inc.	La Jolla, CA
Osiris Therapeutics, Inc.	Columbia, MD
Pozen Inc.	Chapel Hill, NC
Raptor Pharmaceuticals Corp.	Novato, CA
Sucampo Pharmaceuticals, Inc.	Bethesda, MD
Supernus Pharmaceuticals, Inc.	Rockville, MD

Company	Location
Vanda Pharmaceuticals, Inc.	Rockville, MD
XenoPort, Inc.	Santa Clara, CA

With respect to our employees and non-senior management, we will also take into consideration regional market data in determining appropriate compensation packages, and we have in the past relied on Radford to provide us with such data.

Elements of Our Compensation Program and Why We Chose Each

Main Compensation Components

Our company-wide compensation program, including for our NEOs, is broken down into three main components: base salary, performance cash bonuses and potential long-term compensation in the form of stock options or restricted stock units (RSUs). We believe these three components constitute the minimum essential elements of a competitive compensation package in our industry. We also have a Performance Long Term Incentive Plan (which we refer to herein as the LTIP) for our NEOs and selected senior officers of ours, which compensates such employees with RSUs based on our achievement of certain pre-determined revenue performance goals.

Salary

Base salary is used to recognize the experience, skills, knowledge and responsibilities required of our NEOs as well as recognizing the competitive nature of the biopharmaceutical industry. This is determined partially by evaluating our peer companies as well as the degree of responsibility and experience levels of our NEOs and their overall contributions to our company. Base salary is one component of the compensation package for NEOs; the other components being cash bonuses, annual equity grants, a long-term incentive plan and our benefit programs. Base salary is determined in advance whereas the other components of compensation are awarded in varying degrees following an assessment of the performance of a NEO. This approach to compensation reflects the philosophy of our board of directors and its Compensation Committee to emphasize and reward, on an annual basis, performance levels achieved by our NEOs.

Performance Cash Bonus Plan

We have a performance cash bonus plan under which bonuses are paid to our NEOs based on achievement of our performance goals and objectives established by the Compensation Committee and/or our board of directors as well as on individual performance. The bonus program is discretionary and is intended to: (i) strengthen the connection between individual compensation and our achievements; (ii) encourage teamwork among all disciplines within our company; (iii) reinforce our pay-for-performance philosophy by awarding higher bonuses to higher performing employees; and (iv) help ensure that our cash compensation is competitive. Depending on the cash position of ours, the Compensation Committee and our board of directors have the discretion after consulting with our CEO to not pay cash bonuses in order that we may conserve cash and support ongoing development programs and commercialization efforts. Regardless of our cash position, we consistently grant annual merit-based stock options (and, more recently in the case of senior executives, RSUs) to continue incentivizing both our senior management and our employees.

Based on their employment agreements, each NEO is assigned a target payout under the performance cash bonus plan, expressed as a percentage of base salary for the year. Actual payouts under the performance cash bonus plan are based on the achievement of corporate performance goals and an assessment of individual performance, each of which is separately weighted as a component of such officer's target payout. For the NEOs, the corporate goals receive the highest weighting in order to ensure that the bonus system for our management team is closely tied to our corporate performance. Each employee also has specific individual goals and objectives as well that are tied to the overall corporate goals. For employees, mid-year and end-of-year progress is reviewed with the employees' managers.

Equity Incentive Compensation

We view long-term compensation, currently in the form of stock options and RSUs, generally vesting in annual increments over three years (other than awards under our LTIP, which vest immediately if awarded), as a tool to align the interests of our NEOs and employees generally with the creation of stockholder value, to motivate our employees to achieve and exceed corporate and individual objectives and to encourage them to remain employed by us. While cash compensation is a significant component of employees' overall compensation, the Compensation Committee and our board of directors (as well as our NEOs) believe that the driving force of any employee working in a small biotechnology company should be strong equity participation. We believe that this not only creates the potential for substantial longer term corporate value but also serves to motivate employees and retain their loyalty and commitment with appropriate personal compensation. The Compensation Committee believes that because stock options and RSUs have a three-year vesting schedule that begins one year after the date of the award, the equity grants constitute a significant retention incentive and a tool to foster continuity of management, an important factor in a company with a relatively low number of employees. Our equity awards are granted under our 2011 Equity Incentive Plan (as the same may be amended, supplemented or superseded from time to time, which we refer to herein as the 2011 Equity Incentive Plan)

Performance Long Term Incentive Plan

In December 2012, in anticipation of the commencement of substantial revenue generation operations by means of product commercialization, the Compensation Committee approved our LTIP. The LTIP is designed as an incentive for our senior management (including our NEOs) to generate revenue for us.

The LTIP consists of RSUs (which, for purposes of our 2011 Equity Incentive Plan, are defined as and considered (and which we refer to herein as) Performance RSUs), which are rights to acquire shares of our common stock. All Performance RSUs granted under the LTIP will be granted under our 2011 Equity Incentive Plan as "Performance Compensation Awards" under such plan. The participants in the LTIP are either NEOs or senior officers of ours.

The term of the LTIP began with our fiscal year ended December 31, 2012 and lasts through our fiscal year ended December 31, 2019. The total number of Performance RSUs covered by the LTIP is 1,078,000, of which an aggregate of 978,000 were awarded in 2012 (and an aggregate of 35,000 in 2015). The Performance RSUs under the LTIP did not vest upon granting, but instead are subject to potential vesting each year over the 8 year term of the LTIP depending on the achievement of revenue by us, as reported in our Annual Report on Form 10-K. During 2013, 2014 and 2015, an aggregate of 8,986, 4,447 and 21,356 Performance RSUs vested, respectively. Performance RSUs will be valued on the day of issuance and will vest annually on the last day preceding the first open trading window after filing our Annual Report on Form 10-K based on the revenue achieved during the prior fiscal year as a proportion of the total cumulative revenue target for the entire term of the LTIP (which we call the Predefined Cumulative Revenue). Predefined Cumulative Revenue is a predefined aggregate revenue target for the entire term of the LTIP that was determined by the Compensation Committee in conjunction with our executive management. The Predefined Cumulative Revenue may be adjusted by the Compensation Committee upon the occurrence of extraordinary corporate events during the term of the LTIP (such as acquisitions by us of revenue generating businesses or assets).

Other Compensation

In addition to the main components of compensation outlined above, we also provide contractual severance and/or change in control benefits to the NEOs as well as Dr. Niraj Vasisht, our Senior Vice President—Product Development and Chief Technology Officer (who was promoted to NEO status as of January 1, 2016), to Albert J. Medwar, our Vice President, Corporate and Business Development, to Stephana Patton, our Vice President and General Counsel, to Scott Plesha, our Senior Vice President of Sales, to Enoch Bortey, Ph.D., our Vice President Clinical Biostatistics and Data Systems, and to Joseph Lockhart, our Vice President Manufacturing and Supply Chain. The change in control benefits for all applicable persons has a "double trigger." A double-trigger means that the executive officers will receive the change in control benefits described in the agreements only if there is both (1) a Change in Control of our company (as defined in the agreements) and (2) a termination by us of the applicable person's employment "without cause" or a resignation by the applicable persons for "good reason" (as defined in the agreements) within a specified time period prior to or following the Change in Control. We believe this double trigger requirement creates the potential to maximize stockholder value because it prevents an unintended windfall to management as no benefits are triggered solely in the event of a Change in Control while providing appropriate incentives to act in furtherance of a change in control that may be in the best interests of the stockholders. We believe these severance or change in control benefits are important elements of our compensation program that assist us in retaining talented individuals at the executive and senior managerial levels and that these arrangements help to promote stability and continuity of our executives and senior management team. We also believe that the interests of our stockholders will be best served if the interests of these members of our management are aligned with theirs. Furthermore, we believe that providing change in control benefits lessens or eliminates any potential reluctance of members of our management to pursue potential change in control transactions that may be in the best interests of the stockholders. Finally, we believe that it is important to provide severance benefits to members of our management, to promote stability and to focus on the job at hand.

We also provide benefits to the executive officers that are generally available to all regular full-time employees of ours, including our medical and dental insurance, life insurance and a 401(k) match for all individuals who participate in the 401(k) plan. At this time, we do not provide any perquisites to any of our NEOs. Further, we do not have deferred compensation plans, pension arrangements or post-retirement health coverage for our executive officers or employees. All of our employees not specifically under contract are "at-will" employees, which mean that their employment can be terminated at any time for any reason by either us or the employee. Our NEOs (as well as certain of our senior managers) have employment agreements that provide lump sum compensation in the event of their termination without cause or, under certain circumstances, upon a Change of Control.

Determination of Compensation Amounts

A number of factors impact the determination of compensation amounts for our NEOs, including the individual's role in our company and individual performance, length of service with us, competition for talent, individual compensation package, assessments of internal pay equity and industry data. Stock price performance has generally not been a significant factor in determining annual compensation because the price of our common stock is subject to a variety of factors outside of our control.

Industry Survey Data

In collaboration with Radford, each year our Compensation Committee establishes a list of peer companies to best assure ourselves that we are compensating our executives on a fair and reasonable basis, as set forth above under the heading "Objectives of our Compensation Program." We also utilize Radford-prepared data for below-executive level personnel, which data focuses on similarly-sized life science companies in the Southeastern region of the United States. The availability of peer data is used by the Compensation Committee strictly as a guide in determining compensation levels with regard to salaries, cash bonuses and performance related annual equity grants to all employees. However, the availability of this data does not imply that the Compensation Committee is under any obligation to exactly follow peer companies in compensation matters.

Determination of Base Salaries

As a guideline for NEO base salary, we perform formal benchmarks against respective comparable positions in our established peer group. Our guideline is to set targeted NEO salary ranges between the 25th and 50th percentile for comparable positions within our peer group. We then adjust salaries based on our assessment of our NEOs' levels of responsibility, experience, overall compensation structure and individual performance. The Compensation Committee has the discretion if it believes circumstances warrant, to go above the 50th percentile of the peer group. The Compensation Committee is not obliged to raise salaries purely on the availability of data. Merit-based increases to salaries of executive officers are based on our assessment of individual performance and the relationship to applicable salary ranges. Cost of living adjustments may also be a part of that assessment. The Compensation Committee, in recent years, has tended to maintain cash compensation levels at or near the 50th percentile but to exceed that level in determining equity compensation. The emphasis on equity compensation reflects the Committee's objective, given that we are only presently engaging in revenue generating operations, to preserve cash in a prudent manner and yet reward personnel for outstanding performance.

Performance Cash Bonus Plan

Concurrently with the beginning of each calendar year, preliminary corporate goals that reflect our business priorities for the coming year are prepared by the CEO with input from the other NEOs as well as other officers. These goals are weighted by relative importance. The draft goals and proposed weightings are presented to the Compensation Committee and our full board in January of each year and discussed, revised as necessary, and then approved by our board of directors. The Compensation Committee then reviews the final goals and their weightings to determine and confirm their appropriateness for use as performance measurements for purposes of the bonus program. The goals and/or weightings may be re-visited during the year and potentially restated in the event of significant changes in corporate strategy or the occurrence of significant corporate events. Following the agreement of our board of directors on the corporate objectives, the goals are then shared with all employees in a formal meeting(s), and are reviewed periodically throughout the year at monthly staff meetings and quarterly board of director meetings.

The performance cash bonus plan for our executive officers and employees in 2015 was adopted by the Compensation Committee in January 2015. The plan sets forth target bonus opportunities, as a percentage of salary, based on the level of responsibility of the position, ranging up to 60% of salary for our CEO, and up to 40% of salary for our NEOs and up to 30% of salary for certain other officers. In setting these percentages, the Compensation Committee determined that the above percentages were reasonable and in line with our peer group. Each employee has the opportunity to achieve up to 100% of his targeted amount, depending on how corporate goals and objectives are achieved, with variances on an "employee by employee" basis to be determined by our CEO in conjunction with the employees' direct report as applicable.

Determination of Equity Incentive Compensation

To assist us in assessing the reasonableness of our equity grant amounts, historically we have reviewed Radford supplied information and, prior to Radford, we used information supplied by Equilar. Such information included equity data from a cross-section of the companies in the above-mentioned surveys. Initial, on-hire stock option grant amounts have generally been targeted at the 25th to 50th percentile for that position or similar industry position, adjusted for internal equity, experience level of the individual and the individual's total mix of compensation and benefits provided in his or her offer package. Initial on-hire grants typically vest over three years.

In granting equity awards in 2015 as well as prior years, the Compensation Committee utilized a methodology that computed the financial value of the equity granted, applying as a general guideline, a peer group percentile ranging from the 50th to the 75th percentile. The Committee, in determining annual equity awards in early 2015 utilized a methodology based upon Radford supplied peer group data, that computes the number of RSUs granted as a percentage of outstanding common stock, generally referencing the 75th percentile. The Committee believed that the change in methodology was appropriate because of the changing characterization of ours from one whose operations were primarily the development of therapeutic prescription drugs to one whose operations included revenue generation through the marketing and sale of FDA-approved drugs.

Also in early 2015, the Compensation Committee approved special equity awards to two NEOs, Mark A. Sirgo our CEO (800,000 RSUs) and Andrew L Finn, Executive Vice President (400,000 RSUs) and to three other officers (an aggregate of 720,000

RSUs), which were above the 100th percentile (when using either of the two methodologies described in the preceding paragraph). These special equity awards took into account several notable company achievements in 2014, including the realization of strategic objectives first established over ten years earlier and the progression of our company from a predominantly research and development enterprise to one launching its first commercial product; FDA approval of BUNAVAIL®; successful outcomes of two clinical trials for BELBUCA™ resulting in the submission to the FDA in December 2014 of an NDA (which was approved in October 2015); a significant increase in 2014 in market capitalization and shareholder value of our company; and continued progress in development of a pipeline of new drug opportunities.

For a discussion of equity awards made in early 2016 for performance in 2015, see "2016 Equity Awards for Performance in 2015" under "Compensation Decisions For Performance in 2015" below.

Equity Grant Practices

All stock options and/or RSUs granted to the NEOs and other executives are approved by the Compensation Committee. Exercise prices for options are set using a 30-day volume weighted average price method, which we define as the closing price of our common stock on the Nasdaq Capital Market on the trading day of the date of grant and the 30 trading days preceding that date. RSU grants are valued on the day of issuance and are vested on the last day preceding an open window after filing our annual report for equity trading. These RSU's will vest annually in one-third increments on the last day preceding an open window after filing our annual report for equity trading for our employees. Grants are generally made: (i) on the employee's start date and (ii) at board of director meetings held each January and following annual performance reviews. However, grants have been made at other times during the year. The size of year-end grants for each NEO is assessed against our internal equity guidelines. Current market conditions for grants for comparable positions and internal equity may also be assessed. Also, grants may be made in connection with promotions or job related changes in responsibilities. In addition, on occasion, the Compensation Committee may make special awards for extraordinary individual or our company performance and, as was the case in early 2015, of achievement over an extended period of time.

Compensation Setting Process

At the January meetings of our board of directors and the Compensation Committee, overall corporate performance and relative achievement of the corporate goals for the prior year are assessed. The relative achievement of each goal is assessed and quantified and the summation of the individual components results in a corporate goal rating, expressed as percentages. The Compensation Committee then approves the final disbursement of salary increases, cash bonuses and option or RSU grants, giving an 80% weight factor to the corporate goal rating, and a 20% weight factor for such other performance criteria the Committee may in its discretion deem relevant at the time of the granting awards.

Also near the end of the year, the CEO evaluates the individual performance of each NEO (other than himself) and provides the Compensation Committee with an assessment of the performance of such NEO. In determining the individual performance ratings of the NEOs, we assess performance against a number of factors, including each NEO's relative contributions to our corporate goals, demonstrated career growth, level of performance in the face of available resources and other challenges, and the respective officer's department's overall performance. This assessment is conducted in a holistic fashion, in contrast to the summation of individual components as is done to arrive at the corporate goal rating.

Following a qualitative assessment of individual NEO's performance, our policies provide guidelines for translating this performance assessment into a numerical rating. Both the initial qualitative assessment and the translation into a numerical rating are made by the Compensation Committee on a discretionary basis. We believe that conducting a discretionary assessment for the individual component of the NEOs' performance provides for flexibility in the evaluation of our NEOs and their adaptability to addressing potential changes in our priorities throughout the year.

The Compensation Committee looks to the CEO's performance assessments of the other NEOs and his recommendations regarding a performance rating for each, as well as input from the other members of our board of directors. These recommendations may be adjusted by the Compensation Committee prior to finalization. For the CEO, the Compensation Committee evaluates his performance, taking into consideration input from the other members of our board of directors, and considers the achievement of overall corporate objectives by both the CEO specifically and our company generally. The CEO is not present during the Compensation Committee's deliberations regarding his compensation.

The CEO also presents any recommended changes to base salary and recommendations for an annual equity grant amount, referencing the equity guidelines, for each of the NEOs (other than himself).

The Compensation Committee has the authority to directly engage, at our expense, any compensation consultants or other advisors (such as Radford) that it deems necessary to determine the amount and form of employee, executive and director compensation. In determining the amount and form of employee, executive and director compensation, the Compensation Committee has reviewed and discussed historical salary information as well as salaries for similar positions at comparable companies. However

the availability of this data does not imply that the Compensation Committee is under any obligation to exactly follow peer companies' compensation practices.

We paid consultant fees to Radford of $0.06 million in 2015. NEOs may have indirect input in the compensation results for other executive officers by virtue of their participation in the performance review and feedback process for the other executive officers.

Compensation Decisions for Performance in 2015

General Assessment of Management Performance in 2015

The Compensation Committee and our board of directors conducted the performance and compensation review for 2015 during January 2016. The Compensation Committee and the board compared performance to the corporate objectives for 2015 as elaborated below.

The corporate objectives for 2015 included the following: (1) with respect to BUNAVAIL®, continuing post-FDA approval development activities, including manufacturing upgrades and several clinical trials, achievement of specified revenue goals and of a specified degree of market penetration, as well as refinement of our sales and marketing plans; (2) with respect to BELBUCA™, supporting our partner Endo with the NDA filing with and responding to questions from the FDA as well as supporting Endo's market launch of the product following FDA approval; (3) with respect to Clonidine Topical Gel, continuing with the commercialization plans for this product candidate upon completion, if successful, of its pivotal Phase 3 clinical trial; and (4) specified objectives in the areas of finance, continued success in ongoing and prospective litigation with respect to our intellectual property and patent portfolio and further development of new product candidates.

With respect to BUNAVAIL®, we failed to meet our initial revenue goals. As a consequence during 2015, we undertook significant changes and modifications to our sales and marketing personnel, including the hiring of a new Senior Vice President of Sales (Scott Plesha), the former head of sales at Salix Pharmaceuticals. We also internalized the managed care function by the hiring of Mike Bullock, also former head of that function at Salix Pharmaceuticals. As a result of some of these changes, in the second half of the year, our commercial efforts resulted in several achievements including, most notably, a key contract with Tennessee Medicaid, making BUNAVAIL® an exclusive preferred product in Tennessee. In addition we had significant growth in the number of doctors prescribing BUNAVAIL® as well as revenue growth. Nevertheless, senior management and the board of directors initiated, in late 2015, a thorough evaluation of our marketing and sales strategies for BUNAVAIL®, making that evaluation a top priority going forward. As discussed further below, our challenges with the commercial launch of BUNAVAIL® in 2015 were (with the concurrence of our CEO) given particular priority by our Compensation Committee in reviewing the 2015 compensation of our NEOs and other officers, particularly equity compensation.

With respect to BELBUCA™, an NDA was filed in December 2014, accepted by the FDA in the first quarter of 2015 and approved in October; a culmination of years of development work by our NEOs, officers and employees. We have provided essential support to our partner Endo in responding to questions from FDA during the NDA review as well as in the Phase 4 post-approval planning and in the market launch of this product which began in February 2016.

With respect to Clonidine Topical Gel, our Phase 3 clinical trial failed to meet the primary efficacy endpoint. Following a thorough data analysis of that trial, we concluded that the data supported a new trial protocol and by the end of 2015, a new Phase 2B trial had been initiated.

Although we experienced challenges particularly with BUNAVAIL® and Clonidine Topical Gel in 2015, we achieved positive outcomes in several other areas which were objectives for 2015. We continued to maintain a sound cash position with a cash balance at year-end of $83.6 million, and in 2015 we continued to successfully protect our patent position and product offerings in federal court and before the U.S. Patent Trial and Appeal Board. Finally, we advanced the development of a buprenorphine depot product including our pre-IND meeting with FDA in November 2015.

2015 Cash Bonus Calculations

Our performance bonus plan for 2015 provided for target payouts to all employees expressed as a percentage of base salary. For our CEO, the target bonus opportunity was 60% of base salary and for our Chief Financial Officer it was 40% of base salary.

After reviewing the achievement of the corporate goals and objectives as noted above and giving weight to the decline in the market capitalization of our company, the Compensation Committee determined that the NEOs should be awarded 50% of their cash bonus targets. A bonus pool, equal to 60% of the aggregate of individual bonus opportunities of all other employees, was established with the CEO having the authority to award individual bonuses from that pool. The cost of such cash bonuses for 2015 performance (but paid in February 2016) was approximately $0.4 million for NEOs and approximately $0.5 million for employees.

2015 Equity Awards for Performance in 2014

In February 2015, equity awards for performance in 2014 were granted to nine corporate officers (including our NEOs) in the form of RSUs. Five of these officers, including two NEOs, all of whom have served in high-level management positions from the early stages of our development, were granted special awards, as described under the caption "Determination of Equity Incentive Compensation". The other four officers were granted RSUs based upon the 75th percentile of our peer group, as measured by the number of shares awarded as a percentage of total outstanding shares of common stock awarded. The RSUs awarded to the nine officers vest annually in one-third equal increments beginning one year after the date of grant. The total amount of the RSUs awarded is 2,102,615 having, on the date of grant, an approximate value of $30.3 million based on a share price of $14.63. As of the filing date of this report, the present value of those RSUs is significantly less.

All other employees of ours (excluding only certain recently-hired persons) were granted stock options priced at the 30-day volume weighted average price of our common stock as of the close the market on February 23, 2015. The amount of options granted was based upon the 50-75th percentile of our peer group, as measured by the salary of the recipient. All options vest annually in one-third equal increments beginning one year after the date of grant. The total amount of options awarded was 77,357, having an approximate value of $1.1 million.

2016 Equity Awards for Performance in 2015

In early 2016, following its review of our corporate performance for 2015, the Compensation Committee approved equity awards in the form of RSUs to the NEOs and other senior executives in amounts at or below the 25th% percentile of our peer group. Specifically 275,000 RSUs were awarded to Dr. Sirgo and 90,000 RSUs to Mr. De Paolantonio, both of which amounts were below the 25th percentile of our peer group when measured by the present monetary value of the awards. Dr. Finn, who retired on December 31, 2015, received an immediate award of 150,000 shares of common stock in fulfillment of our contractual obligation to him under his Retirement Agreement that was entered into in December 2015, as described further below. The total amount of the RSUs awarded to our NEOs and senior management for 2015 performance was 1,090,616 RSUs having, on the date of grant, an approximate value of $4.14 million based on a share price of $3.80.

All other employees of ours (excluding only certain recently-hired persons) were granted stock options priced at the 30-day volume weighted average price of our common stock as of the close the market on January 28, 2016. All options vest annually in one-third equal increments beginning one year after the date of grant. The total amount of options awarded was 73,711, having an approximate value of $0.3 million.

Individual Performance and Compensation of the President and CEO

Dr. Sirgo's base salary in 2015 of $550,000 had been effective January 1, 2015. His 2015 salary was slightly below the 50th percentile of our peer group and therefore was consistent with our compensation philosophy.

For 2015, the Compensation Committee actions with respect to Dr. Sirgo's compensation are primarily a reflection of the disappointing degree to which our corporate objectives were achieved in 2015. In matters not expressed as corporate objectives, but nevertheless of material importance to his performance as CEO, the Compensation Committee determined that Dr. Sirgo performed at a relatively high level, most notably:(1) acquiring executive level personnel to support the changing nature of our operations and to compensate for the retirement of Dr. Finn; (2) acting expeditiously to address a slower and more challenging launch of BUNAVAIL® and laying the foundation for improvements in the marketing and sales of that product; (3) fostering a motivated, productive and harmonious workforce; (4) maintaining sound relationships with our key business partners including Endo and (5) maintaining sound and transparent relationships with our shareholder base and the investment community at large.

Individual Performance and Compensation of the Chief Financial Officer

Mr. De Paolantonio's base salary in 2015 of $350,000 had been effective January 1, 2015. His 2015 salary was approximately at the 50th percentile of our peer group and therefore was consistent with our compensation philosophy.

As with the CEO, the Compensation Committee's actions with respect to Mr. De Paolantonio are primarily a reflection of the disappointing degree to which our objectives were achieved in 2015. That said, Mr. De Paolantonio continues to effectively guide the financial functions, continuing a process, first begun in 2014, of adapting the reporting of financial operating results to reflect the commercialization of our products as well as our research and development activities. Additionally, Mr. De Paolantonio has effectively managed the budget and forecasting functions, integrated harmoniously with our independent auditors, and holds the confidence of the board of directors.

Individual Performance and Compensation of the Executive Vice President-Product Development

Dr. Finn's base salary in 2015 of $375,000 had been effective January 1, 2015. His 2015 salary was approximately at the 50th percentile of our peer group and therefore is consistent with our compensation philosophy.

On December 16, 2015, we announced that Dr. Finn would voluntarily retire in good standing from his position effective as of December 31, 2015 (which we refer to as the Retirement Date).

In connection with this development, on December 16, 2015, we and Dr. Finn entered into a Retirement Agreement setting forth our mutual understandings regarding Dr. Finn's retirement. Along with containing customary terms and conditions, under the Retirement Agreement Dr. Finn was entitled to receive (i) a $375,000 retirement bonus, payable quarterly in advance following his retirement, (ii) a customary cash bonus for services rendered by Dr. Finn during 2015 and (iii) a customary equity bonus for services rendered by Dr. Finn during 2015, to be determined in accordance with our prevailing compensation policies and procedures. In addition: (i) Dr. Finn will be allowed to retain all of his fully vested options to purchase shares of our common stock received under our equity incentive plans for the remaining life of such options, so long as such options have fully vested on or before the Retirement Date, and (ii) all unvested restricted stock units previously issued under our equity incentive plans and held by Dr. Finn as of the Retirement Date were cancelled and, in lieu thereof, Dr. Finn was awarded a one-time issuance of shares of our common stock based upon a net present valuation of the cancelled restricted stock units as set forth in the Retirement Agreement (which resulted in an issuance of 513,221 shares of common stock). The Compensation Committee and our board of directors approved the Retirement Agreement in recognition of Dr. Finn's many years of outstanding contributions, particularly in his management of our drug development activities.

Accounting and Tax Considerations

ASC 718. On January 1, 2006, we began accounting for share-based payments in accordance with the requirements of Accounting Standards Codification 718 (ASC 718), Share-Based Payments. To date, the adoption of ASC 718 has not impacted our stock option granting practices.

Internal Revenue Code Section 162(m). Beginning for our fiscal year ending December 31, 2014, we began to take into account the limitations on the deductibility of base salary or bonus amounts as required under Section 162(m) of the Internal Revenue Code since the aggregate salary and bonus payments for certain of our NEOS were above the $1,000,000 deductibility limitation. These limitations did not, however, impact the Compensation Committees' compensation analysis in 2015.

Section 409A. Section 409A of the Internal Revenue Code of 1986, as amended generally changes the tax rules that affect most forms of deferred compensation that were not earned and vested prior to 2005. Under Section 409(A), deferred compensation is defined broadly and may potentially cover compensation arrangements such as severance or change in control pay outs and the extension of the post-termination exercise periods of stock options. We take Code Section 409A into account, where applicable, in determining the timing of compensation paid to our executive officers.

Code Sections 280G and 4999. Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (Code Sections 280G and 4999) limit our ability to take a tax deduction for certain "excess parachute payments" (as defined in Code Sections 280G and 4999) and impose excise taxes on each NEO who receives "excess parachute payments" in connection with his or her severance from us in connection with a change in control. We consider the adverse tax liabilities imposed by Code Sections 280G and 4999, as well as other competitive factors, when structuring post-termination compensation payable to our executive officers and generally provide a mechanism for a "better after tax" result for the NEO, which we believe is a reasonable balance between our interests, on the one hand, and the executive's compensation on the other.

Compensation Risk Assessment

In reviewing our compensation policy and practices for its NEOs as well as for other employees, the Compensation Committee evaluated whether any unnecessary risk-taking was associated with our compensation policies. The Compensation Committee did not identify any risks arising from our compensation policies and practices reasonably likely to have a material adverse effect on us.

Compensation Committee Independence

All members of the Compensation Committee are independent directors and do not have any formal ties or relationship with any members of management or their relatives.

Item 11. Executive Compensation.

The following table sets forth all compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2015, 2014 and 2013. Individuals we refer to as our "named executive officers" include our Chief Executive Officer and our most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2015.

Name and principal position(*)	Year	Salary ($)	Bonus ($)	Stock Awards ($) (22)	Option Awards ($) (19)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mark A. Sirgo,									
Pharm.D. President,	2015	550,000	143,700(1)	11,770,904(2)	—	—	—	21,323(3)	12,485,927
Chief Executive Officer	2014	469,441	281,976	2,591,977(4)	—	—	—	33,286(5)	3,376,680
and Director	2013	462,734	276,552	1,760,708(6)	—	—	—	23,849(7)	2,523,843
Ernest R. De Paolantonio,									
CPA MBA	2015	350,000	52,500(9)	1,509,450(10)	—	—	—	34,704(11)	1,946,654
Chief Financial Officer,	2014	294,231	76,664	227,054(12)	—	—	—	33,716(13)	631,665
Secretary and Treasurer (8)	2013	61,154	—	—	213,870	—	—	—	275,024
Andrew L. Finn, Pharm.D.	2015	375,000	64,800(15)	5,876,085(16)	—	—	—	23,649(17)	6,339,534
Executive VP of	2014	307,013	124,140	1,365,995(18)	—	—	—	38,958(19)	1,836,106
Product Development(14)	2013	313,514	124,680	672,961(20)	—	—	—	28,185(21)	1,139,340

(*) Table does not include information regarding Niraj Vasisht, Ph.D., Senior Vice President and Chief Technology Officer, who became a named executive officer as of January 1, 2016. See description of Dr. Vasisht's employment agreement below.
(1) The bonus disclosed in this item of $143,700 relates to 2014, but was contingent upon board approval, which occurred January 2015.
(2) The stock awards disclosed in this item consists of 800,000 unvested executive RSU grants during 2015 with a fair market value (or FMV) of $14.63, which will vest in equal amounts over three years, and 8,189 vested RSUs FMV of $8.17 as issued during 2015 from the LTIP.
(3) Includes: $8,073 of health insurance premiums paid and 401(k) matching of $13,250 paid in 2015.
(4) The stock awards disclosed in this item consists of 290,511 unvested executive RSU grants during 2014 with a FMV of $8.87, which will vest in equal amounts over three years, and 1,705 vested RSUs with a FMV of $9.04 as issued during 2014 from the LTIP.
(5) Includes: Vacation payout of $11,076, $14,385 of health insurance premiums paid and 401(k) matching of $14,385 paid in 2014.
(6) The stock awards disclosed in this item consists of 420,000 unvested executive RSU grants during 2013 with a FMV of $4.16, which will vest in equal amounts over three years, and 3,446 vested RSUs as issued during 2013 with a FMV of $3.96 from the LTIP.
(7) Includes: $9,392 of health insurance premiums paid and 401(k) matching of $14,457 paid in 2013.
(8) Ernest R. DePaolantonio was hired as Chief Financial Officer on October 9, 2013.
(9) The bonus disclosed in this item of $52,500 relates to 2014, but was contingent upon board approval, which occurred January 2015.
(10) The stock awards disclosed in this item consists of 103,175 unvested executive RSU grants during 2015 with a FMV of $14.63, which will vest in equal amounts over three years.
(11) Includes: $21,454 of health insurance premiums paid and 401(k) matching of $13,250 paid in 2015.
(12) The stock awards disclosed in this item consists of 25,598 unvested executive RSU grants during 2014 with a FMV of $8.87, which will vest in equal amounts over three years.
(13) Includes: $18,099 of health insurance premiums paid, 401(k) matching of $11,417 and $4,200 of relocation expenses paid in 2014.
(14) Andrew L. Finn executed a retirement agreement effective December 31, 2015.
(15) The bonus disclosed in this item of $64,800 relates to 2014, but was contingent upon board approval, which occurred January 2015.
(16) The stock awards disclosed in this item consists of 400,000 unvested executive RSU grants during 2015 with a FMV of $14.63, which will vest in equal amounts over three years, and 2,948 vested RSUs FMV of $8.17 as issued during 2015 from the LTIP.
(17) Includes: $10,399 of health insurance premiums paid and 401(k) matching of $13,250 paid in 2015.
(18) The stock awards disclosed in this item consists of 153,387 unvested executive RSU grants during 2014 with a FMV of

$8.87, which will vest in equal amounts over three years, and 614 vested RSUs with a FMV of $9.04 as issued during 2014 from the LTIP.
(19) Includes: Vacation payout of $6,585, $9,810 of health insurance premiums paid and 401(k) matching of $22,563 paid in 2014.
(20) The stock awards disclosed in this item consists of 160,601 unvested executive RSU grants during 2013 with a FMV of $4.16, which will vest in equal amounts over three years, and 1,240 vested RSUs as issued during 2013 with a FMV of $3.96 from the LTIP.
(21) Includes: $9,392 of health insurance premiums paid and 401(k) matching of $18,793 paid in 2013.
(22) The reported amounts represent the aggregate grant date fair value of the awards computed in accordance with Financial Accounting Standards Board Account Standards Codification Topic 718, Stock Compensation, as modified or supplemented, or FASB ASC Topic 718.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Except as set forth below, we currently have no written employment agreements with any of our officers, directors, or key employees. All directors and officers have executed confidentiality and noncompetition agreements with us.

The following is a description of our current executive employment agreements:

Mark A. Sirgo, Pharm.D., President and Chief Executive Officer - Dr. Sirgo's current employment agreement, dated February 22, 2007, as amended, is subject to successive, automatic one-year extensions unless either party gives notice of non-extension to the other party at least 30 days prior to the end of the applicable term. The agreement includes a base salary, target bonus of up to 50% of his base salary (which was subject to modification with the approval of our Compensation Committee and is now 60%), and other employee benefits. Under the terms of his agreement, Dr. Sirgo received base salary in 2015 of $550,000 per year and a bonus of $143,700, which related to 2014 performance.

We may terminate Dr. Sirgo's employment agreement without cause and Dr. Sirgo may resign upon 30 days advance written notice. We may immediately terminate Dr. Sirgo's employment agreement for Good Cause (as defined in the agreement). Upon the termination of Dr. Sirgo's employment for any reason, Dr. Sirgo will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Dr. Sirgo is terminated during the term of the employment agreement other than for Good Cause (as defined in the employment agreement), or if Dr. Sirgo terminates his employment for Good Reason (as defined in the employment agreement), Dr. Sirgo is entitled to a lump sum severance payment equal to 1 times the sum of his annual base salary plus a pro-rata annual bonus based on his target annual bonus. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Dr. Sirgo will equal the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary, multiplied by 2. In addition, Dr. Sirgo's employment agreement will terminate prior to its scheduled expiration date in the event of Dr. Sirgo's death or disability.

Dr. Sirgo's employment agreement also includes a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Ernest R. De Paolantonio, CPA, MBA, Chief Financial Officer, Secretary and Treasurer - Mr. De Paolantonio's current employment agreement, dated October 1, 2013 includes a base salary of $300,000, target bonus of up to 35% of his base salary (which is subject to modification by our Compensation Committee), and other employee benefits. Under the terms of his agreement, Mr. De Paolantonio received base salary in 2015 of $350,000 per year and a bonus of $52,500, which bonus was related to 2014 performance.

We may terminate Mr. De Paolantonio's employment agreement without cause and Mr. De Paolantonio may resign without notice. We may immediately terminate Mr. De Paolantonio's employment agreement for Good Cause (as defined in the agreement). Upon the termination of Mr. De Paolantonio's employment for any reason, Mr. De Paolantonio will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Mr. De Paolantonio is terminated during the term of the employment agreement other than for Good Cause (as defined in the employment agreement), or if Mr. De Paolantonio terminates his employment for Good Reason (as defined in the employment agreement), Mr. De Paolantonio is entitled to a lump sum severance payment equal to 1 times the sum of his annual base salary. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Mr. De Paolantonio will equal to 1 times the sum of his then current annual base salary. In addition, Mr. De Paolantonio's employment agreement will terminate prior to its scheduled expiration date in the event of Mr. De Paolantonio's death or disability.

Andrew L. Finn, Pharm.D., Executive Vice President of Product Development — Dr. Finn's current employment agreement, dated February 22, 2007, as amended, was subject to successive, automatic one-year extensions unless either party gave notice of non-extension to the other party at least 30 days prior to the end of the applicable term. The agreement included a base salary, target bonus of up to 50% of his base salary (which was subject to modification with the approval of our Compensation Committee and is now 40%), and other employee benefits. Under the terms of his agreement, Dr. Finn received base salary in 2015 of $375,000 per year and a bonus of $64,800, which bonus related to 2014 performance.

Dr. Finn's employment agreement also included a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement.

On December 16, 2015, we announced that Dr. Finn would voluntarily retire in good standing from his position, effective as of December 31, 2015 (the "Retirement Date"). The decision by Finn to retire from his position did not involve any disagreement with us on any matter relating to our operations, policies or practices.

In connection with this development, on December 16, 2015, we and Dr. Finn entered into a Retirement Agreement (the "Agreement") setting forth the mutual understandings of us and Dr. Finn regarding his retirement from our company. Along with containing customary terms and conditions, under the Agreement, Dr. Finn received or will receive (i) a $375,000 retirement bonus, payable quarterly in advance following his retirement, (ii) a customary cash bonus for services rendered by Dr. Finn during 2015, which was determined in accordance with our prevailing compensation policies and procedures and (iii) a customary equity bonus for services rendered by Dr. Finn during 2015, which was determined in accordance with our prevailing compensation policies and procedures. In addition: (i) Dr. Finn will be allowed to retain all of his fully vested options to purchase our common stock received under our equity incentive plans for the remaining life of such options, so long as such options have fully vested on or before the Retirement Date, and (ii) all unvested restricted stock units previously issued under our equity incentive plans and held by Dr. Finn as of the Retirement Date will be cancelled and, in lieu thereof, Dr. Finn will be awarded a one-time issuance of our common stock based upon a net present valuation of the cancelled restricted stock units as set forth in the Retirement Agreement. Pursuant to the cancellation of Dr. Finn's unvested RSUs, in January 2016 we issued to Dr. Finn 513,221 shares of our common stock.

Niraj Vasisht, Ph.D., Senior Vice President and Chief Technology Officer - Dr. Vasisht's current employment agreement, dated October 1, 2008, as amended, is subject to successive, automatic one-year extensions unless either party gives notice of non-extension to the other party at least 30 days prior to the end of the applicable term. The agreement includes a base salary, target bonus of up to 40% of his base salary (which was subject to modification with the approval of our Compensation Committee and is now 50%), and other employee benefits. Under the terms of his agreement, Dr. Vasisht received base salary in 2015 of $310,000 per year and a bonus of $57,400, which related to 2014 performance.

We may terminate Dr. Vasisht's employment agreement without cause and Dr. Vasisht may resign upon 30 days advance written notice. We may immediately terminate Dr. Vasisht's employment agreement for Good Cause (as defined in the agreement). Upon the termination of Dr. Vasisht 's employment for any reason, Dr. Vasisht will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Dr. Vasisht is terminated during the term of the employment agreement other than for Good Cause (as defined in the employment agreement), or if Dr. Vasisht terminates his employment for Good Reason (as defined in the employment agreement), Dr. Vasisht is entitled to a lump sum severance payment equal to 1 times the sum of his annual base salary plus a pro-rata annual bonus based on his target annual bonus. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Dr. Vasisht will equal the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary, multiplied by 1.5. In addition, Dr. Vasisht's employment agreement will terminate prior to its scheduled expiration date in the event of Dr. Vasisht's death or disability.

Dr. Vasisht's employment agreement also includes a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Outstanding equity awards

The following table summarizes outstanding unexercised options, unvested stocks and equity incentive plan awards held by each of our name executive officers, as of December 31, 2015.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Prices ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not vested ($)
Mark A. Sirgo, Pharm.D	—	—	—	—	—	—	—	361,660(2)	1,732,351
	—	—	—	—	—	—	—	140,000(3)	670,600
	—	—	—	—	—	—	—	193,674(4)	927,698
	—	—	—	—	—	—	—	800,000(5)	3,832,000
	33,026	—	—	1.96	2/15/22	—	—	—	—
	45,421	—	—	1.78	2/9/22	—	—	—	—
	25,000	—	—	3.47	7/20/21	—	—	—	—
	22,369	—	—	3.55	2/25/21	—	—	—	—
	25,000	—	—	2.26	7/21/20	—	—	—	—
	34,265	—	—	2.43	7/21/20	—	—	—	—
	37,348	—	—	3.90	1/21/20	—	—	—	—
	25,000	—	—	5.40	7/22/19	—	—	—	—
	100,000	—	—	4.83	4/30/19	—	—	—	—
	9,175	—	—	3.05	1/22/19	—	—	—	—
	13,661	—	—	2.01	7/24/18	—	—	—	—
	48,448	—	—	2.85	1/31/18	—	—	—	—
	20,000	—	—	4.13	7/25/17	—	—	—	—
	434,000	—	—	6.63	4/13/17	—	—	—	—
	45,891	—	—	2.42	1/26/17	—	—	—	—
Ernest R. De Paolantonio, CPA MBA	—	—	—	—	—	—	—	35,000(2)	167,650
	—	—	—	—	—	—	—	17,065(4)	81,741
	37,106	18,553(1)	—	5.39	10/17/23	—	—	—	—
Andrew L. Finn, Pharm.D (6)	—	—	—	—	—	—	—	130,198(2)	623,648
	—	—	—	—	—	—	—	53,533(3)	256,423
	—	—	—	—	—	—	—	102,258(4)	489,816
	—	—	—	—	—	—	—	400,000(5)	1,916,000
	18,128	—	—	1.96	2/15/22	—	—	—	—
	31,165	—	—	1.78	2/9/22	—	—	—	—
	15,348	—	—	3.55	2/25/21	—	—	—	—
	20,873	—	—	2.43	7/21/20	—	—	—	—
	22,751	—	—	3.90	1/21/20	—	—	—	—
	7,439	—	—	3.05	1/22/19	—	—	—	—
	33,231	—	—	2.01	7/24/18	—	—	—	—
	39,282	—	—	2.85	1/31/18	—	—	—	—
	100,000	—	—	6.63	4/13/17	—	—	—	—
	37,209	—	—	2.42	1/26/17	—	—	—	—

(1) These unvested options will vest on October 17, 2016.

(2) Unvested stock awards consist of Restricted Stock Units from our Long Term Incentive Plan (as defined under our 2011 Equity Incentive Plan) and which we refer to as Performance RSUs, which are rights to acquire shares of our common stock.

(3) Unvested stock awards consist of Restricted Stock Units (as defined under our 2011 Equity Incentive Plan) which are rights to acquire shares of our common stock. These remaining unvested RSUs vest on September 21, 2016.

(4) Unvested stock awards consist of Restricted Stock Units (as defined under our 2011 Equity Incentive Plan) which are rights to acquire shares of our common stock. These unvested RSUs vest as to one half on September 21, 2016 and the remaining half on February 22, 2017.

(5) Unvested stock awards consist of Restricted Stock Units (as defined under our 2011 Equity Incentive Plan) which are rights to acquire shares of our common stock. These unvested RSUs vest as to one third on September 21, 2016, one third on February 23, 2017, and the remaining third on February 23, 2018.

(6) Per Retirement Agreement, all RSUs have been terminated at January 1, 2016 and replaced with a single share issuance of 513,221 shares of our common stock.

Outstanding Equity Awards Narrative Disclosure

Amended and Restated 2001 Incentive Plan

In July 2011, our original Amended and Restated 2001 Incentive Plan expired. Options to purchase 1,938,039 shares of common stock were outstanding as of December 31, 2015 under the Amended and Restated 2001 Incentive Plan. Although the Amended and Restated 2001 Incentive Plan expired, the 1,938,039 options still outstanding under such plan are still exercisable. In April 2011, our board approved, and in July 2011, our stockholders approved a new 2011 Equity Incentive Plan, which is discussed below.

2011 Equity Incentive Plan

Our 2011 Equity Incentive Plan was originally comprised of 4,200,000 shares of our common stock. The purpose of the 2011 Equity Incentive Plan is: (i) to align our interests and recipients of options under the plan by increasing the proprietary interest of such recipients in our growth and success, and (ii) to advance our interests by providing additional incentives to officers, key employees and well-qualified non-employee directors and consultants who provide services to us, who are responsible for our management and growth, or otherwise contribute to the conduct and direction of our business, operations and affairs. The Compensation Committee of our board of directors administers our incentive plan, selects the persons to whom options are granted and fixes the terms of such options. In July 2013, 2014 and 2015, our stockholders approved increases to our 2011 Equity Incentive Plan in the amounts of 2,600,000, 2,000,000 and 2,250,000, respectively.

Options may be awarded during the ten-year term of the plan to our employees (including employees who are directors), or consultants who are not employees and our other affiliates. Our plan provides for the grant of options that qualify as incentive stock options, or Incentive Stock Options, under Section 422A of the Internal Revenue Code of 1986, as amended, and options which are not Incentive Stock Options, or Non-Statutory Stock Options, as well as restricted stock and other awards. Only our employees or employees of our subsidiaries may be granted Incentive Stock Options. Our affiliates or consultants or others as may be permitted by our board of directors, may be granted Non-Statutory Stock Options.

Options to purchase 3,397,529 shares of our common stock at prices ranging from $1.38 to $16.57 are outstanding at December 31, 2015. There were no options granted during 2015 whose exercise price was lower than the estimated market price of the stock at the grant date.

Options issued during 2015 to employees and consultants under the 2011 Equity Incentive Plan totaled 684,629 shares, at exercise prices ranging from $5.36 to $13.09. There were no options issued to directors and officers under the 2011 Equity Incentive Plan during 2015 as we have migrated to the issuance of RSUs.

Option Exercises and Stock Vested

The following information sets forth stock options exercised by the executive officers during the year ended December 31, 2015:

	OPTION AWARDS		STOCK AWARDS	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
Mark A. Sirgo, Pharm.D.	69,000	223,200	245,026	3,483,925
Ernest R. De Paolantonio, CPA MBA	—	—	8,533	122,961
Andrew L. Finn, Pharm.D.	—	—	107,611	1,533,885

Pension Benefits

None of our employees participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our Compensation Committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our company's best interests.

Nonqualified Deferred Compensation

None of our employees participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our company's best interests.

Grants of Plan-Based Awards in 2015

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stocks or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Closing stock price on Award date ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
		Threshold ($)	Target ($)	Maximum ($)	Threshold (#)	Target (#) (1)	Maximum (#)					
Mark A. Sirgo, Pharm.D.	2/23/15					800,000						$11,704,000
Ernest R. De Paolantonio, CPA MBA	2/23/15					103,175						1,509,450
Andrew L. Finn, Pharm.D (2)	2/23/15					400,000						5,852,000

(1) The stock awards disclosed in this item consists of RSUs issued under our 2011 Equity Incentive Plan with a FMV of $14.63, which vest in thirds beginning September 2016,

(2) Per Retirement Agreement, all RSUs have been terminated at January 1, 2016 and replaced with a single share issuance of 513,221 shares of our common stock.

Narrative to Grants of Plan Based Awards Table

See Compensation Discussion and Analysis above for complete description of the targets for payment of annual incentives, as well as performance criteria on which such payments were based.

Options granted to employees vest over 36 months beginning on the first anniversary of the grant date at which time 33% of such options vest. These options expire in 10 years and are outstanding for as long as the individual is an active employee. Employee options qualify as Incentive Stock Options.

Potential Payments Under Severance/Change in Control Arrangements

The table below sets forth potential payments payable to our current executive officers in the event of a termination of employment under various circumstances. For purposes of calculating the potential payments set forth in the table below, we have assumed that (i) the date of termination was December 31, 2015 and (ii) the stock price was $4.79, which was the closing market price of our common stock on December 31, 2015, the last business day of the 2015 fiscal year.

Name	If Company Terminates Executive Without Cause or Executive Resigns with Good Reason($)	Termination Following a Change in Control without Cause or Executive Resigns with Good Reason($)
Mark A. Sirgo, Pharm.D.		
Cash Payment	$ 846,154(1)	$ 1,671,154(1)
Acceleration of Options	—	738,166(2)
Total Cash and Benefits	**$ 846,154**	**$ 2,409,320**
Ernest R. De Paolantonio, CPA MBA		
Cash Payment	$ 533,104(1)	$ 358,104(1)
Acceleration of Options	—	—
Total Cash and Benefits	**$ 533,104**	**$ 358,104**

(1) Includes severance payment and accrued and unused vacation time as of December 31, 2015.
(2) Determined by taking excess of the fair market value of our common stock on December 31, 2015, less the exercise price of each accelerated option.
(3) Dr. Finn is not included in the above table as he voluntarily retired at December 31, 2015.

For each of our executive officers, in their employment agreements the term "change of control" means the occurrence of any one or more of the following events (it being agreed that, with respect to paragraphs (i) and (iii) of this definition below, a "change of control" shall not be deemed to have occurred if the applicable third party acquiring party is an "affiliate" of our company within the meaning of Rule 405 promulgated under the Securities Act of 1933, as amended):

(i) An acquisition (whether directly from our company or otherwise) of any voting securities of our company by any person or entity, immediately after which such person or entity has beneficial ownership of forty percent (40%) or more of the combined voting power of our then outstanding voting securities.

(ii) The individuals who, as of the date hereof, are members of the our board of directors cease, by reason of a financing, merger, combination, acquisition, takeover or other non-ordinary course transaction affecting our company, to constitute at least fifty-one percent (51%) of the members of our board of directors; or

(iii) Approval by our board of directors and, if required, our stockholders of, or our execution of any definitive agreement with respect to, or the consummation of (it being understood that the mere execution of a term sheet, memorandum of understanding or other non-binding document shall not constitute a change of control):

(A) A merger, consolidation or reorganization involving our company, where either or both of the events described in clauses (i) or (ii) above would be the result;

(B) A liquidation or dissolution of or appointment of a receiver, rehabilitator, conservator or similar person for, or the filing by a third party of an involuntary bankruptcy against, our company; or

(C) An agreement for the sale or other disposition of all or substantially all of the assets of our company to any person or entity (other than a transfer to a subsidiary of our company).

The cash component (as opposed to option accelerations) of any change of control payment would be structured as a one-time cash severance payment.

Compensation of Directors Summary Table

DIRECTOR COMPENSATION

Name (a)	Fees Earned or Paid in Cash ($)	Stock Awards ($)(7)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Frank E. O'Donnell, Jr.	346,850(1)	5,885,538(2)	—	—	—	20,808(3)	6,253,196
William B. Stone	80,750	279,300(4)	—	—	—	—	360,050
John J. Shea (5)	51,250	186,200(6)	—	—	—	—	237,450
Samuel P. Sears, Jr.	63,750	186,200(6)	—	—	—	—	249,950
Thomas W. D'Alonzo	47,000	186,200(6)	—	—	—	—	233,200
Charles J. Bramlage	48,750	186,200(6)	—	—	—	—	234,950
Barry I. Feinberg	51,250	186,200(6)	—	—	—	—	237,450

(1) Compensation for serving as Executive Chairman, which includes $71,850 as bonus, which relates to 2014 performance.
(2) The stock awards disclosed in this item consists of 4,105 vested RSUs issued in 2015 with a FMV of $8.17 under our LTIP and 400,000 unvested RSUs issued as executive grants in 2015 with a FMV of $14.63 which vest in thirds beginning in 2016. Does not include 181,313 unvested RSUs to be issued under our LTIP upon the achievement of certain performance criteria.
(3) Includes $20,808 in health benefits paid in 2015.
(4) The stock awards disclosed in this item consists of 30,000 RSUs issued in 2015 with a FMV of $9.31 for serving on the board which half vested in 2015 and the remaining half vest in 2016.
(5) Mr. Shea retired from our board of directors effective December 31, 2015. He is entitled to no further compensation after this date, but is entitled to receive the equity awards granted at the July 2016 annual meeting, which are for 2015 service.
(6) The stock awards disclosed in this item consists of 20,000 RSUs issued in 2015 with a FMV of $9.31 for serving on the board which half vested in 2015 and the remaining half vest in 2016.

(7) The reported amounts represent the aggregate grant date fair value of the awards computed in accordance with Financial Accounting Standards Board Account Standards Codification Topic 718, Stock Compensation, as modified or supplemented, or FASB ASC Topic 718.

Narrative to Director Compensation

The Compensation Committee of our board of directors reviews the Director Remuneration Policy, which establishes the compensation our directors earn for serving on our board of directors and individual committees. The policy follows (all annual cash retainers are paid quarterly in arrears):

- $45,000 annual cash retainer to each board member.
- $10,000 annual cash retainer to the Lead Director.
- $20,000 annual cash retainer to the Chairman of the Audit Committee.
- $15,000 annual cash retainer to the Chairman of the Compensation Committee.
- $1,000 annual cash retainer to the Chairman of the Nominating & Corporate Governance Committee.
- $1,000 annual cash retainer to each non-Chairman Audit Committee member.
- $7,500 annual cash retainer to each non-Chairman Compensation Committee member.
- $5,000 annual cash retainer to each non-Chairman Nominating & Corporate Governance Committee member.
- 20,000 restricted stock units of our common stock per year, to each director.
- 10,000 additional restricted stock units of our common stock per year to the Lead Director.
- New directors will earn a pro-rated portion (based on months to be served in the fiscal year in which they join) of cash and restricted stock units.

Options granted previously to directors have vested immediately. These options expire in 10 years and are outstanding for the life of the option. Director options qualify as Non-Statutory Stock Options.

In July 2013, we amended our Director Remuneration Policy to reflect the new cash retainer to directors, plus the migration to RSUs instead of options. The total number of RSUs granted during the year ended December 31, 2015 was 150,000, of which 75,000 vested upon issuance in August 2015 and 75,000 vest in August 2016.

Performance Long Term Incentive Plan

In December 2012, by unanimous written consent following significant planning and discussion (as well as discussion with our outside compensation consultant Radford), the Committee approved the LTIP. The LTIP is designed as an incentive for our senior management (including our NEOs) to generate revenue for our company.

The LTIP consists of RSUs (as defined under our 2011 Equity Incentive Plan) which are rights to acquire shares of our common stock. All Performance RSUs granted under the LTIP will be granted under our 2011 Equity Incentive Plan (as the same may be amended, supplemented or superseded from time to time) as “Performance Compensation Awards” under such plan. The participants in the LTIP are either NEOs or senior officers of our company. Dr. Finn will also be entitled to participate in the 2015 LTIP award per his retirement agreement.

The term of the LTIP began with our fiscal year ended December 31, 2012 and lasts through our fiscal year ended December 31, 2019. The total number of Performance RSUs covered by the LTIP is 1,078,000, of which 978,000 were awarded in 2012 and 35,000 were awarded November 2015 (the remaining 195,198 Performance RSUs being reserved for future hires, which includes forfeitures). A total of 21,356, 4,447 and 8,986 RSUs vested during the years ended December 31, 2015, 2014 and 2013, respectively. The Performance RSUs under the LTIP did not vest upon granting, but instead are subject to potential vesting each year over the 8 year term of the LTIP depending on the achievement of revenue by our company, as reported in our Annual Report on Form 10-K. Performance RSUs will be valued on the day of issuance and will vest annually on the last day preceding the first open window after filing our Annual Report on Form 10-K based on the revenue achieved during the prior fiscal year as a proportion of the total cumulative revenue target for the entire term of the LTIP (which we call the Predefined Cumulative Revenue). Predefined Cumulative Revenue is a predefined aggregate revenue target for the entire term of the LTIP that was determined by the Committee in conjunction with our executive management. The Predefined Cumulative Revenue may be adjusted by the Committee upon the occurrence of extraordinary corporate events during the term of the LTIP (such as acquisitions by our company of revenue generating businesses or assets).

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the Compensation Committee of our board of directors, or other committee serving an equivalent function. None of the members of our Compensation Committee has ever been our employee or one of our officers.

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

The following table sets forth, as of March 7, 2016, by: (i) each of our directors, (ii) all persons who, to our knowledge, are the beneficial owners of more than 5% of the outstanding shares of common stock, (iii) each of the executive officers, and (iv) all of our directors and executive officers, as a group. Each person named in this table has sole investment power and sole voting power with respect to the shares of common stock set forth opposite such person's name, except as otherwise indicated. Unless otherwise indicated, the address for each person listed below is in care of BioDelivery Sciences International, Inc., 4131 ParkLake Avenue, Suite #225, Raleigh, NC 27612.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class as of March 7, 2016(1)
Broadfin Capital, LLC(2)	5,188,794	9.70%
Armistice Capital, LLC (3)	3,132,000	5.86%
Federated Investors Inc./PA/ (4)	2,960,554	5.54%
Blackrock, Inc. (5)	2,867,492	5.36%
FMR, LLC(6)	2,703,352	5.06%
Hopkins Capital Group II, LLC(7)	1,685,490	3.15%
Frank E. O'Donnell, Jr., M.D.(8)	2,005,161	3.74%
Mark A. Sirgo, Pharm.D.(9)	2,056,723	3.78%
Ernest R. De Paolantonio, CPA MBA(10)	46,489	*
Niraj Vasisht, Ph.D.(11)	231,916	*
William B. Stone(12)	312,675	*
Samuel P. Sears, Jr(13)	64,363	*
Thomas W. D'Alonzo (14)	141,379	*
Charles J. Bramlage (15)	19,300	*
Barry I. Feinberg (16)	53,500	*
All Directors and Officers as a group (9 persons)	4,931,506	8.95%

* Less than 1%

(1) Based on 53,467,206 shares of common stock outstanding as of March 7, 2016 and shares beneficially owned by the referenced parties as described below.

(2) Based on 13G/A filed with the SEC on February 12, 2016 by Broadfin Capital, LLC.

(3) Based on 13G filed with the SEC on January 21, 2016 by Armistice Capital LLC.

(4) Based on 13G/A filed with the SEC on February 11, 2016 by Federated Investors, Inc. /PA/

(5) Based on 13G filed with the SEC on January 28, 2016 by Blackrock, Inc.

(6) Based on 13G filed with the SEC on February 12, 2016 by FMR, LLC.

(7) The address for Hopkins Capital Group II, LLC is 324 S Hyde Park, Suite 350, Tampa, FL. 33606.

(8) Dr. O'Donnell is our Executive Chairman of the Board and a Director. Includes the shares owned by Hopkins Capital Group II, LLC, as to which Dr. O'Donnell disclaims beneficial interest (see note 7). Excludes 167,500 shares owned by The Francis E. O'Donnell, Jr. Irrevocable Trust #1, of which Dr. O'Donnell's sister, Kathleen O'Donnell, is trustee, and as to which Dr. O'Donnell disclaims beneficial interest. In addition, this number includes 124,671 shares owned personally by Dr. O'Donnell and options to purchase 195,000 shares of our common stock, all of which is currently exercisable. Does not include 70,000 shares of unvested RSUs which vest September 21, 2016. Does not include 96,837 shares of unvested RSUs which vest in one half September 21, 2016 and the remaining half February 2017. Does not include 400,000 shares of unvested RSUs which vest in thirds beginning September 21, 2016. Also does not include 181,313 shares of unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved. Dr. O'Donnell's address is 865 Longboat Club Road, Longboat Key FL. 34228.

(9) Includes 1,138,119 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Includes options to purchase 918,604 shares of common stock, all of which are currently exercisable. Does not include 140,000 shares of unvested RSUs which vest September 21, 2016. Does not include 193,674 shares of unvested RSUs which vest in one half September 21, 2016 and the remaining half February 2017. Does not include 800,000 shares of unvested RSUs which vest in thirds beginning September 21, 2016. Also does not include 361,660 unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved. Dr. Sirgo's address is 606 Wayne Drive, Raleigh, NC. 27609.

(10) Mr. De Paolantonio is our Chief Financial Officer, Secretary and Treasurer. Includes 9,383 shares owned by Mr. De Paolantonio. Includes options to purchase 37,106 shares of common stock, all of which are currently exercisable. Excludes options to purchase 18,553 shares of common stock which are not currently exercisable. Does not include 17,065 shares of unvested RSUs which vest one half September 21, 2016 and the remaining half February 2017. Does not include 103,175 shares of unvested RSUs which vest in thirds beginning September 21, 2016. Mr. De Paolantonio's address is 4209 Lassiter Mill Road, Raleigh, NC. 27609.

(11) Dr. Vasisht is our Senior Vice President and Chief Technology Officer as of January 1, 2016. Includes 67,420 shares owned by Dr. Vasisht. Includes options to purchase 164,496 shares of common stock, all of which are currently exercisable. Does not include 33,333 shares of unvested RSUs which vest one half September 21, 2016 and the remaining half January 2017. Does not include 27,666 shares of unvested RSUs which vest September 21, 2016. Does not include 49,960 shares of unvested RSUs which vest one half September 21, 2016 and the remaining half February 2017. Does not include 200,000 shares of unvested RSUs which vest in thirds beginning September 21, 2016. Also does not include 106,087 unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved. Dr. Vasisht's address is 230 Shillings Chase, Cary, NC. 27518.

(12) Mr. Stone is a Director. Includes 97,675 shares owned and options to purchase 215,000 shares of our common stock, all of which are currently exercisable. Does not include 15,000 shares of unvested RSUs which will vest August 2016. Mr. Stone's address is 11120 Geyer Downs Lane, Frontenac MO. 63131.

(13) Mr. Sears is a Director. Includes 47,000 shares owned and options to purchase 17,363 shares of our common stock, all of which are currently exercisable. Does not include 10,000 shares of unvested RSUs which will vest August 2016. Mr. Sears' address is 2 Spring Avenue, S. Hamilton, MA. 01982.

(14) Mr. D'Alonzo is a Director. Includes 76,379 shares owned and options to purchase 65,000 shares of our common stock, all of which are currently exercisable. Does not include 10,000 shares of unvested RSUs which will vest August 2016. Mr. D'Alonzo's address is 81 Seagate Drive, Unit 503, Naples, FL. 34103.

(15) Mr. Bramlage is a Director. Includes 19,300 shares owned. Does not include 10,000 shares of unvested RSUs which will vest August 2016. Mr. Bramlage's address is 7707 Sutton Place, New Albany, OH. 43054

(16) Dr. Feinberg is a Director. Includes 53,500 shares owned. Does not include 10,000 shares of unvested RSUs which will vest August 2016. Dr. Feinberg's address is 3 Somerset Downs, St. Louis, MO. 63124.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table indicates shares of common stock authorized for issuance under our 2011 Equity Incentive Plan as of December 31, 2015:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)	Weighted-average exercise price of outstanding options, warrants and rights (2)	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	7,695,683	$ 5.42	1,926,599
Equity compensation plans not approved by security holders	—	—	—
Total	7,695,683	$ 5.42	1,926,599

(1) Includes 1,938,039 shares of common stock underlying options previously granted under our Amended and Restated 2001 Incentive Plan, which are still exercisable despite the fact that such plan expired July 2011.

(2) Weighted average exercise price does not include restricted stock units.

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

As of December 31, 2001, our board of directors appointed an audit committee consisting of independent directors. This committee, among other duties, is charged to review, and if appropriate, ratify all agreements and transactions which had been entered into with related parties, as well as review and ratify all future related party transactions. The audit committee and/or our independent directors independently reviewed, ratified and/or approved, as the case may be, the agreements described below. From time to time, after compliance with our internal policies and procedures, we have entered into related party contracts, some of which were amended subsequently in accordance with the same policies and procedures.

The following is a listing of our related party transactions:

On November 30, 2000, we entered into an agreement with Biotech Specialty Partners, LLC, or BSP, an emerging alliance of early stage biotechnology and specialty pharmaceutical companies. BSP to date has not distributed any pharmaceutical products.

Under this agreement, BSP will serve as a nonexclusive distributor of our products in consideration of a ten (10%) percent discount to the wholesale price, which our board of directors has determined to be commercially reasonable. BSP has waived its rights under this agreement with respect to Arius' products which include the BEMA® technology. Hopkins Capital Group, which is affiliated with Dr. Frank E. O'Donnell, Jr., our Executive Chairman of the Board and a director, are affiliated as stockholders, and Dr. O'Donnell is a member of the management of BSP.

As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to "promoters" as that term is commonly understood by the SEC and state securities authorities.

We believe that the terms of the above transactions with affiliates were as favorable to us or our affiliates as those generally available from unaffiliated third parties. At the time of certain of the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present board of directors includes five independent directors which constitute a majority as required by NASDAQ Stock Market rules. We believe that William B. Stone, Samuel P. Sears, Jr., Thomas W. D'Alonzo, Charles J. Bramlage and Barry I. Feinberg qualify as independent directors for NASDAQ Stock Market purposes.

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

Item 14. Principal Accountant Fees and Services.

Audit Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the year ended December 31, 2015 and 2014 totaled $171,200 and $151,200, respectively. The above amounts include interim procedures and audit fees, as well as attendance at audit committee meetings.

Audit-Related Fees. The aggregate fees billed by Cherry Bekaert LLP for audit-related fees for the years ended December 31, 2015 and 2014 were $21,500 and $20,000, respectively. The fees were provided in consideration of services consisting of review and update procedures associated with registration statements and other SEC filings.

Tax Fees. The aggregate fees billed by Romeo, Wiggins & Company, LLP for professional services rendered for tax compliance, were $33,275 for the year ended December 31, 2015. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for tax compliance, were $20,000 for the year ended December 31, 2014. The fees were provided in consideration of services consisting of preparation of tax returns and related tax advice.

All Other Fees. None

The Audit Committee of our board of directors has established its pre-approval policies and procedures, pursuant to which the Audit Committee approved the foregoing audit and non-audit services provided by Cherry Bekaert LLP in 2015 and tax services from Romeo, Wiggins & Company, LLP in 2015. Consistent with the Audit Committee's responsibility for engaging our independent auditors, all audit and permitted non-audit services require pre-approval by the Audit Committee. The full Audit Committee approves proposed services and fee estimates for these services. The Audit Committee chairperson has been designated by the Audit Committee to approve any audit-related services arising during the year that were not pre-approved by the Audit Committee. Any non-audit service must be approved by the full Audit Committee. Services approved by the Audit Committee chairperson are communicated to the full Audit Committee at its next regular meeting and the Audit Committee reviews services and fees for the fiscal year at each such meeting. Pursuant to these procedures, the Audit Committee approved the foregoing audit services provided by Cherry Bekaert LLP.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Number	Description
3.1	Articles of Incorporation of the Company (1)
3.2	Amended and Restated Bylaws of the Company (22)
3.3	Certificate of Amendment to the Company's Certificate of Incorporation creating a staggered board of directors, dated July 25, 2008 (16)
3.4	Certificate of Elimination, dated February 12, 2009, for the Company's Series A Non-Voting Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Non-Voting Convertible Preferred Stock (14)
3.5	Certificate of Amendment to the Company's Certificate of Incorporation increasing the number of authorized shares, dated July 22, 2011 (27)
4.1	Form of Common Stock Purchase Warrant, dated April 20, 2010, issued by the Company to certain institutional investors (20)
4.2	Certificate of Designation of Series A Non-Convertible Preferred Stock, dated November 20, 2012 (33)
4.3	Form of Common Stock Purchase Warrant, dated July 5, 2013, issued by the Company to Midcap Financial SBIC, LP (31)
10.1	Amended and Restated 2001 Incentive Plan (2)
10.2	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (3)
10.3	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (3)
10.4	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (3)
10.5	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (3)
10.6	Clinical Development and License Agreement, dated as of July 14, 2005, among Clinical Development Capital LLC, the Company and Arius Pharmaceuticals, Inc. (4)+
10.7	Supply Agreement, dated October 17, 2005, by and between Aveva Drug Delivery Systems, Inc., Arius Pharmaceuticals, Inc. and the Company (5)
10.8	Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC IV, LLC (6)
10.9	Amendment No. 2, dated as of May 16, 2006, to that certain Clinical Development and License Agreement, dated as of July 14, 2005, between the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC (6)
10.10	Amended and Restated Registration Rights Agreement, dated as of May 16, 2006, by and between the Company and CDC IV, LLC (6)
10.11	Amendment No. 1 to Amended and Restated 2001 Incentive Plan (7)
10.12	Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT USA, Inc. and Arius Two, Inc. (8)+
10.13	License and Development Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (8)+
10.14	BEMA Fentanyl Supply Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (8)+
10.15	Sublicensing Consent, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (8)+
10.16	Sublicensing Consent and Amendment, dated August 2, 2006, by the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC (8)+
10.17	Letter agreement, dated August 2, 2006, between Meda AB, Arius Pharmaceuticals, Inc, Arius Two, Inc. and the Company (8)

Number	Description
10.18	Notice of Breach and Demand for Dispute Resolution, sent August 30, 2006, from the Company to CDC IV, LLC (9)
10.19	Notice of Breach and Termination, received August 30, 2006, from CDC IV, LLC to the Company (10)
10.20	Process Development Agreement, effective December 15, 2006, between LTS Lohmann Therapie-Systeme AG and the Company (11)+
10.21	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Mark A. Sirgo (12)
10.22	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Andrew L. Finn (12)
10.23	Employment Agreement, dated February 22, 2007, between the Company and James A. McNulty (12)
10.24	Dispute Resolution Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (13)
10.25	Amendment to Clinical Development and License Agreement, dated March 9, 2007, between the Company and CDC IV, LLC (13)
10.26	Registration Rights Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (13)
10.27	Subscription Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (14)
10.28	Second Amended and Restated Registration Rights Agreement, dated April 10, 2007, between the Company and Laurus Master Fund, Ltd. (11)
10.29	License and Development Agreement, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc. and Meda AB (15)+
10.30	BEMA Fentanyl Supply Agreement, dated September 5, 2007, between the Company and Meda AB (15)+
10.31	Sublicensing Consent dated September 5, 2007, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (15)+
10.32	License Agreement dated, September 5, 2007, by and between Arius Two, Inc., and Arius Pharmaceuticals, Inc. (15)+
10.33	Intellectual Property Assignment Agreement dated, September 5, 2007 by and between QLT USA, Inc. and Arius Two. (15)+
10.34	Assignment of Patent and Trademarks, dated September 5, 2007. (15)
10.35	BEMA Acquisition Consent, amendment and waiver, dated September 5, 2007, between the Company and CDC IV, LLC (15)
10.36	Sublicensing Consent and Amendment, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc., CDC IV, LLC and Meda AB. (15)+
10.37	Royalty Purchase and Amendment Agreement, dated as of September 5, 2007 between BioDelivery Sciences International, Inc., and CDC IV, LLC (15)+
10.38	Amendment to the Clinical Development and License Agreement, dated as of July 14, 2005, amendment dated as of September 5, 2007, by and among CDC IV, LLC, the Company, Arius Pharmaceuticals, Inc., and Arius Two, Inc. (15)+
10.39	Dispute Resolution Agreement, dated September 5, 2007 by and between the Company and CDC IV, LLC (15)
10.40	Acknowledgement by CDC, dated September 5, 2007, of the License and Development Agreement made as of September 5, 2007 between the Company, Arius Pharmaceutical, Inc. and Meda AB (15)
10.41	Letter Amendment, effective January 2, 2009, between the Company, Arius Pharmaceuticals, Inc. and Meda AB relating to European commercialization rights for ONSOLIS® (17)+
10.42	Amendment to License and Development Agreement, effective January 2, 2009, between the Company, Arius Pharmaceuticals, Inc. and Meda AB relating to the North American commercialization rights for ONSOLIS® (17)+
10.43	Amendment Consent (EU), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (17)
10.44	Amendment Consent (NA), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (17)
10.45	Process Development Agreement, dated February 8, 2008, between the Company and LTS (18)+
10.46	Amendment to Amended and Restated 2001 Incentive Plan of the Company, dated November 19, 2008 (18)
10.47	Master Clinical Development Agreement, dated February 12, 2009, between the Company and Premier Research International LLC (19)+
10.48	Proposal for Clinical Research Services, dated March 13, 2009, between the Company and Premier Research International

Number	Description
	LLC (19)+
10.49	Securities Purchase Agreement, dated April 20, 2010, between the Company and certain institutional investors. (20)
10.50	License and Supply Agreement, dated May 26, 2010, between the Company, Arius Pharmaceuticals and KunWha Pharmaceutical Co., Ltd (21)+
10.51	License and Supply Agreement, dated October 4, 2010, between the Company, Arius Pharmaceuticals and TTY Biopharm Co., Ltd. (23)+
10.52	Securities Purchase Agreement, dated March 11, 2011, between the Company and certain institutional investors. (24)
10.53	Amendment to Clinical Development and License Agreement, effective May 12, 2011, between the Company, Arius, Arius Two, Inc., CDC V, LLC and NB Athyrium. (25)
10.54	2011 Equity Incentive Plan (26)
10.55	License and Development Agreement, dated January 5, 2012, by and among the Company, Arius, Arius Two and Endo (28) (44)+
10.56	Manufacturing, Supply, and License Agreement dated April 26, 2012 between the Company, Arius Pharmaceuticals and LTS Lohmann Therapie-Systeme AG (29)+
10.57	Placement Agency Agreement, dated November 27, 2012, between the Company and William Blair & Company, L.L.C, JMP Securities LLC and Roth Capital Partners, LLC (30)
10.58	Subscription Agreement, dated November 28, 2012, between the Company and certain investors (30)
10.59	License Agreement, dated March 26, 2013, between the Company and Arcion Therapeutics, Inc (31)+
10.60	Amendment No. 1 to 2011 Equity Incentive Plan (32)
10.61	Credit and Security Agreement, dated July 5, 2013, by and among, the Company, Arius, Arius Two and Midcap Financial SBIC, LP (33)+
10.62	Conditional Offer of Employment, dated October 1, 2013, between the Company and Ernest R. De Paolantonio (34)
10.63	Sales Agreement, dated November 29, 2013, between the Company and Cantor Fitzgerald & Co. (35)
10.64	Securities Purchase Agreement, dated February 7, 2014, between the Company and certain institutional investors. (36)
10.65	Master Services Agreement, dated September 25, 2013, between the Company and Quintiles Commercial US, Inc. (37)+
10.66	Amendment No. 2 to 2011 Equity Incentive Plan (38)
10.67	First Amendment to Credit and Security Agreement, dated July 3, 2014, between the Company, Arius, Arius Two and Midcap Financial SBIC, LP. (39)
10.68	Development and Exclusive License and Option Agreement, dated October 27, 2014, by and between the Company and Evonik Corporation. (40)+
10.69	Definitive Assignment and Revenue Sharing Agreement, dated January 23, 2015, by and among the Company, Arius and Meda AB (41)+
10.70	Performance Long Term Incentive Plan (42)
10.71	Amended and Restated Credit and Security Agreement, dated May 29, 2015, by and among the Company, Arius, Arius Two and Midcap Financial Trust (43)+
10.72	Amendment No. 3 to 2011 Equity Incentive Plan (44)
10.73	Sales Agreement, dated July 2, 2015, between the Company and Cantor Fitzgerald & Co. (45)
10.74	Letter Agreement, dated November 13, 2015, by and between the Company and Shea. (46)
10.75	Retirement Agreement, dated December 16, 2015, by and between the Company and Andrew Finn. (47)
10.76	Employment Agreement, dated October 1, 2008, by and between the Company and Niraj Vasisht. (47)
10.77	Extension Agreement, dated February 27, 2016, by and among the Company, Arius and Meda AB.*
21.1	Subsidiaries of the Registrant *
23.1	Consent of Cherry Bekaert LLP*
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as

Number	Description
	adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#
101.ins	XBRL Instance Document
101.sch	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Calculation Linkbase Document
101.def	XBRL Taxonomy Definition Linkbase Document
101.lab	XBRL Taxonomy Label Linkbase Document
101.pre	XBRL Taxonomy Presentation Linkbase Document

* Filed herewith
\+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
\# A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
‡ Confidential treatment extension of confidential treatment previously granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2 is currently pending with the Securities and Exchange Commission.
(1) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(2) Previously filed with Form 10-QSB/A, September 2, 2003.
(3) Previously filed with Form 8-K, August 26, 2004.
(4) Previously filed with Form 8-K, July 21, 2005.
(5) Previously filed with Form 10-QSB, November 10, 2005.
(6) Previously filed with Form 8-K, May 22, 2006.
(7) Previously filed as Annex A to Schedule 14A, June 27, 2006.
(8) Previously filed with Form 8-K, August 9, 2006.
(9) Previously filed with Form 8-K, August 31, 2006.
(10) Previously filed with Form 8-K, August 31, 2006.
(11) Previously filed with Form 10-K, April 17, 2007.
(12) Previously filed with Form 8-K, February 22, 2007.
(13) Previously filed with Form 8-K, March 16, 2007.
(14) Previously filed with Form 8-K, February 13, 2009.
(15) Previously filed with Form 8-K, September 10, 2007.
(16) Previously filed with Form 8-K, July 28, 2008.
(17) Previously filed with Form 8-K, January 6, 2009.
(18) Previously filed with Form 10-K, March 20, 2009.
(19) Previously filed with Form 10-Q, May 15, 2009.
(20) Previously filed with Form 8-K, April 20, 2010.
(21) Previously filed with Form 8-K, May 27, 2010.
(22) Previously filed with Form 8-K, July 23, 2010.
(23) Previously filed with Form 8-K, October 8, 2010.
(24) Previously filed with Form 8-K, dated March 16, 2011.
(25) Previously filed with Form 8-K, dated May 13, 2011.
(26) Previously filed with PRE14A, dated June 13, 2011
(27) Previously filed with Form 8-K, dated July 25, 2011.
(28) Previously filed with Form 8-K, dated January 11, 2012.
(29) Previously filed with Form 8-K, dated September 19, 2012.
(30) Previously filed with Form 8-K, dated November 28, 2012.
(31) Previously filed with Form 8-K, dated April 1, 2013.
(32) Previously filed with PRE14A, dated June 12, 2013
(33) Previously filed with Form 8-K, dated July 11, 2013.
(34) Previously filed with Form 8-K, dated October 23, 2013.

(35) Previously filed with Form S-3, dated November 29, 2013.
(36) Previously filed with Form 8-K, dated February 10, 2014.
(37) Previously filed with Form 10-Q, dated May 9, 2014.
(38) Previously filed with PRE14A, dated June 10, 2014.
(39) Previously filed with Form 10-Q, dated August 7, 2014.
(40) Previously filed with Form 8-K, dated October 31, 2014.
(41) Previously filed with Form 8-K, dated January 28, 2015.
(42) Previously filed with Form 10-K, March 16, 2015.
(43) Previously filed with Form 8-K, dated June 4, 2015.
(44) Previously filed with DEF14A, dated June 5, 2015.
(45) Previously filed with Form S-3, dated July 2, 2015.
(46) Previously filed with Form 8-K, dated November 13, 2015.
(47) Previously filed with Form 8-K, dated December 18, 2015.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of BioDelivery Sciences International, Inc.

We have audited the accompanying consolidated balance sheets of BioDelivery Sciences International, Inc. and Subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2015. We also have audited the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting included in Item 9A—Controls and Procedures in the Company's 2015 Annual Report on Form 10-K. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

As discussed in Note 2 to the consolidated financial statements, during 2015, the Company recognized a net loss of approximately $37.7 million and, at December 31, 2015, the Company had incurred cumulative net losses of approximately $243.2 million. Management's plans in regard to this matter are described in Note 2.

/s/ Cherry Bekaert LLP

Raleigh, North Carolina
March 10, 2016

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	December 31, 2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 83,560	$ 70,472
Accounts receivable, net	2,488	3,141
Inventory	2,558	1,828
Prepaid expenses and other current assets	3,933	2,568
Total current assets	92,539	78,009
Property and equipment, net	4,262	3,890
Goodwill	2,715	2,715
Other intangible assets, net	3,256	4,226
Total assets	$ 102,772	$ 88,840
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 19,501	$ 14,429
Notes payable, current maturities, net	6,707	8,000
Deferred revenue, current	1,875	6,772
Total current liabilities	28,083	29,201
Notes payable, less current maturities, net	22,168	3,702
Deferred revenue, long-term	20,000	841
Other long-term liabilities	825	700
Total liabilities	71,076	34,444
Commitments and contingencies (Notes 7 and 14)	—	—
Stockholders' equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,093,155 and 2,139,000 shares of Series A Non-Voting Convertible Preferred Stock outstanding at December 31, 2015 and 2014, respectively.	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 52,730,799 and 51,603,070 shares issued; 52,715,308 and 51,587,579 shares outstanding at December 31, 2015 and 2014, respectively	53	52
Additional paid-in capital	274,891	259,920
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(243,203)	(205,531)
Total stockholders' equity	31,696	54,396
Total liabilities and stockholders' equity	$ 102,772	$ 88,840

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	Year Ended December 31,		
	2015	2014	2013
Revenues:			
Product sales	$ 4,157	$ 76	$ —
Product royalty revenues	1,406	3,407	1,773
Research and development reimbursements	909	12,712	2,783
Contract revenue	41,759	22,749	6,800
Total revenues	48,231	38,944	11,356
Cost of sales	8,101	4,939	2,082
Expenses:			
Research and development	20,624	34,285	53,327
Selling, general and administrative	54,685	38,460	12,349
Total expenses	75,309	72,745	65,676
Loss from operations	(35,179)	(38,740)	(56,402)
Interest expense, net	(2,518)	(2,016)	(903)
Derivative (loss) gain	—	(13,167)	121
Other income (expense), net	25	(295)	(210)
Net loss	$ (37,672)	$ (54,218)	$ (57,394)
Basic and diluted loss per share	$ (0.72)	$ (1.12)	$ (1.51)
Weighted average common stock shares outstanding, basic and diluted	52,384,876	48,355,200	37,941,044

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE DATA)

	Preferred Stock Series A		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances, December 31, 2012	2,709,300	$ 3	37,497,703	$ 38	$143,703	$ (47)	$ (93,919)	$ 49,778
Stock-based compensation	—	—	—	—	3,327	—	—	3,327
Stock option exercise	—	—	115,667	—	357	—	—	357
Restricted stock awards	—	—	80,498	—	—	—	—	—
Warrant derivative liability reclassified to equity	—	—	—	—	11	—	—	11
Warrant exercises	—	—	10,000	—	50	—	—	50
Shares issued to Arcion in acquisition of research and development license	—	—	500,516	1	2,072	—	—	2,073
Warrants issued in connection with notes payable	—	—	—	—	986	—	—	986
Net loss	—	—	—	—	—	—	(57,394)	(57,394)
Balances, December 31, 2013	2,709,300	$ 3	38,204,384	$ 39	$150,506	$ (47)	$ (151,313)	$ (812)
Stock-based compensation	—	—	—	—	6,883	—	—	6,883
Stock option exercise	—	—	1,332,563	1	4,579	—	—	4,580
Restricted stock awards	—	—	473,893	—	—	—	—	—
Warrant derivative liability reclassified to equity	—	—	—	—	17,478	—	—	17,478
Warrant exercises	—	—	1,999,153	2	7,739	—	—	7,741
Cashless exercise of warrants	—	—	218,367	—	—	—	—	—
Shares issued pursuant to registered direct offering, net	—	—	7,500,000	8	58,174	—	—	58,182
Shares issued pursuant to an at the market offering, net	—	—	1,304,410	1	14,479	—	—	14,480
Short swing profit return	—	—	—	—	82	—	—	82
Conversion of preferred shares to common shares	(570,300)	(1)	570,300	1	—	—	—	—
Net loss	—	—	—	—	—	—	(54,218)	(54,218)
Balances, December 31, 2014	2,139,000	$ 2	51,603,070	$ 52	$259,920	$ (47)	$ (205,531)	$ 54,396
Stock-based compensation	—	—	—	—	14,249	—	—	14,249
Stock option exercise	—	—	223,923	—	755	—	—	755
Restricted stock awards	—	—	857,677	1	—	—	—	1
Warrant exercises	—	—	284	—	1	—	—	1
Short swing profit return	—	—	—	—	6	—	—	6
Conversion of preferred shares to common shares	(45,845)	—	45,845	—	—	—	—	—
Equity financing costs	—	—	—	—	(40)	—	—	(40)
Net loss	—	—	—	—	—	—	(37,672)	(37,672)
Balances, December 31, 2015	2,093,155	$ 2	52,730,799	$ 53	$274,891	$ (47)	$ (243,203)	$ 31,696

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. DOLLARS, IN THOUSANDS)

	Year Ended December 31,		
	2015	2014	2013
Operating activities:			
Net loss	$(37,672)	$(54,218)	$(57,394)
Adjustments to reconcile net loss to net cash flows from operating activities			
Depreciation	329	123	207
Accretion of debt discount and loan costs	500	642	164
Amortization of intangible assets	970	972	1,140
Derivative loss (gain)	—	13,167	(121)
Impairment loss on assets	—	295	—
Stock-based compensation expense	14,249	6,883	3,327
Purchase of Arcion license with common stock	—	—	2,072
Changes in assets and liabilities:			
Accounts receivable	653	(347)	(2,273)
Inventories	(730)	(1,828)	—
Prepaid expenses and other assets	(1,365)	(2,252)	(68)
Accounts payable and accrued expenses	5,072	4,325	(656)
Deferred revenue	14,262	3,405	(6,500)
Net cash flows from operating activities	(3,732)	(28,833)	(60,102)
Investing activities:			
Purchase of equipment	(701)	(1,603)	(77)
Net cash flows from investing activities	(701)	(1,603)	(77)
Financing activities:			
Proceeds from sales of securities, net of costs incurred	(40)	72,662	—
Proceeds from exercise of stock options	755	4,580	357
Proceeds from exercise of common stock warrants	1	7,741	50
Payment on note payable	(3,335)	(7,333)	—
Proceeds from notes payable	20,667	—	20,000
Return of short swing profits	6	82	—
Payment of deferred financing fees	(533)	—	(241)
Net cash flows from financing activities	17,521	77,732	20,166
Net change in cash and cash equivalents	13,088	47,296	(40,013)
Cash and cash equivalents at beginning of year	70,472	23,176	63,189
Cash and cash equivalents at end of year	**$ 83,560**	**$ 70,472**	**$ 23,176**
Cash paid for interest	$ 1,885	$ 1,386	$ 742
Cash paid for taxes	$ —	$ —	$ 80

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS EXCEPT SHARE DATA)

SUPPLEMENTAL CASH FLOW INFORMATION

Non-cash Financing and Investing Activities:

The Company converted 45,845 shares of Series A Preferred to equal shares of the Company's common stock during the year ended December 31, 2015.

The Company converted 570,300 shares of Series A Preferred to equal shares of the Company's common stock during the year ended December 31, 2014.

The Company reclassified the fair value of derivative liabilities totaling $17.5 million to equity during the year ended December 31, 2014 as a result of the exercise of warrants to which the derivatives related.

The Company reclassified the fair value of derivative liabilities totaling $0.01 million to equity during the year ended December 31, 2013 as a result of the exercise of warrants to which the derivatives related.

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies:

Organization

BioDelivery Sciences International, Inc. and Subsidiaries (the "Company") was incorporated in the State of Indiana on January 6, 1997 and reincorporated as a Delaware corporation in 2002. The Company's subsidiaries are Arius Pharmaceuticals, Inc., a Delaware corporation ("Arius One") and Arius Two, Inc., a Delaware corporation ("Arius Two"), each of which are wholly-owned, and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC, a Delaware limited liability company ("BND").

The Company is a specialty pharmaceutical company that is leveraging its novel, proprietary and patented drug delivery technologies, including the BioErodible MucoAdhesive ("BEMA®") drug delivery technology, to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics, primarily in the areas of pain management and addiction. The Company's development strategy focuses on utilization of the U.S. Food and Drug Administration's ("FDA") 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved therapeutics.

As used herein, the Company's common stock, par value $.001 per share, is referred to as the "Common Stock".

Principles of consolidation

The consolidated financial statements include the accounts of the Company, Arius One, Arius Two and BND. For each period presented BND has been an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Significant accounting policies:

Use of estimates in financial statements

The preparation of the accompanying consolidated financial statements requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

Reclassification

Debt issuance costs previously classified in the accompanying balance sheets as Prepaid expenses and other current assets have been reclassified to Notes payable, less current maturities, net, to effect the issuance of ASU 2015-03 as of December 31, 2014 to conform to the current year presentation (see recent accounting pronouncements in note 1). In addition certain amounts within cash flows from operating activities in the Statements of Cash Flows for the year ended December 31, 2014 were reclassified to conform to the current year presentation. And finally, amounts were reclassified between Machinery & Equipment and Idle Equipment in note 4, for the year ended December 31, 2014. These reclassifications had no effect on the previously reported net cash flows from operations, activities or net losses.

Certain Risks, Concentrations and Uncertainties

The Company relies on certain materials used in its development and third-party manufacturing processes, most of which are procured from two contract manufacturers and two active pharmaceutical ingredient ("API") suppliers for BUNAVAIL®. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company's operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the API from any of these sources could have a material adverse effect on the Company's BUNAVAIL® business, which would affect the Company's financial position and results of operations.

In addition, the Company utilizes only one contract manufacturer to create the BUNAVAIL® laminate and only one contract manufacturer to package the laminate into final product. Although the Company has long term supply agreements with these two vendors, any problems or regulatory issues at either of these vendors could create significant BUNAVAIL® supply delays. Amounts due to these vendors represented approximately 7.15% and 12.3% of total accounts payable as of December 31, 2015 and 2014, respectively.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

Key components used in the manufacture of ONSOLIS® are currently provided by a limited number of suppliers. This could result in the Company's inability to timely obtain an adequate supply of required components and reduce control over pricing, quality and timely delivery. Also, if the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required time frames, if at all, to meet the Company's obligations under certain supply agreements. This could delay timely commercialization efforts causing the Company's obligations to not be fulfilled.

The Company sells its BUNAVAIL® product primarily to large national wholesalers, which in turn may resell the products to smaller or regional wholesalers, retail pharmacies, chain drug stores, government agencies and other third parties. The following table lists the Company's customers that individually comprise greater than 10% of total accounts receivable:

	December 31,	
Customer	2015	2014
Customer A	40%	28%
Customer B	33%	24%
Customer C	16%	20%
Customer D	—	14%
Total	**89%**	**86%**

Cash

The Company places cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation covers $0.25 million for substantially all depository accounts. The Company may from time to time have amounts on deposit in excess of the insured limits. As of December 31, 2015, the Company had approximately $83.6 million, which exceeded these insured limits. As of December 31, 2014, the Company had approximately $70.5 million, which exceeded these insured limits.

Accounts Receivable

The Company typically requires its customers to remit payments within the first 30 to 37 days, depending on the customer and the products purchased. In addition, the Company offers wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company's wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The allowance for prompt payment discounts was $0.05 million as of December 31, 2015 and 2014, respectively.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of December 31, 2015 or 2014. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received. There were no write-offs during the years ending December 31, 2015, 2014, or 2013.

Inventory

Inventories are stated at the lower of cost or market value with costs determined for each batch under the first-in, first-out method and specifically allocated to remaining inventory. Inventory consists of raw materials, work in process and finished goods. Raw materials include API for a product to be manufactured, work in process includes the bulk inventory of laminate prior to being packaged for sale, and finished goods include pharmaceutical products ready for commercial sale.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. There were no allowances recorded at December 31, 2015 or 2014.

Inventory is composed of the following at December 31:

	2015	2014
Raw Materials & Supplies	$ 443	$ 544
Work-in-process	1,216	523
Finished Goods	899	761
Total Inventories	$2,558	$1,828

Property and Equipment

The Company records property and equipment at cost less accumulated depreciation, which is computed on a straight-line basis over its estimated useful lives, generally 3 to ten years.

Due to the postponement of the U.S. re-launch of ONSOLIS® (note 6), related manufacturing equipment, net, totaling $3.7 million has been deemed idle. The Company evaluates the carrying value of the idle equipment when events or changes in circumstances indicate the related carrying amount may not be recoverable. The Company has recorded an impairment of certain equipment during the year ended December 31, 2014 that cannot be used to manufacture BUNAVAIL®, totaling $0.3 million and is recorded as an impairment loss in other income (expenses), net in the accompanying consolidated statements of operations. The remaining idle equipment is being re-tooled and prepared to manufacture BUNAVAIL® to meet product demand in 2016. There was no impairment of equipment recorded during the year ended December 31, 2015 or 2013.

Intangibles and Goodwill

The Company reviews intangible assets with finite lives ("other intangible assets") for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company uses an estimate of the undiscounted cash flows over the remaining life of its other intangible assets, or related group of assets where applicable, in measuring whether the assets to be held and used will be realizable. In the event of impairment, the Company would discount the future cash flows using its then estimated incremental borrowing rate to estimate the amount of the impairment.

There were no impairment charges recognized on finite lived intangibles in 2015, 2014 or 2013.

Intangible assets with finite useful lives are amortized over the estimated useful lives as follows:

	Estimated Useful Lives
Licenses	14 years
U.S. Product rights	10-12 years
EU Product rights	11 years

Goodwill is evaluated for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying amount may not be recoverable. In the course of the evaluation of the potential impairment of goodwill, either a qualitative or a quantitative assessment may be performed. If a qualitative evaluation determines that it's more likely that not that no impairment exists, then no further analysis is performed. If a qualitative evaluation is unable to determine whether it is more likely than not that impairment has occurred, a quantitative evaluation is performed. The quantitative impairment analysis involves a two-step process. Step one involves the comparison of the fair value of the reporting unit to which goodwill relates (the Company's enterprise value) to the carrying value of the reporting unit. If the fair value exceeds the carrying value, there is no impairment. If the carrying value exceeds the fair value of the reporting unit, the Company determines the implied fair value of goodwill and records an impairment charge for any excess of the carrying value of goodwill over its implied fair value. There were no goodwill impairment charges in 2015, 2014 or 2013.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
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1. Nature of business and summary of significant accounting policies (continued):

Deferred revenue

Consistent with the Company's revenue recognition policy, deferred revenue represents cash received in advance for licensing fees, consulting, research and development services and related supply agreements. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue is classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date.

The Company is also deferring its sales of BUNAVAIL® and recognizes these revenues as product is sold through to the end user based on prescriptions filled.

Revenue recognition

Net Product Sales

Product Sales- The Company generally recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for rebates, price adjustments chargebacks and prompt payment discounts. When the Company cannot reasonably estimate the amount of future product returns, it defers revenues until the risk of product return has been substantially eliminated.

As of December 31, 2015 and 2014, the Company had $1.9 million and $0.8 million of deferred revenue related to sales to wholesalers for which future returns could not be reasonably estimated at the time of sale. Deferred revenue is recognized when the product is sold to the end user, based upon prescriptions filled. To estimate product sold to end users, the Company relies on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sales to customers. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, prompt payment and other discounts. Estimated allowances are recorded and classified as accrued expenses in the accompanying balance sheets as of December 31, 2015 and 2014 (Note 3).

Product Returns- Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products. The Company does not believe it has sufficient experience with BUNAVAIL® to estimate its returns at time of exfactory sales. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated which is at the time the product is sold through to the end user.

Rebates- The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program's administrator.

Price Adjustments and Chargebacks- The Company's estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company's listed prices of its products. In the event that the sales mix to third-party payers is different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated and such differences may be significant.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for BUNAVAIL® whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the actual redemption rates as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company's completed programs. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt Payment Discounts- The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 37 days after the invoice date depending on the customer and the products purchased.

Gross to Net Accruals-A significant majority of the Company's gross to net accruals are the result of its voucher program and Medicaid rebates, with the majority of those programs having an accrual to payment cycle of anywhere from one to three months. In addition to this relatively short accrual to payment cycle, the Company receives daily information from the wholesalers regarding their sales of the Company's products and actual on hand inventory levels of its products. During the year

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1. Nature of business and summary of significant accounting policies (continued):

ended December 31, 2015, the three large wholesalers account for approximately 77% of the Company voucher and Medicaid accruals. This enables the Company to execute accurate provisioning procedures. Consistent with the pharmaceutical industry, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products. However, since the Company does not have sufficient experience with measuring returns, at the time of exfactory sales, it records revenue when the risk of product return has been substantially eliminated.

Once the Company has adequate experience with measuring returns, it then can record sales exfactory.

License and Development agreements

The Company periodically enters into license and development agreements to develop and commercialize its products. The arrangements typically are multi-deliverable arrangements that are funded through upfront payments, milestone payments and other forms of payment. The Company currently has multiple license and development agreements that are described in notes 6, 7 and 8. Depending on the nature of the contract these revenues are classified as research and development reimbursements or contract revenue.

Deferred Cost of Sales

The Company defers its cost of sales in connection with BUNAVAIL® sales at time of exfactory sales. These costs are recognized when the product is sold through to the end user. The Company has $1.7 million and $0.7 million of deferred costs of sales for the years ended December 31, 2015 and 2014, respectively, which are included in other current assets in the accompanying balance sheet.

Cost of Sales

The cost of sales includes the direct costs attributable to the production of ONSOLIS® and BREAKYL™. It includes all costs related to creating the product at the Company's contract manufacturing locations in the U.S. and Germany. The Company's contract manufacturers bill the Company for the final product, which includes materials, direct labor costs, and certain overhead costs as outlined in applicable supply agreements. Cost of sales also includes royalty expenses that the Company owes to third parties.

For BUNAVAIL®, cost of sales includes raw materials, production costs at the Company's' two contract manufacturing sites, quality testing directly related to the product, and depreciation on equipment that we have purchased to produce BUNAVAIL®. It also includes any batches not meeting specifications and raw material yield loss. Yield losses and batches not meeting specifications are expensed as incurred. Cost of sales is recognized as actual product is sold through to the end user.

Research and Development Expenses

Research and development expenses consist of product development expenses incurred in identifying, developing and testing product candidates. Product development expenses consist primarily of labor, benefits and related employee expenses for personnel directly involved in product development activities; fees paid to professional service providers for monitoring and analyzing clinical trials; expenses incurred under joint development agreements; regulatory costs; costs of contract research and manufacturing of inventory used in testing and clinical trials; and the cost of facilities used by the Company's product development personnel.

Product development expenses are expensed as incurred and reflect costs directly attributable to product candidates in development during the applicable period and to product candidates for which the Company has discontinued development. Additionally, product development expenses include the cost of qualifying new current Good Manufacturing Practice ("cGMP") third-party manufacturers for the Company's product candidates, including expenses associated with any related technology transfer. All indirect costs (such as salaries, benefits or other costs related to the Company's accounting, legal, human resources, purchasing, information technology and other general corporate functions) associated with individual product candidates are included in general and administrative expenses.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
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1. Nature of business and summary of significant accounting policies (continued):

Advertising

Advertising costs, which include promotional expenses and the cost of placebo samples, are expensed as incurred. Advertising expenses were $4.3 million, $4.8 million and $0 for the years ended December 31, 2015, 2014 and 2013, respectively, and are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

Shipping and Handling Costs

Shipping and handling costs are included in selling, general and administrative expenses and totaled $0.06 million for the years ended December 31, 2015 and 2014, respectively. There were no shipping costs for the year ended December 31, 2013.

Stock-based compensation

The Company uses the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (warrants and options). The fair value of each option and warrant is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of the Company's Common Stock and other factors estimated over the expected term of the options. The expected term of options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

In applying the Black-Scholes options-pricing model, assumptions are as follows:

	2015	2014	2013
Expected price volatility	73.00%-76.78%	73.00%-78.05%	77.59%-81.65%
Risk-free interest rate	1.25%-1.68%	1.58%-1.70%	0.70%-1.60%
Weighted average expected life in years	6 years	6 years	5-6 years
Dividend yield	—	—	—

Fair Value of Financial Assets and Liabilities

The Company measures the fair value of financial assets and liabilities in accordance with generally accepted accounting principles of the United States ("GAAP") which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (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. GAAP also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. GAAP describes three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

Derivative instruments

The Company generally does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, the Company has entered into certain other financial instruments and contracts, such as debt financing arrangements and freestanding warrants with features that are either not afforded equity classification, embody risks not clearly and closely related to host contracts, or may be net-cash settled by the counterparty. These instruments are required to be carried as derivative liabilities, at fair value, in the Company's consolidated financial statements.

The Company estimated fair values of derivative financial instruments using the Black-Scholes option valuation technique because it embodied all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
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1. Nature of business and summary of significant accounting policies (continued):

to fairly value these instruments. Estimating fair values of derivative financial instruments required the development of significant and subjective estimates that may, and were likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques were highly volatile and sensitive to changes in the Company's trading market price which was high-historical volatility. Since derivative financial instruments were initially and subsequently carried at fair values, the Company's operating results reflected the volatility in these estimates and assumption changes.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers," which supersedes the revenue recognition requirements of Accounting Standards Codification

("ASC") Topic 605, "Revenue Recognition" and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. In July 2015, the FASB agreed to defer the effective date of the standard from January 1, 2017 to January 1, 2018, with an option that permits companies to adopt the standard as early as the original effective date. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In April 2015, the FASB issued ASU 2015-03, "Interest - Imputation of Interest". The issuance of ASU 2015-03 is part of the FASB's initiative to simplify the presentation of debt issuance costs. Under the new guidance, debt issuance costs related to a recognized debt liability must be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The amortization of such costs should continue to be calculated using the interest method and be reported as interest expense. The guidance is effective for the Company in the first quarter of fiscal 2016, with early adoption permitted. The Company early adopted the guidance during the fourth quarter of fiscal 2015 and reclassified debt issuance costs, of $0.8 million at December 31, 2014, and expanded disclosure.

The FASB's new leases standard ASU 2016-02 Leases (Topic 842) was issued on February 25, 2016. ASU 2016-02 is intended to improve financial reporting about leasing transactions. The ASU affects all companies and other organizations that lease assets such as real estate, airplanes, and manufacturing equipment. The ASU will require organizations that lease assets referred to as "Lessees" to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. An organization is to provide disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements concerning additional information about the amounts recorded in the financial statements. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet the new ASU will require both types of leases (i.e. operating and capital) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases. The leasing standard will be effective for calendar year-end public companies beginning after December 15, 2018. Public companies will be required to adopt the new leasing standard for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption will be permitted for all companies and organizations upon issuance of the standard. For calendar year-end public companies, this means an adoption date of January 1, 2019 and retrospective application to previously issued annual and interim financial statements for 2018 and 2017. Lessees with a large portfolio of leases are likely to see a significant increase in balance sheet assets and liabilities. See Note 14 for the Company's current lease commitments. The Company is currently in the process of evaluating the impact that this new leasing ASU will have on its financial statements.

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2. Liquidity:

At December 31, 2015, the Company had cash and cash equivalents of approximately $83.6 million. The Company used $3.7 million of cash from operations during the twelve months ended December 31, 2015 and had stockholders' equity of $31.7 million, versus $54.4 million at December 31, 2014. The Company expects that it has sufficient cash to manage the business into approximately the middle of 2017, although this estimation assumes that the Company does not accelerate the development of existing, or acquire other drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect the Company's cash requirements.

Additional capital may be required to support the Company's ongoing commercialization activities for BUNAVAIL®, the anticipated commercial relaunch of ONSOLIS®, the continued development of Clonidine Topical Gel and Buprenorphine Depot Injection or other products which may be acquired or licensed by the Company, and for general working capital requirements. Based on product development timelines and agreements with the Company's development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all.

3. Accounts payable and accrued liabilities:

The following table represents the components of accounts payable and accrued liabilities as of December 31:

	2015	2014
Accounts payable	$10,177	$ 9,072
Accrued price adjustments	2,207	1,094
Accrued rebates	2,581	231
Accrued chargebacks	65	14
Accrued compensation and benefits	1,917	945
Accrued royalties	431	770
Accrued clinical trial costs	584	36
Accrued manufacturing costs	183	427
Accrued sales and marketing costs	880	1,163
Accrued other	476	677
Total accounts payable and accrued expenses	$19,501	$14,429

4. Property and Equipment:

Property and equipment, summarized by major category, consist of the following as of December 31:

	2015	2014
Machinery & Equipment	$ 580	$ 680
Computer Equipment & Software	460	344
Office furniture & Equipment	200	110
Leasehold Improvements	53	9
Idle Equipment	4,983	4,432
Total	6,276	5,575
Less Accumulated Depreciation	(2,014)	(1,685)
Total property, plant & equipment, net	$ 4,262	$ 3,890

Depreciation expense for years ended December 31, 2015, 2014 and 2013 was approximately $0.3 million, $0.1 million and $0.2 million, respectively.

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5. Other Intangible Assets:

Other intangible assets, net, consisting of product rights and licenses are summarized as follows:

December 31, 2015	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net	Weighted average Useful Life
Product Rights	$ 9,050	$ (6,177)	$ 2,873	9.13
Licenses	1,900	(1,517)	383	1.72
Total Intangible Assets	$ 10,950	$ (7,694)	$ 3,256	10.85

December 31, 2014	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net	Weighted average Useful Life
Product Rights	$ 9,050	$ (5,302)	$ 3,748	9.14
Licenses	1,900	(1,422)	478	1.66
Total Intangible Assets	$ 10,950	$ (6,724)	$ 4,226	10.80

The Company incurred amortization expense on other intangible assets of approximately $1.0 million, $1.0 million and $1.1 million for the years ended December 31, 2015, 2014 and 2013, respectively. Estimated aggregate future amortization expenses for other intangible assets for each of the next five years and thereafter are as follows:

Years ending December 31,	
2016	$ 970
2017	925
2018	657
2019	657
2020	47
	$3,256

6. License and Development Agreements:

The Company periodically enters into license and development agreements to develop and commercialize its products. The arrangements typically are multi-deliverable arrangements that are funded through upfront payments, milestone payments, royalties and other forms of payment to the Company. The Company's most significant license and development agreements are as follows:

Meda License, Development and Supply Agreements

In August 2006 and September 2007, the Company entered into certain agreements with Meda AB ("Meda"), a Swedish company to develop and commercialize the Company's ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered utilizing the Company's BEMA® technology. The agreements relate to the United States, Mexico and Canada ("Meda U.S. Agreements") and to certain countries in Europe ("Meda EU Agreements"). They carry license terms that commenced on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of the patents, which begin to expire in 2020.

The Company determined that, upon inception of both the U.S. and EU Meda arrangements, all deliverables were considered one combined unit of accounting. As such, all cash payments from Meda that were related to these deliverables were initially recorded as deferred revenue. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain deliverables associated with research and development services were delivered to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, $59.7 million of the aggregate milestones and services revenue was recognized as revenue in fiscal year 2009.

The Company has determined that it is acting as a principal under the Meda Agreements and, as such, will record product supply revenue, research and development services revenue and other services revenue amounts on a gross basis in The Company's consolidated financial statements.

On March 12, 2012, the Company announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide Risk Evaluation and Mitigation Strategy ("REMS") until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of

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6. License and Development Agreements (continued):

Meda License, Development and Supply Agreements (continued)

the color in the mucoadhesive layer, raised by the FDA during an inspection of the Company's North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. ("Aveva"). While the appearance issues do not affect the product's underlying integrity, safety or performance, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of the color in the mucoadhesive layer of ONSOLIS® was found to be specific to a buffer used in its formulation. The Company modified the formulation and as of the date of this report has more than 12 months of stability data on the reformulated product that shows no signs of microcrystal formation or color changes.

On January 27, 2015, the Company announced that it had entered into an assignment and revenue sharing agreement with Meda to return to the Company the marketing authorization for ONSOLIS® for the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. Following return of the US marketing authorization from Meda, the Company submitted a prior approval supplement for the new formulation to the FDA in March 2015 that was approved in July 2015. In connection with the return of the U.S. marketing authorization by Meda to the Company in January 2015, the remaining U.S.-related deferred revenue of $1.0 million was recorded as contract revenue during the year ended December 31, 2015. U.S. related deferred revenue of $0.2 million was recorded as contract revenue during the years ended December 31, 2014 and 2013.

Recent efforts to extend the Company's supply agreement with its ONSOLIS® manufacturer, Aveva, which is now a subsidiary of Apotex, Inc. ("Apotex"), have been unsuccessful and the agreement expired. However, the Company has identified an alternate supplier and requested guidance from the FDA on the specifics required for obtaining approval to supply product from this new vendor. This will in part help the Company to better determine when ONSOLIS® may be available to the marketplace and help assist the Company as they seek a new commercial partnership arrangement. Based on the Company's current estimates, they believe that they will submit the necessary documentation to FDA for qualification of the new manufacturer by the fourth quarter of 2016 and have approval by the first half of 2017.

Endo License and Development Agreement

In January 2012, the Company entered into a License and Development Agreement with Endo Pharmaceuticals, Inc. ("Endo") pursuant to which the Company granted Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company's BELBUCA™ product and to complete U.S. development of such product candidate for purposes of seeking FDA approval (the "Endo Agreement"). BELBUCA™ is for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BELBUCA™ and to sell the product worldwide. Although Endo has obtained all such necessary rights, the Company had agreed under the Endo Agreement to be responsible for the completion of certain clinical trials regarding BELBUCA™ (and to provide clinical trial materials for such trials) necessary to submit a New Drug Application ("NDA") to the FDA, which occurred in December 2014 and was accepted February 2015, in order to obtain approval of BELBUCA™ in the U.S., which occurred October 2015). The Company was responsible for development activities through the filing of the NDA in the U.S., while Endo was responsible for the development following the NDA submission as well as the manufacturing, distribution, marketing and sales of BELBUCA™ on a worldwide basis. In addition, Endo was responsible for all filings required in order to obtain regulatory approval of BELBUCA™.

Pursuant to the Endo Agreement, the Company has received (or is expected to receive upon satisfaction of applicable conditions) the following payments (some portion(s) of which will be utilized by the Company to support its development obligations under the Endo Agreement with respect to BELBUCA™):

- $30 million non-refundable upfront license fee (earned in January 2012);
- $15 million for enhancement of intellectual property rights (earned in May 2012);
- $20 million for full enrollment in two clinical trials ($10 million earned in January 2014 and $10 million earned in June 2014);
- $10 million upon FDA acceptance of filing NDA (earned in February 2015);
- $50 million upon regulatory approval, earned in October 2015 and received in November 2015, with the revenue recognition treatment for $20 million of such $50 million payment deferred due to the fact that all or a portion of such

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6. License and Development Agreements (continued):

Endo License and Development Agreement (continued)

$20 million is contingently refundable to Endo based on a third party generic introduction in the U.S. during the patent extension period from 2020 to 2027. Should such introduction occur any time during the 2020 to 2027 period, a refund would be due to Endo based on the number of complete calendar months beyond December 31, 2019 where the first generic was sold over the denominator of 84 months multiplied by $20 million. For example, if a generic product were to be introduced in the U.S. in January of 2026, that would mean that 72 of the 84 months of patent exclusivity would have been earned and 12 months would have to be refunded. The calculation would be 12/84, multiplied by $20 million, for a refund of $2.9 million. The method of the refund payment to Endo would be made first by crediting against milestone payments owed to the Company, second by reducing the royalty by 50% until the $2.9 million is paid back, and third by the Company making a payment in the amount due to Endo. Otherwise, the $20 million will be earned as revenue each month over the patent extension period from 2020 to 2027;

- up to an aggregate of $55 million based on the achievement of four separate post-approval sales thresholds; and
- sales-based royalties in a particular percentage range on U.S. sales of BELBUCA™, and royalties in a lesser range on sales outside the United States, subject to certain restrictions and adjustments.

The Company has assessed its arrangement with Endo and the Company's deliverables thereunder at inception to determine: (i) the separate units of accounting for revenue recognition purposes, (ii) which payments should be allocated to which of those units of accounting and (iii) the appropriate revenue recognition pattern or trigger for each of those payments. The assessment requires subjective analysis and requires management to make judgments, estimates and assumptions about whether deliverables within multiple-element arrangements are separable and, if so, to determine the amount of arrangement consideration to be allocated to each unit of accounting.

At the inception of the Endo arrangement, the Company determined that the Endo Agreement was a multi-deliverable arrangement with three deliverables: (1) the license rights related to BELBUCA™, (2) services related to obtaining enhanced intellectual property rights through the issuance of a particular patent and (3) clinical development services. The Company concluded that the license delivered to Endo at the inception of the Endo Agreement has stand-alone value. It was also determined that there was a fourth deliverable, the provision of clinical trial material ("CTM"). The amounts involved are, however, immaterial and delivered in essentially the same time frame as the clinical development services. Accordingly, the Company did not separately account for the CTM deliverable, but considers it part of the clinical development services deliverable.

The initial non-refundable $30 million license fee was allocated to each of the three deliverables based upon their relative selling prices using best estimates. The analysis of the best estimate of the selling price of the deliverables was based on the income approach, the Company's negotiations with Endo and other factors, and was further based on management's estimates and assumptions which included consideration of how a market participant would use the license, estimated market opportunity and market share, the Company's estimates of what contract research organizations would charge for clinical development services, the costs of clinical trial materials and other factors. Also considered were entity specific assumptions regarding the results of clinical trials, the likelihood of FDA approval of the subject product and the likelihood of commercialization based in part on the Company's prior agreements with the BEMA® technology.

Based on this analysis, $15.6 million of the up-front license fee was allocated to the license and $14.4 million to clinical development services (which is inclusive of the cost of CTM). Although the intellectual property component was considered a separate deliverable, no distinct amount of the up-front payment was assigned to this deliverable because the Company determined the deliverable to be perfunctory. The amount allocated to the license was recognized as revenue in fiscal year 2012. The portion of the upfront license fee allocated to the clinical development services deliverable of $14.4 million is being recognized as those services are performed. The Company estimated that such clinical development services would extend into the first half of 2015. Such services were completed by March 2015 and resulted in the recognition of $0.4 million, $2.5 million and $6.3 million as contract revenue in fiscal years, 2015, 2014 and 2013, respectively, in the accompanying consolidated statements of operations.

The term of the Endo Agreement shall last, on a country-by-country basis, until the later of: (i) 10 years from the date of the first commercial sale of BELBUCA™ in a particular country or (ii) the date on which the last valid claim of the Company's patents covering BELBUCA™ in a particular country has expired or been invalidated. The Endo Agreement shall be subject to termination by Endo, at any time, upon a specific timeframe of prior written notice to the Company and under certain other conditions by either party as specified in the Endo Agreement.

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6. License and Development Agreements (continued):

Endo License and Development Agreement (continued)

The remaining milestone payments are expected to be recognized as revenue as they are achieved, except that $20 Million of the $50 million regulatory approval milestone received in November for the Patent Life Extension is contingently refundable from 2020 to 2027 and revenue related to such contingently refundable milestone has been deferred for future recognition. The $20 million will be earned over the extended 84 month patent period as it is contingently refundable pending a generic product commercially launched in the U.S. during the patent extension period. Sales threshold payments and sales-based royalties will be recognized as they accrue under the terms of the Endo Agreement.

The Company is reimbursed by Endo for certain contractor costs when these costs go beyond set thresholds as outlined in the Endo Agreement. Endo reimburses the Company for this spending at cost and the Company receives no mark-up or profit. The gross amount of these reimbursed research and development costs are reported as research and development reimbursement revenue in the accompanying consolidated statements of operations. The Company acts as a principal, has discretion to choose suppliers, bears credit risk and may perform part of the services required in the transactions. Therefore, these reimbursements are treated as revenue to the Company. The actual expenses creating the reimbursements are reflected as research and development expense.

Beginning in March 2014, total reimbursable contractor costs exceeded a set threshold, at which point all such expenses are to be borne at a rate of 50% by Endo and 50% by the Company. Endo has continued to reimburse the Company for 100% of such costs, with 50% thereof to be taken by Endo as a credit against potential future milestones associated with achievement of certain regulatory events. As of December 31, 2014, the Company has recorded approximately $6 million of such cumulative payment in deferred revenue current in the accompanying consolidated balance sheet. This credit amount was deducted from the $50 million regulatory approval milestone earned by the Company in October 2015. During the years ended December 31, 2015, 2014 and 2013, the Company recognized $0.9 million, $12.7 million and $2.8 million, respectively, of reimbursable expenses related to the Endo Agreement, which is recorded as research and development reimbursement revenue on the accompanying consolidated statement of operations.

On December 23, 2014, the Company and Endo announced the submission of a NDA for BELBUCA™ to the FDA, which was accepted February 23, 2015. On October 26, 2015, the Company and Endo announced that the FDA approved BELBUCA™ (on October 23, 2015). FDA approval of BELBUCA™ triggered a milestone payment to the Company from Endo of $50 million pursuant to the Endo Agreement, less approximately $6 million of the aforementioned cumulative pre-payments received and recorded in deferred revenue, current in the accompanying consolidated balance sheet. The Company received payment of such milestone in November 2015. The company deferred $20 million of such $50 million payment having been deferred under GAAP due to the fact that all or a portion of such $20 million is contingently refundable to Endo. The $20 million will be earned over the extended 84 month patent extension period from 2020 to 2027 as it is contingently refundable in the event a generic product is commercially launched in the U.S. That leaves the remaining amount from this $50 million milestone of $30 million recognized as revenue during the year ended December 31, 2015.

On February 22, 2016, the Company and Endo announced the commercial availability of BELBUCA™ buccal film. BELBUCA™, distributed and promoted by Endo, is now available nationwide.

7. License Obligations:

Arcion License Agreement

On March 26, 2013, the Company entered into a license agreement with Arcion Therapeutics, Inc. (the "Arcion Agreement") pursuant to which Arcion granted to the Company an exclusive commercial world-wide license, with rights of sublicense, under certain patent and other intellectual property rights related to in-process research and development to develop, manufacture, market, and sell gel products containing clonidine (or a derivative thereof) for the treatment of painful diabetic neuropathy ("PDN") and other indications (the "Arcion Products").

Pursuant to the Arcion Agreement, the Company is responsible for using commercially reasonable efforts to develop and commercialize Arcion Products, including the use of such efforts to conduct certain clinical trials within certain time frames.

The Company is required to make the following payments to Arcion:

- $2.5 million upon filing and acceptance by the FDA of an NDA with respect to an Arcion Product, which will be payable, at the Company's option, in cash or unregistered shares of Common Stock (with such shares being subject to a nine month lock-up and certain limitations on sale thereafter); and

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7. License Obligations (continued):

Arcion License Agreement

- up to a potential $60 million in cash payments upon achieving certain pre-determined sales thresholds in the U.S., none of which occur prior to achieving at least $200 million in U.S. net sales.

In addition, the Company shall pay Arcion $35 million in cash on initial FDA approval of an Arcion Product, unless: (i) the Company does not receive at least $70 million in FDA approval-related milestone payments from its US sublicensees (if any sublicenses are involved) with respect to the Arcion Product, in which case the Company shall pay Arcion a prorated amount between $17.5 million and $35 million based on the total amount of such milestone payments received by the Company and its affiliates from its sublicenses (if any sublicenses are involved); or (ii) the FDA requires or recommends the performance of a capsaicin challenge test (to see if C-fiber function is present in the skin by determining if subjects experience pain, and to determine pain intensity if present) as a precondition or precursor to the prescribing of the Arcion Product (as a condition of approval, a labeling requirement, or otherwise), in which case such milestone shall be reduced to $17.5 million, but the first and second sales threshold payments (as part of the $60 million in cash payments) described above shall each be increased by $8 million.

All milestone payments due to Arcion under the Arcion Agreement are payable only once each.

In addition to the milestones set forth above, the Company will pay royalties to Arcion based upon sales of Arcion Products by the Company, its affiliate and sub-licensees (if any), all as defined in the Arcion Agreement.

In addition, in the event the amount due upon FDA approval of the Arcion Product in the U.S. is less than $35 million for any reason other than an FDA requirement or recommendation of a capsaicin challenge test, as described above, the Company shall pay Arcion a portion of any milestone payments received by the Company and its affiliates from their sublicensees on the basis of any events occurring in the U.S. following FDA approval but prior to (and including) first commercial sale of an Arcion Product in the U.S., and certain of the payments to Arcion referred to above shall also be subject to upward adjustment (with such upward adjustments payable in the form of cash or unregistered shares of the Company's Common Stock, as elected solely by the Company), until such time as the sum of all such additional payments and upward adjustments (including the value of any issuances of stock, if elected by the Company) and the initial amount paid on the initial FDA approval totals $35 million.

The term of the Arcion Agreement continues, on a country-by-country and product-by-product basis, until the earlier of (i) the expiration of the royalty term for a particular Arcion Product in a particular country or (ii) the effective date of termination by either party pursuant to customary termination provisions. The royalty term for any given country is the later of (i) the first date there are no valid claims against any Arcion patent, (ii) expiration of patent exclusivity or (iii) tenth anniversary of the first commercial sale.

On March 30, 2015, the Company announced that the primary efficacy endpoint in its initial Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, the Company initiated a second study. The study incorporated significant learnings from previously conducted studies and involved tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. The final study subject is expected to complete treatment by the end of 2016.

Evonik definitive Development and Exclusive License Option Agreement:

On October 27, 2014, the Company entered into a definitive Development and Exclusive License Option Agreement (the "Development Agreement") with Evonik Corporation, ("Evonik") to develop and commercialize an injectable, extended release, microparticle formulation of buprenorphine for the treatment of opioid dependence (the "Evonik Product"). Under the Development Agreement, the Company also has the right to pursue development of the Evonik Product for pain management.

Under the Development Agreement, Evonik has also granted to the Company two exclusive options to acquire exclusive worldwide licenses, with rights of sublicense, to certain patents and other intellectual property rights of Evonik to develop and commercialize certain products containing buprenorphine. If such options are exercised, such licenses would be memorialized in the Evonik License Agreement (as defined below).

Pursuant to the Development Agreement, Evonik is responsible for using commercially reasonable efforts to develop a formulation for the Evonik Product in accordance with a work plan mutually agreed upon by the parties (the "Evonik Project").

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7. License Obligations (continued):

Evonik definitive Development and Exclusive License Option Agreement (continued):

Should the Evonik Project proceed past the formulation stage, Evonik also has the right to manufacture clinical and commercial supplies of Evonik Product, such manufacturing arrangement to be negotiated by the parties in good faith in a formal License and Supply Agreement(s) (the "Evonik License Agreement"), with such Evonik License Agreement covering Evonik's intellectual property rights to be entered into between the parties if certain conditions are met and terms are mutually agreed upon.

Should Evonik and the Company enter into the License Agreement following the attainment of a Phase 1 ready formulation of the Evonik Product for one or both of the opioid dependence or pain management indications, the Company would pay Evonik a non-refundable, non-creditable one-time payment in conjunction with certain future regulatory filings and approvals and royalties on net sales of the Evonik Product.

The Development Agreement contains customary termination provisions, and the Company may additionally terminate the Development Agreement at any time after the completion of certain enumerated tasks as provided in the Development Agreement, for any reason or no reason, by providing written notice of termination to Evonik. Upon termination of the Development Agreement, Evonik will be paid any amounts owed to Evonik in accordance with the estimated budget for work performed under the Development Agreement through the effective date of termination, including any reasonable, documented, non-cancelable third party costs and any reasonable, documented wind-down costs reasonably incurred by Evonik in connection with the Evonik Project. Should the Company terminate for reasons other than for a material, uncured breach by Evonik or Evonik's bankruptcy, Evonik shall have the right to use any and all data and intellectual property generated under the Evonik Project for any purpose.

8. Other license agreements and acquired product rights:

Kunwha License Agreement

In May 2010, the Company entered into a License and Supply Agreement (the "Kunwha License Agreement") with Kunwha to develop, manufacture, sell and distribute the Company's BEMA® Fentanyl product in the Republic of Korea (the "Kunwha Territory"). BEMA® Fentanyl is marketed as ONSOLIS® in North America. The Kunwha License Agreement was for a term beginning on May 26, 2010 until the date of expiration of the patents, or July 23, 2027, whichever is later.

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Kunwha Territory, while the Company will retain all other licensing rights to the Licensed Product not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million (net of taxes approximating $0.25 million) and was responsible to make certain milestone payments which could have aggregated up to $1.3 million (net of taxes approximating $1.1 million). In August 2015, Kunwha paid to the Company a milestone payment of $0.3 million towards the aggregate total of $1.3 million, however, the Kunwha License Agreement was terminated on August 31, 2015.

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement with TTY Biopharm Co., Ltd. ("TTY") for the exclusive rights to develop and commercialize BEMA® Fentanyl in the Republic of China, Taiwan. The agreement results in potential milestone payments to the Company of up to $1.3 million, which include an upfront payment of $0.3 million that was received in 2010. In addition, the Company will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filing of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The term of the agreement with TTY is for the period from October 4, 2010 until the date fifteen years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

On July 29, 2013, the Company announced the regulatory approval of BEMA® Fentanyl in Taiwan, where the product will be marketed under the brand name PAINKYL™. The approval in Taiwan resulted in a milestone payment of $0.3 million to the Company, which was received in the third quarter 2013, and recorded as contract revenue in the accompanying consolidated statement of operations for the year ended December 31, 2013.

In February 2016, the Company received a payment of $0.2 million from TTY, which related to royalties based on product purchased by TTY of PAINKYL™ in Taiwan.

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9. Note Payable:

On May 29, 2015, the Company entered into a $30 million secured loan facility (the "Loan") with MidCap Financial Trust, as agent and lender ("MidCap"), pursuant to the terms and conditions of that certain Amended and Restated Credit and Security Agreement, dated as of May 29, 2015 (the "Credit Agreement"), between the Company and MidCap. The Credit Agreement is a restatement, amendment and modification of a prior Credit and Security Agreement, dated as of July 5, 2013 (the "Prior Agreement") between the Company, MidCap Financial SBIC, LLP, a predecessor to MidCap, and certain lenders thereto. The Credit Agreement restructures, renews, extends and modifies the obligations under the Prior Agreement and the other financing documents executed in connection with the Prior Agreement (the "Prior Loan"). The Company received net Loan proceeds in the aggregate amount of approximately $20.1 million and will use the Loan proceeds for general corporate purposes or other activities of the Company permitted under the Credit Agreement.

The Loan has a term of 42 months, with interest only payments for the first 12 months. The interest rate is 8.45% plus a LIBOR floor of 0.5% (total of 8.95% at December 31, 2015), with straight line amortization of principal payments commencing on June 1, 2016, in an amount equal to $1 million per month. Upon execution of the Credit Agreement, the Company paid to MidCap a closing fee from the prior loan of approximately $0.4 million. Upon repayment in full of the Loan, the Company is obligated to make a final payment fee equal to 2.75% of the aggregate Loan amount. The 2.75% exit fee has been recorded as deferred loan costs, the current portion of which is included in notes payable, current maturities, net and the long-term portion is in note payable, less current maturities, net, being amortized over the life of the loan. The amounts payable are recorded as other long-term liabilities.

In addition, the Company may prepay all or any portion of the Loan at any time subject to a prepayment premium of: (i) 5% of the Loan amount prepaid in the first year following the execution of the Credit Agreement and (ii) 3% of the Loan amount prepaid in each year thereafter.

The obligations of the Company under the Credit Agreement are secured by a first priority lien in favor of MidCap on substantially all of the Company's existing and after-acquired assets, but excluding certain intellectual property and general intangible assets of the Company (but not any proceeds thereof). The obligations of the Company under the Credit Agreement are also secured by a first priority lien on the equity interests held by the Company. The Company entered into and reaffirmed, as applicable, customary pledge and intellectual property security agreements to evidence the security interest in favor of MidCap.

Under the Credit Agreement, the Company is subject to affirmative covenants which are customary for financings of this type, including, but not limited to, the obligations of the Company to: (i) maintain good standing and governmental authorizations, (ii) provide certain information and notices to MidCap, (iii) deliver quarterly and annual financial statements to MidCap, (iv) maintain insurance, property and books and records, (v) discharge all taxes, (vi) protect their intellectual property and (vii) generally protect the collateral granted to MidCap.

The Company is also subject to negative covenants customary for financings of this type, including, but not limited to, that they may not: (i) enter into a merger or consolidation or certain change of control events without complying with the terms of the Credit Agreement, (ii) incur liens on the collateral, (iii) incur additional indebtedness, (iv) dispose of any property, (v) amend material agreements or organizational documents, (vi) change their business, jurisdictions of organization or their organizational structures or types, (vii) declare or pay dividends (other than dividends payable solely in Common Stock), (viii) make certain investments or acquisitions except under certain circumstances as set forth in the Credit Agreement, or (ix) enter into certain transactions with affiliates, in each case subject to certain exceptions provided for in the Credit Agreement. Notwithstanding the foregoing, the Credit Agreement amends certain negative covenants contained in the Prior Agreement such that (i) licensing and acquisitions are added as permitted business activities of the Company and (ii) the Company is no longer required to obtain the prior written consent of MidCap for any in-licensing, product or entity acquisitions by the Company by way of merger or consolidation, so long as no event of default has occurred and certain financial metrics are adhered to.

The Credit Agreement provides for several events of default under the Loan. Upon the occurrence of any event of default, the Company's obligations under the Credit Agreement will bear interest at a rate equal to the lesser of: (i) 4% above the rate of interest applicable to such obligations immediately prior to the occurrence of the event of default and (ii) the maximum rate allowable under law.

The debt discount is related to warrants on the Prior Loan, which was amended in 2015. The discount is being amortized to interest expense over the life of the amended loan.

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The following table represents future maturities of the MidCap obligation as of December 31, 2015:

2016	$ 7,000
2017	12,000
2018	11,000
Total maturities	$30,000
Unamortized discount and loan costs	(1,125)
Total Midcap obligation	$28,875

10. Derivative Financial Instruments:

The following tabular presentation reflects the components of derivative financial instruments for the year ended December 31:

	2015	2014	2013
Derivative (loss) gain in the accompanying statements of operations is related to the individual derivatives as follows:			
Free standing warrants assets, related party	—	$ —	$ (51)
Free standing warrants liabilities	—	(13,167)	172
	$—	$(13,167)	$121

	2015	2014	2013
Shares into which derivative liability can be settled:			
Free standing warrants	—	—	1,999,436

11. Income taxes:

The Company did not record income tax expense in 2015, 2014 or 2013 as it had incurred net operating losses. The Company has recognized valuation allowances for all deferred tax assets for years ending 2015, 2014 and 2013. Reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	2015	2014	2013
Federal statutory income tax rate	34.00%	34.00%	34.00%
State taxes, net of federal benefit	3.45	3.45	3.45
Permanent differences-derivative loss (gain)	—	(9.10)	0.11
Permanent differences-other	(4.66)	2.24	(1.07)
Research and development ("R&D") credit	0.95	2.73	4.91
Other	0.64	0.61	0.64
Increase in valuation allowance	(34.38)	(33.93)	(42.04)
	0.00%	0.00%	0.00%

The tax effects of temporary differences and net operating losses that give rise to significant components of deferred tax assets and liabilities consist of the following:

	December 31,	
Deferred tax assets (liabilities)	**2015**	**2014**
Deferred revenue	$ 7,490	$ 315
Basis difference in equipment	(1,013)	(975)
Basis difference in intangibles	1,122	1,102
Accrued liabilities and other	1,563	360
R&D credit	11,138	11,316
Stock options	1,151	462
Net operating loss carry-forward	63,509	59,481
	84,960	72,061
Less: valuation allowance	(84,960)	(72,061)
	$ —	$ —

In accordance with GAAP, the Company is required to reduce any deferred tax asset by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the

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11. Income taxes (continued):

amount which is more likely than not to be realized. As a result, the Company recorded a valuation allowance with respect to all of the Company's deferred tax assets.

The Company has a federal net operating loss carry forward ("NOLs") of approximately $168 million as of December 31, 2015. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the NOLs and other deductions which are available to the Company. The portion of the NOLs incurred prior to May 16, 2006 is subject to this limitation. As such, the use of these NOLs to offset taxable income is limited to approximately $1.5 million per year. The Company's State NOLS are approximately $178 million as of December 31, 2015. These loss carryforwards expire principally beginning in 2020 through 2035 for federal and 2030 for state purposes.

12. Stockholders' equity:

Common Stock

In November 2013, the Company filed a shelf registration statement which registered up to $75 million of the Company's securities for potential future issuance, and such registration statement was declared effective on December 18, 2013.

Concurrent with the filing of such registration statement, the Company established an "at-the-market" offering program utilizing the universal shelf registration for up to $15 million of Common Stock. In January 2014, the Company sold 658,489 shares of Common Stock under such offering program for approximate net proceeds of $3.9 million. In September and October 2014, the Company sold 529,010 and 116,911 shares of Common Stock, respectively, under such offering program for approximate net proceeds of $8.7 million and $1.9 million, respectively.

On February 7, 2014, the Company entered into a definitive Securities Purchase Agreement with certain institutional investors relating to a registered direct offering by the Company of 7,500,000 shares of the Company's Common Stock, par value $.001 per share. The shares were sold at a price of $8.00 per share, yielding net offering proceeds of $58.2 million. The offering price per share was determined based on an approximately 3.1% discount to the closing price of the Common Stock on February 7, 2014.

On July 2, 2015, the Company filed a shelf registration statement which registered up to $150 million of the Company's securities for potential future issuance, and such registration statement was declared effective on July 13, 2015. Concurrent with the filing of such registration statement, the Company established an "at-the-market" offering program utilizing the universal shelf registration for up to $40 million of Common Stock.

During the years ended December 31, 2015, 2014 and 2013, Company employees, directors and affiliates exercised approximately 0.2 million, 1.3 million and 0.1 million stock options, respectively, with net proceeds to the Company of approximately $0.8 million, 4.6 million and $0.4 million, respectively.

Preferred Stock

The Company had authorized five million "blank check" shares of $.001 par value convertible preferred stock. On December 3, 2012, the Company closed a registered direct offering, issuance and sale of Series A Preferred. The final amount of Series Preferred issued in the offering was an aggregate of 2,709,300 shares of Series A Preferred. In the event of the Company's liquidation, dissolution or winding up, holders of the Series A Preferred will receive a payment equal to $.001 per share of Series A Preferred before any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred, the holders of Series A Preferred will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

During the year ended December 31, 2015, 45,845 shares of Series A Preferred were converted to equal shares of the Company's common stock. At December 31, 2015, 2,093,155 shares of Series A Preferred were outstanding and 2,290,700 shares of "blank check" preferred stock remain authorized but undesignated. During the year ended December 31, 2014, 570,300 shares of Series A Preferred were converted to equal shares of the Company's common stock. There were no conversions of Series A Preferred during the year ended December 31, 2013.

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12. Stockholders' equity (continued):

Restricted Stock Units

During the year ended December 31, 2015, 2,421,911 RSUs, were granted to members of the Company's executive officers, board of directors and employees, with a fair market value of approximately $33.5 million. The fair value of restricted units is determined using quoted market prices of the Common Stock and the number of shares expected to vest. These RSUs were issued under the Company's 2011 Equity Incentive Plan, as amended, and vest in equal installments over three years for executive officers and employees, and vest half in August 2015 and half in the following year for the board of directors. Restricted stock activity during the year ended December 31, 2015 was as follows:

	Number of Restricted Shares	Weighted Average Fair Market Value Per RSU
Outstanding at January 1, 2015	2,849,076	$ 7.91
Granted:		
Executive officers	2,102,615	14.63
Directors	150,000	9.31
Employees	169,296	8.03
Vested	(857,677)	13.06
Forfeitures	(115,156)	10.85
Outstanding at December 31, 2015	4,298,154	$ 10.23

Performance Long Term Incentive Plan

In December 2012, the Company's Board of Directors (the "Board") approved the BDSI Performance Long Term Incentive Plan ("LTIP"). The LTIP is designed as an incentive for the Company's senior management to generate revenue for the Company. The LTIP consists of RSUs (which are referred to in this context as Performance RSUs) which are rights to acquire shares of Common Stock. All Performance RSUs granted under the LTIP will be granted under the Company's 2011 Equity Incentive Plan (as the same may be amended, supplemented or superseded from time to time) as "Performance Compensation Awards" under such plan. The participants in the LTIP are either named executive officers or senior officers of the Company.

The term of the LTIP began with the Company's fiscal year ended December 31, 2012 and lasts through the fiscal year ended December 31, 2019. The total number of Performance RSUs covered by the LTIP is 1,078,000, of which 978,000 were awarded in 2012 (with 100,000 Performance RSUs being reserved for future hires and of that reserve, 35,000 Performance RSUs were awarded in 2015). The Performance RSUs under the LTIP did not vest upon granting, but instead are subject to potential vesting each year over the 8 year term of the LTIP depending on the achievement of pre-defined revenue amounts by the Company, as reported in its Annual Report on Form 10-K. During the years ended December 31, 2015, 2014 and 2013, a total of 21,356, 4,447 and 8,986 RSUs vested, respectively, subject to performance criteria.

Stock options

The Company has a 2011 Equity Incentive Plan. During the 2015 Annual Meeting of Stockholders (the "Annual Meeting"), stockholders approved an amendment to the Company's 2011 Equity Incentive Plan to increase the number of shares of common stock authorized for issuance under the plan by 2,250,000 shares from 8,800,000 to 11,050,000.

An additional 1,938,039 shares of Common Stock underlying options previously granted under the Company's Amended and Restated 2001 Incentive Plan remain outstanding and exercisable. The Company's Amended and Restated 2001 Incentive Plan expired in July 2011 and no new securities may be issued thereunder. Options may be awarded during the ten-year term of the 2011 Equity Incentive Plan to Company employees, directors, consultants, sales force and other affiliates.

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12. Stockholders' equity (continued):

Stock option activity for the years ended December 31, 2015, 2014 and 2013 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2013	4,279,919	$ 3.70	$ 4,572
Granted in 2013:			
Officers and Directors	55,659	$ 5.39	
Others	223,135	4.47	
Exercised	(115,667)	3.25	
Forfeitures	(250,119)	2.89	
Outstanding at December 31, 2013	4,192,927	$ 3.82	$ 9,146
Granted in 2014:			
Others	420,480	13.86	
Exercised	(1,332,563)	3.48	
Forfeitures	(84,744)	5.26	
Outstanding at December 31, 2014	3,196,100	$ 4.32	$ 22,881
Granted in 2015:			
Others	684,629	8.14	
Exercised	(235,480)	3.52	
Forfeitures	(247,720)	12.65	
Outstanding at December 31, 2015	3,397,529	$ 5.42	$ 3,124

Options outstanding at December 31, 2015 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.00 – 5.00	1,722,191	3.96	$ 2.98	
$5.01 – 10.00	1,411,006	5.28	$ 6.69	
$10.01 – 15.00	131,797	9.07	$ 12.59	
$15.01 – 20.00	132,535	8.76	$ 16.38	
	3,397,529			$ 3,124

Options exercisable at December 31, 2015 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.00 – 5.00	1,689,064	3.90	$ 2.95	
$5.01 – 10.00	799,926	2.06	$ 6.33	
$10.01- 15.00	7,915	8.56	$ 12.44	
$15.01- 20.00	6,279	8.74	$ 15.95	
	2,503,184			$ 3,114

The weighted average grant date fair value of options granted during the years ended December 31, 2015, 2014 and 2013 was $4.99, $7.18 and $3.28, respectively. There were no options granted during the years ended December 31, 2015, 2014 or 2013 whose exercise price was lower than the estimated market price of the stock at the grant date.

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12. Stockholders' equity (continued):

Nonvested stock options as of December 31, 2015, and changes during the year then ended, are as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Intrinsic Value
Nonvested at January 1, 2015	655,547		
Granted	684,629		
Vested	(207,797)		
Forfeited	(238,034)		
Nonvested at December 31, 2015	894,345	$ 9.12	$ 10

As of December 31, 2015, there was approximately $25.22 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next four years.

Warrant:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements.

The Company issued warrants to purchase 357,356 shares of Common Stock at a price of $4.20 in connection with a loan financing in July 2013 (note 9). The warrants had a fair value of approximately $1 million at the date of the grant. These warrants were exercised during 2014 and are no longer outstanding.

Reclassification of derivative liability to equity

During the year ended December 31, 2014, warrants by various investors were exercised to purchase 2,217,520 shares of Common Stock at prices ranging from $3.12 to $5.00 per share. Until the time of exercise, 1,999,153 of the aforementioned warrants were treated as a derivative liability. Upon exercise of the warrants, these amounts were reclassified to equity based on the fair value on the date of exercise.

During the year ended December 31, 2013, warrants by an investor were exercised to purchase 10,000 shares of Common Stock at $5.00 per share. Until the time of exercise, the aforementioned warrants were treated as a derivative liability. Upon exercise of the warrants, these amounts were reclassified to equity based on the fair value on the date of exercise.

Earnings Per Share

During the year ended December 31, 2015, 2014 and 2013, outstanding stock options, RSUs, warrants and convertible preferred stock of 9,788,838, 8,184,460 and 11,406,369, respectively, were not included in the computation of diluted earnings per share, because to do so would have had an antidilutive effect.

Recovery of Stockholder Short Swing Profit

During the years ended December 31, 2015 and 2014, an executive officer of the Company paid a total of approximately $0.006 million to the Company and three executive officers of the Company paid a total of approximately $0.08 million to the Company, respectively, representing the disgorgement of short swing profits under Section 16(b) under the Exchange Act. The amount was recorded as additional paid-in capital.

13. Retirement plan:

The Company sponsors a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation requirements. Participants may contribute up to 90% of their eligible earnings, as limited by law. The Company makes a matching contribution equal to 100% on the first 5% of participant contributions to the plan. The Company made contributions of approximately $0.2 million in all years, 2015, 2014 and 2013.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

14. Commitments and contingencies:

Operating leases

Since November 2007, the Company has leased space for their corporate offices. Lease expense for the corporate office was $0.3 million, $0.1 million and $0.1 million for each of the years ended December 31, 2015, 2014 and 2013, respectively. The Company leased new space for their corporate offices, which began March 2015 for 89 months.

The future minimum commitment on the new operating lease at December 31, 2015 is as follows:

Years ending December 31,	
2016	$ 318
2017	318
2018	318
2019	318
2020	318
Thereafter	503
	$2,093

Indemnifications

The Company's directors and officers are indemnified against costs and expenses related to stockholder and other claims (i.e., only actions taken in their capacity as officers and directors) that are not covered by the Company's directors and officers insurance policy. This indemnification is ongoing and does not include a limit on the maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost. No events have occurred as of December 31, 2015 which would trigger any liability under the agreement.

Certain Rights of CDC

The Company and CDC IV, LLC ("CDC") are parties to a Clinical Development and License Agreement, dated July 15, 2005 (as amended, the "CDLA") pursuant to which CDC has previously provided funds to the Company for the development of the Company's ONSOLIS® product. CDC is entitled to receive a mid-single digit royalty based on net sales of ONSOLIS®, including minimum royalties of $375,000 per quarter beginning in the second full year following commercial launch. The royalty term expires upon the latter of expiration of the patent or generic entry into a particular country.

In September 2007, in connection with CDC's consent to the North American Meda transaction, the Company, among other transactions with CDC, granted CDC a 1% royalty on sales of the next BEMA® product, which will be BUNAVAIL®. CDC's right to the royalty shall immediately terminate at any time if annual net sales of BUNAVAIL® equal less than $7.5 million in any calendar year following the third anniversary of initial launch of the product and CDC receives $0.02 million in three (3) consecutive quarters as payment for CDC's one percent (1%) royalty during such calendar year

The Company expects to record such royalties as costs of sales occur.

Litigation Related To ONSOLIS®

On November 2, 2010, MonoSol Rx LLC ("MonoSol") filed an action against the Company and its commercial partners for ONSOLIS® in the Federal District Court of New Jersey (the DNJ) for alleged patent infringement and false marking. The Company was formally served in this matter on January 19, 2011. MonoSol claims that the Company's manufacturing process for ONSOLIS®, which has never been disclosed publicly and which the Company and its partners maintain as a trade secret, infringes its patent (United States Patent No. 7,824,588) (the '588 Patent). Of note, the BEMA® technology itself is not at issue in the case, nor is BELBUCA™ or BUNAVAIL®, but rather only the manner in which ONSOLIS®, which incorporates the BEMA® technology, is manufactured. Pursuant to its complaint, MonoSol is seeking an unspecified amount of damages, attorney's fees and an injunction preventing future infringement of MonoSol's patents.

The Company strongly refutes as without merit MonoSol's assertion of patent infringement, which relates to the Company's confidential, proprietary manufacturing process for ONSOLIS®. On September 12, 2011, the Company filed a request for inter partes reexamination in the United States Patent and Trademark Office (USPTO) of MonoSol's '588 Patent demonstrating that all claims of such patent were anticipated by or obvious in the light of prior art references, including several prior art references

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

14. Commitments and contingencies (continued):

not previously considered by the USPTO, and thus invalid. On September 16, 2011, the Company filed a motion for stay pending the outcome of the reexamination proceedings, which subsequently was granted.

In November 2011, the USPTO rejected all 191 claims of MonoSol's '588 Patent. On January 20, 2012, the Company filed requests for reexamination before the USPTO of MonoSol's US patent No 7,357,891 (the '891 Patent), and No 7,425,292 (the '292 Patent), the two additional patents asserted by MonoSol, demonstrating that all claims of those two patents were anticipated by or obvious in the light of prior art references, including prior art references not previously considered by the USPTO, and thus invalid. The USPTO granted the requests for reexamination with respect to MonoSol's '292 and '891 Patents. In its initial office action in each, the USPTO rejected every claim in each patent.

As expected, in the '891 Patent and '292 Patent Ex Parte Reexamination proceedings, MonoSol amended the claims several times and made multiple declarations and arguments in an attempt to overcome the rejections made by the USPTO. These amendments, declarations and other statements regarding the claim language significantly narrowed the scope of their claims in these two patents. In the case of the '891 Patent, not one of the original claims survived reexamination and five separate amendments were filed confirming the Company's position that the patent was invalid. Additionally, the Company believes that arguments and admissions made by MonoSol prevent it from seeking a broader construction during any subsequent litigation by employing arguments or taking positions that contradict those made during prosecution.

A Reexamination Certificate for MonoSol's '891 Patent in its amended form was issued August 21, 2012 (Reexamined Patent No. 7,357,891C1 or the '891C1 Patent). A Reexamination Certificate for MonoSol's '292 Patent in its amended form was issued on July 3, 2012 (Reexamined Patent No. 7,425,292C1 or the '292C1 Patent). These actions by the USPTO confirm the invalidity of the original patents and through the narrowing of the claims in the reissued patents strengthens the Company's original assertion that its products and technologies do not infringe on MonoSol's original patents.

On June 12, 2013, despite the Company's previously noted success in the prior ex parte reexaminations for the '292 and '891 Patents, the Company filed requests for *inter partes* reviews ("IPR") on the narrowed yet reexamined patents, the '292 C1 and '891 C1 Patents, to challenge their validity and continue to strengthen the Company's position. On November 13, 2013, the USPTO decided not to institute the two inter partes reviews for the '891 C1 and '292 C1 Patents. The USPTO's decision was purely on statutory grounds and based on a technicality (in that the IPRs were not filed within what the UPSTO determined to be the statutory period) rather than substantive grounds. Thus, even though the inter partes reviews were not instituted, the USPTO decision preserves the Company's right to raise the same arguments at a later time (e.g., during litigation). Regardless, the Company's assertion that its products and technologies do not infringe the original '292 and '891 Patents and, now, the reexamined '891 C1 and '292 C1 Patents remains the same.

Importantly, in the case of MonoSol's '588 Patent, at the conclusion of the reexamination proceedings (and its appeals process), on April 17, 2014, the Patent Trial and Appeal Board (PTAB) issued a Decision on Appeal affirming the Examiner's rejection (and confirming the invalidity) of all the claims of the '588 Patent. MonoSol did not request a rehearing by the May 17, 2014 due date for making such a request and did not further appeal the Decision to the Federal Court of Appeals by the June 17, 2014 due date for making such an appeal. Subsequently, on August 5, 2014, the USPTO issued a Certificate of Reexamination cancelling the '588 Patent claims.

Based on the Company's original assertion that its proprietary manufacturing process for ONSOLIS® does not infringe on patents held by MonoSol, and the denial and subsequent narrowing of the claims on the two reissued patents MonoSol has asserted against the Company while the third has had all claims rejected by the USPTO, the Company remains very confident in its original stated position regarding this matter. Thus far, the Company has proven that the "original" '292 and '891 patents in light of their reissuance with fewer and narrower claims were indeed invalid and the third and final patent, the '588 patent, was invalid as well with all its claims cancelled. Given the outcomes of the '292, '891 and '588 reexamination proceedings, at a January 22, 2015 status meeting, the Court decided to lift the stay and grant the Company's request for the case to proceed on an expedited basis with a Motion for Summary Judgment to dismiss the action. On September 25, 2015, the Honorable Freda L. Wolfson granted the Company's motion for summary judgment and ordered the case closed. The Company was found to be entitled to absolute intervening rights as to both patents in suit, the '292 and '891 patents and the Company's ONSOLIS® product is not liable for infringing the patents prior to July 3, 2012 and August 21, 2012, respectively. In October 2015, MonoSol appealed the decision of the court to the Federal Circuit. The Company has no reason to believe the outcome will be different and will vigorously defend the appeal. MonoSol filed an appeal with the Federal Circuit and has subsequently decided to withdraw the appeal. On February 25, 2016, MonoSol filed an Unopposed Motion For Voluntary Dismissal Of Appeal,

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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14. Commitments and contingencies (continued):

which was granted by the court on February 26, 2016 and the case dismissed. Thus, the district court's grant of the Summary Judgement of Intervening Rights will stand. In addition, the possibility exists, however, that MonoSol could file another suit alleging infringement of the '292 and '891 patents. The Company believes ONSOLIS® and the Company's other products relying on the BEMA® technology, including BUNAVAIL® and BELBUCA™, do not infringe any amended, reexamined claim from either patent after those dates.

Litigation Related To BUNAVAIL®

On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol (collectively, the RB Plaintiffs) filed an action against the Company relating to its BUNAVAIL® product in the United States District Court for the Eastern District of North Carolina for alleged patent infringement. BUNAVAIL® is a drug approved for the maintenance treatment of opioid dependence. The RB Plaintiffs claim that the formulation for BUNAVAIL®, which has never been disclosed publicly, infringes its patent (United States Patent No. 8,475,832) (the '832 Patent).

On May 21, 2014, the Court granted the Company's motion to dismiss. In doing so, the Court dismissed the case in its entirety. The RB Plaintiffs did not appeal the Court Decision by the June 21, 2014 due date and therefore, the dismissal will stand and the RB Plaintiffs lose the ability to challenge the Court Decision in the future. The possibility exists, however, that the RB Plaintiffs could file another suit alleging infringement of the '832 Patent. If this occurs, based on the Company's original position that its BUNAVAIL® product does not infringe the '832 Patent, the Company would defend the case vigorously (as the Company has done so previously), and the Company anticipates that such claims against the Company ultimately would be rejected.

On September 20, 2014, based upon the Company positions and belief that its BUNAVAIL® product does not infringe any patents owned by the RB Plaintiffs, the Company proactively filed a declaratory judgment action in the United States District Court for the Eastern District of North (EDNC) Carolina, requesting the Court to make a determination that the Company's
BUNAVAIL® product does not infringe the RB Plaintiffs' '832 Patent, US Patent No. 7,897,080 ('080 Patent) and US Patent No. 8,652,378 ('378 Patent). With the declaratory judgment, there is an automatic stay in proceedings. The RB Plaintiffs may request that the stay be lifted, but they have the burden of showing that the stay should be lifted. For the '832 Patent, the
January 15, 2014 IPR was instituted and in June 2015, all challenged claims were rejected for both anticipation and obviousness. In August 2015, the RB Plaintiffs filed an appeal to the Federal Circuit. The Company will vigorously defend this appeal at the Federal Circuit. For the '080 Patent, all claims have been rejected in an inter partes reexamination and the rejection of all claims
as invalid over the prior art has been affirmed on appeal by the PTAB in a decision dated March 27, 2015. In May 2015, the RB Plaintiffs filed a response after the decision to which the Company filed comments. In December 2015 the Board denied MonoSol's request to reopen prosecution, but provided MonoSol an opportunity to file a corrected response. MonoSol filed the request in December 2015 and the Company subsequently filed comments on December 23, 2015. The Company is awaiting a further decision from the Board, which the Company has no reason to believe will be inconsistent with the original decision rendered in March 2015. For the '378 Patent, an IPR was filed on June 1, 2014, but an IPR was not instituted. However, in issuing its November 5, 2014 decision not to institute the IPR, the PTAB construed the claims of the '378 Patent narrowly. As in prior litigation proceedings, the Company believes these IPR and the reexamination filings will provide support for maintaining the stay until the IPR and reexamination proceedings conclude. Indeed, given the PTAB's narrow construction of the claims of the '378 Patent, the Company filed a motion to withdraw the '378 Patent from the case on December 12, 2014. In addition, the Company also filed a joint motion to continue the stay (with RB Plaintiffs) in the proceedings on the same day. Both the motion to withdraw the '378 Patent from the proceedings and motion to continue the stay were granted.

On September 22, 2014, the RB Plaintiffs filed an action against the Company (and the Company's commercial partner) relating to the Company's BUNAVAIL® product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL®, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent No. 8,765,167 ('167 Patent). As with prior actions by the RB Plaintiffs, the Company believes this is another anticompetitive attempt by the RB Plaintiffs to distract the Company's efforts from commercializing BUNAVAIL®. The Company strongly refutes as without merit the RB Plaintiffs' assertion of patent infringement and will vigorously defend the lawsuit. On December 12, 2014, the Company filed a motion to transfer the case from New Jersey to North Carolina and a motion to dismiss the case against the Company's commercial partner. The Court issued an opinion on July 21, 2015 granting the Company's motion to transfer the venue to the EDNC, but denying the Company's motion to dismiss in its entirety as moot. The Company will continue to vigorously defend this case in the EDNC.

In a related matter, on October 28, 2014, the Company filed multiple IPR requests on the '167 Patent demonstrating that certain claims of such patent were anticipated by or obvious in light of prior art references, including prior art references not previously

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
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14. Commitments and contingencies (continued):

considered by the USPTO, and thus, invalid. The USPTO instituted three of the four IPR requests and the Company filed a request for rehearing for the non-instituted IPR. A final decision on the instituted '167 IPRs is expected in May 2016.

On January 22, 2014, MonoSol filed a Petition for IPR on US Patent No. 7,579,019 (the '019 Patent). The Petition asserted that the claims of the '019 Patent are alleged to be unpatentable over certain prior art references. The IPR was instituted on August 6, 2014. An oral hearing was held in April 2015 and a decision upholding all seven claims was issued August 5, 2015. In September 2015, MonoSol requested that the USPTO rehear the IPR. The Company will continue to vigorously defend its '019 patent. The Company expects the USPTO to issue a decision in the first half of 2016.

Litigation related to Actavis

On February 8, 2016, the Company received a purported notice relating to a Paragraph IV certification from Actavis Laboratories UT, Inc. ("Actavis") seeking to find invalid three Orange Book listed patents (the "Patents") relating specifically to BUNAVAIL®. The Paragraph IV certification relates to an Abbreviated New Drug Application (the "ANDA") filed by Actavis with the FDA for a generic formulation of BUNAVAIL®. The Patents subject to Acatvis' certification are U.S. Patent Nos. 7,579,019 ("the '019 Patent"), 8,147,866 and 8,703,177.

The Company believes that Actavis' claims of invalidity of the Patents are wholly without merit and, as the Company has done in the past, intends to vigorously defend its intellectual property. The Company is highly confident that the Patents are valid, as evidenced in part by the fact that the '019 Patent has already been the subject of an unrelated *inter partes* review ("IPR") before the USPTO under which the Company prevailed and all claims of the '019 Patent survived. Although there is a pending request for rehearing of the final IPR decision regarding the '019 Patent pending at the USPTO, the Company believes the USPTO's decision will be upheld. Under the Food Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the "Hatch-Waxman Amendments"), after receipt of a valid Paragraph IV notice, the Company may, and in this case plan to, bring a patent infringement suit in federal district court against Actavis within 45 days from the date of receipt of the certification notice. If such a suit is commenced within this 45 day period, the Company is entitled to receive a 30 month stay on FDA's ability to give final approval to any proposed products that reference BUNAVAIL®. The 30 month stay is expected to preempt any final approval by FDA on Actavis' ANDA until at least August of 2018. In addition, given the FDA approval of BUNAVAIL®, the Company is entitled to three years of market exclusivity for BUNAVAIL® ending in June 2017. Given this timeframe, Actavis' action is not unexpected. In addition, the Company has additional pending intellectual property which, if issued, would be capable of extending the patent life of all three of the Company's BEMA®-related products, including BUNAVAIL®, and potentially be listed in the Orange Book.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

SELECTED QUARTERLY RESULTS (UNAUDITED)

The following table sets forth certain quarterly financial data for the periods indicated (in thousands, except per share data):

	Quarter Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Revenue	$ 13,054	$ 1,733	$ 1,235	$ 32,209
Gross profit	11,930	(888)	(464)	29,552
Income (loss) from operations	(7,800)	(18,681)	(19,652)	10,953
Net (loss) income	(8,193)	(19,211)	(20,439)	10,171
Basic (loss) income per share	(0.16)	(0.37)	(0.39)	0.20
Diluted (loss) income per share	(0.16)	(0.37)	(0.39)	0.20

	Quarter Ended			
	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Revenue	$ 20,690	$ 13,885	$ 1,822	$ 2,547
Gross profit	19,964	13,198	1,359	(516)
Income (loss) from operations	713	(2,041)	(19,059)	(18,353)
Net loss	(4,644)	(6,671)	(25,256)	(17,647)
Basic loss per share	(0.11)	(0.14)	(0.51)	(0.36)
Diluted loss per share	(0.11)	(0.14)	(0.51)	(0.36)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of BioDelivery Sciences International, Inc.

Under date of March 10, 2016, we reported on the consolidated balance sheets of BioDelivery Sciences International, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2015, which are included in BioDelivery Sciences International, Inc.'s Annual Report on Form 10-K. In connection with our audits of the aforementioned consolidated financial statements, we also audited Schedule II – Valuation and Qualifying Accounts and Reserves in BioDelivery Sciences International, Inc.'s Annual Report on Form 10-K. This financial statement schedule is the responsibility of BioDelivery Sciences International, Inc.'s management. Our responsibility is to express an opinion on this financial statement schedule based on our audits. In our opinion, Schedule II - Valuation and Qualifying Accounts and Reserves, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ Cherry Bekaert LLP

Raleigh, North Carolina
March 10, 2016

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Description	Balance at beginning of the period	Charged to income	Charged to other accounts	Deductions	Balance at the end of the period
			(In thousands)		
Valuation allowance for deferred tax assets					
Year ended December 31, 2015:	$ 72,061	$ —	$ 12,899	$ —	$ 84,960
Year ended December 31, 2014:	$ 53,663	$ —	$ 18,398	$ —	$ 72,061
Year ended December 31, 2013:	$ 29,580	$ —	$ 24,083	$ —	$ 53,663
Allowance for rebates					
Year ended December 31, 2015:	$ 231	$ —	$ 2,725	$ (375)	$ 2,581
Year ended December 31, 2014:	$ —	$ —	$ 231	$ —	$ 231
Allowance for price adjustments and chargebacks					
Year ended December 31, 2015:	$ 1,108		$ 6,894	$ (5,730)	$ 2,272
Year ended December 31, 2014:	$ —	$ —	$ 1,542	$ (434)	$ 1,108

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: March 10, 2016

By: /S/ MARK A. SIRGO
Name: **Mark A. Sirgo**
Title: **President and Chief Executive Officer**
(Principal Executive Officer)

By: /s/ Ernest R. De Paolantonio
Name: **Ernest R. De Paolantonio**
Title: **Chief Financial Officer, Secretary and Treasurer**
(Principal Accounting Officer)

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/S/ FRANCIS E. O'DONNELL, JR. **Francis E. O'Donnell, Jr.**	Executive Chairman and Director	March 10, 2016
/S/ MARK A. SIRGO **Mark A. Sirgo**	President, Chief Executive Officer and Director	March 10, 2016
/s/ WILLIAM B. STONE **William B. Stone**	Lead Director	March 10, 2016
/s/ SAMUEL P. SEARS, JR. **Samuel P. Sears, Jr.**	Director	March 10, 2016
/s/ THOMAS W. D'ALONZO **Thomas W. D'Alonzo**	Director	March 10, 2016
/s/ BARRY FEINBERG **Barry Feinberg**	Director	March 10, 2016
/s/ CHARLES BRAMLAGE **Charles Bramlage**	Director	March 10, 2016

Exhibit 10.77

BioDelivery Sciences International, Inc.
4131 ParkLake Avenue
Suite 225
Raleigh, North Carolina 27612
USA

Arius Pharmaceuticals, Inc.
4131 ParkLake Avenue
Suite 225
Raleigh, North Carolina 27612
USA

CONFIDENTIAL

February 27, 2016

Dear Sirs,

Extension of Assignment and Revenue Sharing Agreement

We refer to the Assignment and Revenue Sharing Agreement dated January 23, 2015 (the "**Agreement**") between Meda AB ("**Meda**"), Arius Pharmaceuticals, Inc. ("**Arius**") and BioDelivery Sciences International, Inc. ("**BDSI Parent**"; collectively with Arius, "**BDSI**"). Terms used in this letter shall have the meaning given to them in the Agreement unless specified otherwise.

Clause 3.1 of the Agreement provides that BDSI shall use its Commercially Reasonable Efforts to seek a New Licence of the rights granted under the License and Development Agreement between BDSI and Meda signed 5 September 2007. Under Clause 5 of the Agreement, if BDSI has not identified and agreed terms with a New Licensee, and entered into a New License with such New Licensee, on or before 31 December 2015, Meda has the right, but not the obligation, to demand the reassignment of the Marketing Authorizations in the Territory to Meda and to terminate the Agreement.

Meda and BDSI agree that while BDSI used Commercially Reasonable Efforts, as of the date of this letter, BDSI has not identified and/or agreed terms with a New Licensee or entered into a New License.

The parties hereby agree to extend the period described in Clause 5.1 of the Agreement from on or before 31 December 2015 to on or before 31 December 2016 (the "**Extended Period**"). The parties also agree that during the Extended Period the parties will discuss the possibility of extending the Agreement by another year in the event BDSI has been unable to identify and/or agree terms with a New Licensee,

and enter into a New License prior to the end of the Extended Period. The parties hereby agree that (i) as set out in Clauses 5.1 and 5.3, the final date by which Meda can provide a Reactivation Notice or by which BDSI execute a New License with a New Licensee and (ii) the date referenced in clause (iv) of Section 2.6(a) of the Agreement, will be, in the case of (i) and (ii), extended from 28 February 2016 to 28 February 2017.

The provisions of Sections 7 and 8 of the Agreement shall apply to this letter.

Meda, Arius and BDSI Parent have confirmed their respective agreement to the terms of this letter by signing below.

Signed by /s/ Dr. Jorg-Thomas Dierks

Name: Dr. Jorg-Thomas Dierks

Title: CEO

Date: February 27, 2016

MEDA AB

Signed by /s/ Mark A. Sirgo

Name: Mark A. Sirgo

Title: President & CEO

Date: February 29, 2016

ARIUS PHARMACEUTICALS, INC

Signed by /s/ Mark A. Sirgo

Name: Mark A. Sirgo

Title: President & CEO

Date: February 26, 2016

BIODELIVERY SCIENCES INTERNATIONAL, INC

Exhibit 21.1

Subsidiaries of the Registrant

1. Arius Pharmaceuticals, Inc., a Delaware corporation
2. Arius Two, Inc., a Delaware corporation
3. Bioral Nutrient Delivery, LLC, a Delaware limited liability company

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in each of the Registration Statements on Form S-3 (Nos. 333-133629, 333-133630, 333-135746, 333-143247, 333-149671, 333-157173, 333-156839, 333-173261, 333-192618, 333-179257, 333-205483, and 333-160121) and on Form S-8 (Nos. 333-143590, 333-176476, 333-190796, and 333-206326) of our report dated March 10, 2016 included in this Annual Report on Form 10-K of BioDelivery Sciences International, Inc. (the "Company"), relating to the consolidated balance sheets of the Company as of December 31, 2015 and 2014, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2015, and the effectiveness of internal control over financial reporting for the Company as of December 31, 2015.

/s/ Cherry Bekaert LLP

Raleigh, North Carolina
March 10, 2016

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a)

I, Mark A. Sirgo, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of BioDelivery Sciences International, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant 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 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:

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2016

/s/ Mark A. Sirgo
Mark A. Sirgo
President and Chief Executive Officer

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, Ernest R. De Paolantonio, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of BioDelivery Sciences International, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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:

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2016

/s/ Ernest R. De Paolantonio
Ernest R. De Paolantonio
Chief Financial Officer, Secretary and Treasurer

Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of (18 U.S.C. 1350), the undersigned officer of BioDelivery Sciences International, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2015 (the "Form 10-K") of the Company 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 Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 10, 2016

/s/ Mark A. Sirgo
Mark A. Sirgo, President and Chief Executive Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

Exhibit 32.2

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), the undersigned officer of BioDelivery Sciences International, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2015 (the "Form 10-K") of the Company 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 Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 10, 2016

/s/ Ernest R. De Paolantonio
Ernest R. De Paolantonio, Chief Financial Officer, Secretary and Treasurer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.