BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-K
March 14, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2013

¨ **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.)**

801 Corporate Center Drive, Suite #210

Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

Issuer 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 x

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 x

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 x 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 x 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. Yes ¨ No x

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	x
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 x

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 28, 2013 was approximately $134,206,938 based on the closing sale price of the company s common stock on such date of $4.06 per share, as reported by the NASDAQ Capital Market.

As of March 11, 2014, there were 47,947,817 shares of company common stock issued and 47,932,326 shares of company common stock outstanding.

Table of Contents

BioDelivery Sciences International, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2013

TABLE OF CONTENTS

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.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report and the documents we have filed with the SEC that are incorporated by reference herein contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, 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, proj 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® drug delivery technology platform and any proposed products, product candidates, including our sole approved product, ONSOLIS®, our partnered product candidate, BEMA® Buprenorphine and our other lead product candidates, BUNAVAIL and Clonidine Topical Gel;

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, including for BUNAVAIL , which we are intending to self-commercialize;

our ability, or the ability of our commercial partners to actually develop, commercialize, manufacture or distribute our products and product candidates;

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, 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 upon 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.

Table of Contents

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 proven 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.

In formulating our products and product candidates, we utilize the novel, patent protected and proprietary *BioErodible MucoAdhesive (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 other product candidates, including BUNAVAIL , utilize our BEMA® technology.

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we may seek to acquire or license additional drug delivery technologies or drugs utilizing the delivery or other technologies of other companies. Clonidine Topical Gel, which was licensed from Arcion Therapeutics (or Arcion) in 2013, does 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.

BEMA® Buprenorphine for Chronic Pain

BEMA® Buprenorphine is a partial mu-opioid agonist and a potential treatment for moderate to severe chronic pain. In December 2009, we announced that the primary efficacy endpoint was achieved in a Phase 2 clinical study evaluating the safety and efficacy of a range of doses of BEMA® Buprenorphine. Completion of this Phase 2 study led to the initiation of a Phase 3 double-blind, randomized, placebo-controlled clinical study which was initiated in the fourth quarter of 2010. On September 28, 2011, we announced the preliminary findings of our randomized, placebo-controlled, Phase 3 clinical study of BEMA® Buprenorphine for the treatment of moderate to severe chronic pain in a mixed opioid naïve and opioid experienced population. The primary endpoint of the study, overall pain intensity difference between BEMA® Buprenorphine and placebo, was not achieved. Following full analysis of the data, we concluded that we encountered a high placebo response in the opioid naïve segment of the patient population, particularly at our starting dose, which we believe accounted for the lack of statistically significant efficacy that was observed in the trial overall. We believe this is an occurrence typical of many pain trials. We believe the totality of the study results favored BEMA® Buprenorphine, including a near statistically significant difference between BEMA®

Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). In addition, when eliminating the group of patients that did not titrate beyond the starting dose, a statistically significant difference between BEMA® Buprenorphine and placebo (p=0.025) was identified. Neither of these subgroups was sufficiently large enough to be powered to show a statistical difference. Overall, the trial, though not successful, provided a wealth of knowledge beneficial in the design of two additional Phase 3 clinical studies, which were initiated in the second half of 2012 under our agreement with Endo Pharmaceuticals, Inc. (or Endo), as described below.

In January 2012, we announced the signing of a worldwide licensing and development agreement for BEMA® Buprenorphine (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 BEMA® Buprenorphine for the treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront license fee, which we received in January 2012; (ii) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events (some of which we received in 2012); (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 BEMA® Buprenorphine in the United States and a mid- to high-single digit royalty on net sales of BEMA® Buprenorphine 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® and Voltaren® Gel. We believe BEMA® Buprenorphine is an excellent fit with Endo s pain portfolio and will, if approved, add a Schedule III opioid to their branded pain franchise. BEMA® Buprenorphine would complement 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, BEMA® Buprenorphine 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., NSAIDs).

Table of Contents

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, will extend the exclusivity of the BEMA® drug delivery technology for BEMA® Buprenorphine (as well as BUNAVAIL , as discussed below) from 2020 to 2027. As a result, we received a milestone payment in the amount of $15 million in May 2012, and also related to the issuance of the patent, will receive an additional milestone payment of $20 million at the time of approval of a New Drug Application (or NDA) by the FDA for BEMA® Buprenorphine for the treatment of chronic pain. Such amounts are included in the aforementioned $95 million in potential milestone payments based on intellectual property and clinical development and regulatory events.

In May 2012, in close collaboration with Endo, we initiated two Phase 3 clinical studies one in an 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 BEMA® Buprenorphine in the treatment of chronic lower back pain in opioid naive patients and a population of patients who were opioid experienced. The studies were designed to address some of the issues encountered in the initial Phase 3 study and included sample size increases, the use of higher doses and multiple adjustments to inclusion/exclusion criteria. Patients titrated to a well-tolerated, effective dose were randomized to either continue on that dose of BEMA® Buprenorphine, 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).

Interim analyses were conducted as part of the Phase III protocol in both the opioid naïve and opioid experienced studies to allow for adjustments to the sample size in order to maintain appropriate study power to detect statistically significant differences between BEMA® Buprenorphine and placebo. The analyses were conducted by an independent biostatistician. We and Endo announced in September 2013 that, as a result of the interim analyses, no sample size adjustment would be necessary to the opioid naïve study and that additional patients would be added to the ongoing opioid experienced. The outcomes of the interim analyses were significant because they utilized actual study data to confirm or adjust sample sizes, and importantly, maintain probability of a successful outcome.

On January 23, 2014, we announced with Endo positive top-line results from the Phase 3 efficacy study of BEMA® buprenorphine in opioid- naïve subjects. The trial successfully met its primary efficacy endpoint in demonstrating that BEMA® Buprenorphine resulted in significantly ($p<0.005$) improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BEMA® Buprenorphine compared to placebo. The most commonly reported adverse events in patients treated with buprenorphine compared to placebo were nausea (10% vs. 8%), vomiting (4% vs. 2%) and constipation (4% vs. 2%). 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. Results from the Phase 3 study in opioid experienced patients is anticipated in mid-2014.

BUNAVAIL (buprenorphine and naloxone buccal film)

In addition, we believe that the widespread use of buprenorphine for the treatment of opioid dependence presents an additional commercial opportunity, and we developed a formulation of BEMA® Buprenorphine 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 Wolters Kluwer, exceeded $1.7 billion in sales in the U.S in 2013.

Pharmacokinetic studies have demonstrated the ability of the BEMA® technology to deliver the high doses of buprenorphine necessary for the treatment of opioid dependence. Following completion of two studies assessing the pharmacokinetics of BUNAVAIL , a meeting was held with FDA in early February 2012, and following the meeting, we announced that we had reached an agreement with the FDA on the development plan for BUNAVAIL , which includes a pivotal pharmacokinetic study comparing BUNAVAIL to Suboxone® in normal volunteers and a supporting safety study in opioid dependent patients. The FDA concurred with our strategy.

In September 2012, we announced the positive outcome of the pivotal pharmacokinetic study comparing BUNAVAIL to Suboxone®. 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®, and that the same parameters for naloxone were similar or less than Suboxone®. 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/naloxone) sublingual tablets or films. A total of 249 patients were enrolled in the study, (191 patients completed) which completed in December

Table of Contents

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.

On July 31, 2013, we submitted the NDA for BUNAVAIL to the FDA for review. The NDA was later accepted for filing in October 2013 and a Prescription Drug User Fee Act (PDUFA) date of June 7, 2014 was assigned, meaning that we expect a response from the FDA on our NDA for BUNAVAIL by that date.

ONSOLIS®

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 have 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 has an experienced sales force with a focus in specialty therapeutic areas including pain, allergy and central nervous system conditions. Meda has secured access to additional markets through acquisition of European businesses from Valeant Pharmaceuticals International, Inc., which we refer to herein as Valeant and a joint venture with Valeant covering Australia, Mexico and Canada.

In 2010, we secured commercialization rights for ONSOLIS® for the remaining worldwide territories through execution of licensing agreements with KUNWHA Pharmaceutical Co., Ltd. (Kunwha), for South Korea and TTY Biopharm Co., Ltd. (TTY) for Taiwan where the product will be marketed as PAINKYL . The following is a summary of the current regulatory and commercial Status of ONSOLIS®/BREAKYL .

Region	Partner	Regulatory Status	Commercial Status
U.S.	Meda Pharmaceuticals	Approved	Launched October 2009
Canada		Approved	Launched 3Q 2011

	Meda Valeant Pharma Canada Inc.		
E.U.	Meda A.B.	Approved	Launched 4Q 2012
Taiwan	TTY Biopharm Ltd.	Approved	Launch anticipated 2Q 2015
Australia	Meda Valeant Pharma Canada Inc.	Filed	
Israel	Meda (sub-licensed to MegaPharma)	Under review	
South Korea	Kunwha Pharmaceutical Co. Ltd.	Pre-registration	

Although we have generated licensing-related and other revenue to date from the commercial sales of an approved product ONSOLIS®/BREAKYL 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 began to be launched on a country by country basis starting in the fourth quarter of 2012. Sales of BREAKYL in 2013 and 2012 amounted to $1.8 million and $1.1 million respectively.

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

Table of Contents

product, and while patients are on treatment, to ensure appropriate use. 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. Prescribers and patients enrolled in other individual REMS programs will also automatically be included into the program. In addition to consistency in educational materials, technological advances will simplify the process of participation and verification of program participation. The TIRF REMS program was implemented in March 2012. It is anticipated that the class-wide REMS puts ONSOLIS® in a better position to compete on its own merits.

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 issues raised by FDA during an inspection of the manufacturing facility of our North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. (which we refer to herein as Aveva). 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. While these changes 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 product specification before additional product can be manufactured and distributed. The source of microcrystal formation and the potential for fading of the product was found to be specific to a buffer used in the manufacturing process for ONSOLIS®. ONSOLIS® has been reformulated and we believe the appearance issues have been resolved. Meda, our commercial partner, is working to determine the content and timing of the submission to FDA. Once submitted, FDA s review of the application may take up to 6 months. If the submission is made before mid-2014, and approved by FDA, the relaunch could occur by years end, otherwise, the relaunch would move to sometime 2015.

Clonidine Topical Gel

In March 2013, we announced our entry into a worldwide licensing agreement with privately held Arcion, where 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 topical clonidine 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.

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 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 gel (p=0.07, n= 182), though the overall results did not reach statistical significance.

Oral medications that are approved for the treatment of painful diabetic neuropathy include anticonvulsants such as Lyrica (pregabalin), the antidepressant Cymbalta® (duloxetine) and the opioid Nucynta® (tapentadol), 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 painful diabetic neuropathy. 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 progress the program directly to Phase 3. It also appears that the FDA recognizes the need for new treatment options for painful diabetic neuropathy by confirming Fast Track designation for the program that could potentially lead to a priority review.

Table of Contents

The feedback from FDA enabled us to initiate the first of two placebo controlled studies in early 2014. If the initial placebo controlled study meets its primary endpoint, the results for which could be available as early as the end of 2014, we could be in a position to initiate the second placebo controlled study in early 2015 with an NDA Submission in 2016.

Additional Overview Information

From our inception through December 31, 2013, we have recorded accumulated losses totaling approximately $151.3 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 product candidates like BUNAVAIL ;
- partnering with other pharmaceutical companies such as Meda and Endo to assist in the distribution of our products like BEMA® Buprenorphine and ONSOLIS®, for which we would expect to receive upfront milestone and royalty payments;
- licensing and joint venture arrangements with third parties, including other pharmaceutical companies whose own proprietary pharmaceutical products may benefit from our drug delivery technologies, or where their product profile would be augmented by the inclusion of our products; 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 Investigational New Drug Applications (known as INDs) or NDAs with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding ONSOLIS®, BEMA® Buprenorphine, BUNAVAIL , Clonidine Topical Gel 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 BioErodible MucoAdhesive (known as 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 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).

Table of Contents

ONSOLIS® and Our BEMA® 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
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 worldwide
BEMA® Buprenorphine	Moderate to severe chronic pain	Phase 3 - NDA filing anticipated late 2014 or early 2015	Partnered worldwide with Endo
BUNAVAIL	Treatment of opioid dependence	PDUFA date June 7, 2014	In-house commercialization
Clonidine Topical Gel	Treatment of painful diabetic neuropathy	Phase 3 study initiated late first quarter 2014.	In-house commercialization for specialty indications possible; primary care rights expected to be partnered

While continuing to work closely with Meda on ONSOLIS® (including on regulatory approvals in other worldwide jurisdictions except for Taiwan where we are working with TTY and in South Korea where we are working with Kunwha), we are presently dedicating much of our corporate resources to developing BEMA® Buprenorphine and BUNAVAIL . Depending on the availability of corporate resources and market opportunities, we may elect to develop other BEMA® formulations that we may identify.

BEMA® Formulated Products and Product Candidates

ONSOLIS®

Approved by the FDA in July 2009 and commercially launched in October 2009, ONSOLIS® (fentanyl buccal soluble film) is an approved treatment for the management of breakthrough pain (pain that breaks through the effects of other medications being used to control persistent pain) in patients with cancer, eighteen years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain. ONSOLIS® is a formulation of the narcotic fentanyl delivered through our BEMA® technology.

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Under our agreements with Meda, we receive a double digit royalty on the net sales of ONSOLIS® and also have the potential to receive milestone payments based on achieving certain predetermined sales targets. In May 2010, ONSOLIS® was approved by the Canadian regulatory authorities. ONSOLIS® is marketed in Canada by Meda Valeant Pharma Canada, Inc., a joint venture between Meda and Valeant Canada Limited. Approval was also obtained in the E.U. in October 2010, where it is marketed by Meda under the tradename BREAKYL . In May 2010, we announced a commercialization and supply agreement with Kunwha, for BEMA® Fentanyl in South

Korea, and in October 2010, a licensing agreement was secured with TTY, for exclusive rights to develop and commercialize the product in Taiwan. These licensing deals provide the opportunity for ONSOLIS®/BREAKYL to be commercialized in all regions globally.

In 2012, the leading company in the fast-acting fentanyl market was Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA), which completed an acquisition of Cephalon, Inc. in October 2011. Teva markets both the branded (Actiq®) and generic formulations of fentanyl transmucosal lozenge. Additional generic manufacturers include Covidien PLC (NYSE:COV) and Activis, Inc. (NYSE:ACT). Teva introduced a second transmucosal fentanyl product, Fentora® in late 2006. Additional transmucosal formulations of fentanyl approved and currently marketed include, Abstral®, a sublingual tablet, from Galena Pharma., a nasal spray formulation from DepoMed sold under the trade name Lazanda® and a sublingual spray from Insys Therapeutics, Inc., known as Subsys that was approved in January 2012. We believe that ONSOLIS® may offer advantages over the marketed and pipeline fentanyl products in terms of ease of use and other attributes; however, we recognize the substantial increase in competition in the category. In total, the combined sales of the transmucosal fentanyl products exceeded $332 million in 2013 according to data from Wolters Kluwer.

BEMA® Buprenorphine for Chronic Pain

This product candidate utilizes the BEMA® technology to deliver the opioid analgesic buprenorphine (low dose) for the treatment of moderate to severe chronic pain. Buprenorphine is a marketed opioid analgesic which has comparable efficacy to morphine but with a lower propensity for abuse and addiction and fewer typical opioid side effects. The lower potential for abuse and addiction places BEMA® Buprenorphine as a Schedule III controlled substance versus the majority of the other potent opioids, such as

Table of Contents

morphine and oxycodone, which are Schedule II controlled substances. We believe that this attribute will help create a broader market opportunity for BEMA® Buprenorphine as many doctors are, for fear of addiction, reluctant to prescribe narcotics, particularly on a chronic basis. Also, since buprenorphine is a Schedule III controlled substance, physicians will be able to phone, fax or otherwise electronically deliver the prescription to the pharmacy with refills permitted for up to 6 months, thus making chronic therapy easier for both the patient and the physician. Refills are not permitted for Schedule II controlled substances, requiring the patient to obtain a new prescription from the doctor s office and take such prescription to the pharmacy each time the medication is required.

In January 2012, we announced the signing of a worldwide licensing and development agreement for BEMA® Buprenorphine with Endo. Under terms of the agreement, Endo will be responsible for the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. Endo will commercialize BEMA® Buprenorphine outside the U.S. through its own efforts or through regional partnerships. Both companies will collaborate on the planning and finalization of the Phase 3 clinical development program and regulatory strategy for BEMA® Buprenorphine for chronic pain. We will maintain responsibility for the conduct of planned clinical studies leading up to the submission of the NDA. Endo will have the responsibility of submitting the NDA and managing the interactions with the FDA.

On January 23, 2014, we announced with Endo positive top-line results from the Phase 3 efficacy study of BEMA® Buprenorphine in opioid- naïve subjects. The trial successfully met its primary efficacy endpoint in demonstrating that BEMA® Buprenorphine resulted in significantly ($p<0.005$) improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BEMA® Buprenorphine compared to placebo. The most commonly reported adverse events in patients treated with buprenorphine compared to placebo were nausea (10% vs. 8%), vomiting (4% vs. 2%) and constipation (4% vs. 2%). Results from the Phase 3 study in opioid experienced patients is anticipated in mid-2014.

BEMA® Buprenorphine 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 BEMA® Buprenorphine will be differentiated based on the following features:

- efficacy similar to morphine, but unlike morphine, is a Schedule III narcotic. Such regulatory designation 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;

- broad applicability across a wide spectrum of patients with varying types of moderate to severe pain, and can be used as a sole-therapy or in combination with less potent analgesics such as non-steroidal anti-inflammatory drugs (NSAIDS);

- longer half life which allows for less frequent dosing, thus potentially increasing patient compliance;

- established safety profile (based on other dosage forms currently in the marketplace both in the U.S. and Europe) compared to agents in development; and

improved tolerability, including a lower incidence of constipation and, based on its Schedule III designation, a lower propensity for addiction and abuse versus other opioid analgesics.

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 BEMA® Buprenorphine could be an ideal next step product for patients with incomplete pain relief on non-narcotic analgesics.

The pain market is well established, with many pharmaceutical companies marketing innovative products as well as generic versions of older, non-patent protected products. In 2013, according to data from Wolters Kluwer, the U.S. opioid market exceeded $10 billion in annual sales. Due to the ability of BEMA® Buprenorphine to potentially participate in the chronic pain market, we estimate that BEMA® Buprenorphine for chronic pain has the potential to exceed $500 million in annual peak sales.

BUNAVAIL

We are also developing a higher dose formulation of BEMA® Buprenorphine combined with the abuse deterrent naloxone for the maintenance treatment of opioid dependence. Because of its lower propensity for abuse and addiction, BUNAVAIL may serve as a treatment for opioid dependence by preventing opioid addicted patients withdrawal symptoms and cravings. In 2013, total sales of Suboxone® film (an FDA approved product for opioid dependence) in the U.S. exceeded $1.3 billion. We believe BUNAVAIL has the potential to offer advantages over Suboxone® film and the more recently approved generic tablets. We estimate that BUNAVAIL for the maintenance treatment of opioid dependence has the potential to achieve over $250 million in annual peak sales. The NDA submission was accepted by FDA in October 2013 and a PDUFA data of June 7, 2014, was assigned.

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 to existing drugs for the creation of

Table of Contents

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. 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:

seven, 14 or 28-day multiple dose toxicity studies in a single species of animals,

pharmacokinetic evaluation of the new dosage form in humans,

stability data of the drug substance,

description of drug product components,

description and validation of manufacturing process,

one year stability data on 3 commercial scale batches of drug product, and

depending on the drug product, may include:

(i) one or more placebo controlled clinical study 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 drugs that have established markets and an opportunity to introduce a new form of delivery of that product in order to meet an unmet market need. As a result of employing well known drugs in novel technologies, we believe health care providers will be familiar with the drugs and accustomed to prescribing them. As with ONSOLIS®, BEMA® Buprenorphine, BUNAVAIL and Clonidine Topical Gel, 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 BEMA® Buprenorphine

On January 6, 2012, we announced the signing of a world-wide licensing and development agreement for BEMA® Buprenorphine with Endo. Under terms of the agreement, Endo will be responsible for the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. Endo will commercialize BEMA® Buprenorphine outside the U.S. through its own efforts or through regional partnerships. In the U.S., both companies will collaborate on the planning and finalization of the Phase 3 clinical development program and regulatory strategy for BEMA® Buprenorphine for chronic pain. We will maintain responsibility for the conduct of planned clinical studies leading up to the submission of the NDA. Endo will have the responsibility of submitting the NDA and managing the interactions with the FDA.

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 BEMA® Buprenorphine 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 BEMA® Buprenorphine (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 have become eligible for an additional milestone payment of $20 million which will be paid at the time of approval of a NDA by the FDA for BEMA® Buprenorphine. Additionally, we achieved another milestone with the locking of the database for our phase III opioid naive clinical study on January 17, 2014. For the achievement of this milestone, per the terms of the agreement, we are 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.

Table of Contents

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.

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.

Also, pursuant to the North American license agreement with Meda, we have been granted certain rights to co-promote ONSOLIS® using our own sales force (which we currently do not have), with financial support by Meda for such efforts. In addition, Meda is subject to certain minimum sales representative calls and advertising and promotional expenditure requirements under the North American license agreement and has agreed to support all future costs of clinical development, such as additional indications for ONSOLIS® that do not involve studies in support of the NDA.

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 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.

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 BEMA® Buprenorphine 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.

Aveva Drug Delivery Systems. Effective October 17, 2005, we entered into an agreement with Aveva Drug Delivery Systems, Inc. pursuant to which Aveva acts as our North American supplier of ONSOLIS® for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of ONSOLIS® for the United States, Mexico and Canada.

Our supply agreement with Aveva runs for a term of four years from the first commercial sale of ONSOLIS® (October 2009) and can be renewed for subsequent two year terms. Either we or Aveva can terminate the agreement on advanced written notice.

Table of Contents

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 issues raised by FDA during an inspection of the manufacturing facility of our North American manufacturing partner for ONSOLIS®, Aveva. 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. While these changes 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 product specification before additional product can be manufactured and distributed. The source of microcrystal formation and the potential for fading of the product was found to be specific to a buffer used in the manufacturing process for ONSOLIS®. ONSOLIS® has been reformulated and we believe the appearance issues have been resolved. Meda, our commercial partner, is working to determine the content and timing of the submission to FDA. Once submitted, FDA s review of the application may take up to 6 months. If the submission is made before mid-2014, and approved by FDA, the relaunch could occur by years end, otherwise, the relaunch would move to sometime 2015.

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 European Union.

On September 13, 2012, we executed a Manufacturing, Supply, and License Agreement, effective April 26, 2012, with LTS, under which LTS will manufacture and supply us our BREAKYL product for distribution outside of the U.S. and Canada. We are required to supply BREAKYL product to Meda, Kunwha, and TTY pursuant to our obligations under certain license and supply agreements under which Meda, Kunwha, and TTY develop and commercialize the BREAKYL product. In conjunction with the agreement, LTS has waived all royalties on products that they produce. This does not preclude royalties that we owe to LTS if we produce BREAKYL with another company.

For BUNAVAIL , we have certain manufacturing arrangements in place on a purchase order basis and will seek to secure long term supply contracts as we move closer to potential FDA approval and commercial launch. 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.

During 2006 and 2007, we were a party to disputes with CDC. On September 5, 2007, in connection with CDC s consent to the Meda North American licensing transaction, we and CDC entered into a Dispute Resolution Agreement (DRA) pursuant to which we and CDC agreed to waive and dismiss with prejudice all current disputes between us and CDC. As a condition to CDC s entry into the DRA and its consent to the Meda North American licensing transaction, we and CDC entered into a Royalty Purchase and Amendment Agreement, dated September 5, 2007 (the RPAA) pursuant to which: (i) we granted CDC a right of first refusal on our financings, which replaced a right of first negotiation on financings previously held by CDC (the ROFR) and (ii) we granted CDC a 1% royalty on sales of the next BEMA® product, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval (the Next BEMA® Product). The ROFR terminated in accordance with its terms as of February 28, 2014 because, as provided for in the RPAA, we maintained a volume weighted average stock price of $9.00 per share for ten (10) trading days during any twenty (20) consecutive trading day period.

In connection with the 1% royalty grant: (i) CDC shall have the option to exchange its royalty rights to the Next BEMA® Product 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

Table of Contents

initial commercial launch of the Next BEMA® Product, 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 the Next BEMA® Product 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 the Next BEMA® Product. 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 (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® technologies is conducted through 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, 2013, 2012 and 2011, we spent approximately $53.3 million, $35.4 million and $20.8 million, respectively, on research and development expenses, and such expenses represented approximately 81%, 78% and 73%, 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 year ended December 31, 2013, we have incurred $2.8 million in such research and development expenses that are reimbursable by Endo to us. These reimbursable expenses are due from Endo and are the primary balance within the accounts receivable on the accompanying consolidated balance sheet at December 31, 2013. In addition, these reimbursable expenses are the primary activity within the reimbursable revenue account in the accompanying consolidated statement of operations as of December 31, 2013.

Competition

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 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, 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.

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

Table of Contents

prescription products have been introduced in the U.S. Among the products to receive FDA approval are ONSOLIS® (BDSI/Meda), Suboxone® film (Reckitt Benckiser) and Zuplenz® (MonoSolRx/Praelia). Leading companies in the development and manufacture of thin film technologies include LTS Lohmann Therapie-Systeme AG, ARx LLC and MonoSol Rx LLC (MonoSol) though each has been focused on oral dissolvable thin films. 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 of each dose based on how the BEMA® technology adheres to the buccal membrane and dissolves at a predetermined rate. Our clinical trials have demonstrated that the BEMA® technology is an effective means of drug delivery that is well tolerated and offers convenience to patients.

ONSOLIS®

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. (NASDAQ:TEVA), 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 year, newer products entries, particularly Subsys® (fentanyl sublingual spray from Insys) have gained significant market share. Additional competitors include Galena Biopharma which licensed from Orexo and subsequently relaunched 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). Furthermore, the FDA imposed a requirement that a Risk Evaluation and Mitigation Strategy, or REMS, be required for all transmucosal fentanyl products. The class-wide REMS requirement includes education, healthcare provider and patient registration, and other elements to assure safe use. The FDA has the authority to remove from the market products that do not abide by the mandated REMS. In order for ONSOLIS® to be approved and launched, a REMS program needed to be accepted by the FDA and put in place prior to launch. In October 2009, ONSOLIS® was launched in the U.S. with an accompanying restrictive REMS program.

Despite the requirement that all transmucosal fentanyl products have an approved REMS, the FDA did not reach agreement with Teva on a REMS program for Fentora® or Actiq® until July 21, 2011, nearly two years after the approval of ONSOLIS®. Teva announced initiation of their REMS program in mid-October 2011. The absence of a REMS program for competing fentanyl products resulted in an un-level competitive environment and a highly unfavorable selling environment for ONSOLIS®.

The FDA eventually abandoned individual REMS programs through the creation of a consortium consisting of all manufacturers of transmucosal fentanyl products. The goal of the group was to develop one single REMS program covering all products in the class. 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 under a single program which will 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 addition to consistency in

educational materials, technological advances will simplify the process of participation and verification of program participation. The full program was implemented in March 2012, and the U.S. re-launch of ONSOLIS® is expected to occur under the new class-wide REMS upon availability of product supplies. At that point, it is anticipated that ONSOLIS® will be in a better position to compete on its own merits.

In 2013, the overall market for transmucosal fentanyl products for breakthrough pain according to Wolters Kluwer, totaled $332 million in the U.S. The first approved product for the management of breakthrough cancer pain was Actiq® (oral transmucosal fentanyl citrate) which, according to Wolters Kluwer, generated $15 million in sales in 2013. Total sales for generic versions of Actiq®, available from multiple manufacturers including Covidien, Teva and Activis, according to Wolters Kluwer totaled $79 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 Wolters Kluwer, generated $126 million in sales in 2013.

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. Abstral® was licensed from Orexo AB. 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 2013 and cumulative sales totaled $4 million at year end.

Table of Contents

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, has led to rapid growth. In 2013, Subsys® achieved a prescription market share in excess of 23%, or $102 million in sales.

Other potent pain products are also in development, including 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 these potential 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 or products in development 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)	Galena Biopharma	Sublingual tablet	Marketed
Lazanda® (fentanyl nasal spray)	DepoMed	Nasal spray	Marketed
Subsys® (fentanyl sublingual spray)	INSYS Therapeutics	Sublingual spray	Marketed
Fastanix/NAL 1239	NAL Pharmaceuticals	Orally dissolving film	Phase 2 (U.S.)
ARX-02	AcelRx Pharmaceuticals	Nanotab containing sufentanil	Phase 2 (U.S.)

During 2011, the first transmucosal fentanyl products were approved in Canada for the treatment of breakthrough cancer pain. During that year, Abstral was launched in Canada by Paladin and ONSOLIS® was launched by Meda Valeant. Canada represents a new and potentially important market given that it is estimated that up to 180,000 people suffer from cancer breakthrough pain. It is anticipated that other formulations of fentanyl will become available in Canada.

In Europe, the total market for transmucosal fentanyl products continues to grow with the availability of new formulations. 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).

BEMA® Buprenorphine (chronic pain)

A number of products may be competitors to BEMA® Buprenorphine for the treatment of chronic pain. A potential focus will be to position BEMA® Buprenorphine as a step up from NSAIDs instead of, or prior to, the common practice of prescribing hydrocodone containing combinations or the more addictive Schedule II narcotics. Indications for such use include pain associated with lower back and severe arthritis conditions. Marketed competitors for these indications include Tramadol (Ultram® ER from PriCara and Ryzolt® from Purdue), hydrocodone containing combination and extended release (Zohydro®) formulations, Butrans® (buprenorphine transdermal patch from Purdue) and the potent opioids such as OxyContin® from Purdue, Avinza® from Pfizer, Kadian® from Actavis and Duragesic® from Johnson & Johnson and others. Other competition includes multiple new chemical entities in clinical development with different mechanisms of action as well as 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 BEMA® Buprenorphine.

Additionally, abuse deterrent formulations of pain products are currently being marketed, in clinical development or under FDA review. These formulations, such as Embeda® and, Exalgo®, as well as new formulations of OxyContin® and Opana® ER use a variety of technologies to try and minimize abuse. Abuse deterrent products are likely to play an increasingly important role in prescribing, potentially even replacing the original product. An advantage of BEMA® Buprenorphine 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.

Table of Contents

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. 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 2013 totaled $141 million and continue to steadily grow. While limited information is available, other formulations of buprenorphine may also be in early stages of development for the treatment of pain.

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, 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. BEMA® Buprenorphine is anticipated to fall within the existing class-wide REMS program. Also, in late 2013, the FDA recommended the re-classification of hydrocodone containing combinations from Schedule III to Schedule II. Such a move will make access to hydrocodone more difficult, since Schedule II products require written prescriptions and cannot be prescribed with refills.

BUNAVAIL

We are also developing BUNAVAIL , a higher dose version of buprenorphine combined with naloxone, an abuse deterrent, which has been developed for the maintenance treatment of opioid dependence. The total market for buprenorphine containing products for opioid dependence exceeded $1.7 billion in 2013. The products currently marketed for this indication include Suboxone®, a sublingual tablet and film formulation of buprenorphine combined with the abuse deterrent agent naloxone, a sublingual tablet, Zubsolv and generic formulations of both buprenorphine and buprenorphine/naloxone tablets. Suboxone® film achieved sales of over $1.3 billion in the U.S. in 2013.

In September 2012, Reckitt Benckiser PLC (LSE:RB), the manufacturer of Suboxone® sublingual tablets and films, 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 issued 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.

The actions taken by Reckitt Benckiser as well as patient preference for a film formulation of Suboxone® resulted in significant conversion of the Suboxone® market to the branded film formulation. In 2013, the sublingual film formulation of Suboxone® accounted for over 95% of total Suboxone® prescription sales.

Generic buprenorphine/naloxone tablet formulations were launched in early 2013 by Actavis and Amneal Pharmaceuticals. The remaining prescription volume for Suboxone® tablets was rapidly converted to generics; however, the impact of generic buprenorphine/naloxone tablets on Suboxone® film sales has been limited to date. In 2013, generic buprenorphine/naloxone tablets accounted for 11% of total buprenorphine/naloxone sales. It is anticipated that additional generics will enter the market, though the timing is unclear.

In terms of competition, in addition to Suboxone®, in 2011, 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. The future status of Probuphine is currently uncertain and the product is not anticipated to enter the market in the near term.

A sublingual tablet, referred to as Zubsolv® or OX219, was approved by FDA in July 2013 and subsequently launched in September. 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

Table of Contents

of breakthrough cancer pain. In July 2013 Orexo announced the establishment of a commercial partnership with Publicis Healthcare Solutions. Orexo maintained overall commercial responsibility as part of the agreement, as well as all rights to Zubsolv® in the US market. Publicis has responsibility for the execution of all field-based promotion activities through use of their contract sales representatives and medical support to health care practitioners through deployment of a dedicated medical scientific liaison team. The sales efforts for Zubsolv® are supported by approximately 35 40 contract sales representatives 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 2013 totaled over $3 million in the U.S. At the end of December 2013, Zubsolv® had achieved a weekly prescription market share of just over 2%.

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 from Nanotherapeutics, Inc., which has completed Phase 1 studies, a pre-IND sublingual spray formulation from Insys and a sustained release depot formulation of buprenorphine for injection in Phase 2 development by Reckitt Benckiser.

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, 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.

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 topical clonidine 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. 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 topical clonidine 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.

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 topical clonidine 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.

Oral medications that are approved for the treatment of painful diabetic neuropathy include anticonvulsants such as Lyrica (pregabalin), the antidepressant Cymbalta® (duloxetine) and the opioid Nucynta® (tapentadol), 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.

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.

Table of Contents

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 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 BEMA® Buprenorphine and BUNAVAIL do not infringe MonoSol s patents, at least because they do not meet the limitations of the claims of MonolSol 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. On January 23, 2013, the USPTO issued a Right of Appeal Notice rejecting all of the claims in the 588 Patent for the third time, and an oral hearing for the appeal, in which both parties will have an opportunity to make arguments before the Patent Trial & Appeal Board (PTAB), has been scheduled for March 26, 2014.

We have been granted non-exclusive license rights, under certain conditions, to European Patent No. 0 949 925, controlled by LTS to market ONSOLIS® and BEMA® Buprenorphine within the countries of the European Union. We do not believe that we require licenses under any other patents for our BEMA®-based products in Europe, however, freedom to operate searches and analyses are ongoing. We have not conducted freedom to operate searches and analyses for our other proposed products.

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 BEMA® Buprenorphine. 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 BEMA® Buprenorphine and BUNAVAIL in the United States from 2020 to 2027. In January 2014, the USPTO allowed US Patent Application No. 13/590,094, which, once officially granted as a patent, 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) 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 United States Patent and Trademark office 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 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 has until July 22, 2014 to decide whether to institute the requested inter partes review. An inter partes review, if instituted, could invalidate or validate in whole or in part, this patent. Accordingly, we plan on defending our US Patent No. 7,579,019 vigorously in any inter partes review proceedings.

Table of Contents

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

Clonidine Gel Product

On March 26, 2013, we entered into a definitive Exclusive License Agreement (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.

Manufacturing

We rely and plan to rely on third-party manufacturers to produce our products for research as well as for commercial purposes. We are currently party to the following manufacturing arrangements and, except as described below, we do not presently have any other manufacturing arrangements with respect to our candidate products:

ONSOLIS®

Effective October 17, 2005, we entered into an agreement with Aveva pursuant to which Aveva will supply ONSOLIS® to us for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of ONSOLIS® for the United States and Canada.

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 issues raised by FDA during an inspection of the manufacturing facility of our North American manufacturing partner for ONSOLIS®, Aveva. 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. While these changes 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 product specification before additional product can be manufactured and distributed. The source of microcrystal formation and the potential for fading of the product was

found to be specific to a buffer used in the manufacturing process for ONSOLIS®. ONSOLIS® has been reformulated and we believe the appearance issues have been resolved. Meda, our commercial partner, is working to determine the content and timing of the submission to FDA. Once submitted, FDA s review of the application may take up to 6 months. If the submission is made before mid-2014, and approved by FDA, the relaunch could occur by years end, otherwise, the relaunch would move to sometime 2015.

Effective December 15, 2006, we entered into a Process Development Agreement with LTS and a commercial Supply Agreement on April 26, 2012. 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 manufactured BREAKYL which was first launched in the European Union in September 2012.

BEMA® Buprenorphine

Effective February 8, 2008, we entered into a Process Development Agreement with LTS pursuant to which LTS will undertake process development and scale-up activities and supply BEMA® Buprenorphine. The technical operations and CMC activities have been transitioned from us to Endo over the course of the past year. Commercial supply agreements will be negotiated by Endo.

Table of Contents

BUNAVAIL

We will continue to outsource manufacturing to third-party manufacturers, in compliance with the FDA and other international regulatory agencies applicable Good Manufacturing Practices. We routinely seek manufacturing partners for our products and formulations and believe that such commercial manufacturing arrangements are likely to be available to us. We are also routinely seeking backup manufacturers to our current agreements.

Clonidine Gel

Bulk manufacture of initial clinical trial supplies have been made by Frontage and individual dose units packaged by Tapemark. Other manufacturers are being considered for future development needs as well as registration and commercial supplies.

We have and intend to purchase component raw materials from various suppliers. As our product candidates near market introduction, we intend to seek multiple suppliers of all required components although there may not be more than one at that time.

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, use of contract sales organizations, or use of our own yet-to-be-constituted sales organization. We have already implemented this strategy with regard to our approved product, ONSOLIS®/ BREAKYL with our licensing agreements with Meda world-wide except Taiwan (TTY) and South Korea (Kunwha) and our worldwide license and development agreement with Endo for BEMA® Buprenorphine for chronic pain.

For BUNAVAIL , we have substantially completed our plans to self-commercialize this product assuming FDA approval. Our current plan is to outsource the manufacturing effort as well as selectively use external partners to build our sales capability, although unlike with our partnered products, we will have significantly more control over all commercialization efforts.

In the longer-term, we will consider the possibility of becoming a fully-integrated pharmaceutical company capable of selling our own products in specialty pharmaceutical markets through our own sales force while leaving with partners promotional responsibilities for the large primary care audiences.

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 European Union, 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 fifteen European countries including Germany, France and the U.K.

North America

In September 2007, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for ONSOLIS®, under which Meda is responsible for the sales, marketing and distribution of ONSOLIS® in the U.S., Canada and Mexico. The agreement specifies that ONSOLIS® will be detailed in the primary position for a specified duration among target prescribers, and that we will have the option for a future co-promotion of ONSOLIS® to be subsidized by Meda. Additionally, Meda is responsible for all post-approval clinical studies and label expansion trials.

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 are to be supported by a therapeutic specialty sales force assembled by Meda to target oncologists and pain management specialists treating cancer breakthrough pain. A specialty sales force consisting of experienced and well trained sales representatives were put in place to promote ONSOLIS® to target healthcare providers. These individuals were supported by several internal functions at Meda including marketing, medical affairs and managed care personnel. Sales efforts would be supported through marketing activities, which include journal advertising in select oncology and pain management medical journals, trade show exhibits, medical education, peer selling programs and electronic and internet promotional activities. During active sales promotion, sales representatives would have materials available for healthcare providers and their patients to support education on breakthrough cancer pain and the use of ONSOLIS®.

Meda is also responsible for the management of a Risk Evaluation and Mitigation Strategy, or REMS, program for ONSOLIS®. The FDA has mandated that a REMS be required for all transmucosal fentanyl products. The REMS requirement includes education,

Table of Contents

healthcare provider and patient registration, and other elements to assure safe use. The FDA has the authority to remove from the market products that do not abide by the mandated REMS. In order for ONSOLIS® to be approved and launched, a REMS program needed to be accepted by the FDA and put in place prior to launch. Despite this requirement, the FDA did not reach an agreement with Teva on a REMS program for Fentora® or Actiq® until July 21, 2011, nearly two years after the approval of ONSOLIS®. The absence of a REMS program for competing fentanyl products during this time period resulted in an un-level competitive environment and a highly unfavorable selling environment for ONSOLIS®.

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 under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program also ends the disparity in prescribing requirements for ONSOLIS® compared to similar products. The full program was implemented in March 2012.

ONSOLIS® was approved by the Canadian regulatory authorities in May 2010, and is 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 is 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® until the product formulation can be modified to address two appearance issues raised by FDA following an inspection of the Aveva manufacturing facility where ONSOLIS® is produced. Specifically, the FDA identified the formation of microscopic crystals and a fading of the color during the 24-month shelf life of the product. While these changes 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 product specification before additional product can be manufactured and distributed. Therefore, the U.S. re-launch and additional manufacturing of ONSOLIS® has been postponed until such product appearance issues have been resolved. See Manufacturing above.

Additional Territories

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.

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. The agreement results in potential milestone payments of up to $1.275 million, which included the upfront payment of $0.3 million and royalties based on net sales. 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.

We believe that utilizing commercial partners to market and sell ONSOLIS®/BREAKYL 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.

BEMA® Buprenorphine for Chronic Pain

We announced the signing of a world-wide licensing and development agreement for BEMA® Buprenorphine with Endo in January 2012. Under terms of the agreement, Endo will be responsible for the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine 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® and Voltaren® Gel. Endo s long experience in pain includes a very strong sales and marketing capability, with sales representatives that are well established in the offices of high value healthcare practitioners who are high prescribers of opioids and other pain products.

Table of Contents

We believe that BEMA® Buprenorphine is an excellent fit to Endo s pain portfolio and will, if approved by the FDA, 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 will be responsible for all sales and marketing at the time of launch 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 will commercialize BEMA® Buprenorphine outside the U.S. through its own efforts or through regional partnerships. We believe that BEMA® Buprenorphine 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. NSAIDs).

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 have 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 make self-commercialization both a feasible and attractive option. In total, approximately 90% of all prescriptions are written by fewer than 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 virtually full coverage of the prescriber base with a relatively small sales force. Sales force sizing estimates suggest that a field sales force less than 50 could reach the identified target audience with the necessary frequency. 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 substantially completed in early 2014. We will utilize internal resources to provide the strategic direction and oversight of specialized contractor resources, including a Contract Sales Organization (CSO), that will provide the sales, managed markets and medical affairs support. Although we presently intend to commercialize BUNVAIL on our own, we would remain open to the possibility of licensing or partnership arrangements should the arrangement be in the best interest of the company and its shareholders at any point.

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.

Table of Contents

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 Trials

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 Trials

Clinical trials involve 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 trials are 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.

We have in the past and will continue to rely upon third party contractors to advise and assist us in the preparation of our INDs and the conduct of clinical trials that will be conducted under the INDs.

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 investigation, 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 Risk Evaluation and Mitigation Strategy (REMS) plan if required.

Table of Contents

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 (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. BEMA® Buprenorphine 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. It is expected that BUNAVAIL will fall within the existing REMS, which is also 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.

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.

Table of Contents

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 11, 2014, we have 24 full-time employees. Twelve are involved in our clinical development program and operations and twelve handle our administration and accounting. Advanced degrees and certifications of our staff include four Ph.Ds, two Pharm.Ds, one M.D., three CPAs, four 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, 2013, we have recorded significant losses. Our accumulated deficit at December 31, 2013 was approximately $151.3 million. As of December 31, 2013, we had working capital of approximately $1.6 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 an approved product ONSOLIS and such revenue has been minimal to date due to the fact that ONSOLIS® has 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, mostly relating to ONSOLIS® and more recently with BEMA® Buprenorphine and BUNAVAIL and Clonidine Topical

Table of Contents

Gel. 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.

Until we have a larger royalty revenue stream from Meda on ONSOLIS® , reach future milestone and royalty payments under the Endo licensing agreement for BEMA® Buprenorphine for chronic pain or successfully commercialize BUNAVAIL , we will likely need to raise additional capital to continue our operations from time to time, 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. 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, 2013, we had cash of approximately $23.2 million, which was augmented by a $60 million registered offering in February 2014. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, the anticipated commercial launch of BUNAVAIL , the completion of the Phase 3 clinical program for BEMA® Buprenorphine for Chronic Pain, the anticipated Phase 3 clinical program for Clonidine Topical Gel, and potential new product development) that our current working capital will be sufficient to satisfy our contemplated cash requirements through second quarter 2015, 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.

Depending on the timing and receipt of milestone payments from our commercial partnership with Meda and 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 the aforementioned development and launch 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.

Our Credit Agreement with MidCap Financial SBIC, LP (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 July 2013, we entered into a Credit Agreement with MidCap whereby we received a loan in the aggregate amount of $20 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 or assume certain debt;

merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;

change the nature of our business;

change our organizational structure or type;

amend, modify or waive any of our organizational documents;

license, transfer or dispose of certain assets;

grant certain types of liens on our assets;

make certain investments;

pay cash dividends;

enter into material transactions with affiliates; and

amend or waive provisions of material agreements in certain manners.

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

Table of Contents

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.

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 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 commercial-scale manufacturing arrangements and marketing and distribution capabilities for 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®);
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;
- 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.

Table of Contents

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 will be our first product that we plan to commercialize ourselves assuming regulatory approval.

We have no experience as a company in self-commercializing pharmaceutical products, which heightens the risks related to our anticipated self-commercialization of BUNAVAIL .

To date, we have partnered our products with larger pharmaceutical companies, who have taken primary responsibility for development and commercialization activities for such products. We are presently anticipating that we will self-commercialize BUNAVAIL if FDA approval is obtained during 2014. As a company, we have never been primarily responsible for manufacturing, supply chain, sales and marketing efforts for one of our products, and therefore our efforts with BUNAVAIL will be our initial efforts in this regard. There is a risk that we may be unable

to adequately execute, either on our own or through third parties, 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.

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.

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 agreements with Meda and Endo as well as our manufacturing development and supply agreements with Aveva and LTS relating to ONSOLIS® and with LTS relating to BREAKYL . For BUNAVAIL , we have manufacturing arrangements in place on a purchase order basis and will seek to secure long term supply contracts as we move closer to potential FDA approval and commercial launch.

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, would substantially disrupt or delay our research and development and commercialization activities, including our in-process

Table of Contents

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. This is particularly true with regard to our relationship with Meda, who is our worldwide (outside of Taiwan and South Korea) commercialization partner for our one approved product ONSOLIS®.

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 collaborative agreements with Meda, we are responsible for paying certain costs relating to ONSOLIS®. In addition, under our licensing and development agreement with Endo, we are responsible for supporting the clinical development of BEMA® Buprenorphine 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 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. Annual aggregate limits include $2 million for general liability, with $1 million for each occurrence; product liability is $5 million for aggregate and $5 million per occurrence; 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. 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® 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 a lawsuit by a third party who claims 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;

Table of Contents

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 drug delivery device technology space is competitive. There is a risk that a court of law in the United States or elsewhere could determine that ONSOLIS® or another 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 ONSOLIS® or BUNAVAIL .

We have been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market ONSOLIS® and BEMA® Buprenorphine 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 lawsuit with MonoSol has 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. 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 (including, without limitation, ONSOLIS®). 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. 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.

Table of Contents

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.

Except for our agreements with Aveva and LTS, we do not have long-term agreements with most of our suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. As it is the primary manufacturer of our only approved product, ONSOLIS® , our relationship with Aveva is particularly important to us, and any loss of or material diminution of Aveva s 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. We do not carry interruption insurance for any such loss. Any loss of or interruption in the supply of components from Aveva 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 is primarily in the 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 dependent on third parties for our formulation development, manufacturing and the

packaging of our products. This is particularly true with respect to Aveva, the primary manufacturer of our only approved product, ONSOLIS®. 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, subsequently, to launch and maintain the marketing of 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, such as Meda, 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 Aveva 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 2010 when Aveva experienced certain adverse equipment and regulatory issues leading to the temporary stoppage of manufacturing of all products at that site, which impacted our and our partners commercial plans. Additionally, in March 2012, 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

Table of Contents

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 agreements with Meda and Endo) to engage in sales, marketing and distribution efforts around our products and product candidates. This will also be the case in our anticipated self-commercialization activities with BUNAVAIL . 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. There is a risk that healthcare providers may respond negatively to this class-wide REMS program in a manner similar to the original ONSOLIS® REMS program that we were required to implement prior to the adoption of the class-wide REMS. Should this occur, Meda s ability to generate revenue from sales of ONSOLIS® in the U.S. and Canada, once the appearance and related formulation issues have been resolved and the product is relaunched in the U.S. and Canada, could be materially compromised,

which would result in low royalty payments to us. 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. BEMA® Buprenorphine 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 will fall 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.

We will be subject to risks if we seek to develop our own sales force.

If we choose to develop our own sales and marketing capability, including in connection with any exercise by us of our co-promotion rights with respect to ONSOLIS® under our agreements with Meda or with respect to our BEMA® Buprenorphine product under our agreements with Endo or with respect to our anticipated self-commercialization efforts for BUNAVAIL , we may be impeded in these efforts given that our experience in developing a fully integrated commercial organization is limited. If we choose to establish a fully integrated commercial organization, we will likely incur substantial expenses in developing, training and managing such an organization. We may be unable to build a fully integrated commercial organization on a cost effective basis, or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

Table of Contents

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 rely, 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 one product, ONSOLIS®, the product 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 investigational new drug application, or 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,

Table of Contents

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 BEMA® Buprenorphine did not meet its primary endpoint and therefore we were required to conduct new trials. In our licensing and development agreement with Endo, we are responsible for the conduct of planned clinical studies leading up to the submission of an NDA for BEMA® Buprenorphine. Conducting a new clinical trial in accordance with the FDA requirements has required significant additional capital, and we will not be able to commercialize and sell our BEMA® Buprenorphine product until we are able to meet our primary endpoints for both trials and obtain subsequent FDA approval.

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 additional, 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 BEMA® Buprenorphine for the treatment of moderate to severe chronic pain to meet its primary endpoint, which we announced September 2011.

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.

Table of Contents

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 product, ONSOLIS®, and two of our lead product candidates, BEMA® Buprenorphine and BUNAVAIL , 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 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 ONSOLIS® and in our lead product candidates BEMA® Buprenorphine and BUNAVAIL (fentanyl and buprenorphine, respectively) are listed by the DEA as Schedule II and III 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 ONSOLIS®, BEMA® Buprenorphine and BUNAVAIL and potentially other of our product candidates 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 one approved product, ONSOLIS®) 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.

Table of Contents

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 Meda to sell ONSOLIS® (if, in the U.S. and Canada, the appearance and related formulation issues described elsewhere herein have been resolved and distribution has resumed), and our ability to commercialize our product candidates 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 product liability policy that includes coverage for our clinical trials, with an annual aggregate limit of $5 million with a $5 million limit per occurrence. It is possible that this coverage will be insufficient to protect us from future claims. 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 like Meda are required to provide insurance in connection with specific products like ONSOLIS®, 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.

Table of Contents

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 (the PPACA). The Healthcare and Education Reconciliation Act of 2010 (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 (collectively referred 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 Meda to sell ONSOLIS® (once it is reformulated and placed back on the market in the U.S. and Canada) and our ability to commercialize our product candidates with partners such as Endo or otherwise 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.

Table of Contents

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 Management and Affiliate Transactions

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. 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.

Executive officers, directors and entities affiliated with them 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 12.70% 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.

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 (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.

Table of Contents

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 your investment in our securities could decline in value.

Since our initial public offering in June 2002, there has only been a relatively limited public market for our securities and there is a risk that an active trading market in our securities may not be adequately maintained. In addition, 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 could result in extreme fluctuations in the price of our securities, which could cause a decline in the value of your securities. 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 issued and outstanding 2,709,300 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.

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 11, 2014, there are 47,947,817 shares of common stock issued and 47,932,326 shares of common stock outstanding and there were 2,709,300 shares 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 2,709,300 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.

Table of Contents

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 11, 2014: (i) 3,592,947 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $4.08 per share, (ii) 1,841,792 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.62 per share and (iii) 2,709,300 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.

Table of Contents

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 executive offices are located in Raleigh, North Carolina. The lease, which commenced November 2007 for 63 months, was amended September 2012 for an additional 24 months. This approximately 5,500 square foot space has remaining base rent of $148,471 payable through February 2015. 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.

Our finance and accounting offices are located in Tampa, Florida. We share this office space with a related company and pay $2,841 on a monthly basis for approximately 1696 square feet of office space occupied by our four full-time employees in this office.

Item 3. Legal Proceedings.

Readers are advised that the following disclosure regarding our ongoing litigation with MonoSol 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 (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 BEMA® Buprenorphine 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 February 23, 2011, we filed our initial answer in this case. In our answer, we stated our position that our products, methods and/or components do not infringe MonoSol s 588 Patent because they do not meet the limitations of any valid claim of such patent. Moreover, in our answer, we stated our position that MonoSol s 588 Patent is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law.

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 in court a motion for stay pending the outcome of the reexamination proceedings, which subsequently was granted due to the results of the USPTO proceedings as described below.

On November 28, 2011, we announced that we were informed by the USPTO that it had 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

Table of Contents

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.

In February and March 2012, respectively, the USPTO granted the requests for reexamination we filed with respect to MonoSol s 292 and 891 Patents. In its initial office action in each, the USPTO rejected every claim in each patent. Based on the action of the USPTO on these three patent reexaminations, the court in our case with MonoSol conducted a status conference on March 7, 2012, at which it granted our motion to stay the case pending final outcome of the reexamination proceedings in the USPTO.

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.

Inter partes reviews, a new USPTO process to review the patentability of one or more claims of patents, was enacted in September, 2012. As such, on June 12, 2013, despite our previously noted success in the prior ex parte reexaminations for the 292 and 891 Patents, we availed ourselves of this new process and filed requests for inter partes reviews on the narrowed yet reexamined patents, the 292C1 and 891C1 Patents, to challenge their validity and continue to strengthen our position. This inter partes review process allows us to actively participate in the reviews and address any of MonoSol s arguments and representations made during the review process, which heightens our ability to invalidate these patents. On November 13, 2013, the USPTO decided not to institute the two inter partes reviews for the 891C1 and 292C1 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 891C1 and 292C1 Patents remains the same.

Importantly, in the case of MonoSol s 588 Patent, the USPTO on July 20, 2012 issued a second Office Action closing prosecution and rejecting for a second time all claims as anticipated or obvious. It also rejected the amended claims proposed by MonoSol as unclear and lacking support. Then, on January 23, 2013, the USPTO issued a Right of Appeal Notice, rejecting all claims of the 588 Patent and closing reexamination proceedings. This action confirms that all claims of this patent are also invalid, but unlike 292 and 891, the USPTO has not found that any amended or narrower claims should be granted. On February 22, 2013, MonoSol filed both a Notice of Appeal to the Board of Patent Appeals and Interferences and a Request for Continuing Examination of the 588 Patent. On March 12, 2013, we filed a petition requesting the USPTO to deny MonoSol s February 22, 2013 Request to Continue Examination and to allow the proceedings to go to an appeal. Subsequently, on July 3, 2013, the USPTO denied MonoSol s February 22,

2013 Request to Continue Examination. After reviewing MonoSol s Appeal Brief (filed June 24, 2013) and our Respondent s Brief (filed July 24, 2013), the USPTO formally initiated the appeals process with the Examiner s Answer on August 8, 2013, which affirmed the rejection of all the claims in the 588 Patent. An oral hearing for the appeal, in which both parties will have an opportunity to make arguments before the Patent Trial & Appeal Board (PTAB) has been scheduled for March 26, 2014.

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, 588, has had all claims rejected and appears to have had a similar fate. Importantly, we will continue to defend this case vigorously, and we anticipate that MonoSol s claims against us will ultimately be rejected.

Table of Contents

Litigation Related To BUNAVAIL

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 proposed treatment for 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). We believe this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL .

We believe that this action is in response to a 2013 decision wherein the FDA recently ruled in favor of our position in two Citizen Petitions filed by the RB Plaintiffs that sought to prevent the FDA from accepting and filing our NDA for BUNAVAIL . The two Citizen Petitions, filed on December 2, 2011 and August 13, 2013, respectively, included requests that the FDA refuse to accept for filing any NDAs submitted using the 505 (b)(2) regulatory pathway for buprenorphine/naloxone products consisting of a polymer film for application to the buccal mucosal membranes (such as BUNAVAIL), unless such application references the NDA for Suboxone® (buprenorphine/naloxone) sublingual film (and not the Suboxone® sublingual tablet NDA). Suboxone® is an approved product for opioid dependence. The requirement to reference the Suboxone® film formulation, which is under patent exclusivity with Orange Book-listed patents, including the 832 Patent, was aimed at delaying the eventual approval of BUNAVAIL . FDA did not agree with these arguments and in its decision on September 18, 2013, it denied the requests and subsequently, accepted and filed the BUNAVAIL NDA.

We believe that the RB Plaintiff s claim of patent infringement has no more validity than the recently rejected Citizen Petitions, but is being used as another anticompetitive attempt to distract us in our efforts toward commercializing BUNAVAIL . We look forward to the FDA s review of the BUNAVAIL NDA as it moves toward the June 7, 2014 PDUFA date when we expect a response from FDA on our NDA for BUNAVAIL . In the meantime, we strongly refute as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit.

On December 13, 2013, we filed a motion to dismiss RB Plaintiff s suit based on insufficient pleadings and lack of standing. In response, RB Plaintiffs filed its opposition to our motion to dismiss on January 22, 2014. We filed our reply to RB s opposition to our motion to dismiss on February 10, 2014.

On January 15, 2014, we filed a request for inter partes review in the USPTO of the 832 Patent demonstrating that certain claims of such patent 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. On January 31, 2014, we filed in Court a motion for stay pending the outcome of the inter partes review proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

Table of Contents

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 2013 and 2012, as reported by the NASDAQ Capital Market, is set forth below.

Quarterly Common Stock Price Ranges

Fiscal Year 2013, Quarter Ended:	High	Low
March 31, 2013	$ 4.94	$ 3.52
June 30, 2013	$ 5.74	$ 3.86
September 30, 2013	$ 5.55	$ 4.05
December 31, 2013	$ 6.09	$ 4.16

Fiscal Year 2012, Quarter Ended:	High	Low
March 31, 2012	$ 2.55	$ 0.80
June 30, 2012	$ 4.54	$ 2.39
September 30, 2012	$ 6.48	$ 4.26
December 31, 2012	$ 6.89	$ 3.87

As of March 11, 2014, we had approximately 121 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.

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, 2013:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)[1]	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders	6,549,719	$ 3.86	2,555,228

Equity compensation plans not approved by security holders				
Total	6,549,719	$	3.86	2,555,228

(1) Includes 3,192,596 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.

Stock Performance

The following graph shows a comparison of the five year total cumulative returns of an investment of $100 in cash on December 31, 2008 in (i) our common stock (ii) the Nasdaq Composite Index (iii) the Nasdaq Biotechnology Index and (iv) the Amex 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).

Table of Contents

Comparison of cumulative total return on investment since December 31, 2008:

	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013
BioDelivery Sciences Int l, Inc.	$ 100.00	$ 135.52	$ 122.41	$ 27.93	$ 148.62	$ 203.10
Nasdaq Composite (U.S. Companies)	100.00	143.89	168.22	165.19	191.47	264.84
Nasdaq Biotechnology	100.00	115.63	132.98	148.69	196.12	324.80
Amex Pharmaceutical	100.00	113.33	112.11	122.03	135.45	171.55

Item 6. Selected Financial Data.

The statements of operations data and statements of cash flows data for the years ended December 31, 2013, 2012 and 2011 and the balance sheet data as of December 31, 2013 and 2012 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, 2010 and 2009 and the balance sheet data as of December 31, 2011, 2010 and 2009 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.

	Fiscal Year				
	2013	2012	2011	2010	2009
	(Dollars in thousands, except per share data)				
Statements of Operations Data:					
Total revenue	$ 11,356	$ 54,542	$ 3,263	$ 3,405	$ 62,815
Operating (loss) income	(56,402)	7,062	(26,988)	(16,319)	40,129
Net (loss) income	(57,394)	1,652	(23,325)	(13,033)	33,047
Diluted net (loss) income per share	(1.51)	0.05	(0.82)	(0.56)	1.54
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 23,176	$ 63,189	$ 10,750	$ 18,209	$ 23,873
Total assets	38,005	75,739	23,645	33,580	39,678
Accumulated deficit	(151,313)	(93,919)	(95,572)	(72,246)	(59,214)
Total stockholders (deficit) equity	(812)	49,777	4,120	9,786	14,458
Statements of Cash Flows Data:					
Net cash flows from operating activities	$ (60,103)	$ 12,187	$ (23,275)	$ (11,682)	$ 18,190

Table of Contents

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.

Background of Our Company

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of proven therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. From the founding of our predecessor in 1995 through 2002, we were a development stage company and exited the development stage upon our execution of a license agreement relating to a prior delivery technology which we are no longer developing.

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, the 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 BEMA® Buprenorphine for chronic pain and are working with Endo to complete U.S. development of the product for purposes of seeking FDA approval. 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 painful diabetic neuropathy and other indications.

We expect to continue 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 up-front payments. We may also seek to commercialize products such as BUNAVAIL on our own or in conjunction with third parties. We anticipate that funding for the next several years will come primarily from milestone payments and royalties from Meda and Endo, potential revenues from sales of BUNAVAIL , potential sale of securities, collaborative research agreements, including those with pharmaceutical companies and potential exercises of our warrants.

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 BEMA® Buprenorphine 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 milestone (iii) royalty revenue from Meda from sales of ONSOLIS®; (iv) up-front 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) revenue from the sale of a royalty stream in 2004, (vi) research and collaboration revenues, including research revenues in 2010 and 2013 from TTY and Kunwha and (vii) minimal royalty revenue from a license with Accentia. Most of these types of revenue are generally not repeating or predictable. Therefore, we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future, particularly until we generate recurring revenue from product sales, with the foremost opportunity being potential revenue from sales of BUNAVAIL , should that product receive FDA approval.

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.

Table of Contents

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 2013, 2012 or 2011.

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 2013, 2012 or 2011.

Fair market value accounting (derivative liability)

The most significant estimate that could have a material effect on net (loss) gain is the fair market value accounting for our derivative liability. Our derivative liability consists of free standing warrants that are 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 are posted to the derivative gain (loss) in other (loss) income. We utilize 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 ending December 31, 2012, a $3.50 increase in the value of our stock was the primary cause of the $5.6 million derivative loss. During the year ending 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 of $1.58. The result was a $0.1 million derivative gain.

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 during 2013, we assumed no dividend yield, risk-free interest rates ranging from 0.70% to 1.60%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor ranging from 77.59% to 81.65% and option exercise prices ranging from $4.33 to $5.39.

We also use the Black Scholes option pricing model as the primary basis for valuing our derivative liabilities at each reporting date (both embedded and free-standing derivatives). The underlying assumptions used in this determination are primarily the same as are used in the determination of stock-based compensation discussed in the previous paragraph except contractual lives of the derivative instruments are utilized rather than expected option terms.

Revenue Recognition

Meda License, Development and Supply Agreements

In August 2006 and September 2007, we entered into certain agreements with Meda to develop and commercialize the ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered utilizing the BEMA® technology. The aforementioned

Table of Contents

agreements relate to the United States, Mexico and Canada (such agreements, the Meda U.S. Agreements) and to certain countries in Europe (such agreements, the Meda EU Agreements , together with Meda U.S. Agreements, the Meda Agreements). They carry license terms that commence 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 recognize revenue associated with the Meda Agreements in accordance with GAAP related to multiple deliverables. Our deliverables under the Meda Agreements, including our related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 5 to the accompanying financial statements.

We have determined that upon inception of both the U.S. and EU Meda arrangements all deliverables to each arrangement are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable and the research and development efforts provided do not have stand-alone value apart from the license. As such, all cash payments from Meda related to these deliverables prior to FDA approval in July 2009 were recorded as deferred revenue. All cash payments from Meda for upfront and milestone payments and research and development services provided are nonrefundable. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain research and development services deliverables were deliverable 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. The first commercial sale in a European country occurred in October 2012. As a result, $17.5 million was recognized as revenue, which included $5.0 million in milestones received during the year ended December 31, 2012. At December 31, 2013, there was remaining deferred revenue of $1.3 million which is related to the Meda research and development services. As time progresses, we will continue to estimate the time required for ongoing obligations, and adjust the remaining deferred revenue accordingly on a quarterly basis.

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. The estimated portion of the upfront payments of approximately $1.2 million (under the Meda U.S. Agreements) and $0.1 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided through expiration of the license terms, as defined above.

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 the Endo Agreement with Endo pursuant to which we granted to Endo an exclusive commercial world-wide license to develop, manufacture, market and sell our BEMA® Buprenorphine product and to

complete U.S. development of such product candidate for purposes of seeking FDA approval.

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BEMA® Buprenorphine 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 BEMA® Buprenorphine (and providing clinical trial materials for such trials) necessary to submit a NDA to the FDA in order to obtain approval of BEMA® Buprenorphine in the U.S., in each case pursuant to a development plan set forth in the Endo Agreement (as it may be amended pursuant to the Endo Agreement). 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 BEMA® Buprenorphine on a worldwide basis. In addition, Endo is responsible for all filings required in order to obtain regulatory approval of BEMA® Buprenorphine.

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 BEMA® Buprenorphine):

$30 million non-refundable upfront license fee (received January 17, 2012);

Table of Contents

up to an aggregate of $95 million in six separate potential milestone payments based on the following pre-defined events: (i) enhancement of intellectual property rights (two milestones aggregating $35 million in potential milestone payments, including $15 million upon issuance of a certain patent covering the product which was received May 2012), (ii) clinical development (two milestones aggregating $20 million in potential milestone payments) and (iii) regulatory events (two milestones aggregating $40 million in potential milestone payments);

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 BEMA® Buprenorphine, 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 and in accordance with the revenue recognition criteria, we determined that: the Endo Agreement is a multi-deliverable arrangement with three deliverables: (1) the license rights related to BEMA® Buprenorphine, (2) services related to obtaining enhanced intellectual property rights through the issuances 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 because Endo obtained, at the inception of the Endo Agreement, all of the rights and knowledge necessary to fully exploit its license without our further involvement. 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 have not separately accounted for the CTM deliverable, but consider it part of the clinical development services deliverable.

The initial non-refundable $30 million license fee was required to be 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.

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. In April 2012, the patent being sought by us was granted as described further below, and in May 2012, the applicable intellectual property milestone payment of $15 million was received and recognized as revenue. The amount allocated to the license was recognized as revenue in January 2012.

The portion of the upfront license fee allocated to the clinical development services deliverable ($14.4 million) is being recognized as those services are performed. We estimate that such performance will extend into the first half of 2015. Based on the estimated proportion of those services performed in 2013, $5.2 million of that amount was recognized in 2012 and $6.3 million was recognized in 2013. As a result, $2.9 million remains deferred at December 31, 2013.

We analyzed the milestone payments noted above to determine if such milestones are substantive. This determination included an analysis of our performance to achieve each milestone, the enhancement of value of the delivered items, the timing of performance related to the milestone, and the reasonability of the milestone relative to all the deliverables and payment terms. We concluded that each of the milestones are substantive.

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 BEMA® Buprenorphine in a particular country or (ii) the date on which the last valid claim of our patents covering BEMA® Buprenorphine in a particular country has expired or been invalidated. The Endo Agreement shall be subject to termination: (i) by Endo, at any time, upon a specific amount of prior written notice to us, (ii) by Endo and us upon mutual written agreement, (iii) by either party upon a material default or breach of the Endo Agreement and such default or breach is not cured within a specified timeframe, (iv) the voluntary or involuntary bankruptcy of either party or (v) by us if Endo does not meet certain diligence obligations outside of the United States.

Table of Contents

On February 16, 2012, we announced that the U.S. Patent and Trademark Office issued a Notice of Allowance regarding our patent application (No. 13/184306), which patent will extend the exclusivity of the BEMA® drug delivery technology for our BEMA® Buprenorphine and BUNAVAIL product candidates from 2020 to 2027. On April 17, 2012, we announced that this patent was granted. As a result, pursuant to the Endo Agreement, we received a milestone payment from Endo in the amount of $15 million in May 2012. As discussed above, this milestone had been evaluated to be a substantive milestone, and therefore was recognized as revenue when the milestone was received.

The remaining milestone payments are expected to be recognized as revenue as and if they are achieved (including the $10 million milestone payment received February 2014 as a result of the Phase 3 database lock for opioid naive patients), except that one milestone is contingently refundable for a period of time. Revenue related to that milestone is expected to be recognized as refund provisions as defined in the agreement expire. Sale threshold payments and sales-based royalties will be recognized as they occur under the terms of the Endo Agreement.

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.

Research Revenues

Research revenue amounts are recognized as revenue under various contractor agreements with third parties. This is shown as research fees on the accompanying consolidated statements of operations.

Contract Revenue

In 2013, we recognized as revenue $0.2 million in previously deferred revenue related to our agreement with Meda associated with ONSOLIS®. In 2012, we recognized as revenue $17.5 million in previously deferred revenue as a result of the E.U. launch of BREAKYL . In 2013 and 2011, respectively, we received and recognized as revenue $0.3 million which related to our license agreement with TTY.

We also earned contract revenue as a result of Endo up-front and milestone payments related to our BEMA® Buprenorphine product in 2013 and 2012. We recognized in 2012, revenue of $15.6 million associated with receipt of the $30 million non-refundable up-front license payment, and the $14.4 million balance of which was recorded as deferred revenue to be recognized as the related clinical development services are rendered. Based on the estimated proportion of those services performed through December 31, 2012 and 2013, respectively $5.2 million was recognized as revenue in fiscal year 2012 and $6.3 million was recognized as revenue in fiscal year 2013. As a result, $2.9 million remains deferred at December 31, 2013. In addition, in May 2012 we received and recognized as revenue $15 million associated with an intellectual property milestone.

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 exceed $45 million. In 2013, we recognized $2.8 million of reimbursable expenses related to our Endo agreement. This is shown as reimbursable revenue on the accompanying consolidated statements of operations.

Cost of Product Royalties

The cost of product royalties includes the direct costs attributable to the production of ONSOLIS®. We do not take ownership of the subject product (i.e., we have no inventory) as such product is transferred to Meda immediately in accordance with terms of our contractual arrangements with Meda and its commercial supplier, Aveva. While Aveva manufactures the product for us, and Meda s royalty payments to us include an amount related to cost of goods, ownership and title to the product, including insurance risk, belong to Aveva from raw material through completion and inventory of the subject product, and then to Meda upon shipment of such subject product. This is in accordance with our contracts with Aveva and Meda, which identify the subject product as FOB manufacturer.

Table of Contents

Cost of Product Royalties includes all costs related to creating the products at our contract manufacturer. Only costs that are tied to the production of the products are considered cost of product royalties. Our contract manufacturer for ONSOLIS®, Aveva, bills us for the material cost used in creating the product along with direct labor costs, certain overhead costs, and an established profit margin as outlined in the supply agreement. This is shown as cost of product royalties on the accompanying consolidated statements of operations. Cost of product royalties also includes royalty expenses owed to third parties. These royalty expenses are directly related to the products sold during the period.

Results of Operations

For the Year Ended December 31, 2013 Compared to the Year Ended December 31, 2012

Product Royalty Revenues. We recognized $1.8 million and $1.1 million in product royalty revenue during the years ended 2013 and 2012, respectively, under our license agreement with Meda. The increase in product royalty revenues can be attributed to the commercial launch of BREAKYL in the EU in October 2012.

Research Revenues. We recognized $0.01 million of revenue related to a research and development agreement with Meda during the year ended 2012. There were no such research revenue during the year ended 2013.

Contract Revenues. We recognized $6.3 million and $35.8 million in contract revenue during the years ended 2013 and 2012, respectively, under our license agreement with Endo. We recognized $0.06 million and $17.5 million in previously deferred revenue from Meda as a result of the E.U. launch and $0.2 million and $0.1 million as a result of ongoing development service obligations related to the Meda agreement in 2013 and 2012, respectively. We recognized $0.3 million in contract revenue during the year ended 2013 related to our license agreement with TTY.

Research and Development Reimbursements. We recognized $2.8 million of reimbursable revenue related to our agreement with Endo during the year ended 2013. There was no such reimbursable revenue during the year ended 2012.

Cost of Product Royalties. We incurred $2.1 million and $1.9 million in cost of product royalties during the years ended 2013 and 2012, respectively, related to direct costs attributable to the production of ONSOLIS®. This includes both manufacturing costs and royalties owed to CDC and Athyrium. We are required to pay royalties of $0.375 million per quarter to CDC and Athyrium under a Clinical Development and License Agreement entered into in 2005, and most recently amended in May 2011.

Research and Development Expenses. During the years ended December 31, 2013 and 2012, research and development expenses totaled $53.3 million and $35.4 million, respectively. The increase in research and development expenses can be attributed to two pivotal pain studies and one safety trial pursuant to the Endo Agreement for our Buprenorphine chronic pain program. The safety trial did not begin until October 2012. In addition, the two pivotal pain studies in 2013 had more patients and corresponding recruiting activities than were experienced in the corresponding prior year period. Our scientific staff continues to work toward development and application of our BEMA® delivery technology, which includes ONSOLIS®, BEMA® Buprenorphine for chronic pain and BUNAVAIL for the treatment of opioid dependence. We also began development activities for Topical Clonidine Gel for painful diabetic neuropathy. Research and development expenses generally include contractor services, compensation for scientific personnel and other costs directly related to the development and application of drug technologies.

We anticipate a significant reduction in our research and development spending starting in the fourth quarter of 2013 and continuing into 2014 based on the completion of the BUNAVAIL NDA work and the winding down of the

clinical trial programs for BEMA® Buprenorphine for Chronic Pain.

General and Administrative Expenses. During the years ended December 31, 2013 and 2012, general and administrative expenses totaled $12.3 million and $10.1 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. The increase in general and administrative expenses can be attributed to an increase in professional service fees including legal expenses and additional incentive cash compensation due to performance against established pre-defined company objectives.

Interest Expense, Net. 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 related to associated with the July 2013 secured loan facility from MidCap. These 2013 costs were partially offset by interest income of $0.3 million. During the year ended December 31, 2012, we had interest income of $0.3 million.

Derivative Gain (Loss). Derivative gain (loss) in 2013 and 2012 is related to the adjustment of derivative liabilities to fair value as of December 31, 2013 and 2012, respectively. Derivatives are primarily free-standing warrants. The warrants are measured using Black-Scholes calculations. A major component of the calculation is our stock price. During the year ending 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 2012, our stock price increased by $3.49 per share. This increased our warrant liability, and correspondingly caused the $5.6 million derivative loss.

Table of Contents

Income Tax Expense and tax net operating loss carryforwards. We had federal and state net operating loss carryforwards (NOL) of approximately $109 million and $100 million at December 31, 2013 as compared to federal and state NOLs of $45 million and $38.8 million as of December 31, 2012. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 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, 2012 Compared to the Year Ended December 31, 2011

Product Royalty Revenues. We recognized $1.1 million and $2.7 million in product royalty revenue during the years ended 2012 and 2011, respectively, under our license agreement with Meda. The decrease in product royalty revenues can be attributed to the postponement of the U.S. relaunch of ONSOLIS®.

Research Revenues. We recognized $0.01 million and $0.2 million of revenue related to a research and development agreement with Meda during the years ended 2012 and 2011, respectively.

Contract Revenues. We recognized $35.8 million in contract revenue during the year ended 2012 under our license agreement with Endo. We recognized $17.5 million in previously deferred revenue from Meda as a result of the E.U. launch and $0.1 million as a result of ongoing development service obligations related to the Meda agreement in 2012. We recognized $0.3 million in contract revenue during the year ended 2011 which related to our license agreement with TTY.

Cost of Product Royalties. We incurred $1.9 million and $1.8 million in cost of product royalties during the years ended 2012 and 2011, respectively, related to direct costs attributable to the production of ONSOLIS®. This includes both manufacturing costs and royalties owed to CDC and Athyrium. We are required to pay royalties to CDC and Athyrium under a Clinical Development and License Agreement entered into in 2005, and most recently amended in May 2011, in the amount of $0.375 million per quarter.

Research and Development Expenses. During the years ended December 31, 2012 and 2011, research and development expenses totaled $35.4 million and $20.8 million, respectively. The increase in research and development expenses can principally be attributed to higher costs associated with the BEMA® Buprenorphine clinical trial and BUNAVAIL program in 2012. Our scientific staff continued to work toward increased development and application of our BEMA® technologies, but particularly with respect to BEMA® Buprenorphine, BUNAVAIL and ONSOLIS®. Funding of this research in 2012 and 2011 was obtained through license revenue, sponsored research revenue, exercise of options by employees and directors and sales of company securities. Research and development expenses generally include compensation for scientific personnel, research supplies, facility rent, manufacturing equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the our drug delivery technologies.

General and Administrative Expenses. During the years ended December 31, 2012 and 2011, general and administrative expenses totaled $10.1 million and $7.7 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. The increase in general and administrative expenses can be attributed to an increase in

professional service fees including legal expenses and additional incentive cash compensation due to performance against established company objectives.

Interest Income, Net. During the year ended December 31, 2012 we had interest income of $0.3 million compared to $0.2 million for the corresponding period in 2011. The increase in interest income can be attributed to the higher cash balances in 2012.

Derivative (Loss) Gain. Derivative (loss) gain in 2012 and 2011 is related to the adjustment of derivative liabilities to fair value as of December 31, 2012 and 2011, respectively. Derivatives are primarily free-standing warrants. The warrants are measured using Black-Scholes calculations. A major component of the calculation is our stock price. During 2012, our stock price increased by $3.49 per share. This increased our warrant liability, and correspondingly caused the derivative loss. During 2011, our stock declined by $2.74 per share, which was the primary cause of the 2011 derivative gain.

Income Tax Expense and tax net operating loss carryforwards. We had federal and state net operating loss carryforwards (NOL) of approximately $45 million and $38.8 million at December 31, 2012 as compared to federal and state NOLs of $51 million and $45.4 million as of December 31, 2011. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 for state purposes. In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if,

Table of Contents

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 2013, we continued to dedicate our corporate resources to our portfolio of products utilizing the BEMA® technology. This included:

- two Phase 3 clinical studies of BEMA® Buprenorphine;
- a clinical safety study for BUNAVAIL and the preparation and subsequent NDA filing;
- re-formulation of ONSOLIS® to correct cosmetic defects; and
- preparation activity of the first Phase 3 clinical study of Clonidine Topical Gel.

Clinical research expenses in 2013 were primarily dedicated to Phase 3 studies for BEMA® Buprenorphine for the treatment of chronic pain; and completion of the safety study and NDA for BUNAVAIL .

The projected dates for filing INDs or filing or 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:

BEMA® Buprenorphine. BEMA® Buprenorphine is our second analgesic product using the BEMA® technology. We have conducted multiple Phase 1 studies with BEMA® Buprenorphine, one Phase 2 study in acute pain, and one Phase 3 efficacy study in a mixed population of opioid naïve and opioid experienced patients for the treatment of moderate to severe chronic pain. Additional new Phase 3 studies to evaluate the efficacy and safety of BEMA® Buprenorphine in the treatment of opioid naïve and experienced patients with chronic pain were ongoing in 2013. The Phase 3 study in opioid naïve patients completed in early 2014, and the results were positive.

Due to the ability of BEMA® Buprenorphine to participate in the key chronic pain market, we believe that BEMA® Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion dollar U.S. market for opioid

analgesics, which would translate to over $500 million in peak annual sales. We do not expect to generate any royalty revenue from sales of BEMA® Buprenorphine, if ever, until at least 2015. A license and development agreement was finalized with Endo for the worldwide rights to BEMA® Buprenorphine for chronic pain in January 2012.

The risks to our company associated with the BEMA® Buprenorphine project include: (i) inability to develop and manufacture a stable formulation suitable for commercial use; (ii) slow patient enrollment in clinical trials; (iii) failure of clinical trials (as was experienced in 2011); (iv) product safety issues; (v) failure of or delay by the FDA to approve our NDA; (vi) failure of a commercial partner or us to effectively launch and sell the product; and (vii) lack of funding to advance the program. A technical or commercial failure of BEMA® Buprenorphine 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.

BUNAVAIL . A higher dose formulation of BEMA® Buprenorphine combined with the abuse deterrent naloxone has been developed for the treatment of opioid dependence. In 2013, a safety study was completed in 249 patients with opioid dependence who were converted from Suboxone® tablets or films. Upon successful study completion, the NDA for BUNAVAIL was compiled and submitted in July 2013. The FDA has assigned a PDUFA date of June 7, 2014. Up to the point of approval, the risk exists that BUNAVAIL may not receive an approval on its PDUFA date, or may not receive an approval at any point. While we believe the existing NDA is adequate to support an approval, the FDA may make a determination that the available data does not support the efficacy or safety of BUNAVAIL , or they may determine that there is inadequate CMC data. In addition, during NDA review FDA inspections of clinical, manufacturing, packaging and testing facilities may reveal concerns that would impact the review and approval of the NDA.

Table of Contents

Clonidine Topical Gel. A Phase 3 clinical study assessing the efficacy and safety of Clonidine Topical Gel will be conducted in 2014. 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 gel (p=0.07, n= 182), though the overall results did not reach statistical significance.

We plan to conduct a Phase 3 clinical study of Clonidine Topical Gel in an enriched population of patients who have documented evidence of functioning pain receptors . The study is anticipated to complete recruitment in late 2014 with results possible by early 2015. 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 clinical or commercial use; (ii) slow patient enrollment in clinical trials; (iii) failure of clinical trials; (iv) product safety issues; (v) failure of or delay by the FDA to approve our NDA; (vi) failure of a commercial partner or us to effectively launch and sell the product; and (vii) 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, 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 BEMA® Buprenorphine product candidate. We intend to finance our research and development, commercialization efforts and our working capital needs from existing cash, royalty revenue, new sources of debt 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 2011, significant sources of operating cash were $14 million in net proceeds from a private placement offering of common stock. During 2012, we received a $30 million, non-refundable license fee under the Endo Agreement. In addition, in May 2012, we received an additional $15 million milestone payment from Endo due to our achievement of a certain intellectual property-related milestone. In November 2012, we closed a registered direct offering of our common stock and newly designated Series A Non-Voting Convertible Preferred Stock, par value $.001 per share. The final amount of securities issued in the offering was an aggregate of (i) 6,791,887 shares of Common Stock and (ii) 2,709,300 shares of Series A Preferred Stock. The net proceeds to us, after deducting placement agent fees, the corporate finance fee and estimated offering expenses, was approximately $38.4 million.

In July 2013, we entered into a $20 million secured loan facility pursuant to a Credit and Security Agreement (the Credit Agreement) with MidCap. 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. Cantor Fitzgerald & Co. is the placement agent for such offering program. In January 2014, we sold 658,489 shares of common stock under such offering program for approximate gross proceeds of $4 million.

In January, 2014, we announced positive top-line results from our pivotal Phase 3 efficacy study of BEMA® Buprenorphine in opioid- naive subjects. The locking of the database for the opioid naive study has triggered a $10

million milestone payment from Endo per our licensing agreement, and was received February, 2014.

In December 2013 and January and February of 2014, a warrant holder exercised an aggregate of 10,000 and 515,000 shares of common stock underlying a warrant for proceeds to us of $0.05 million and $2.6 million, respectively.

From January through March 2014, our employees and directors exercised approximately 0.7 million stock options, which net proceeds to us was $2.2 million.

In February, 2014, we 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 our common stock, par value $.001 per share. The shares were sold at a price of $8.00 per share, yielding gross offering proceeds of $60 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.

We anticipate that the cash used in operations and our investment in our facilities will continue beyond our ONSOLIS® agreements with Meda; pending reformulation of ONSOLIS® our agreement with Endo regarding BEMA® Buprenorphine for chronic pain as we 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 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 in BEMA®.

Table of Contents

At December 31, 2013, we had cash and cash equivalents of approximately $23.2 million. We used $60.1 million of cash from operations during the twelve months ended December 31, 2013 and had stockholders deficit of $0.8 million, versus equity of $49.8 million at December 31, 2012. Our existing cash balances are anticipated by management to be sufficient to fully fund our operations through the second quarter of 2015.

Additional capital may be required to support our commercialization activities for BUNAVAIL , or should BUNAVAIL not be approved, to fund any additional requirements the FDA may request prior to considering it for approval; clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of our agreement with Endo), the reformulation project for and anticipated commercial relaunch of ONSOLIS®, planned development of Clonidine Topical Gel produced for painful diabetic neuropathy 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 2014 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, 2013 are as follows:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 148,471	$ 118,665	$ 29,806	$	$
Employment agreements	1,251,370	1,251,370			
Secured loan facility	20,000,000	7,333,333	12,666,667		
Interest on secured loan facility	2,340,756	1,480,562	860,194		
Exit fee on secured loan facility	700,000		700,000		
Minimum royalty expenses*	9,000,000	1,500,000	3,000,000	3,000,000	1,500,000
Total contractual cash obligations**	$ 33,440,597	$ 11,683,930	$ 17,256,667	$ 3,000,000	$ 1,500,000

* 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 BEMA® Buprenorphine 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.

Table of Contents

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. Our cash equivalents include Ultra Short Term Government Funds. 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 $250,000 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, 2013, we had approximately $22.8 million, which exceed 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 to various holders underlying shares of our common stock. These warrant investments are 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.

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, 2013, 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 in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed 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

Table of Contents

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, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Changes in Certifying Officer

During our fourth fiscal quarter of 2013, one of our Company s Certifying Officers was replaced, and a new officer was appointed. The Company does not believe that the change in a Certifying Officer will materially affect, or is 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 accounting principles generally accepted in the United States of America, 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, 2013. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2013.

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 11, 2014 are as follows:

Name	Age	Position(s) Held
Frank E. O Donnell, Jr., M.D.	64	Executive Chairman and Director
Mark A. Sirgo, Pharm.D.	60	President, Chief Executive Officer and Director
Ernest R. De Paolantonio	60	Chief Financial Officer and Secretary
Andrew L. Finn, Pharm.D	64	Executive Vice President of Product Development
William B. Stone	70	Lead Director
John J. Shea	87	Director
William S. Poole	67	Director
Samuel P. Sears, Jr	70	Director
Thomas W. D Alonzo	70	Director

Table of Contents

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 64, 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 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 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 60, 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 serves on the Board of Directors and as Chairman of the Compensation Committee of Salix Pharmaceuticals, Inc. (NASDAQ:SLXP), a specialty pharmaceutical company specializing in gastrointestinal products since 2008. 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 60, has been our Chief Financial Officer since October of 2013 and has over 35 years of varied financial and business experience in the pharmaceutical industry. 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.

Andrew L. Finn, Pharm.D., age 64, has been our Executive Vice President of Product Development since January 2007. He joined the company in August 2004 upon our acquisition of Arius Pharmaceuticals, of which he was a

co-founder. Dr. Finn has previously served as our Senior Vice President of Product Development and Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn has over 30 years experience in pharmaceutical product development. Prior to his involvement with Arius, he was, from 2000 to 2003, Executive Vice President of Product Development at POZEN Inc. with responsibilities for formulation development, non-clinical development, clinical research and regulatory affairs. He participated in the POZEN activities leading up to the initial public offering and submitted marketing applications in Europe and the U.S. for two migraine products. From 1996 to 1999, Dr. Finn was Co-Founder and Chief Executive Officer of enVision Sciences, a regulatory and clinical service company. From 1991 to 1996, he was Vice President of Clinical Research and Biometrics for Solvay Pharmaceuticals, where he oversaw NDA submissions in the areas of inflammatory bowel disease, osteoporosis prevention and treatment of obsessive-compulsive disorder. Prior to this, he spent 10 years in positions of increasing responsibility at Glaxo Inc., where he oversaw a number of NDA submissions, including Zofran for chemotherapy induced nausea and vomiting. Dr. Finn is qualified to serve on our management team because of his extensive experience in specialty biopharmaceutical companies. Dr. Finn received his BS in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

William B. Stone, age 70, 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

Table of Contents

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.

John J. Shea, age 87, has been a member of our board of directors since March 2002 and serves as Chairman of the Nominating and Corporate Governance Committee of our board of directors. He is currently the head of his own firm J. Shea Inc. and has also been a Quality Systems Adviser with Quintiles, a private consulting firm. Mr. Shea has also served in the capacity of Director of Quality Assurance and was responsible for the implementation of quality assurance procedures in a number of public companies. From 1987-1989, he served as Director of Quality Assurance at NeoRx Corporation. Mr. Shea was also the Director of Corporate Quality Assurance at Hexcel Corporation from 1980-1987. Mr. Shea has also served as the quality assurance person for other companies including, Teledyne Relays, Ortho Diagnostics, Inc. and Bio Reagents & Diagnostics, Inc. He is a member of the (North Carolina) Dare County Airport Authority and Audit Committee. Mr. Shea is qualified to serve on our board of directors because of his extensive business experience in the pharmaceutical industry. Mr. Shea earned a B.S. in Chemistry at Bethany College.

William S. Poole, age 67, has been a member of our board of directors since April 2005 and served as Chairman of the Compensation Committee of our board of directors until 2013. He has extensive experience in the biopharmaceutical and medical device industries for over thirty years. From 1972 to early 1996, Mr. Poole worked for Lederle Laboratories, a Division of American Cyanamid Company. During his 24-year career at Cyanamid, Mr. Poole held positions of increasing responsibility and held the position of World-Wide Division President of the Medical Device Division when Wyeth acquired Cyanamid in 1995. He later served as President, North American Pharmaceuticals, of Novo Nordisk Pharmaceuticals, and also as President of Biovail Pharmaceuticals. In both of these companies, Mr. Poole was instrumental in aggressively growing revenue, building solid management teams and dramatically improving profitability. As President of these firms, Mr. Poole had total P&L responsibility and directly managed vice presidents in charge of each business department within the organizations. In recent years, Mr. Poole has acted as a private consultant and, until his appointment to the board, Mr. Poole served as a member of the Commercial Advisory Board of our subsidiary, Arius Pharmaceuticals. Mr. Poole was Acting President/CEO of Spherics, Inc., a biotechnology company focusing on unique delivery mechanisms of certain drugs for the treatment of CNS diseases during 2007 and 2008. Mr. Poole is qualified to serve on our board of directors because of his extensive business experience in the pharmaceutical industry. Mr. Poole earned a B.A. in Psychology at Boston University.

Samuel P. Sears, Jr., age 70, 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 70, 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. 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

Table of Contents

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

Key Employees

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

James A. McNulty, *CPA*, served as our Secretary, Treasurer and Chief Financial Officer from 2000 until October 2013. He currently serves as our Senior Vice President - Finance and Treasurer. Since 2000, Mr. McNulty served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture investing activities. Hopkins Capital Group is owned and controlled by Dr. Francis E. O Donnell, Jr. He is also Secretary of HedgePath Pharmaceuticals, Inc., (OTCBB: HPPI), a clinical stage biopharmaceutical company developing therapeutics for cancer patients. Mr. McNulty also served part-time from 2004 through October 2013 as the Treasurer and Corporate Secretary of Accentia, a holding company with commercialization assets in specialty pharmaceuticals and biologics, and from 2003 to 2007 as Chief Financial Officer for Biovest International, Inc. He served as CFO of Star Scientific, Inc. from 1998 - 2000. During 2000 - 2002 he served as CFO/COO of American Prescription Providers, Inc. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, which became one of Florida s largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He is a Director of Quantum Technology Sciences, Inc., a private company. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, a member of the American and Florida Institutes of CPA s and is a board member of the Tampa Bay chapter of Financial Executives International.

Niraj Vasisht, Ph.D. has been our Senior Vice President of Product Development and Chief Technical Officer since October 2008. He joined the company in February 2005 as the Vice President of Product Development. Dr. Vasisht heads the chemistry, manufacturing and control operations for BDSI pipeline products. He directs and oversees the product design, formulation development, quality control, process engineering, validation and stability testing of the drug product and CTM and commercial manufacturing operations at our vendor sites worldwide. In addition, he is responsible for creation of relevant intellectual property, provides risk assessment for the development program, and provides technical and strategic leadership to the business development function. He evaluates technical suitability of drug delivery platforms and candidate molecules suitable for the technology. Dr. Vasisht serves as BDSI s pharmaceutical development representative for FDA interactions for NDA and MAA filings. Dr. Vasisht is known worldwide for his expertise in microencapsulation based controlled release and drug delivery technologies. From 1994 to 2005, Dr. Vasisht held positions of increasing responsibility at Southwest Research Institute where he ultimately served as the Director of Microencapsulation, Pharmaceutical Development and Nanomaterials and was responsible for leading the group that provides research and development and product development services to pharmaceutical, consumer health, and nutraceutical companies. Dr. Vasisht is the inventor/co-inventor on multiple patents in drug delivery. Dr. Vasisht received a BTech 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.

Albert J. Medwar, M.B.A. has been our Vice President of Marketing and Corporate Development since joining the company in April 2007, with over 20 years of experience in marketing, sales, and marketing research. Prior to joining the 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.

George K. Ng, J.D. has been our Senior Vice President & General Counsel since joining the company in December 2012, with over 10 years of combined experience in pharmaceuticals and the law. Mr. Ng heads our legal, compliance and intellectual property functions. Prior to joining the company, Mr. Ng held various senior management positions, including Head of Legal, Chief Compliance Officer and Chief Intellectual Property Counsel, with publicly-traded, global biotechnology and pharmaceutical companies, including Spectrum Pharmaceuticals, Inc. and Alpharma, Inc., with oversight over legal, intellectual property, litigation

Table of Contents

and compliance matters. Additionally, Mr. Ng has held responsibility for being the legal lead in due diligence, negotiations, and contract preparation for multiple business development transactions, including U.S. and ex-U.S. licenses, global collaboration agreements and intellectual property and product acquisitions. Previously, in private practice, Mr. Ng was a partner in two AMLAW 200 law firms where he had leadership roles, including establishing the life sciences practice group for one firm and heading it as the national co-chair. In his private practice positions, Mr. Ng s responsibilities included patent and trademark prosecution, licensing and litigation support, with areas of expertise including drug delivery technologies and medical devices. Mr. Ng earned a Juris Doctor (J.D.) degree in law from the University of Notre Dame School of Law and a Bachelor of Arts and Sciences (B.A.S.) dual degree in Biochemistry & Economics from the University of California, Davis.

David Acheson has been our Vice President of Sales and Managed Markets since joining the company in December 2013, with over 18 years of sales and commercial experience. Prior to joining the company, Mr. Acheson was with CSL Behring as the National Director of Sales, Immunology and Pulmonary for two specialty teams focused in rare and orphan diseases. Mr. Acheson also led the full build and deployment of the sales organization for Pacira Pharmaceuticals Inc., an emerging specialty pharmaceutical company focused on the clinical and commercial development of products focused in the post-surgical pain market. Mr. Acheson s pharmaceutical and biotech career began with Roche Pharmaceuticals where he worked as a Sales Representative, Medical Center Representative, and Division Sales Manager. After his success in the hospital and oncology supportive care arena at Roche, Mr. Acheson joined MedPointe/Meda Pharmaceuticals where he worked in multiple areas of responsibility as a District Sales Manager, Regional Sales Director, and National Sales Director in the respiratory business. Also at Meda, Mr. Acheson served as the National Sales Director, Pain and Supportive Care Team and responsible for building a full pain and oncology supportive care division of the company from start-up operations, deploying a full sales team as well as operational needs within the company. Prior to his work in the pharmaceutical and biotech industry, Mr. Acheson was with American Cyanamid Company in their Ag-Chemical Division, serving in multiple levels of responsibility. Mr. Acheson has experience in a number of complex markets such as pain, palliative care, immunotherapy, and orphan disease state products, many of which had afforded him a great deal of involvement in the equally complex managed markets settings, developing and pulling through payer strategies as well as partnerships at the distribution and channel level. Mr. Acheson received a Bachelor degree in Business from the University of Nebraska at Lincoln.

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;

Table of Contents

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 2013, Dr. O Donnell received the following compensation for his service as Executive Chairman: $230,460 in cash compensation, $138,276 bonus, $6,770 in stock awards and $22,859 in benefits paid in 2013. 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, John J. Shea, William S. Poole, Samuel P. Sears, Jr. and Thomas W. D Alonzo 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.

Meetings of the Board of Directors and Stockholders

Our board of directors met in person and telephonically 13 times during 2013 and also acted by unanimous written consent. Each member of our board of directors was present at eighty-five (85%) percent or more 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 2013 Annual Meeting of Stockholders.

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.

Audit Committee

Our board of directors has an Audit Committee, composed of William B. Stone, William S. Poole and Samuel P. Sears, Jr., 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 five times during 2013. Each member of the Audit Committee was present at one hundred (100%) percent 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 of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually) and performs several functions. 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;

Table of Contents

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 assistance 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 John J. Shea, William B. Stone and Thomas W. D Alonzo. Mr. Shea 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 2013 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, 801 Corporate Center Drive, Suite #210, Raleigh, NC 27607. 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 2013, we did not pay any fees to any third parties to assist in the identification of nominees. During 2013, 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 William S. Poole. Mr. Sears serves as chairman of this committee. The compensation committee met six times during 2013.

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 2013, 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 $42,988 in 2013.

Strategic Development Committee

Our board of directors also has a Strategic Development Committee (formerly known as the Risk Management Committee), which committee was reconstituted in October 2013 having been originally formed in August 2011. Pursuant to a charter of the Strategic Development Committee approved by our board, the purpose and mandate of the Committee is to provide assistance to the board and the Company s management in fulfilling the board and executive management s responsibilities to the stockholders, potential stockholders and investment community by efficiently assisting management in identifying, assessing, processing and monitoring the execution of strategic business opportunities (such as acquisitions, dispositions, licenses, joint ventures, commercial partnerships, financings and similar extraordinary transactions) created by or presented to the Company and other strategic matters related to the Company in an effort to create sustainable value for the Company and its stockholders. The Strategic Development Committee is composed of three members: William S. Poole, John J. Shea and Thomas D Alonzo. William S. Poole serves as chairman of this committee. The Strategic Development Committee met two times during 2013.

Table of Contents

The Strategic Development Committee shall be advisory in nature and shall not have the power to direct or approve the day-to-day management and operations of the Company, such power being vested in the Company s executive management, subject to the oversight and approval of the board of directors. The Strategic Development Committee shall consist of three independent members of the board, although as provided for in Article VII below, the Strategic Development Committee may, in its discretion appoint, one or more executive subcommittees consisting of one or more independent or management directors to fulfill any or all of the Strategic Development Committee s duties. Each Strategic Development Committee member shall serve until such member s successor is duly elected and qualified or until such member s earlier resignation, removal from office, death or incapacity. The members of the Strategic Development Committee may be removed, with or without cause, only by a majority vote of the board. Vacancies shall be filled only by a majority of the board at the next Board meeting following the occurrence of the vacancy or as soon as practicable thereafter. The Strategic Development Committee meets with such frequency and at such intervals as it shall determine is necessary to carry out its duties and responsibilities.

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 2013, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, except that a grant issued to our director Thomas W. D Alonzo on June 3, 2013 was reported on Form 4 filed on June 19, 2013, shares purchased by our President and CEO, Mark A. Sirgo, on June 17, 2013 was reported on Form 4 filed on June 24, 2013 and new hire options to our Chief Financial Officer, Ernest R. De Paolantonio, on October 17, 2013 was reported on Forms 3 and 4 filed on October 23, 2013.

Compensation Committee Report*

Our Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis (CD&A) included in this Annual Report. Based on that review and discussion, the Compensation Committee has recommended to the board of directors that the CD&A be included in this Annual Report.

Submitted by:

The Compensation Committee of the Board of Directors

/s/ Samuel J. Sears Jr, Chairman
/s/ William B. Stone
/s/ William S. Poole

* The information contained in this Compensation Committee Report shall not be deemed to be soliciting material or filed or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), except to the extent that we specifically request that the information be treated as soliciting material or specifically incorporate it by reference into a document filed under the Securities Act of 1933, as amended, or the Exchange Act.

Compensation Discussion and Analysis

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

Table of Contents

We currently employ three executive officers, each of whom serves as a Named Executive Officer (or NEO) for purposes of Securities and Exchange Commission (SEC) reporting: (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 and Chief Financial Officer; and (3) Andrew L. Finn, Pharm.D., our Executive Vice President of Product Development.

This Compensation Discussion and Analysis (CD&A), sets forth our philosophies underlying the compensation for our executive officers and our employees generally.

Objectives of Our Compensation Program

The Committee s philosophy seeks to align the interests of our stockholders, officers and employees by tying compensation to individual and company performance, both directly in the form of salary or annual cash incentive payments, and indirectly in the form of 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 is a long-term proposition and outcomes may not be measurable for several years. Therefore, in order to build long-term value for our company and its 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 current company activities but also reflects contributions to building long-term value.

We utilize the services of the Radford Group, an AON consulting company (Radford) to review compensation programs of peer companies in order to assist the Committee in determining the compensation levels for our NEOs, as well as for other employees of our company. 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 biennially as we do not believe that material differences will occur over a shorter period. However, we may review the peer group more often should circumstances warrant such action. The current peer group used to evaluate NEO compensation for the fiscal year ended December 31, 2013 includes the following companies:

Company	Location
AcelRX Pharmaceuticals, Inc.	Redwood City, CA
Agenus, Inc.	Lexington, MA
Amicus Therapeutics	Cranbury, NJ
Anacor Pharmaceuticals, Inc.	Palo Alto, CA
ArQule, Inc.	Woburn, MA
BioCyrst Pharmaceuticals	Durham, NC

Cempra, Inc.	Chapel Hill, NC
Cytokinetics, Inc.	South San Francisco, CA
Dyax Corp.	Burlington, MA
Galena BioPharma, Inc.	Lake Oswego, OR.
Heron Therapeutics, Inc. (formerly A.P. Pharma, Inc.)	Redwood City, CA
Inovio Pharmaceuticals, Inc.	San Diego, CA
Insmed Inc.	Richmond, VA
OncoGenex Pharmaceuticals, Inc.	Bothell, WA
Oncothyreon, Inc.	Seattle, WA
Pozen Inc.	Chapel Hill, NC
Raptor Pharmaceuticals Corp.	Novato, CA
Sunesis Pharmaceuticals , Inc.	South San Francisco, CA
Targacept, Inc.	Winston-Salem, NC
Threshold Pharmaceuticals , Inc.	Redwood City, CA
Vanda Pharmaceuticals, Inc.	Rockville, MD
Zalicus Inc.	Cambridge, MA
Ziopharm Oncology, Inc.	New York, NY

Table of Contents

With respect to our employees and non-senior management, we will also take into consideration local 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 for our NEOs and selected senior officers of our company.

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.

Performance Bonus Plan

We have a performance bonus plan under which bonuses are paid to our NEOs based on achievement of extraordinary company performance goals and objectives established by the Committee and/or the 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 company s 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 the company, the Committee and our board of directors have decided, from time to time and after consulting with the Chief Executive Officer, to not pay cash bonuses in order that we may conserve cash and support ongoing development programs. Regardless of our cash position, we consistently grant annual merit-based stock options (and, more recently, 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 bonus plan, expressed as a percentage of base salary for the year. Actual payouts under the performance 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, 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 the company. While cash compensation is a significant component of

employees overall compensation, the Committee and the 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.

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 BDSI Performance Long Term Incentive Plan (which we refer to as 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 Restricted Stock Units (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. 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.

Table of Contents

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 (with 100,000 Performance RSUs being reserved for future hires). 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. During 2013, 8,986 Performance RSUs vested. 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).

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 James A. McNulty, our Senior Vice President - Finance and Treasurer, Dr. Niraj Vasisht, our Senior Vice President Product Development and CTO, to Albert J. Medwar, our Vice President of Marketing, to George Ng, our Senior Vice President and General Counsel and to David L. Acheson, our Vice President Sales and Managed Markets. 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. Further, we believe that the interests of our stockholders will be best served if the interests of these members of our management are aligned with theirs. 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. We also believe that it is important to provide severance benefits to members of our management, to promote stability and 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 the company, 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 means 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 contracts 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 the company and individual performance, competition for talent, each NEO s total compensation package, assessments of internal pay equity and industry data. Stock price performance has generally not been a 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, we previously determined to establish and maintain a list of peer companies to best assure ourselves that we are compensating our executives on a fair and reasonable basis. We have established two peer group reviews with Radford. The first group is for NEOs, which is based on a national review and was set forth above under the heading Objectives of our Compensation Program. The second is intended for non-NEOs and focuses on similar sized companies located on the East Coast. The availability of peer data is used by the Committee strictly as a guide in determining compensation levels with regard to salaries, cash bonuses and performance related annual stock option grants to all employees. However, the availability of this data does not imply that the 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. In the event that a particular NEO salary meets the 50th percentile, the Committee has the authority, should it desire, or if it is deemed warranted, to go above that level but not to exceed the 75th percentile of the peer group. The Committee has the flexibility to raise this level in the event it becomes necessary; however the 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.

Table of Contents

Performance 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 executive officers. These goals are weighted by relative importance. The draft goals and proposed weightings are presented to the Committee and the board of directors and discussed, revised as necessary, and then approved by the board of directors in January of each year. The 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 with the 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 bonus plan for our executive officers in 2013 was adopted by the Committee in January 2009. 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 Chief Executive Officer, and up to 40% of salary for our NEOs and up to 30% of salary for certain other officers. In setting these percentages, the Committee determined that the above percentages were reasonable and in line with other companies at our stage of development. 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 Chief Executive Officer 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 stock option 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. The Committee agreed at the July 2012 board of directors meeting that NEO s and our other officers above the Director level would be able to achieve on an annual basis, a target equity grant up to the 50th percentile as determined by the peer group. Depending on the performance of the company, the NEO s and other officers were able to receive beyond 100% of their targeted annual equity grant, but not in an amount to exceed the 75th percentile of the peer group. With respect to Director, and below, based on peer data, employees target equity grant is up to the 50th percentile as determined, but not to exceed the 75th percentile of the peer group. However, the availability of this data does not imply that the Committee is under any obligation to exactly follow its peer companies and has the flexibility to make annual adjustments. It is generally expected that the target amount would be granted if 100% performance is achieved.

Equity Grant Practices

All stock options or RSUs granted to the NEOs are approved by the 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 company employees. Grants are generally made: (i) on the employee s start date and (ii) at board of directors 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 Committee may make additional special awards for extraordinary individual or company performance.

Compensation Setting Process

Near the end of the year and at an in person meeting held each January, the board of directors and Committee assess our overall corporate performance and discuss the relative achievement of the corporate goals. The relative achievement of each goal is assessed and quantified and the summation of the individual components results in the corporate goal rating. The independent directors of the board (three of whom comprise the Committee) meet in executive session or confer privately to further discuss and approve the final corporate goals rating, expressed as a percentage. A majority vote of the committee is sufficient to approve the final disbursement of salary increases, cash bonuses and option or RSU grants.

Also near the end of the year, the CEO evaluates the individual performance of each NEO (other than himself) and provides the Committee with an assessment of the performance of each other 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.

Table of Contents

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 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 company priorities throughout the year.

The 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 the board of directors. These recommendations may be adjusted by the Committee prior to finalization. For the CEO, the Committee evaluates his performance, taking into consideration input from the other members of the board of directors, and considers the achievement of overall corporate objectives by both the CEO specifically and the company generally. The CEO is not present during the 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 Committee has the authority to directly engage, at our Company s 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 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 Committee is under any obligation to exactly follow peer companies compensation practices.

We paid consultant fees to Radford of $42,988 in 2013. 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.

2013 Compensation Decisions

General Assessment of Management Performance in 2013

The Committee and the board of directors conducted the performance and compensation review for 2013 during January and February of 2014. In assessing our performance towards the achievement of stated corporate goals for the year, the Committee and the board of directors agreed that the results, when compared to the objectives, were 100% achieved. There were many critical goals that needed to be addressed and followed with critical attention to detail throughout the year, and our company was able to achieve those goals.

The primary focus of management and employees was on the continuing development of BUNAVAIL and, in conjunction with Endo, our BEMA® Buprenorphine chronic pain program.

With respect to BUNAVAIL , the Company completed key clinical studies and, after meeting with the FDA, submitted a NDA in the third quarter. In addition, the Company identified manufacturing and supply sources for BUNAVAIL and completed arrangements with those sources. The Company also developed extensive plans for the commercialization of BUNAVAIL and made several significant management hires in anticipation of a product launch, pending FDA approval in the second half of 2014.

With respect to the Company s BEMA® Buprenorphine chronic pain program, the Company and its development partner, Endo, completed one key clinical trial, triggering a milestone payment by Endo to the Company, and

proceeded toward the completion of a second clinical trial. The Company maintained a productive and collaborative relationship with Endo during the year.

Further in 2013, the Company completed a licensing agreement for topical clonidine, initiated the FDA approval process for clonidine with a meeting with the FDA, and developed plans for clinical studies to be initiated in 2014. Finally, the Company s patent position was advanced with several important filings with and decisions by, the U.S. Patent Office.

2013 Performance Assessments and Bonus Calculations

For 2013, our performance bonus plan set the following target payouts, expressed as a percentage of base salary. For our CEO, the target bonus opportunity was 60% of base salary, for our Chief Financial Officer the target bonus opportunity was 35% of base salary and for our Executive Vice President, Product Development the target bonus opportunity was 40% of base salary.

The elements that the Committee and the board of directors established as our overall corporate goals for 2013 included a variety of development and operational objectives. The 2013 goals were established in January 2013. The objectives were development/clinical, commercial, financial and operational in nature.

Table of Contents

During January and February 2014, the Committee and the board of directors considered year-end compensation for 2013 performance. Specifically, the Committee and the board of directors observed and recognized that the following key Corporate Objectives were 100% met:

- Completed clinical studies for BUNAVAIL and submitted a NDA to the FDA;
- Identified and secured manufacturing and supply sources, and developed a comprehensive commercialization plan, for BUNAVAIL and expanded the Company s management capability with key personnel hires; and
- Successfully continued its arrangements with Endo for the development for our BEMA® Buprenorphine chronic pain program.

These and other accomplishments reflected the efforts of all our employees, including the NEOs, and were taken into account by the Committee in providing our NEOs and employees with equity grants, performance cash bonus awards and salary increases.

During the July 2013 Board of Directors meeting, the Committee and board of directors agreed to make salary adjustments for many employees and approved the issuance of 50% of each employee s annual cash bonus target. This action was taken to recognize the positive completion of company objectives at mid-year. Additionally, this was done to recognize all of our employees efforts and to further motivate our employees to continue their efforts for the remainder of the year and to ensure positive completion of all of our 2013 corporate objectives. The cost associated with this action amounted to a total increase in salaries of approximately $0.11 million, and the cost of providing for the issuance of 50% of cash bonuses was approximately $0.62 million in the aggregate. In January 2014, the Committee agreed that each employee would receive 100% of the target cash bonuses for the full year 2013, which is approximately $1.31 million in the aggregate (50% was previously paid pursuant to the above July 2013 approved adjustments).

The Equity Bonus Awards were granted at an amount equal to the 75th percentile of the Radford Group recommendations, to be paid out as follows: (i) Company employees at or above the position of vice president will be granted their Equity Bonus Awards in RSUs at a ratio of 1.5 Stock options: 1 RSU; (ii) Company employees at or below the position of senior director will be granted their Equity Bonus Awards in stock options to be priced at the 30-day volume weighted average price of the Company s common stock as of the close of January 30, 2014. The total options for this award amounted to 95,796 options, have a value of approximately $0.5 million and vest annually in one-third increments. The total RSUs for this award amounted to 897,500, have an approximate value of $8 million and vest annually in one-third increments.

As a special recognition award to two of our key employees, for their efforts during 2013, 50,000 RSUs were granted to each employee in January 2014, which have an approximate value of $0.8 million and vest annually in one-third increments.

Individual Performance and Compensation of the President and CEO

The Committee approved an increase in Dr. Sirgo s base salary at our July 2013 board of directors meeting to be effective January 1, 2014. As a result, Dr. Sirgo s base salary increased from $460,920 to $479,357, based on the

Committee s review of peer companies and the strong company and personal performance relating to Dr. Sirgo.

In evaluating Dr. Sirgo s individual performance for 2013, the Committee, with input from the other board members, concluded that the following salient factors warranted his salary increase: Dr. Sirgo s leadership in the continuing and timely development of both BUNAVAIL and the BEMA® Buprenorphine chronic pain program; his guidance in the development and initial implementation of commercialization plans for BUNAVAIL ; his exemplary representation of the Company with the investment community, including the Company s institutional shareholders; and the overall advancement of the Company s corporate strategies. The Committee therefore approved that Dr. Sirgo should receive 100% of his cash bonus target, which is 60% of his 2013 salary. The Committee further approved that Dr. Sirgo should receive 100% of his annual equity award at the 75th percentile of our company s peer group. This award, which was granted and priced on February 20, 2014, is subject to shareholder approval, and composed of 290,511 RSUs. These RSU s (valued at $2.6 million) will vest annually in one-third increments. Dr. Sirgo s cash bonus totaled $0.276 million, or 60% of base salary, of which half was paid in August 2013 and half was paid in February 2014.

Compensation Highlights for the other Executive Officers

Chief Financial Officer

Mr. De Paolantonio joined our Company in October 2013 and his base salary was set at $300,000.

In evaluating Mr. De Paolantonio individual performance for 2013, the Committee, with input from the other board members, concluded that Mr. DePaolantonio while joining the company in October immersed himself in the company s financial and forward looking strategy particularly around the BUNAVAIL launch preparedness and provided immediate and impactful financial guidance in this regard. Mr. De Paolantonio will play a key role in the commercial operations of the BUNAVAIL launch going forward particularly as it relates to supply chain and distribution. The Committee therefore approved that Mr. De Paolantonio should receive a pro-rated portion of his cash bonus target, which is 35% of his 2013 salary. The Committee further approved that Mr. De Paolantonio should receive a pro-rated portion of his annual equity award at the 75th percentile of our company s peer group. This award,

Table of Contents

which was granted and priced on February 20, 2014, is subject to shareholder approval, and composed of 25,598 RSUs. These RSU s (valued at $0.2 million) will vest annually in one-third increments. Mr. De Paolantonio s cash bonus was $0.024 million, which was a pro-rated portion of 35% of base salary, which was paid in February 2014.

Executive Vice President Product Development

The Committee approved an increase in Dr. Finn s base salary at our July 2013 board of directors meeting to be effective January 1, 2014. As a result, Dr. Finn s salary increased from $311,700 to $324,168, based on the Committee s review of peer companies and the strong company and personal performance relating to Dr. Finn.

In evaluating Dr. Finn s individual performance for 2013, the Committee, with input from the other board members, concluded that Dr. Finn was instrumental in the prosecution and completion of clinical studies for both BUNAVAIL and the BEMA® Buprenorphine chronic pain program, in the filing submission with the FDA of the NDA for BUNAVAIL , and in the advancement of the Company s development of a clonidine topical gel product. The Committee therefore approved that Dr. Finn should receive 100% of his annual equity award at the 75th percentile of the company peer group. This award, which was granted on February 20, 2014, is subject to shareholder approval and is composed of 153,387 RSUs. These RSU s (valued at $1.4 million) will vest annually in one-third increments. Dr. Finn s cash bonus totaled $0.124 million, or 40% of base salary, of which half was paid in August 2013 and half was paid in February 2014.

Severance and Change in Control Benefits

The change in control benefits for all applicable persons have 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 the 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.

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). At this time, we do not have a policy to factor in 162(m) limitations into the determination of base salary or bonus amounts since the aggregate salary and bonus payments for each individual are below the $1,000,000 deductibility limitation.

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 our company 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.

Table of Contents

Compensation Risk Assessment

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

Compensation Committee Independence

All members of the 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, 2013, 2012 and 2011. 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, 2013.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (17)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mark A. Sirgo, Pharm.D. President, Chief Executive Officer and Director	2013	$ 462,734	$ 276,552[1]	$ 13,508[2]				$ 23,849[3]	$ 776,643
	2012	$ 435,612							$ 786,103
			$ 184,842		$ 116,709			$ 48,940[4]	$ 667,654
	2011	$ 413,920							
			$ 184,842		$ 107,382[5]			$ 22,176[6]	
Ernest R. De Paolantonio, CPA MBA Chief Financial Officer and Secretary[7]	2013	$ 61,154			$ 213,870				$ 275,024
	2012								
	2011								
James A. McNulty, CPA Senior Vice President Finance and Treasurer[8]	2013	$ 309,132	$ 122,927[9]	$ 4,861[2]				$ 30,558[10]	$ 467,478
	2012	$ 303,441	$ 88,475		$ 77,864			$ 29,255[11]	$ 499,035
					$ 36,269				
	2011	$ 300,118	$ 73,720					$ 29,529[12]	$ 439,636
Andrew L. Finn, Pharm.D. Executive VP of Product Development	2013	$ 313,514	$ 124,680[13]	$ 4,861[2]				$ 28,185[14]	$ 471,240
	2012	$ 296,785	$ 87,900					$ 36,755[15]	$ 495,124

2011	$ 283,387	$ 60,515	$ 73,684 $ 34,321	$ 18,222[16]	$ 396,445

(1) The bonus disclosed in this item of $276,552 includes $138,276 related to 2012, but was contingent upon board approval, which occurred January 2013.
(2) The stock awards disclosed in this item consists of vested RSUs issued in 2013 under our LTIP.
(3) Includes: $9,392 of health insurance premiums paid and 401(k) matching of $14,457 paid in 2013.
(4) Includes: Vacation payout of $26,618, $9,822 of health insurance premiums paid and 401(k) matching of $12,500 paid in 2012.
(5) The compensation disclosed in this item included 25,000 stock options granted as compensation for serving as a director.
(6) Includes: $9,926 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2011.
(7) Ernest R. DePaolantonio was hired as Chief Financial Officer on October 9, 2013
(8) James A. McNulty was Chief Financial Officer until October 9, 2013, and then became our Senior Vice President Finance and Treasurer. Effective October 9, 2013, he is no longer considered a named executive officer of our company.
(9) The bonus disclosed in this item of $122,927 includes $61,463 related to 2012, but was contingent upon board approval, which occurred January 2013.
(10) Includes: $17,545 of health insurance premiums paid and 401(k) matching of $13,013 paid in 2013.
(11) Includes: $16,755 of health insurance premiums paid and 401(k) matching of $12,500 paid in 2012.

Table of Contents

(12) Includes: $17,279 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2011.
(13) The bonus disclosed in this item of $124,680 includes $62,340 related to 2012, but was contingent upon board approval, which occurred January 2013.
(14) Includes: $9,392 of health insurance premiums paid and 401(k) matching of $18,793 paid in 2013.
(15) Includes: Vacation payout of $13,894, $10,361 of health insurance premiums paid and 401(k) matching of $12,500 paid in 2012.
(16) Includes: $10,411 of health insurance premiums paid and 401(k) matching of $7,811 paid in 2011.
(17) Aggregate grant date fair value according to ASC 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 2013 of $462,374 per year and a bonus of $276,552, which bonus was composed of $138,276 related to 2012 and $138,276 related to 2013 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 and Secretary - Mr. De Paolantonio s current employment agreement, dated October 1, 2013 includes a base salary, 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 2013 of $61,154.

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.

James A. McNulty, CPA, Senior Vice President Finance and Treasurer Through December 31, 2007, Mr. McNulty served as part-time Chief Financial Officer, devoting approximately 50% of his time to our company. Beginning January 1, 2008 through October 9, 2013, Mr. McNulty devoted substantially all of his time to our company as Chief Financial Officer, Secretary and Treasurer. On October 9, 2013, Mr. McNulty voluntarily relinquished his position as CFO and became our Senior Vice President Finance and Treasurer. Mr. McNulty s current employment agreement, dated February 22, 2007, was amended October 18, 2013 to reflect this new position. No other changes were made to the original agreement, which is subject to successive, automatic one-year

Table of Contents

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 40%), and other employee benefits. Under the terms of his agreement, Mr. McNulty received base salary in 2013 of $309,132 per year and a bonus of $122,926, which bonus composed of $61,463 related to 2012 and $61,463 related to 2013 performance.

We may terminate Mr. McNulty s employment agreement without cause and Mr. McNulty may resign upon 30 days advance written notice. We may immediately terminate Mr. McNulty s employment agreement for Good Cause (as defined in the employment agreement). Upon the termination of Mr. McNulty s employment for any reason, Mr. McNulty 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. McNulty is terminated during the term of his employment agreement other than for Good Cause (as defined in the employment agreement), or if Mr. McNulty terminates his employment for Good Reason (as defined in the employment agreement), Mr. McNulty 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 Mr. McNulty 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, the employment agreement will terminate prior to its scheduled expiration date in the event of Mr. McNulty s death or disability. The employment agreement also includes a 2 year non-competition, non-solicitation and confidentiality covenants on terms identical to his former employment agreement with us, except that if Mr. McNulty s employment is terminated upon a Change of Control, the non-competition period will be 18 months. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Andrew L. Finn, Pharm.D., Executive Vice President of Product Development Dr. Finn 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 40%), and other employee benefits. Under the terms of his agreement, Dr. Finn received base salary in 2013 of $313,514 per year and a bonus of $124,680, which bonus composed of $62,340 related to 2012 and $62,340 related to 2013 performance.

We may terminate Dr. Finn s employment agreement without cause and Dr. Finn may resign upon 30 days advance written notice. We may immediately terminate Dr. Finn s employment agreement for Good Cause (as defined in the agreement). Upon the termination of Dr. Finn s employment for any reason, Dr. Finn 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. Finn is terminated during the term of the employment agreement other than for Good Cause (as defined in the employment agreement), or if Dr. Finn terminates his employment for Good Reason (as defined in the employment agreement), Dr. Finn 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. Finn 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. Finn s employment agreement will terminate prior to its scheduled expiration date in the event of Dr. Finn s death or disability.

Dr. Finn s employment agreement also includes a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement, except that if Dr. Finn s employment is terminated

upon a Change of Control, the non-competition period will be 18 months. 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, 2013.

Table of Contents

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 (#)	Option 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								371,554[4]	$ 2,188,453
								420,000[5]	$ 2,473,800
	33,026			$ 1.96	2/15/22				
	15,140	30,281[1]		$ 1.78	2/9/22				
	25,000			$ 3.47	7/20/21				
	14,912	7,457[2]		$ 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				
	70,985			$ 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				
	49,000			$ 3.03	12/1/15				
	20,000			$ 2.94	8/22/15				
	5,147			$ 3.40	10/21/14				
Ernest R. De Paolantonio, CPA MBA		55,659[3]		$ 5.39	10/17/23				
James A. McNulty, CPA[6]								133,760[4]	$ 787,846
								154,735[5]	$ 911,389
	10,977	21,956[1]		$ 1.78	2/9/22				

	10,812	5,407[2]	$ 3.55	2/25/21		
	24,844		$ 2.43	7/21/20		
	27,080		$ 3.90	1/21/20		
	100,000		$ 4.83	4/30/19		
	12,275		$ 3.05	1/22/19		
	100,000		$ 6.63	4/13/17		
	3,235		$ 3.40	10/21/14		
Andrew L. Finn, Pharm.D					133,760[4]	$ 787,846
					160,601[5]	$ 945,940
	18,128		$ 1.96	2/15/22		
	10,388	20,777[1]	$ 1.78	2/9/22		
	10,232	5,116[2]	$ 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		
	10,603		$ 2.05	7/27/16		
	49,000		$ 3.03	12/1/15		
	8,929		$ 2.94	7/28/15		
	5,147		$ 3.40	10/21/14		

Table of Contents

(1) Of the unvested stock options, half of the unvested stock options will vest on February 9, 2014, and another half will vest on February 9, 2015.
(2) These remaining stock options will vest on February 25, 2014.
(3) Of the unvested stock options, one third of the unvested stock options will vest on October 17, 2014, another third will vest on October 17, 2015 and the remaining third will vest on October 17, 2016.
(4) 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.
(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.
(6) James A. McNulty was Chief Financial Officer until October 9, 2013, and then became our Senior Vice President Finance and Treasurer. Effective October 9, 2013, he is no longer considered a named executive officer of our company.

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 3,192,596 shares of common stock were outstanding as of December 31, 2013 under the Amended and Restated 2001 Incentive Plan. Although the Amended and Restated 2001 Incentive Plan expired, the 3,192,596 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 is 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 its 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.

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 4,192,927 shares of our common stock at prices ranging from $1.38 to $6.63 are outstanding at December 31, 2013. There were no options granted during 2013 whose exercise price was lower than the estimated market price of the stock at the grant date.

Options issued during 2013 to employees under the 2011 Equity Incentive Plan totaled 278,794 shares, at exercise prices ranging from $4.33 to $5.39. There were no options issued to directors and officers under the 2011 Equity Incentive Plan during 2013 (other than new hire options to our new Chief Financial Officer) as we have migrated to the issuance of RSUs.

Table of Contents

Option Exercises and Stock Vested

The following information sets forth stock options exercised by the executive officers during the year ended December 31, 2013:

	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.			3,446	$ 13,508
Ernest R. De Paolantonio, CPA MBA				
James A. McNulty, CPA [1]			1,240	$ 4,861
Andrew L. Finn, Pharm.D.			1,240	$ 4,861

(1) James A. McNulty was Chief Financial Officer until October 9, 2013, and then became our Senior Vice President Finance and Treasurer. Effective October 9, 2013, he is no longer considered a named executive officer of our company.

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

	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	All Other Option Awards: Number of Securities Underlying	Exercise or Base Price of Option	Closing stock price on Award	Gra Date Valu Stock

e	Grant Date	Threshold ($)	Target ($)	Maximum ($)	Threshold (#)	Target (#)	Maximum (#)	Stocks or Units (#)	Options (#)	Awards ($/Sh)	date ($/Sh)	Opt Awa
A. , n.D.[1]	3/18/13					3,446						$ 13
t R. De ntonio, MBA	10/17/13					55,659[2]				$ 5.39	$ 5.63	$ 213
A. ulty, 3)	3/18/13					1,240						$ 4
ew L. n.D [4]	3/18/13					1,240						$ 4

Table of Contents

(1) Does not include 371,554 unvested RSUs to be issued under our LTIP upon the achievement of certain pre-defined performance criteria, and 420,000 unvested RSUs which will vest in thirds beginning 2014.
(2) Employee stock options granted as award.
(3) Does not include 133,760 unvested RSUs to be issued under our LTIP upon the achievement of certain pre-defined performance criteria, and 154,735 unvested RSUs which will vest in thirds beginning 2014. James A. McNulty was Chief Financial Officer until October 9, 2013, and then became our Senior Vice President Finance and Treasurer. Effective October 9, 2013, he is no longer considered a named executive officer of our company.
(4) Does not include 133,760 unvested RSUs to be issued under our LTIP upon the achievement of certain performance criteria, and 160,601 unvested RSUs which will vest in thirds beginning 2014.

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, 2013 and (ii) the stock price was $5.89, which was the closing market price of our common stock on December 31, 2013, the last business day of the 2013 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	$ 723,276[1]	$ 1,414,656[1]
Acceleration of Options		$ 1,686,354[2]
Total Cash and Benefits	**$ 723,276**	**$ 3,101,010**
Ernest R. De Paolantonio, CPA		
Cash Payment	$ 447,512[1]	$ 297,512[1]
Acceleration of Options		$ 27,830[2]
Total Cash and Benefits	**$ 447,512**	**$ 325,342**

James A. McNulty, CPA (3)				
Cash Payment	$	471,015(1)	$	701,503(1)
Acceleration of Options			$	462,073(2)
Total Cash and Benefits	**$**	**471,015**	**$**	**1,163,576**
Andrew L. Finn, Pharm.D.				
Cash Payment	$	474,135(1)	$	707,910(1)
Acceleration of Options				971,348(2)
Total Cash and Benefits	**$**	**474,135**	**$**	**1,679,258**

Table of Contents

(1) Includes severance payment and accrued and unused vacation time as of December 31, 2013.
(2) Determined by taking excess of the fair market value of our common stock on December 31, 2013, less the exercise price of each accelerated option.
(3) James A. McNulty was Chief Financial Officer until October 9, 2013, and then became our Senior Vice President Finance and Treasurer. Effective October 9, 2013, he is no longer considered a named executive officer of our company.

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 ($)(4)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings	All Other Compensation ($)	Total ($)

	($)		($)	
Frank E. O Donnell, Jr.	$ 368,736[1]	$ 6,770[2]	$ 22,859[3]	$ 398,365
William B. Stone	$ 69,000	$ 67,350[4]		$ 136,350
John J. Shea	$ 52,500	$ 44,900[5]		$ 97,400
William S. Poole	$ 100,325[6]	$ 44,900[7]		$ 145,225
Samuel P. Sears, Jr.	$ 52,000	$ 84,650[8]		$ 136,650
Thomas W. D Alonzo	$ 33,500	$ 61,431[9]		$ 94,931

(1) Compensation for serving as Executive Chairman, which includes $138,276 as bonus, composed of $69,138 for 2012 and $69,138 for 2013.
(2) The stock awards disclosed in this item consists of vested RSUs issued in 2013 under our LTIP. Does not include 186,273 unvested RSUs to be issued under our LTIP upon the achievement of certain performance criteria.
(3) Includes $22,859 in health benefits paid in 2013.
(4) Does not include 15,000 unvested RSUs which will vest in August 2014.
(5) Does not include 10,000 unvested RSUs which will vest in August 2014.
(6) Includes compensation of $48,326 for serving as Chairman of the board-level Risk Management Committee and associated sub-committee.

Table of Contents

(7) Does not include 10,000 unvested RSUs which will vest in August 2014.
(8) Does not include 10,000 unvested RSUs which will vest in August 2014.
(9) Does not include 10,000 unvested RSUs which will vest in August 2014.

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 advance):

$40,000 annual cash retainer to each board member.

$10,000 annual cash retainer to the Lead Director.

$15,000 annual cash retainer to the Chairman of the Audit Committee.

$15,000 annual cash retainer to the Chairman of the Strategic Development Committee

$10,000 annual cash retainer to the Chairman of the Compensation Committee.

$7,500 annual cash retainer to the Chairman of the Nominating & Corporate Governance Committee.

$7,500 annual cash retainer to each non-Chairman Audit Committee member.

$7,500 annual cash retainer to each non-Chairman of the Strategic Development Committee

$5,000 annual cash retainer to each non-Chairman Compensation Committee member.

$4,000 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, 2013 was 121,978, of which 66,978 vested upon issuance in August 2013 and 55,000 vest in August 2014.

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.

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 (with 100,000 Performance RSUs being reserved for future hires). A total of 8,986 RSUs vested during the year ended December 31, 2013. 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.

Table of Contents

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

The following table sets forth, as of March 11, 2014, 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., 801 Corporate Center Drive, Suite #210, Raleigh, NC 27607.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class as of March 11, 2014[1]
Federated Investors Inc.[2]	5,583,000	11.65%
Broadfin Capital, LLC[3]	3,472,054	7.24%
Deerfield Management Co/NY[4]	4,151,163	8.66%
Baker Brothers Life Sciences, L.P.[5]	2,985,005	6.23%
FMR LLC[6]	2,927,631	6.11%
Adage Capital Partners GP LLC[7]	2,800,000	5.84%
Hopkins Capital Group II, LLC[8]	2,425,490	5.06%
Frank E. O Donnell, Jr., M.D.[9]	2,776,751	5.76%
Mark A. Sirgo, Pharm.D.[10]	1,890,860	3.87%
Ernest R. De Paolantonio, CPA MBA[11]	1,000	*
Andrew L. Finn, Pharm.D.[12]	975,487	2.02%
William B. Stone[13]	278,175	*
John J. Shea[14]	25,805	*
William S. Poole[15]	276,190	*
Samuel P. Sears, Jr[16]	41,216	*
Thomas W. D Alonzo[17]	90,625	*
All Directors and Officers as a group (9 persons)	6,356,109	12.70%

* Less than 1%

(1) Based on 47,932,326 shares of common stock outstanding as of March 11, 2014 and shares beneficially owned by the referenced parties as described below.

(2) Based on 13G filed with the SEC on March 10, 2014 by Federated Investors Inc.

(3) Based on a Schedule 13G/A filed with the SEC on February 14, 2014 by Broadfin Capital, LLC who has shared voting and investment power over the shares held.

(4) Based on a Schedule 13G/A filed with the SEC on February 14, 2014 and registered direct offering participation on February 10, 2014 by Deerfield Management Co./NY who has shared voting and investment power over the shares held. Includes 3,580,863 shares of our common stock and 570,300 shares of Series A Preferred stock, which shares are owned by Deerfield Special Situations Funds, L.P., Deerfield Special Situations International Master Fund, L.P. and Deerfield Partners, L.P.

(5) Based on a Schedule 13G/A filed with the SEC on February 14, 2014, Felix J. Baker and Julian C. Baker have voting and investment power over the shares held by Baker Brothers Life Sciences, L.P. Includes 846,005 shares of our common stock and up to a maximum potential of 2,139,000 shares of Series A Preferred stock, of which

184,686 shares are owned by 667, L.P. and 45,845 shares owned by 14159, L.P. The Series A Preferred is only exercisable to the extent that the holders thereof together with their affiliates would beneficially own, for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, no more than 9.98% of the outstanding shares of Common Stock of the Issuer after exercise. As a result of this restriction, the number of shares that may be issued upon conversion of the Series A Preferred by the above holders may change depending upon changes in the outstanding shares.

(6) FMR is an investment adviser registered under Section 203 of the Investment Advisers Act of 1940 and has the sole dispositive rights on the shares owned by various investment companies registered under Section 8 of the Investment Company Act of 1940, which owns 2,916,731 shares or 6.14%. The several investment companies each have the sole voting power to vote the shares owned by them.

(7) Based on a Schedule 13G filed with the SEC on December 6, 2012, Adage Capital Partners GP, LLC who has shared voting and investment power over the shares held.

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

(9) 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 4). 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

Table of Contents

Dr. O Donnell disclaims beneficial interest. Also excludes 4,577 shares of common stock owned by Dr. O Donnell s sister. In addition, this number includes 96,261 shares owned personally by Dr. O Donnell and options to purchase 255,000 shares of our common stock, all of which is currently exercisable. Does not include 140,000 shares of unvested RSUs which vest one half February 2015 and the remaining half February 2016. Also does not include 186,273 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.

(10) Includes 913,250 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Includes options to purchase 977,610 shares of common stock, all of which are currently exercisable. Excludes options to purchase 15,141 shares of common stock which are not currently exercisable. Does not include 280,000 shares of unvested RSUs which vest one half February 2015 and the remaining half February 2016. Also does not include 371,554 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.

(11) Mr. De Paolantonio is our Chief Financial Officer and Secretary. Includes 1,000 shares owned by Mr. De Paolantonio. Excludes options to purchase 55,659 shares of common stock which are not currently exercisable. Mr. De Paolantonio s address is 3478 Renaissance Park Place Cary, NC. 27513.

(12) Dr. Finn is our Executive Vice President of Clinical Development and Regulatory Affairs. Includes 660,450 shares owned by Dr. Finn. Includes options to purchase 315,037 shares of common stock, all of which are currently exercisable. Excludes options to purchase 10,389 shares of common stock which are not currently exercisable. Does not include 107,067 shares of unvested RSUs which vest one half February 2015 and the remaining half February 2016. Also does not include 133,760 unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved. Dr. Finn s address is 3104 Raymond Street, Raleigh, NC. 27607.

(13) Mr. Stone is a Director. Includes 63,175 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 2014. Mr. Stone s address is 11120 Geyer Downs Lane, Frontenac MO. 63131.

(14) Mr. Shea is a Director. Includes 13,305 shares owned and options to purchase 12,500 shares of our common stock, all of which are currently exercisable. Does not include 10,000 shares of unvested RSUs which will vest August 2014. Mr. Shea s address is 290 Wax Myrtle Trail, Southern Shores, NC. 27949.

(15) Mr. Poole is a Director. Includes 18,690 shares owned and options to purchase 257,500 shares of our common stock, all of which are currently exercisable. Does not include 10,000 shares of unvested RSUs which will vest August 2014. Mr. Poole s address is 7813 Hardwick Drive, Raleigh, NC. 27615.

(16) Mr. Sears is a Director. Includes 23,853 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 2014. Mr. Sears address is 1 Fieldstone Drive, Winchester, MA. 01890.

(17) Mr. D Alonzo is a Director. Includes 25,625 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 2014. Mr. D Alonzo s address is 908 Vance St, Raleigh, NC. 27608.

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:

Hopkins Capital Group and affiliates

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.

Table of Contents

Other

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, John J. Shea, William S. Poole, Samuel P. Sears, Jr. and Thomas W. D Alonzo 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, 2013 and 2012 totaled $148,900 and $135,850, 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, 2013 and 2012 were $53,638 and $45,711, respectively.

Tax Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for tax compliance, for the years ended December 31, 2013 and 2012 were $20,000 and $18,600, respectively.

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, tax and non-audit services provided by Cherry Bekaert LLP in 2013. 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.

Table of Contents

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 (24)
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 (28)
4.1	Form of Common Stock Purchase Warrant, dated April 20, 2010, issued by the Company to certain institutional investors (22)
4.2	Certificate of Designation of Series A Non-Convertible Preferred Stock, dated November 20, 2012 (31)
4.3	Form of Common Stock Purchase Warrant, dated July 5, 2013, issued by the Company to Midcap Financial SBIC, LP (33)
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)+

Table of Contents

Number	Description
10.17	Letter agreement, dated August 2, 2006, between Meda AB, Arius Pharmaceuticals, Inc, Arius Two, Inc. and the Company (8)
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)

Table of Contents

Number	Description
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 LLC (19)+
10.49	Separation Agreement and General Claims release, effective September 1, 2009, between the Company and Dr. Raphael J. Mannino (20)
10.50	Emezine Settlement Agreement, dated December 30, 2009, between the Company, Accentia, Arius Pharmaceuticals, Inc. and TEAMM (21)
10.51	Form of Warrant for the Company to purchase 2,000,000 shares of Biovest International, Inc. from Accentia (21)
10.52	Securities Purchase Agreement, dated April 20, 2010, between the Company and certain institutional investors. (22)
10.53	License and Supply Agreement, dated May 26, 2010, between the Company, Arius Pharmaceuticals and KunWha Pharmaceutical Co., Ltd (23)+
10.54	License and Supply Agreement, dated October 4, 2010, between the Company, Arius Pharmaceuticals and TTY Biopharm Co., Ltd. (25)+
10.55	Securities Purchase Agreement, dated March 11, 2011, between the Company and certain institutional investors. (26)
10.56	Amendment to Clinical Development and License Agreement, effective May 12, 2011, between the Company, Arius, Arius Two, Inc., CDC V, LLC and NB Athyrium. (27)
10.57	License and Development Agreement, dated January 5, 2012, by and among the Company, Arius, Arius Two and Endo (29)+
10.58	Manufacturing, Supply, and License Agreement dated April 26, 2012 between the Company, Arius Pharmaceuticals and LTS Lohmann Therapie-Systeme AG (30)+
10.59	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 (31)
10.60	Subscription Agreement, dated November 28, 2012, between the Company and certain investors (31)
10.61	License Agreement, dated March 26, 2013, between the Company and Arcion Therapeutics, Inc (32)+
10.62	Credit and Security Agreement, dated July 5, 2013, by and among , the Company, Arius, Arius Two and Midcap Financial SBIC, LP (33)+
10.63	Conditional Offer of Employment, dated October 1, 2013, between the Company and Ernest R. De Paolantonio (34)

10.64	Sales Agreement, dated November 29, 2013, between the Company and Cantor Fitzgerald & Co. (35)
10.65	Securities Purchase Agreement, dated February 7, 2014, between the Company and certain institutional investors. (36)
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 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.*#

Table of Contents

Number	Description
101.ins	XBRL Instance Document
101.xsd	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.

(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 10-Q, November 3, 2009.
(21) Previously filed with Form 8-K, December 31, 2009.
(22) Previously filed with Form 8-K, April 20, 2010.
(23) Previously filed with Form 8-K, May 27, 2010.
(24) Previously filed with Form 8-K, July 23, 2010.
(25) Previously filed with Form 8-K, October 8, 2010.
(26) Previously filed with Form 8-K, dated March 16, 2011.
(27) Previously filed with Form 8-K, dated May 13, 2011.
(28) Previously filed with Form 8-K, dated July 25, 2011.
(29) Previously filed with Form 8-K, dated January 11, 2012.
(30) Previously filed with Form 8-K, dated September 19, 2012.
(31) Previously filed with Form 8-K, dated November 28, 2012.

(32) Previously filed with Form 8-K, dated April 1, 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC.

INDEX TO FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors 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, 2013 and 2012, and the related consolidated statements of operations, stockholders (deficit) equity and cash flows for each of the years in the three-year period ended December 31, 2013. We also have audited the Company s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 1992 (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 2013 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, 2013 and 2012, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2013 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, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 1992 (COSO).

As discussed in Note 2 to the consolidated financial statements, during 2013, the Company recognized a net loss of approximately $57 million and, at December 31, 2013, the Company had incurred cumulative net losses of approximately $151 million. Management s plans in regard to this matter are described in Note 2.

/s/ Cherry Bekaert LLP

Tampa, Florida

March 14, 2014

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2013 AND 2012

	2013	2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,175,809	$ 63,189,307
Accounts receivable	2,794,040	520,812
Prepaid expenses and other current assets	630,657	226,064
Total current assets	26,600,506	63,936,183
Equipment, net	178,168	2,835,707
Idle equipment, net (note 1)	2,844,718	
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,900,000	1,900,000
Acquired product rights	9,050,000	9,050,000
Accumulated amortization	(5,753,502)	(4,770,516)
Total other intangible assets	5,196,498	6,179,484
Derivative asset, warrant		50,300
Other assets	470,535	21,976
Total assets	$ 38,005,425	$ 75,738,650
LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 10,415,981	$ 10,755,049
Notes payable, current maturities	7,333,333	
Deferred revenue, current (notes 5 and 6)	2,927,088	7,990,231
Derivative liabilities (note 10)	4,315,183	4,497,977
Total current liabilities	24,991,585	23,243,257
Notes payable, less current maturities	11,844,706	
Deferred revenue, long-term	1,281,485	2,718,180
Other long-term liabilities	700,000	
Total liabilities	38,817,776	25,961,437
Commitments and contingencies (notes 10 and 14)		

Stockholders (deficit) equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized in 2013 and 2012; 2,709,300 shares of Series A Non-Voting Convertible Preferred Stock outstanding in 2013 and 2012	2,709	2,709
Common Stock, $.001 par value; 75,000,000 shares authorized in 2013 and 2012; 38,204,384 and 37,497,703 shares issued; 38,188,893 and 37,482,212 shares outstanding in 2013 and 2012, respectively	38,204	37,499
Additional paid-in capital	150,506,927	143,703,583
Treasury stock, at cost, 15,491 shares, 2013 and 2012	(47,183)	(47,183)
Accumulated deficit	(151,313,008)	(93,919,395)
Total stockholders (deficit) equity	(812,351)	49,777,213
Total liabilities and stockholders (deficit) equity	$ 38,005,425	$ 75,738,650

See notes to consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

	2013	2012	2011
Revenues:			
Product royalty revenues	$ 1,773,215	$ 1,082,742	$ 2,716,452
Research revenue		13,375	227,668
Research and development reimbursements	2,782,830		
Contract revenue	6,799,838	53,446,309	318,800
Total revenues	11,355,883	54,542,426	3,262,920
Cost of product royalties	2,082,183	1,909,785	1,756,629
Expenses:			
Research and development	53,326,777	35,365,662	20,805,177
General and administrative	12,302,364	10,114,689	7,608,090
Related party general and administrative	46,500	90,500	81,000
Total expenses	65,675,641	45,570,851	28,494,267
(Loss) income from operations	(56,401,941)	7,061,790	(26,987,976)
Interest (expense) income, net	(902,658)	280,709	188,701
Derivative gain (loss)	121,228	(5,594,152)	3,463,453
Other (expenses) income, net	(210,242)	32,954	10,706
	(991,672)	(5,280,489)	3,662,860
(Loss) income before taxes	(57,393,613)	1,781,301	(23,325,116)
Income tax expense		(129,120)	
Net (loss) income attributable to common stockholders	$ (57,393,613)	$ 1,652,181	$ (23,325,116)
Basic:			
Weighted average common stock shares outstanding	37,941,044	30,546,581	28,322,477
Basic earnings per share	$ (1.51)	$ 0.05	$ (0.82)
Diluted:			

Diluted weighted average common stock shares outstanding	37,941,044	30,689,235	28,322,477
Diluted earnings per share	$ (1.51)	$ 0.05	$ (0.82)

See notes to consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS (DEFICIT) EQUITY

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

	Preferred Stock Series A		Common Stock		Additional Paid-In			Total Stockholders (Deficit)
	Shares	Amount	Shares	Amount	Capital	Treasury Stock	Accumulated Deficit	Equity
Balances, January 1, 2011		**$**	24,038,445	$ 24,039	$ 82,055,934	$ (47,183)	$ (72,246,460)	$ 9,786,330
Stock-based compensation					1,226,724			1,226,724
Stock option exercise			129,888	130	349,546			349,676
CDC warrant derivative reclassified to equity					336,747			336,747
Exercise of CDC warrants			601,120	601	1,748,658			1,749,259
Private placement offering, net shares issued upon vesting of equity awards			4,807,693	4,808	13,991,965			13,996,773
Net loss							(23,325,116)	(23,325,116)
Balances, December 31, 2011		$	29,577,146	$ 29,578	$ 99,709,574	$ (47,183)	$ (95,571,576)	$ 4,120,393
Stock-based compensation					1,619,269			1,619,269
Stock option exercise			789,305	789	2,053,311			2,054,100
Restricted stock awards			57,500	58	(58)			
Warrant derivative liability reclassified to					1,037,237			1,037,237

equity								
Warrant exercises			281,865	282	920,737			921,019
Private placement offering, net	2,709,300	2,709	6,791,887	6,792	38,363,513			38,373,014
Net income							1,652,181	1,652,181
Balances, December 31, 2012	2,709,300	$ 2,709	37,497,703	$ 37,499	$ 143,703,583	$ (47,183)	$ (93,919,395)	$ 49,777,213
Stock-based compensation					3,327,014			3,327,014
Stock option exercise			115,667	115	357,166			357,281
Restricted stock awards			80,498	80	(80)			
Warrant derivative liability reclassified to equity					11,266			11,266
Warrant exercises			10,000	10	49,990			50,000
Shares issued to Arcion in acquisition of research and development license			500,516	500	2,071,636			2,072,136
Warrants issued in connection with notes payable					986,352			986,352
Net loss							(57,393,613)	(57,393,613)
Balances, December 31, 2013	2,709,300	$ 2,709	38,204,384	$ 38,204	$ 150,506,927	$ (47,183)	$ (151,313,008)	$ (812,351)

See notes to consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

	2013	2012	2011
Operating activities:			
Net (loss) income	$ (57,393,613)	$ 1,652,181	$ (23,325,116)
Adjustments to reconcile net (loss) income to net cash flows from operating activities			
Depreciation	207,441	465,929	444,527
Accretion of debt discount	164,391		
Amortization of intangible assets	1,139,832	1,020,878	890,980
Derivative (gain) loss	(121,228)	5,594,152	(3,463,453)
Stock-based compensation expense	3,327,014	1,619,269	1,226,724
Purchase of Arcion license with common stock	2,072,136		
Changes in assets and liabilities:			
Accounts receivable	(2,273,228)	(419,680)	530,544
Prepaid expenses and other assets	(68,928)	3,822	6,226
Accounts payable and accrued expenses	(656,795)	5,567,962	407,441
Income taxes payable		129,120	
Deferred revenue	(6,499,838)	(3,446,309)	7,133
Net cash flows from operating activities	(60,102,816)	12,187,324	(23,274,994)
Investing activities:			
Purchase of equipment	(76,893)	(38,550)	(286,973)
Purchase of intangible assets		(1,050,000)	
Net cash flows from investing activities	(76,893)	(1,088,550)	(286,973)
Financing activities:			
Proceeds from sales of securities		38,373,014	13,996,773
Proceeds from exercise of stock options	357,281	2,054,100	349,676
Proceeds from exercise of common stock warrants	50,000	921,019	1,749,259
Proceeds from notes payable and warrants	20,000,000		
Payment of deferred financing fees	(241,070)		
(Repayment of) proceeds from related party advances, net		(7,805)	7,805
Net cash flows from financing activities	20,166,211	41,340,328	16,103,513
Net change in cash and cash equivalents	(40,013,498)	52,439,102	(7,458,454)
Cash and cash equivalents at beginning of year	63,189,307	10,750,205	18,208,659

Cash and cash equivalents at end of year	**$ 23,175,809**	**$ 63,189,307**	**$ 10,750,205**
Cash paid for interest	$ 742,097	$	$
Cash paid for taxes	$ 80,457	$	$

See notes to consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

SUPPLEMENTAL CASH FLOW INFORMATION

Non-cash Financing and Investing Activities:

The Company reclassified derivative liabilities of $11,266 to equity during the year ended December 31, 2013 as a result of the exercise of warrants to which the derivatives related.

The Company reclassified derivative liabilities of $1,037,237 to equity during the year ended December 31, 2012 as a result of the exercise of warrants to which the derivatives related.

The Company reclassified derivative liabilities of $336,747 to equity during the year ended December 31, 2011 as a result of the exercise of warrants to which the derivatives related.

See notes to consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

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

Organization:

BioDelivery Sciences International, Inc. (the Company) was incorporated in the State of Indiana on January 6, 1997 and reincorporated as a Delaware corporation in 2002. The Company and its subsidiaries, 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) are collectively referred herein to as the Company.

The Company is a specialty pharmaceutical company that is leveraging its novel, proprietary and patented 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 oncology supportive care. 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. BND is currently and has for several years been an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Significant accounting policies:

Cash and cash equivalents:

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. The Company s cash equivalents include Ultra Short Term Government Funds. Because of the short-term maturities of the Company s cash and cash equivalents, the Company does not believe that an increase in market rates would have a significant impact on the realized value of its investments. The Company places cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation covers $250,000 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, 2013, the Company had approximately $22.8 million, which exceed these insured limits.

Revenue recognition:

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 up-front payments, milestone payments and other forms of payment. The Company currently has multiple license and development agreements that are described in notes 5, 6, 7 and 8.

Meda License, Development and Supply Agreement:

General

The Company entered into license, development and supply agreements (collectively, the Meda Agreements) with Meda AB, a Swedish company (Meda), in September 2007 (covering the United States, Canada and Mexico) and August 2006 (covering certain countries in Europe) to develop and commercialize the Company s sole FDA-approved and marketed product, ONSOLIS® (fentanyl buccal soluble film), a treatment with an initial indication for breakthrough cancer pain. ONSOLIS® is a product consisting of the narcotic fentanyl formulated with the Company s patented BEMA® technology. The Company s deliverables under the Meda Agreements, including the Company s related rights and obligations, contractual cash flows and performance periods, are more fully described in note 5.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Nature of business and summary of significant accounting policies (continued):

License and product development research and development services revenue

Based on the Company s assessment of each arrangement, all deliverables under the Meda Agreements have been accounted for as one combined unit of accounting and, as such, all cash payments from Meda (upfront payments and product development research and development services revenue) related to these deliverables were recorded as deferred revenue. Upon delivery of the license rights to Meda in October 2009, the Company recognized revenue associated with the license and the research and development services rendered related to development of the ONSOLIS® product through the date of FDA and other governmental approval. A portion of the upfront payments have been attributed to the Company s continuing obligation to participate in joint committees with Meda and to provide certain other specified services and this revenue will be recognized as services are provided through expiration of the license agreements.

Endo License and Development Agreement:

General

The Company entered into a worldwide license and development agreement (the Endo Agreement) with Endo Pharmaceuticals, Inc. (Endo) in January 2012 to develop and commercialize the Company s product candidate BEMA® Buprenorphine. BEMA® Buprenorphine is a partial mu-opioid agonist and a potential treatment for moderate to severe chronic pain. The Company s deliverables under the Endo Agreement, including the Company s related rights and obligations, contractual cash flows and performance periods, are more fully described in note 6.

License and product development research and development services revenue

Upon delivery of the license rights for BEMA® Buprenorphine to Endo in January 2012, the Company recognized revenue of $15.6 million of the $30 million non-refundable up-front license fee, with the balance of $14.4 million recorded as deferred revenue to be recognized as the related research and development services are rendered. Of the amount deferred, the Company recognized $5.2 million as revenue in 2012 and $6.3 million as revenue in 2013. In addition, in May 2012 the Company received and recognized $15 million in revenue associated with an intellectual property milestone under the Endo Agreement.

Arcion License Agreement:

General

The Company entered into a definitive exclusive license agreement (the Arcion Agreement) with Arcion in March 2013 pursuant to which Arcion agreed to grant 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), alone or in combination with other active ingredients, for topical administration for the treatment of painful diabetic neuropathy and other indications (the Arcion Products). The Arcion Agreement, including the Company s related rights and obligations, contractual cash flows and performance periods, are more fully described in note 7.

Upon receipt of the license rights for clonidine from Arcion in March 2013, the Company made a payment to Arcion of $2.1 million in unregistered Common Stock in exchange for in-process research and development that has been recorded as research and development expense for the year ended December 31, 2013. The Company is also 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.

Contract Revenue

The Company earned contract revenue as a result of Meda up-front and milestone payments related to ONSOLIS®. Upon FDA approval of ONSOLIS® in July 2009, and the subsequent commercial launch of ONSOLIS® in October 2009, the Company recognized this contract revenue. The Company also recognized contract revenue as a result of the approval and subsequent launch of BREAKYL in the E.U. in 2012.

The Company also earned contract revenue related to two similar license, development and supply agreements covering different territories: (i) Kunwha Pharmaceutical Co., Ltd., a Republic of Korea corporation (Kunwha), to develop, manufacture, sell and distribute BEMA® Fentanyl in the Republic of Korea, and (ii) TTY Biopharm Co., Ltd., a Taiwanese company (TTY), to develop, manufacture, sell and distribute the Company s BEMA® Fentanyl product in Taiwan. Upfront payments from Kunwha and TTY are recorded as contract revenue upon receipt. The Company earned contract revenues in 2011 and 2013 related to milestones from TTY upon government approvals.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Nature of business and summary of significant accounting policies (continued):

Research and Development Reimbursements

The Company is reimbursed by Endo for certain contractor costs when these costs go beyond set thresholds as outlined in the License and Development Agreement dated January 5, 2012 between the Company and Endo. 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 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.

Cost of Product Royalties

The cost of product royalties 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 product royalties also includes royalty expenses that the Company owes to third parties.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on behalf of the Company.

Certain Risks, Concentrations and Uncertainties

The Company s product candidates under development require approval from the FDA or other international regulatory agencies prior to commercial sales. For those product candidates that have not yet been so approved, there is a risk that they will not receive necessary approval. If approval is denied or delayed, it may have a material adverse impact on the Company. In addition, the Company s products compete in rapidly changing, highly competitive markets which are characterized by advances in scientific discovery, changes in customer requirements, evolving regulatory requirements and developing industry standards. Any failure by the Company to anticipate or to respond adequately to scientific developments, changes in customer requirements, changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services could have a material adverse effect on the Company s business, operating results and future cash flows.

Accounts receivable from one customer (Endo) accounted for 99.6% and from another customer (Meda) accounted for 83% of the Company s trade accounts receivable at December 31, 2013 and December 31, 2012, respectively. Deferred

revenue balances relate to the Meda and Endo Agreements at December 31, 2013 and 2012. The Company depends significantly upon the collaboration with Meda and Endo, and its activities may be impacted if these relationships are disrupted.

Key components used in the manufacture of ONSOLIS® are currently provided by a sole or 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 the Meda supply agreements. This could delay timely commercialization efforts by Meda, causing the Company to lose royalty revenue and potentially harming its reputation.

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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Nature of business and summary of significant accounting policies (continued):

Equipment

Office and manufacturing equipment are carried 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 5), related manufacturing equipment, net, totaling $2.8 million has been deemed idle, and has been reclassified to idle equipment, net in the accompanying consolidated balance sheet as of December 31, 2013. 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 not recorded any impairment of this equipment during the year ended December 31, 2013 because; (i) the Company believes that the equipment will be utilized again once ONSOLIS® is re-launched and (ii) the equipment will be used in the manufacturing of BUNAVAIL if approved by the FDA.

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 long-lived 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 was no impairment charges recognized on finite lived intangibles in 2013, 2012 or 2011.

Intangible assets with finite useful lives are amortized over the estimated useful lives as follows:

	Estimated Useful Lives
Licenses	15 years
U.S. Product rights	10-12 years
EU Product rights	11 years

The Company incurred amortization expense on other intangible assets of approximately $1.0 million, $1.0 million and $0.9 million for the years ended December 31, 2013, 2012 and 2011, 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,	
2014	$ 970,356
2015	970,356
2016	970,356
2017	970,356
2018	970,356
Thereafter	344,718
	$ 5,196,498

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 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 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 2013, 2012 or 2011.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Nature of business and summary of significant accounting policies (continued):

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.

Net (loss) income per common share:

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per common share computations for the years ended December 31, 2013, 2012 and 2011.

	December 31,		
	2013	**2012**	**2011**
Basic:			
Net (loss) income attributable to common stockholders	$ (57,393,613)	$ 1,652,181	$ (23,325,116)
Weighted average common shares outstanding	37,941,044	30,546,581	28,322,477
Basic earnings per common share	$ (1.51)	$ 0.05	$ (0.82)
Diluted:			
Effect of dilutive securities:			
Net (loss) income attributable to common stockholders	(57,393,613)	1,652,181	(23,325,116)
Adjustments to income for dilutive options and warrants			
	(57,393,613)	1,652,181	(23,325,116)
Weighted average common shares outstanding	37,941,044	30,546,581	28,322,477
Effect of dilutive options and warrants		142,654	

Diluted weighted average common shares outstanding	37,941,044	30,689,235	28,322,477
Diluted earnings per common share	$ (1.51)	$ 0.05	$ (0.82)

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. Common equivalent shares from stock options and warrants using the treasury stock method, are also included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the years ended December 31, 2013, 2012 and 2011, outstanding stock options and warrants of 6,549,719, 5,509,075 and 7,847,052, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

1. Nature of business and summary of significant accounting policies (continued):

In applying the Black Scholes options-pricing model, assumptions are as follows:

	2013	2012	2011
Expected price volatility	77.59%-81.65%	81.96%-83.69%	69.05%-77.75%
Risk-free interest rate	0.70%-1.60%	0.62%-1.02%	0.90%-1.99%
Weighted average expected life in years	5-6 years	5-6 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 estimates fair values of derivative financial instruments using the Black-Scholes option valuation technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary to fairly value these instruments. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the Company s trading market price which has high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company s income will reflect the volatility in these estimate and assumption changes.

Recent accounting pronouncements:

In July 2012, the FASB issued ASU 2012-02 Testing Indefinite-Lived Intangible Assets for Impairment (ASU 2012-02) in order to reduce the cost and complexity of performing an impairment test for indefinite-lived intangible assets by simplifying how an entity tests those assets for impairment and to improve consistency in impairment testing guidance. The new guidance allows an entity the option to make a qualitative assessment about the likelihood that an indefinite-lived intangible asset is impaired to determine whether it should perform a quantitative impairment test. ASU 2012-02 was effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 and early adoption was permitted.

The Company adopted this standard on January 1, 2013. The adoption of this standard had no material impact on the Company s consolidated financial statements.

2. Liquidity and management s plans:

Since inception, the Company has financed its 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 its worldwide license and development agreement with Meda regarding ONSOLIS® and revenue generated as a result of its January 2012 agreement with Endo regarding its BEMA® Buprenorphine product candidate. The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, royalty revenue, 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

2. Liquidity and management s plans (continued):

Significant new financing and operating sources during the year ended December 31, 2013 consisted of:

- approximately $19.8 million in net proceeds from secured loan facility from MidCap Financial SBIC, LP, as agent and lender (MidCap) (See note 9);
- approximately $2.8 million in research and development reimbursements under the Endo agreement;
- approximately $1.8 million in net royalties under the Meda agreements;
- approximately $0.3 million in contract revenue from licensing and supply agreement (see note 8); and
- approximately $0.4 million from the exercise of stock options and warrants.

Significant new financing and operating sources during the year ended December 31, 2012 consisted of:

- approximately $45 million in upfront and milestone payments from the Endo license agreement (see note 6);
- approximately $38.4 million in net proceeds from a registered direct offering of Common Stock and newly designated Series A Non-Voting Convertible Preferred Stock, par value $.001 per share (the Series A Preferred) in November 2012;
- approximately $17.5 million in contract revenue from the Meda license agreement. (see note 5);
- approximately $2.1 million from the exercise of stock options; and
- approximately $0.9 million from the exercise of Common Stock warrants.

Significant financing and operating sources during the year ended December 31, 2011 consisted of:

- approximately $14 million in net proceeds from a private placement offering of Common Stock in March 2011;
- approximately $1 million in net royalties;
- approximately $1.7 million from the exercise of Common Stock warrants;
- approximately $0.3 million in contract revenue from licensing and supply agreement (see note 8);
- approximately $0.2 million in research revenues from various contractor agreements; and
- approximately $0.3 million from the exercise of Common Stock options.

On July 5, 2013, the Company, together with Arius One and Arius Two, entered into a $20 million secured loan facility pursuant to a Credit and Security Agreement (the Credit Agreement) with MidCap. The Company received net proceeds in the aggregate amount of $19.8 million and is using the loan proceeds for general corporate purposes or other activities permitted under the Credit Agreement. (See note 9).

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. Concurrently 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. Cantor Fitzgerald & Co. is the placement agent for such offering program. In January 2014, the Company sold 658,489 shares of common stock under such offering program for approximate gross proceeds of $4 million.

On January 23, 2014, the Company announced positive top-line results from its pivotal Phase 3 efficacy study of BEMA® Buprenorphine in opioid- naive subjects. The locking of the database for the opioid naive study has triggered a $10 million milestone payment from Endo per the Company s licensing agreement. Such payment was received in February, 2014.

In December 2013 and January and February of 2014, a warrant holder exercised an aggregate of 10,000 and 515,000 shares of common stock underlying a warrant for proceeds to the Company of $0.05 million and $2.6 million, respectively.

From January through March 2014, Company employees and directors exercised approximately 0.7 million stock options, which net proceeds to the Company was $2.2 million.

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 gross offering proceeds of $60 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

2. Liquidity and management s plans (continued):

At December 31, 2013, the Company had cash and cash equivalents of approximately $23.2 million. The Company used $60.1 million of cash from operations during the twelve months ended December 31, 2013. As of December 31, 2013, the Company had stockholders (deficit) equity of $(0.8) million, versus $49.8 million at December 31, 2012. The Company s existing cash, together with other expected cash inflows from other milestones and royalties, are anticipated by management to be sufficient to fully fund the Company s operations through the second quarter of 2015.

Additional capital may be required to support commercialization activities for BUNAVAIL , clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of our agreement with Endo), the reformulation project for and anticipated commercial relaunch of ONSOLIS®, planned development of Clonidine Topical Gel produced for painful diabetic neuropathy 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.

3. Research and development arrangements and related party transactions:

In June 2012, the Company entered into an agreement to terminate its license agreement with the University of Medicine and Dentistry of New Jersey (UMDNJ) and certain sublicenses related to the Bioral® drug delivery technology previously developed by the Company under such license. Under this agreement, the Company agreed to assign to UMDNJ its know-how to the Bioral® technology. All sublicenses related to the Bioral® technology have been formally terminated, and the Company has assigned to UMDNJ its know-how and patent rights to the Bioral® technology in consideration of 10% of future potential revenues collected by UMDNJ for commercialization of Bioral® formulated Amphotericin B products and 3.5% for non-Bioral® formulated Amphotericin B products which utilize such patent rights and know-how. We have not earned any revenue from UMDNJ on commercialization of the aforementioned products during 2013 or 2012.

Previously, the Company rented office space for accounting and administrative staff in Tampa, Florida from Accentia Biopharmaceuticals, Inc., a former related party (Accentia), and shared one employee, with personnel costs paid based on the approximate time spent on Company activities. Rent payments to Accentia were $0.03 million for year ended 2013 and $0.06 million for years 2012 and 2011, respectively, and are included in general and administrative costs, related party.

In 2009, as part of a settlement arrangement, the Company received a warrant from Accentia, a former related party, to purchase two million shares of common stock of Biovest International, Inc. (Biovest) held by Accentia. Biovest was a majority-owned subsidiary of Accentia. During the year ended December 31, 2013, Biovest filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code with the United States Bankruptcy Court.

On July 9, 2013, the plan became effective, which canceled all outstanding common stock and warrants. As a result, the warrants had no value as of December 31, 2013 and the reduction of value is included in derivative gain (loss) in the consolidated statement of operations for the year ended December 31, 2013.

4. Equipment:

Equipment consists of the following:

	December 31,	
	2013	**2012**
Office and laboratory equipment	$ 4,761,418	$ 4,366,797
Less accumulated depreciation	(1,738,532)	(1,531,090)
	$ 3,022,886	$ 2,835,707
Less idle equipment	(2,844,718)	
	$ 178,168	$ 2,835,707

Depreciation expense for years ended December 31, 2013, 2012 and 2011 was approximately $0.2 million, $0.5 million and $0.4 million, respectively.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

5. Meda License, Development and Supply Agreements:

In August 2006 and September 2007, the Company entered into certain agreements with Meda to develop and commercialize the ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered utilizing the BEMA® technology. The aforementioned agreements relate to the United States, Mexico and Canada (such agreements, the Meda U.S. Agreements) and to certain countries in Europe (such agreements, the Meda EU Agreements , together with Meda U.S. Agreements, the Meda Agreements). They carry license terms that commence 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 are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable and the research and development efforts provided do not have stand-alone value apart from the license. As such, all cash payments from Meda that were related to these deliverables were 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 deliverable 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. The first commercial sale in a European country occurred in October 2012. As a result, $17.5 million was recognized as revenue, which included $5.0 million in milestones received during the year ended December 31, 2012. At December 31, 2013, there was remaining deferred revenue of $1.3 million which is related to the Meda research and development services. As time progresses, the Company will continue to estimate the time required for ongoing obligations, and adjust the remaining deferred revenue accordingly on a quarterly basis.

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. The Company earned $1.8 million and $1.1 million in product royalty revenue for the years ended December 31, 2013 and 2012, respectively. The Company has incurred cost of product royalties of approximately $2.1 million and $1.9 million for the years ended December 31, 2013 and 2012, respectively, which included minimum royalty expenses that the Company is obligated to pay CDC IV, LLC (CDC) and NB Athyrium LLC (Athyrium) regardless of actual sales.

Upon delivery of the license to Meda, the Company determined that each of the undelivered obligations had 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. The Company 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 the Company. The Company has obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged to the Company 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 have been 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. The estimated portion of the upfront payments of

approximately $1.2 million (under the Meda U.S. Agreements) and $0.1 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided through expiration of the license terms, as defined above.

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 REMS until the product formulation could be modified to address two appearance-related issues raised by FDA during an inspection of the manufacturing facility of the Company s North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. (Aveva). 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. While these changes 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 product specification before additional product can be manufactured and distributed.

The source of microcrystal formation and the potential for fading of the product was found to be specific to a buffer used in the manufacturing process for ONSOLIS®. ONSOLIS® has been reformulated and the Company s believes the appearance issues have been resolved. Meda, the Company s commercial partner, is working to determine the content and timing of the submission to FDA. Once submitted, FDA s review of the application may take up to 6 months. If the submission is made before mid-2014, and approved by FDA, the relaunch could occur by years end, otherwise, the relaunch would move to sometime 2015.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

5. Meda License, Development and Supply Agreements (continued):

On May 21, 2012, the Company announced receipt of a pre-launch milestone payment of $2.5 million from Meda in conjunction with the first country registration and pricing approval for BREAKYL (tradename for ONSOLIS® in the EU). A final milestone payment related to the EU of $2.5 million was paid at the time of commercial launch, which occurred in October 2012. BREAKYL is commercialized in the EU by Meda.

On September 13, 2012, the Company executed a Manufacturing, Supply, and License Agreement, effective April 26, 2012, with LTS Lohmann Therapie-Systeme AG (LTS), under which LTS will manufacture and supply the Company its BREAKYL product for distribution outside of the U.S. and Canada. The Company is required to supply BREAKYL product to Meda, Kunwha and TTY pursuant to its obligations under certain license and supply agreements under which Meda, Kunwha, and TTY develop and commercialize the BREAKYL product. In conjunction with the agreement, LTS has waived all royalties on products that they produce. This does not preclude royalties that the Company owes to LTS if the Company produces BREAKYL with another company.

6. Endo License and Development Agreement:

In January 2012, the Company entered into a License and Development Agreement (the Endo Agreement) with Endo pursuant to which the Company granted to Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company s BEMA® Buprenorphine product and to complete U.S. development of such product candidate for purposes of seeking FDA approval.

Pursuant to the Endo Agreement, Endo has obtained all rights necessary to complete the clinical and commercial development of BEMA® Buprenorphine and to sell the product worldwide. Although Endo has obtained all such necessary rights, the Company has agreed under the Endo Agreement to be responsible for the completion of certain clinical trials regarding BEMA® Buprenorphine (and providing clinical trial materials for such trials) necessary to submit a NDA to the FDA in order to obtain approval of BEMA® Buprenorphine in the U.S., in each case pursuant to a development plan set forth in the Endo Agreement (as it may be amended pursuant to the Endo Agreement). The Company is 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 BEMA® Buprenorphine on a worldwide basis. In addition, Endo is responsible for all filings required in order to obtain regulatory approval of BEMA® Buprenorphine.

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 BEMA® Buprenorphine):

$30 million non-refundable upfront license fee (received January 17, 2012);

up to an aggregate of $95 million in six separate potential milestone payments based on the following pre-defined events: (i) enhancement of intellectual property rights (two milestones aggregating $35 million in potential milestone payments, including $15 million upon issuance of a certain patent covering the product, which was received May 2012), (ii) clinical development (two milestones aggregating $20 million in potential milestone payments) and (iii) regulatory events (two milestones aggregating $40 million in potential milestone payments);

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 BEMA® Buprenorphine, 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 is a multi-deliverable arrangement with three deliverables: (1) the license rights related to BEMA® Buprenorphine, (2) services related to obtaining

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

6. Endo License and Development Agreement (continued):

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 because Endo obtained, at the inception of the Endo Agreement, all of the rights and knowledge necessary to fully exploit its license without the Company s further involvement. 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 has not separately accounted 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 (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 the Company determined the deliverable to be perfunctory. In April 2012, the patent being sought by the Company was granted as described further below, and in May 2012, the applicable intellectual property milestone payment of $15 million was received and recognized as revenue. The amount allocated to the license was recognized as revenue in January 2012.

The portion of the upfront license fee allocated to the clinical development services deliverable ($14.4 million) is being recognized as those services are performed. The Company estimates that such clinical development services will extend into the first half of 2015. Based on the estimated proportion of those services performed through December 31, 2013, $5.2 million was recognized as revenue in fiscal year 2012 and $6.3 million was recognized as revenue in fiscal year 2013. As a result, $2.9 million remains deferred at December 31, 2013.

The Company analyzed the milestone payments noted above to determine if such milestones are substantive. This determination included an analysis of the Company s performance to achieve each milestone, the enhancement of value of the delivered items, the timing of performance related to the milestone, and the reasonability of the milestone relative to all the deliverables and payment terms. The Company concluded that each of the milestones is substantive.

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 BEMA® Buprenorphine in a particular country or (ii) the date on which the last valid claim of the Company s patents covering BEMA® Buprenorphine in a particular country has expired or been invalidated. The Endo Agreement shall be subject to termination: (i) by Endo, at any time, upon a specific amount of prior written notice to the Company, (ii) by Endo and the Company upon mutual written agreement, (iii) by either party upon a material default or breach of the Endo Agreement and such default or breach is not cured within a specified timeframe, (iv) the voluntary or involuntary bankruptcy of either party or (v) by the Company if Endo does not meet certain diligence obligations outside of the United States.

On February 16, 2012, the Company announced that the U.S. Patent and Trademark Office issued a Notice of Allowance regarding its patent application (No. 13/184306), which patent will extend the exclusivity of the BEMA® drug delivery technology for the Company s BEMA® Buprenorphine and BUNAVAIL™ product candidates from 2020 to 2027. On April 17, 2012, the Company announced that this patent was granted. As a result, pursuant to the Endo Agreement, the Company received a milestone payment from Endo in the amount of $15 million in May 2012. As discussed above, this milestone had been evaluated to be a substantive milestone, and therefore was recognized as revenue when the milestone was received.

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

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

6. Endo License and Development Agreement (continued):

On January 23, 2014, the Company announced positive top-line results from its pivotal Phase 3 efficacy study of BEMA® Buprenorphine in opioid- naive subjects. The locking of the database for the opioid naive study has triggered a $10 million milestone payment from Endo per the Company s licensing agreement that was received during February, 2014.

7. Arcion License Agreement:

On March 26, 2013, the Company entered into a definitive Exclusive License Agreement (the Arcion Agreement) with Arcion pursuant to which Arcion agreed to grant 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), alone or in combination with other active ingredients, for topical administration for the treatment of painful diabetic neuropathy 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.

Upon execution of the Arcion Agreement, the Company issued to Arcion 500,516 unregistered shares of Common Stock (having a fair market value of $2.1 million), which shares are subject to a nine month lock-up and certain limitations on sale thereafter. The issuance of such shares (delivered April 2013) was exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) thereof. In addition, 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, payable at the Company s option, in cash or unregistered shares of Common Stock (with such shares also being subject to a nine month lock-up and certain limitations on sale thereafter); and

- 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 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 described above shall each be increased by $8 million.

All milestone payments due Arcion under the Arcion Agreement are payable only once each.

In addition to the milestones set forth above, the Company will pay Arcion:

- a low single digit royalty on the Company s and its affiliates net sales of Arcion Products in the U.S.;
- a low double digit percentage of all sales-based payments received by the Company and its affiliates with respect to sublicensees sales of Arcion Products in the U.S.;
- a low single digit royalty on all net sales of Arcion Products outside the U.S.; and
- a low double digit percentage of all milestone payments received by the Company and its affiliates from their sublicensees that are triggered by the receipt of regulatory approval of the Arcion Product in certain jurisdictions outside of the U.S.

The aforementioned sales royalties are subject to certain reductions, on a country-by-country and product-by-product basis, under certain agreed upon circumstances. 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

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

7. Arcion License Agreement (continued):

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. Further, the Company may, in its sole discretion, terminate the Arcion Agreement upon certain notice to Arcion. Upon expiration of the Agreement pursuant to clause (i) above with respect to a particular Arcion Product and country, the Company and its affiliates shall have the perpetual, unrestricted, irrevocable, fully-paid, royalty-free exclusive right, with rights of sublicense, to make, have made, use, sell, offer for sale, and import such Arcion Product in such country.

In conjunction with this transaction, the March 2013 payment to Arcion of $2.1 million in unregistered Common Stock was for in-process research and development and has been recorded as research and development expense in the consolidated statement of operations for the year ended December 31, 2013.

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 is 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 will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes approximating $1.1 million). In addition, Kunwha will pay royalties to the Company based on Net Sales (as defined in the Kunwha License Agreement) and will purchase all supplies of BEMA® Fentanyl from

the Company.

Kunwha will be responsible for payment of all costs associated with BEMA® Fentanyl in the Kunwha Territory. Kunwha and the Company will own any Improvements (as defined in the Kunwha License Agreement) made exclusively by such party with respect to BEMA® Fentanyl and will jointly own any Improvements that are the product of collaboration.

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement with 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 includes 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 (15) years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

On November 7, 2011, the Company announced that TTY had submitted a New Drug Application (NDA) for marketing authorization of BEMA® Fentanyl to the Taiwan Food and Drug Administration. This triggered a milestone payment to the Company of approximately $0.3 million, which was received November 2011 and recorded as contract revenue in the accompanying consolidated statements of operations for the year ended December 31, 2011.

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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

8. Other license agreements and acquired product rights (continued):

Agreement with Tolmar to Purchase BEMA® Rights

In September 2007, the Company purchased all North American (U.S., Canada and Mexico) assets related to the BEMA® drug delivery technology from TOLMAR Therapeutics, Inc (Tolmar) for $7 million, consisting of $3 million in cash and a promissory note of $4 million, $2 million of which was paid in July 2009 following approval of ONSOLIS® in the U.S., and $2 million of which is due within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA®-based products reach $30 million. To secure the Company s obligation to pay the remaining $2 million amount when due, Tolmar was granted a security interest in the North American BEMA® assets, subject to a license of those assets from Tolmar to us for North America that would be granted to us on the original license terms upon any exercise of rights under such security interest.

On January 5, 2012, the Company and Arius Two executed a letter agreement with Tolmar and its parent company, TOLMAR Holding, Inc., whereby the parties agreed that, if Arius Two paid Tolmar $1.05 million by February 28, 2012, Tolmar would accept such payment as satisfaction in full of the remaining $2 million outstanding under the Tolmar note (pursuant to which the Company acquired the North American rights to the BEMA® technology) and, upon receipt of such payment (i) the related security agreements, security interests, liens, guaranties and payment obligations with respect to such note and the assets securing its repayment would terminate, (ii) Tolmar would execute a corresponding release and (iii) neither the Company nor Arius Two will have any further payment obligations to Tolmar under the note or BEMA® acquisition documents, except with respect to certain indemnification obligations of Arius Two. Arius Two paid the $1.05 million contemplated by the letter agreement on January 6, 2012, fully satisfying the outstanding balance of the note, and Tolmar subsequently executed its final release of the related security interests contemplated by the letter agreement. As a result, the Company now owns all rights to the BEMA® technology on a worldwide basis.

9. MidCap Secured Loan Facility:

On July 5, 2013, the Company, Arius One and Arius Two (the Borrowers) entered into a $20 million secured loan facility (the Loan Transaction and such loan, the Loan) with MidCap as agent and lender pursuant to the terms and conditions of the Credit Agreement. The Company received net proceeds in the aggregate amount of $19.8 million and will use the Loan proceeds for general corporate purposes or other activities of the Borrower permitted under the Credit Agreement.

In addition, pursuant to the Loan Transaction, the Company issued to MidCap a warrant (the MidCap Warrant) to purchase 357,356 unregistered shares of Common Stock, which warrant has an exercise price of $4.20 per share, the 20-day volume-weighted average share price of the Common Stock prior to the closing of the Loan. The MidCap Warrant is exercisable for a term of five (5) years and contains cashless exercise provisions and customary,

anti-dilution protection provisions. The proceeds of the secured loan facility were allocated to the note payable and Midcap warrants (which qualified for equity accounting) based on their relative fair values, as follows:

Note payable	$ 19,013,648
MidCap warrant	986,352
Total proceeds	$ 20,000,000

The resulting debt discount is being amortized to interest expense over the 3 year life of the loan.

The fair value of the warrants was determined based upon the Black Scholes valuation model using the following key assumptions:

Market price of stock	$ 4.41
Term of warrant	5 years
Volatility	81.05%
Risk free interest rate	2.9%

The Loan has a term of 36 months with interest only payments until February 1, 2014. The interest rate is 8.45% plus a LIBOR floor of 0.5% (total of 8.95% at December 31, 2013). Upon execution of the Credit Agreement, the Company paid to MidCap a closing fee of 0.5% of the aggregate Loan amount. Upon repayment in full of the Loan, the Company is obligated to make a final payment fee equal to 3.5% of the aggregate Loan amount. The 3.5% exit fee has been recorded as deferred loan costs, the current portion of which is included in prepaid expenses and other current assets and the long-term portion in other assets. Additionally, the liability associated with the exit fee has been recorded in other long-term liability in the accompanying 2013 consodilated balance sheet. The assets associated with this exit fee are accreted to interest expense through the maturity of the Midcap Loan. 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 of the Loan and (ii) 3% of the Loan amount prepaid in each year thereafter. In addition, if the Company receives the second of two anticipated database lock milestone payments (the Database Lock Payments) from Endo in connection with the Endo Agreement, the

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

9. MidCap Secured Loan Facility (continued):

Company may prepay 50% of the principal amount of the Loan then outstanding and, concurrently and at the Company s election, either: (i) pay to MidCap a cash prepayment fee of 2% of the principal amount of the Loan and all obligations thereunder outstanding as of the date of prepayment or (ii) issue to MidCap a warrant (in a form substantially similar to the MidCap Warrant) to purchase shares of Common Stock equal to 2.0% of the prepayment amount, with the number of shares being calculated using the Black-Scholes pricing model.

The obligations of the Borrowers under the Credit Agreement are secured by a first priority lien in favor of MidCap on substantially all of the Borrowers existing and after-acquired assets, but excluding certain of the Borrowers intellectual property and general intangible assets of the Borrowers (but not any proceeds thereof). The obligations of the Company under the Loan Agreement are also secured by a first priority lien on the equity interests held by the Company in Arius One, Arius Two and BND. The Borrowers entered into customary pledge and intellectual property security agreements to evidence the security interest in favor of MidCap.

Under the Credit Agreement, the Borrowers are subject to affirmative covenants which are customary for financings of this type, including, but not limited to, the obligations of the Borrowers to: (i) maintain good standing and governmental authorizations, (ii) provide certain information and notices to MidCap, (iii) deliver monthly and annual financial statements to MidCap, (iv) maintain insurance, (v) discharge all taxes, (vi) protect their intellectual property and (vii) generally protect the collateral granted to MidCap.

The Borrowers are also subject to negative covenants customary for financings of this type, including, but not limited to, that without the prior consent of Midcap, they may not: (i) enter into a merger or consolidation or certain change of control events, (ii) incur liens on the collateral, (iii) incur additional indebtedness, (iii) dispose of any property, (iv) amend material agreements or organizational documents, (v) change their jurisdictions of organization or their organizational structures or types, (vi) declare or pay dividends (other than dividends payable solely in Common Stock), (vii) make certain investments or acquisitions, or (viii) enter into certain transactions with affiliates, in each case subject to certain exceptions provided for in the Credit Agreement, including exceptions that allow the Borrowers to acquire additional products and to enter into licenses and similar agreements provided certain conditions are met.

The Credit Agreement provides that events of default include: (i) failure to make payment of principal or interest on the Loan when required, (ii) failure to perform obligations under the Credit Agreement and related documents, (iii) defaults in other indebtedness and breaches of material agreements of the Borrowers, (iv) if any Borrower shall generally not pay its debts as such debts become due and similar insolvency matters, (v) material adverse changes to the Borrowers (subject to a 10-day notice and cure period), (vi) if the Company ceases to be a publicly-listed and reporting company, (vii) failure to receive the Database Lock Payments by June 30, 2014, and (viii) certain other events, including certain adverse actions taken by the Food and Drug Administration or other governmental authorities. Upon an event of default, the Borrower s obligations under the Credit Agreement may, or in the event of insolvency or bankruptcy will automatically, be accelerated. Upon the occurrence of any event of default, the

Borrower 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 balance of the secured loan facility due to MidCap as of December 31, 2013 is $20 million, and is recorded in the accompanying consolidated 2013 balance sheet, net of unamortized discount of $0.8 million.

The following table represents future maturities of the MidCap obligation as of December 31, 2013:

Years ending December 31,	
2014	$ 7,333,333
2015	8,000,000
2016	4,666,667
Total maturities	20,000,000
Unamortized discount	(821,961)
Total Midcap obligation	$ 19,178,039

10. Derivative Financial Instruments:

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Company s Common Stock, are classified as liabilities when either: (a) the holder

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

10. Derivative Financial Instruments (continued):

possesses rights to net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

The following tabular presentation reflects the components of derivative financial instruments as of December 31, 2013, 2012 and 2011.

	2013	2012	2011
Derivative gain (loss) in the accompanying statements of operations is related to the individual derivatives as follows:			
Free standing warrants assets, related party	$ (50,300)	$ (338,500)	$ (910,231)
Free standing warrants liabilities	171,528	(5,255,652)	4,373,684
	$ 121,228	$ (5,594,152)	$ 3,463,453

The following table summarizes assets and liabilities measured at fair value on a recurring basis at December 31, 2013 and December 31, 2012, respectively:

	2013				2012			
Fair Value Measurements Using:	**Level 1**	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets								
Derivative asset, warrant	$	$	$	$	$	$ 50,300	$	$ 50,300
Liabilities								
Derivative liabilities	$	$ 4,315,183	$	$ 4,315,183	$	$ 4,497,977	$	$ 4,497,977

The table below provides a reconciliation of the beginning and ending balances for the assets and liabilities measured at fair value using significant observable inputs (Level 2). The table reflects net gains and losses for all financial assets and liabilities categorized as Level 2 as of December 31, 2012 and 2013.

Fair Value Measurements Using Significant Observable Inputs (Level 2)

	Value of Warrants	Number of Warrants
Assets:		
Warrant asset as of January 1, 2012	$ 388,540	2,000,000
Decrease in fair value of warrants	(338,240)	
Warrant asset as of December 31, 2012	$ 50,300	2,000,000
Decrease in fair value of warrants	(50,300)	(2,000,000)
Warrant asset as of December 31, 2013	$	
Liabilities:		
Warrant liability as of January 1, 2012	$ 279,302	3,246,301
Decrease due to exercise of warrants	(1,037,237)	(236,865)
Expiration of warrants		(1,000,000)
Increase in fair value of warrants	5,255,912	
Warrant liability as of December 31, 2012	$ 4,497,977	2,009,436
Decrease due to exercise of warrants	(11,266)	(10,000)
Decrease in fair value of warrants	(171,528)	
Warrant liability as of December 31, 2013	$ 4,315,183	1,999,436

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

11. Income taxes:

The Company had income tax expense in 2012 of $0.1 million. The Company did not record income tax expense in 2013 or 2011 as the Company had incurred net operating losses. The Company has recognized valuation allowances for all deferred tax assets for years ending 2013, 2012 and 2011. Reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	Year Ended December 31,		
	2013	2012	2011
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)	0.11	110.51	7.02
Permanent differences-other	(1.07)	44.12	(2.76)
Research and development (R&D) credit	4.91	(129.12)	2.92
Other	0.64	(30.89)	(6.63)
Valuation allowance	(42.04)	(24.82)	(38.00)
	0.00%	7.25%	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)	**2013**	**2012**
Deferred revenue	$ 1,576,186	$ 4,010,493
Basis difference in equipment	(890,387)	(926,735)
Basis difference in intangibles	(501,709)	(618,403)
Accrued liabilities and other	418,300	263,364
R&D credit	10,366,432	8,720,314
Stock options	2,199,794	1,557,756
Net operating loss carry-forward (NOL)	40,494,523	16,575,544
	53,663,139	29,582,333
Less: valuation allowance	(53,663,139)	(29,582,333)
	$	$

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, 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 (NOLs) of approximately $109 million as of December 31, 2013. 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 $100 million as of December 31, 2013. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 for state purposes.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

12. Stockholders equity:

Common Stock

On March 11, 2011, the Company closed a private placement financing, issuance and sale of Common Stock. The final amount of Common Stock issued in the offering was an aggregate of 4,807,693 shares of Common Stock.

On December 3, 2012, the Company closed a registered direct offering, issuance and sale of Common Stock. The final amount of Common Stock issued in the offering was an aggregate of 6,791,887 shares of 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. In January 2014, the Company pulled from the shelf registration 658,489 shares of common stock for approximate proceeds of $4 million.

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. At December 31, 2013, 2,709,300 shares of Series A Preferred were outstanding and 2,290,700 shares of blank check preferred stock remain authorized but undesignated.

Restricted Stock Units:

During the year ended December 31, 2012, a total of 57,500 RSUs were issued to independent directors pursuant to the Company s 2011 Equity Incentive Plan and fully vested September 14, 2012. The expense related to the issuance of these RSUs was approximately $0.3 million in 2012 and was recorded in general and administrative expense in the consolidated statement of operations.

During the year ended December 31, 2013, a total of 1,078,336 RSUs with a fair market value of approximately $4.5 million were granted to members of the Company s senior management. 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. This grant was in lieu of the 2012 annual option grant typically given to senior management in order to bring the

percentage ownership of senior management in line with the senior management of companies in the Company s peer group.

In addition, in June 2013, the Company issued 3,125 RSUs with a fair value of $0.01 million to a new board member, which vested immediately. The Company also issued in August 2013, a total of 118,853 RSUs to board members with a fair value of approximately $0.6 million, of which 63,853 RSUs vested immediately and the remaining 55,000 vest in August 2014.

Performance Long Term Incentive Plan

In December 2012, the Company 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 Restricted Stock Units (as defined under the Company s 2011 Equity Incentive Plan, and which is referred to as Performance RSUs) which are rights to acquire shares of the Company s 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). 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. A total of 8,968 RSUs vested, subject to performance criteria, during the year ended December 31, 2013. The expense related to the issuance of these RSUs

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

12. Stockholders equity (continued):

was approximately $0.03 million in 2012 and $0.9 million in 2013, and was recorded in general and administrative expense in the consolidated statement of operations. The fair value of RSUs is determined using actual market prices of the Common Stock and the number of shares expected to vest.

Stock options:

The Company has a 2011 Equity Incentive Plan, which was approved by stockholders in July 2011 and covers a total of 4,200,000 shares of Common Stock. An additional 3,192,596 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 and other affiliates.

Stock option activity for the years ended December 31, 2013, 2012 and 2011 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2011	4,311,539	$ 3.65	
Granted in 2011:			
Officers and Directors	209,619	$ 3.44	
Others	238,918	3.41	
Exercised	(129,888)	2.69	
Forfeitures	(76,937)	3.09	
Outstanding at December 31, 2011	4,553,251	$ 3.66	$
Granted in 2012:			
Officers and Directors	281,174	$ 2.36	
Others	485,540	2.80	
Exercised	(789,305)	2.60	
Forfeitures	(250,741)	3.26	
Outstanding at December 31, 2012	4,279,919	$ 3.70	$ 4,572,205

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	$ 9,145,780

Options outstanding at December 31, 2013 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	3,230,768	5.48	$ 3.10	
$5.01 10.00	962,159	4.02	$ 6.25	
	4,192,927			$ 9,145,780

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

12. Stockholders equity (continued):

Options exercisable at December 31, 2013 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	2,671,959	4.78	$ 3.03	
$5.01 10.00	906,500	3.66	$ 6.30	
	3,578,459			$ 7,759,365

The weighted average grant date fair value of options granted during the years ended December 31, 2013, 2012 and 2011 was $3.28, $1.97 and $3.43, respectively. There were no options granted during the years ended December 31, 2013, 2012 or 2011 whose exercise price was lower than the estimated market price of the stock at the grant date.

Nonvested stock options as of December 31, 2013, 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, 2013	854,640		
Granted	278,794		
Vested	(342,538)		
Forfeited	(176,428)		
Nonvested at December 31, 2013	614,468	$ 2.59	$ 1,386,415

As of December 31, 2013, there was approximately $4.6 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next six years.

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements.

Warrants outstanding and exercisable at December 31, 2013 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$0.00 5.00	2,356,792	1.44	$ 3.92	$ 4,640,492

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.

Reclassification of derivative liability to equity:

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.

During the year ended December 31, 2012, warrants by various investors were exercised to purchase 281,865 shares of Common Stock at prices ranging from $3.00 to $5.00 per share. Until the time of exercise, 236,865 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

12. Stockholders equity (continued):

During the year ended December 31, 2011, CDC IV, LLC (CDC) exercised warrants to purchase 601,120 shares of Common Stock for $2.91 per share. Until the time of exercise the 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.

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 2013 and $0.1 million in both 2012 and 2011.

14. Commitments and contingencies:

Operating leases:

Since November 2007, the Company has leased space for their corporate offices. The lease expired in January 2013 and was amended for an additional 24 months. Lease expense for the corporate office was $0.1 million for years ended December 31, 2013 and 2012, respectively.

The future minimum commitment on the remaining operating lease at December 31, 2013 is as follows:

Years ending December 31,	
2014	$ 118,665
2015	29,806
	$ 148,471

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, 2013 which would trigger any liability under the agreement.

Certain Rights of CDC

The Company and 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, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval (the Next BEMA® Product). In connection with the 1% royalty grant: (i) CDC shall have the option to exchange its royalty rights to the Next BEMA® Product in favor of royalty rights to a substitute BEMA® product, (ii) the Company shall have the right, no earlier than six (6) months prior to the initial commercial launch of the Next BEMA® Product, 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 the Next BEMA® Product equal less than $7.5 million in any calendar year following the third anniversary of initial launch of the product and CDC receives $18,750 in three (3) consecutive quarters as payment for CDC s one percent (1%) royalty during such calendar year and (iv) CDC shall have certain information rights with respect to the Next BEMA® Product.

The amount of royalties which the Company may be required to pay for the Next BEMA® Product (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, the Company expects to record such royalties, if any, as cost of sales when and if such sales occur.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

14. Commitments and contingencies (continued):

On May 12, 2011, the Company entered into an Amendment to Clinical Development and License Agreement (the CDLA Amendment) by and among CDC V, LLC (CDC), NB Athyrium LLC (Athyrium). Athyrium holds certain rights, acquired from CDC, to receive royalties on sales of ONSOLIS®.

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, the Company recorded $0.3 million as additional cost of product royalties for year ended December 31, 2011. In addition, certain terms of the CLDA were amended and restated to clarify that royalty payments by the Company under the CDLA will be calculated based on Meda s sales of ONSOLIS®, whereas previous Company royalty payments to CDC were calculated based on Company sales of ONSOLIS® to Meda.

The difference between these two calculations resulted in a $1.1 million overpayment by the Company which was recorded as a prepayment. As a result, the Company 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 the Company paid during the first quarter of 2012.

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 (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 BEMA® Buprenorphine 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 its confidential, proprietary manufacturing process for ONSOLIS®. On February 23, 2011, the Company filed its initial answer in this case. In the Company s answer, the Company stated its position that their products, methods and/or components do not infringe MonoSol s 588 Patent because they do not meet the limitations of any valid claim of such patent. Moreover, in the Company s answer, the Company stated its position that MonoSol s 588 Patent is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law.

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 not previously considered by the USPTO, and thus invalid. On September 16, 2011, the Company filed in court a motion for stay pending the outcome of the reexamination proceedings, which subsequently was granted due to the results of the USPTO proceedings as described below.

On November 28, 2011, the Company announced that it was informed by the USPTO that it had 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 additiona 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.

In February and March 2012, respectively, the USPTO granted the requests for reexamination we filed with respect to MonoSol s 292 and 891 Patents. In its initial office action in each, the USPTO rejected every claim in each patent. Based on the action of the USPTO on these three patent reexaminations, the court in the Company s case with MonoSol conducted a status conference on March 7, 2012, at which it granted the Company s motion to stay the case pending final outcome of the reexamination proceedings in the USPTO.

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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

14. Commitments and contingencies (continued):

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.

Inter partes reviews, a new USPTO process to review the patentability of one or more claims of patents, was enacted in September, 2012. As such, 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 availed ourselves of this new process and filed requests for inter partes reviews on the narrowed yet reexamined patents, the 292C1 and 891C1 Patents, to challenge their validity and continue to strengthen its position. This inter partes review process allows the Company to actively participate in the reviews and address any of MonoSol s arguments and representations made during the review process, which heightens the Company s ability to invalidate these patents. On November 13, 2013, the USPTO decided not to institute the two inter partes reviews for the 891C1 and 292C1 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 891C1 and 292C1 Patents remains the same.

Importantly, in the case of MonoSol s 588 Patent, the USPTO on July 20, 2012 issued a second Office Action closing prosecution and rejecting for a second time all claims as anticipated or obvious. It also rejected the amended claims proposed by MonoSol as unclear and lacking support. Then, on January 23, 2013, the USPTO issued a Right of Appeal Notice, rejecting all claims of the 588 Patent and closing reexamination proceedings. This action confirms that all claims of this patent are also invalid, but unlike 292 and 891, the USPTO has not found that any amended or narrower claims should be granted. On February 22, 2013, MonoSol filed both a Notice of Appeal to the Board of Patent Appeals and Interferences and a Request for Continuing Examination of the 588 Patent. On March 12, 2013, the Company filed a petition requesting the USPTO to deny MonoSol s February 22, 2013 Request to Continue Examination and to allow the proceedings to go to an appeal. Subsequently, on July 3, 2013, the USPTO denied MonoSol s February 22, 2013 Request to Continue Examination. After reviewing MonoSol s Appeal Brief (filed June 24, 2013) and the Company s Respondent s Brief (filed July 24, 2013), the USPTO formally initiated the appeals process with the Examiner s Answer on August 8, 2013, which affirmed the rejection of all the claims in the 588 Patent. An oral hearing for the appeal, in which both parties will have an opportunity to make arguments before the Patent Trial & Appeal Board (PTAB) has been scheduled for March 26, 2014.

Based on the Company s 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 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, 588, has had all claims rejected and appears to have had a similar fate. Importantly, the Company will continue to defend this case vigorously, and anticipates that MonoSol s claims against the Company will ultimately be rejected.

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 proposed treatment for 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). The Company believes this is another anticompetitive attempt by the RB Plaintiffs to distract the Company s efforts from commercializing BUNAVAIL .

The Company believes that this action is in response to a 2013 decision wherein the FDA recently ruled in favor of the Company s position in two Citizen Petitions filed by the RB Plaintiffs that sought to prevent the FDA from accepting and filing the Company s NDA for BUNAVAIL . The two Citizen Petitions, filed on December 2, 2011 and August 13, 2013, respectively, included requests that the FDA refuse to accept for filing any NDAs submitted using the 505 (b)(2) regulatory pathway for buprenorphine/naloxone products consisting of a polymer film for application to the buccal mucosal membranes (such as BUNAVAIL), unless such application references the NDA for Suboxone® (buprenorphine/naloxone) sublingual film (and not the Suboxone® sublingual tablet NDA). Suboxone® is an approved product for opioid dependence. The requirement to reference the Suboxone® film formulation, which is under patent exclusivity with Orange Book-listed patents, including the 832 Patent, was aimed at delaying the eventual approval of BUNAVAIL . FDA did not agree with these arguments and in its decision on September 18, 2013, it denied the requests and subsequently, accepted and filed the BUNAVAIL NDA.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

14. Commitments and contingencies (continued):

The Company believes that the RB Plaintiff s claim of patent infringement has no more validity than the recently rejected Citizen Petitions, but is being used as another anticompetitive attempt to distract the Company in our efforts toward commercializing BUNAVAIL . We look forward to the FDA s review of the BUNAVAIL NDA as it moves toward the June 7, 2014 Prescription Drug User Fee Act (PDUFA) date when we expect a response from FDA on our NDA for BUNAVAIL . In the meantime, the Company strongly refutes as without merit the RB Plaintiffs assertion of patent infringement and will vigorously defend the lawsuit.

On December 13, 2013, the Company filed a motion to dismiss RB Plaintiff s suit based on insufficient pleadings and lack of standing. In response, RB Plaintiffs filed its opposition to the Company s motion to dismiss on January 22, 2014. The Company filed its reply to RB s opposition to the Company s motion to dismiss on February 10, 2014.

On January 15, 2014, the Company filed a request for inter partes review in the USPTO of the 832 Patent demonstrating that certain claims of such patent 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. On January 31, 2014, the Company filed in Court a motion for stay pending the outcome of the inter partes review proceedings.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2013, 2012 AND 2011

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, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Revenue	$ 1,622	$ 2,764	$ 2,997	$ 3,973
Gross profit	1,247	2,074	2,354	3,599
Loss from operations	(13,712)	(13,808)	(17,083)	(11,799)
Net loss	(12,723)	(13,415)	(18,486)	(12,770)
Basic loss per share	(0.34)	(0.35)	(0.49)	(0.33)
Diluted loss per share	(0.34)	(0.35)	(0.49)	(0.33)

	Quarter Ended			
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
Revenue	$ 16,518	$ 16,298	$ 1,875	$ 19,851
Gross profit	16,143	15,923	1,500	19,066
Income (loss) from operations	8,565	7,148	(14,059)	5,408
Net income (loss)	6,751	3,783	(17,477)	8,596
Basic income (loss) per share	0.23	0.13	(0.58)	0.26
Diluted income (loss) per share	0.23	0.12	(0.58)	0.19

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Under date of March 14, 2014, we reported on the consolidated balance sheets of BioDelivery Sciences International Inc., and subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of operations and stockholders (deficit) equity and cash flows for each of the years in the three-year period ended December 31, 2013, 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

Tampa, Florida

March 14, 2014

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Years ended December 31, 2013, 2012 and 2011

Description	Balance at beginning of the period	Charged to income	Charged to other accounts	Balance at the end of the period
		(In millions)		
Valuation allowance for deferred tax assets				
Year ended December 31, 2013:	$ 29.58	$	$ 24.08	$ 53.66
Year ended December 31, 2012:	$ 30.13	$	$ (0.55)	$ 29.58
Year ended December 31, 2011:	$ 21.27	$	$ 8.86	$ 30.13

Table of Contents

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 14, 2014

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 and Secretary (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 14, 2014
/s/ MARK A. SIRGO **Mark A. Sirgo**	President, Chief Executive Officer and Director	March 14, 2014
/s/ WILLIAM B. STONE **William B. Stone**	Lead Director	March 14, 2014
/s/ JOHN J. SHEA **John J. Shea**	Director	March 14, 2014
/s/ WILLIAM S. POOLE **William S. Poole**	Director	March 14, 2014
/s/ SAMUEL P. SEARS, JR. **Samuel P. Sears, Jr.**	Director	March 14, 2014
/s/ THOMAS W. D ALONZO **Thomas W. D Alonzo**	Director	March 14, 2014