BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-K
March 19, 2010
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, 2009

¨ 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: None

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

Common Stock, $.001 par value	**NASDAQ Capital Market**
(Title of class)	

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ¨

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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 30, 2009 was approximately $101,998,704 based on the closing sale price of the company s common stock on such date of $6.68 per share, as reported by the NASDAQ

Capital Market.

As of March 12, 2010, there were 21,200,254 shares of company common stock issued and 21,184,763 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, 2009

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 si terms refer to BioDelivery Sciences International, Inc., a Delaware corporation and its consolidated subsidiaries.

Table of Contents

CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS

This Report, including the documents referred to or incorporated by reference in this Report, includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results may differ materially from those discussed herein, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, expect, anticipate, intend, estimate, plan, project and other similar expressions. In addition, any statements that refer to expect other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements included in this Report or our other filings with the U.S. Securities and Exchange Commission, or SEC, include, but are not necessarily limited to, those relating to:

- our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the BEMA® and Bioral® technology platforms and any proposed products, product candidates or marketed products, including our sole marketed product, ONSOLIS®;
- the domestic and international regulatory process relating to our technologies and proposed products and formulations, including the timing, status and results of our filings with the U.S. Food and Drug Administration and the timing, status and results of non-clinical work and clinical studies;
- our ability to generate commercially viable products, acceptance of our BEMA® and Bioral® technology platforms and our proposed formulations 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;
- the protection and control afforded by our patents and any interest in licensed patents, or our ability to enforce our rights under such patents or licenses;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and product candidates;
- the ability of our commercial partners to market and sell the products we license to them and our expected revenues from such partnerships;
- 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. Please see Risk Factors for additional risks which could adversely impact our business and financial performance. 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 of this Report. 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.

Table of Contents

PART I

Item 1. Description of Business.

Overview

We are a specialty pharmaceutical company that is utilizing licensed and owned proprietary drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, significant new formulations of proven therapeutics. Utilizing our drug delivery technologies, we have developed and are continuing to develop pharmaceutical products aimed principally in the areas of pain management and oncology supportive care.

Our patented drug delivery technologies include:

- *the BioErodible MucoAdhesive (BEMA®) technology*, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek); and

- *the Bioral® cochleate drug delivery technology*, designed for the potential oral delivery of a broad base of products otherwise administered intravenously.

Our first FDA approved product, ONSOLIS® (fentanyl buccal soluble film), as well as our pipeline of developmental stage products, predominately utilize our BEMA® technology. Our current development strategy focuses primarily on our ability to utilize the U.S. Food and Drug Administration 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 technologies. 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 approval approaches of the U.S. Food and Drug Administration, which we refer to herein as the FDA.

On July 16, 2009, we announced the FDA s approval of ONSOLIS®. ONSOLIS® will be marketed in Europe under the name BREAKYL if regulatory approvals are obtained. The FDA approval of ONSOLIS®, together with our satisfactory preparation of launch supplies of ONSOLIS®, triggered the payment to us by our ONSOLIS® commercial partner Meda AB (which we refer to herein as Meda) of approval milestones aggregating $26.8 million. The FDA approval of ONSOLIS® also caused the termination of a security interest in the ONSOLIS® product and related assets which was held by CDC IV, LLC, or CDC, pursuant to a funding arrangement that we previously entered into with CDC in connection with the development of ONSOLIS®. Additionally, the FDA approval triggered a requirement by us to pay an approval milestone of $2.0 million to QLT USA Inc., which we refer to herein as QLT, from which we purchased the BEMA® delivery technology, which payment was made in August 2009.

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda, a leading international specialty pharmaceutical company based in Sweden. Meda s U.S. subsidiary, Meda Pharmaceuticals (formerly Medpointe Pharmaceuticals), located in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets, and sells branded prescription therapeutics. Although Meda was founded in 2001, it draws upon a long history in the U.S. market through its 2007 acquisition of Medpointe Pharmaceuticals (previously known as Carter-Wallace, Inc.). Meda has an experienced, well trained and highly regarded sales force with a focus in specialty therapeutic areas including pain, allergy and central nervous system conditions. Meda has established a track record of commercializing products with their top two products, Astelin®/Astepro® and

Table of Contents

Soma® 250 mg. We believe that Meda has proven their ability to launch products and sustain growth in highly competitive pharmaceutical markets, as demonstrated by Astelin® /Astepro®, which has out-performed competitors in the anti-histamine, nasal steroid and rhinitis markets with regard to total prescription growth. We expect Meda to also effectively compete in the transmucosal opioid market. Meda has secured access to additional markets through acquisition of European businesses from Valeant, and a joint venture with Valeant covering Australia, Mexico and Canada.

Our next planned product utilizing the BEMA® technology is BEMA® Buprenorphine, a potential treatment for moderate to severe pain conditions. Several formulations of BEMA® Buprenorphine were evaluated in a single dose, Phase 1 study started in late November 2008. In March 2009, we announced favorable preliminary results from this Phase 1 study and our intention to commence a Phase 2 efficacy study in June 2009. In December 2009, we announced that the primary efficacy endpoint was achieved in this Phase 2 clinical study. We believe that this endpoint, referred to as SPID 8 (sum of pain intensity difference over 8 hours), is a good indicator of this product candidate s effectiveness in treating chronic pain. In February 2010, we announced promising secondary data from this study.

In addition, we believe that the widespread use of buprenorphine for the treatment of opioid dependence presents an additional commercial opportunity for the product, and we are developing a formulation of BEMA® Buprenorphine (high dose) specifically for the treatment of opioid dependence.

ONSOLIS® and our product candidates such as BEMA® Buprenorphine may also have broader indications. When presented with viable commercial opportunities for broader indications of our products, we will consider developing the product for those uses. We also continue to explore the use of the BEMA® technology with additional pharmaceutical products that may fulfill an unmet medical need. In this regard, in 2009 we began the development of BEMA® Granisetron for the prevention of chemotherapy-induced nausea and vomiting and we anticipate that the development of a BEMA® Triptan for the treatment of migraine may begin in the second half of 2010. We believe that these product candidates and product concepts demonstrate the potential broad applicability of our BEMA® delivery technology.

Our lead Bioral® formulation is an encochleated version of Amphotericin B, a treatment for fungal infections. A single dose Phase 1 study has been performed with Bioral® Amphotericin B. We reported preliminary results in February 2009 where we indicated that plasma concentrations of Amphotericin B were detected in the sample of normal volunteers tested suggesting oral absorption from the Bioral® delivery system. We also believe our Bioral® technology has the potential to be applied to other types of pharmaceutical actives and other therapeutics such as small interfering RNA, or siRNA.

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, among other factors, the fact that ONSOLIS® was only recently launched. Since inception, we have recorded accumulated losses totaling approximately $59.2 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for our product candidates, our goal will be to augment our current sources of revenue and, as applicable, deferred revenue (principally licensing fees), with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

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

commercializing our product candidates, with the ultimate goal of generating revenues from sales of such products;

Table of Contents

partnering with other pharmaceutical companies to assist in the distribution of our products 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

proceeds raised from public and private financings and strategic transactions.

We were incorporated in the State of Indiana on January 6, 1997 and reincorporated as a Delaware corporation in 2002 in connection with our initial public offering.

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 New Drug Applications (known as NDAs) with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding ONSOLIS® or our 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.

Our Drug Delivery Technologies

BEMA® 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, such as nausea and vomiting. We previously licensed the BEMA® drug delivery technology in the United States on an exclusive basis from QLT. In August 2006, we entered into an agreement with QLT to purchase the non-U.S. rights to the BEMA® technology and in September 2007, we entered into an agreement with QLT to purchase the U.S. rights to the BEMA® technology. Payments to QLT for U.S. rights were due in conjunction with FDA approval of a BEMA® product, which we made after the approval of ONSOLIS® in July 2009. Additionally, we will make a single payment of $1 million to QLT concurrently with the approval in Europe of a BEMA® formulated product.

We believe that the BEMA® system 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;

Table of Contents

Permit absorption without patients being required to move the product around in the mouth for absorption, thus avoiding patient intervariability;

Have 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.

Bioral® Technology

Our Bioral® (cochleate) drug delivery technology encapsulates a selected drug or therapeutic in a crystalline structure termed a cochleate cylinder. All of the components of the cochleate cylinder are naturally occurring substances. We believe that the cochleate cylinder has the potential to provide an effective delivery mechanism without forming a chemical bond, or otherwise chemically altering the selected drug or therapeutic. We believe this technology will allow us to take certain drugs that are only available by intravenous injection and convert them to formulations that can be taken orally. Our Bioral® drug delivery technology was developed in collaboration with the University of Medicine and Dentistry of New Jersey, which we refer to herein as UMDNJ, and the Albany Medical College (which we refer to herein, collectively with UMDNJ, as the Universities), each of which has granted us the exclusive worldwide licenses under applicable patents.

ONSOLIS® and Our Product Candidates

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

Product/Formulation	Indication	Development Status	Commercial Status
ONSOLIS®/BREAKYL (U.S./EU trade names)	Breakthrough cancer pain in opiod tolerant patients	NDA Filed October 2007; Complete Response: August 2008; NDA resubmission for REMS: December 2008; FDA Approval: July 2009; EU regulatory submission April 1, 2008	Partnered worldwide with Meda except in Taiwan and South Korea
BEMA® Buprenorphine (low dose)	Moderate to severe pain	Phase 2 results announced: December 2009; Phase 3 planned for first quarter 2011	In-house commercialization for specialty indications possible; primary care rights expected to be partnered
BEMA® Buprenorphine (high dose)	Treatment of opioid dependency	Phase 1 planned for second half 2010	In-house commercialization for specialty indications possible

Table of Contents

Product/Formulation	Indication	Development Status	Commercial Status
BEMA® Granisetron	Nausea and vomiting	IND filing and Phase 1 planned for first half 2010	In-house commercialization for specialty indications possible; primary care rights expected to be partnered
BEMA® Triptan	Migraine headaches	Formulation development planned for 2010	In-house commercialization for specialty indications possible; primary care rights expected to be partnered
Bioral® Amphotercin B	Fungal infections	Phase 1	Partner will be sought in U.S. with co promote option for specialty indication

While continuing to work closely with Meda on the U.S. launch of ONSOLIS® and related regulatory approvals in the E.U. and Canada, we are presently dedicating much of our corporate resources toward progressing our pipeline of BEMA® products, particularly BEMA® Buprenorphine and BEMA® Granisetron. Depending on the availability of corporate resources and market opportunities, we may elect to accelerate or scale back funding for the development of other programs such as BEMA® Triptan or Bioral® Amphotercin B or other opportunities we may identify.

BEMA® Formulated Products

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. This is in addition to all upfront payments and those related to the achievement of specific milestones, such as U.S. and E.U. regulatory approvals.

Datamonitor estimates the global market for branded medications to treat breakthrough pain will reach $1.3 billion by 2017, with the U.S. being the single largest market and likely to account for well over half of global sales. In 2009, the leading fentanyl product for the treatment of breakthrough cancer pain in the U.S. market was Actiq® which is marketed by Cephalon, Inc. (NASDAQ:CEPH) and available as a generic from Barr Laboratories and Watson Pharmaceuticals. Cephalon introduced a second fast dissolving fentanyl product, Fentora® in late 2006. The reported combined retail sales of these products in 2009 were $633 million. We believe that ONSOLIS® may offer advantages over the marketed and pipeline fentanyl products in terms of ease of use and other attributes.

Table of Contents

We believe that ONSOLIS® has the potential to capture a sizeable share of the breakthrough cancer pain market in the U.S., which may ultimately result in annual projected peak sales of over $200 million. After receiving approval for the initial indication of breakthrough cancer pain in opioid tolerant patients, we may pursue an expanded indication that would permit promotion of ONSOLIS® for breakthrough pain in non-cancer patients in partnership with Meda. We expect that an expanded claim for use in non-cancer breakthrough pain would increase our sales for ONSOLIS® if obtained.

BEMA® Buprenorphine (low dose for pain)

This product candidate utilizes the BEMA® technology to deliver the opioid analgesic buprenorphine for the treatment of moderate to severe pain conditions. Buprenorphine is a marketed opioid analgesic which has comparable efficacy to morphine but with a lower propensity for adverse reactions, abuse and addiction. 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 morphine and oxycodone, which are Schedule II. We believe that this attribute will help create a broader market opportunity for BEMA® Buprenorphine as many doctors are reluctant to prescribe narcotics particularly on a chronic basis for the fear of addiction. 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. A prescription for a Schedule II controlled substance must be obtained by the patient from the doctor s office which the patient must then take to the pharmacy. Refills are not permitted for Schedule II controlled substances, requiring the patient to obtain a new prescription each time the medication is required.

We initiated a Phase 1 study that involved two different formulations of buprenorphine in our BEMA® technology. The preliminary results of this study, announced in March 2009, were favorable. Fourteen healthy volunteers participated in this randomized, blinded, cross-over study which compared two formulations of BEMA® Buprenorphine with intravenous buprenorphine and placebo. Following administration of both formulations, buprenorphine plasma concentrations were measureable within 15 minutes and accompanied by changes in pupillometry, a standard measure of opioid pharmacodynamic effect. Notably, this effect was maintained over the 8-hour duration of the study without evidence of significant decline. Local application of the BEMA® films in the mouth was well tolerated. Due to these favorable results, BEMA® Buprenorphine was progressed into Phase 2 clinical development in June 2009.

In December 2009, we announced that the primary efficacy endpoint was achieved in a Phase 2 clinical study conducted in a dental pain model. We believe that this endpoint, called SPID 8 (sum of pain intensity difference over 8 hours), is a good indicator of a product candidate s effectiveness in treating chronic pain. In February 2010, we announced that further analysis of the Phase 2 data revealed a more robust effect of BEMA® Buprenorphine on SPID 8 in patients with more severe pain at baseline (pain score of 7 or greater). In this subset of the data, all three doses (low, medium, and high) of BEMA® Buprenorphine were nearly or actually statistically superior (p= 0.06, 0.03, and 0.02 respectively) to placebo. The key secondary endpoint, TOTPAR 8 (total pain relief over the 8 hour post-dose period) followed the same pattern as the SPID 8 with the high dose statistically superior to placebo and the medium dose nearly significant. No serious adverse events were seen at any dose, and side effects were typical of those seen with a strong opioid.

BEMA® Buprenorphine (low dose) is intended to meet the need for a new narcotic and could 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 equivalent to morphine, but unlike morphine, is a Schedule III narcotic, a regulatory designation that 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;

Table of Contents

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

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

an 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

potential for 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 will 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. According to Datamonitor, the opioid market is estimated to total in excess of $10 billion in sales. Due to the ability of BEMA® Buprenorphine to potentially participate in the chronic pain market, we estimate that BEMA® Buprenorphine (low dose) has the potential to exceed $500 million in annual peak sales.

BEMA® Buprenorphine (high dose for opioid dependence)

We are also investigating a higher dose formulation of BEMA® Buprenorphine for the treatment of opioid dependence. Because of its lower propensity for abuse and addiction, BEMA® Buprenorphine (high dose) may also serve as a treatment for opioid dependence by preventing opioid addicted patients withdrawal symptoms while at the same time maintaining pain control. Currently in the U.S. there are two buprenorphine products approved for this indication with 2009 total retail sales in excess of $900 million. We believe BEMA® Buprenorphine (high dose) has the potential to offer advantages over these products. We estimate that BEMA® Buprenorphine for the treatment of opioid dependence has the potential to achieve between $200 and $300 million in annual peak sales.

We anticipate securing a commercial distribution partnership, similar in structure as our agreement with Meda for ONSOLIS®, for one or both indications of BEMA® Buprenorphine by the end of 2010 or in 2011.

BEMA® Granisetron

This product candidate utilizes the BEMA® technology to deliver the 5-HT3 receptor antagonist Granisetron (marketed as Kytril®), an FDA approved antiemetic to prevent the nausea and vomiting often encountered following cancer chemotherapy and radiation. According to retail sales data from Wolters

Table of Contents

Kluwer, the U.S. market for 5-HT3 antagonists is significant and exceeds $1.7 billion. This product candidate is presently in initial formulation development and we intend to move BEMA® Granisetron into clinical trials in 2010 with the potential to progress to Phase 3 in 2011. We believe that BEMA® Granisetron would have the potential for better tolerance than oral formulations in the presence of nausea and vomiting as well as potential for better and more consistent absorption in the presence of nausea and vomiting.

BEMA® Triptan

This product concept would utilize the BEMA® technology to deliver a triptan , which refers to a class of compounds that FDA has approved for the treatment of migraine headaches. This product candidate is intended to move into formulation development in the second half of 2010. We believe that BEMA® Triptan has the potential for both earlier plasma concentrations and migraine response as well as the potential for better response in presence of nausea and vomiting based on more consistent absorption from the BEMA® technology compared to currently available oral formulations.

Bioral® Formulated Products

Our licensed Bioral® drug delivery technology is based upon encapsulating (or encochleating) drugs to potentially allow for the oral administration of drugs otherwise given by intravenous administration. This encapsulation is designed to entrap the subject drug within a crystal matrix, rather than chemically bonding with the drug. Over the years, biochemists and biophysicists have studied artificial membrane systems to understand their properties and potential applications, as well as to gain insight into the workings of more complex biological membrane systems. In the late 1960 s, scientists began investigating the interactions of divalent cations with negatively charged lipid bilayers. They reported that the addition of calcium ions to small phosphatidylserine vesicles induced their collapse into discs which fused into large sheets of lipid. In order to minimize their interaction with water, these lipid sheets rolled up into crystalline structures, termed cochleates, after the Greek name for a snail with a spiral shell.

Our licensed Bioral® cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our Bioral® cochleate technology are phosphatidylserine, or PS , and calcium. PS is a natural component of essentially all biological membranes, and is most concentrated in the brain.

Research and development of cochleates has been conducted at the Universities for a number of years. In 1995, our predecessor became the exclusive worldwide licensee to develop the cochleate technology and in some cases co-own the patents with the Universities.

Potential Advantages

We believe that our licensed Bioral® drug delivery technology represents a potentially important new delivery mechanism. While the characteristics and benefits of this technology will ultimately be established through FDA clinical trials, our research, based upon non-clinical studies and one Phase 1 study, indicates that our Bioral® encapsulation technology may allow for potential advantages such as oral availability of the subject drug, minimization of side effects and ease of use.

Initial Bioral® Products in Development

We believe a diverse pipeline of products may be developed by applying our Bioral® drug delivery technology to a potentially broad array of established pharmaceuticals. Any intended Bioral®

Table of Contents

product (i.e., drug encapsulated with our drug delivery technology) will, upon completion of development, require separate FDA regulatory approval, and accordingly, will be subject to the uncertainty, time and expense generally associated with the FDA regulatory process. Even though we are targeting FDA approved, market-accepted drugs for use in our Bioral® technology, each of the products currently in development face development hurdles, regulatory requirements and uncertainty before market introduction. Due to our limited corporate resources, we are focusing primarily on our Bioral® Amphotericin B formulation, as described below.

Bioral® Amphotericin B

Fungal infections continue to be a major domestic and international health care problem. Amphotericin B, which is delivered intravenously, is an established, commonly used drug to treat these infections. We are currently developing a Bioral® formulation of Amphotericin B for treatment of fungal infections. If this product gains regulatory approval it could become the first oral amphotericin B product available in the world to treat systemic fungal infections.

Amphotericin B is often used to treat diseases that frequently strike patients with compromised immune systems. The use of the conventional injectable Amphotericin B to treat these infections is often limited by its propensity to cause kidney damage which we believe our Bioral® products may minimize. Bioral® Amphotericin B may also have uses in other diseases such as Leishmaniasis and Chagas disease.

The primary advantage which we are seeking for our proposed Bioral® Amphotericin B product is an oral formulation of the drug. Additional potential advantages include improved safety, extended shelf life, improved cellular uptake and reduced dosage. Assuming that we complete development of Bioral® Amphotericin B and that we obtain FDA approval, we believe that Bioral® Amphotericin B has the potential to provide an effective orally administered version of Amphotericin B which may be more effective and less toxic.

The global antifungal market is projected to grow to over $4 billion by 2016. According to our market research, annually, there are an estimated 500,000 severe fungal infections globally for which we believe Bioral® Amphotericin B may be an appropriate treatment. Our market research indicates that Bioral® Amphotericin B may be able to achieve projected peak sales of approximately $400 million annually for the treatment of esophageal candidiasis.

In February 2007, we announced the acceptance by the FDA of our Bioral® Amphotericin B IND application we made at the end of 2006. This represents the first IND that involves the Bioral® technology. In 2008, we completed the scale up manufacturing of Bioral® Amphotericin B. A single dose Phase 1 study was performed with Bioral® Amphotericin B, and we reported preliminary results in February 2009, where we indicated that plasma concentrations of Amphotericin B were detected in the sample of patients tested suggesting oral absorption from the Bioral® delivery system. Forty-eight healthy volunteers participated in the study, with sixteen recruited for each of three dose groups. In each dose group, twelve volunteers received a single dose of Bioral® Amphotericin B and four received a placebo. Amphotericin B plasma concentrations were measured over a period of fourteen days. The study identified doses that were well-tolerated with no meaningful changes in laboratory safety values including those associated with renal function. The preliminary pharmacokinetic evaluation, available in February 2009, revealed that plasma concentrations were comparable to those seen in prior animal toxicology studies using the same formulation. In previous animal studies we have conducted, doses used in toxicology studies have been shown to produce measureable tissue concentrations and efficacy against the fungal infections candidiasis and aspergillosis.

Table of Contents

In the development of this drug, we have collaborated in the past with the National Institutes of Health, the Public Health Research Institute of New York, the Drugs for Neglected Diseases initiative, or DND*i* and the University of Kentucky. On January 20, 2009, we entered into a Research Collaboration and License Agreement with DND*i*, a not-for-profit foundation, for the development and distribution of Bioral® Amphotericin B. Under our agreement, we and DND*i* will collaborate in assessing the efficacy of Bioral® Amphotericin B in various tropical diseases. Thereafter, DND*i* will be responsible for regulatory approvals in all countries of the world excluding Japan, Australia, New Zealand, Russia, CIS countries, China, and all countries in North America and any country in, or that joins the European Union. DND*i* will also be responsible for the distribution of Bioral® Amphotericin B through public sector non-profit or public benefit agencies for use in African Human Trypanosomiasis (HAT), Chagas disease and both Visceral and Cutaneous Leishmaniasis.

On October 6, 2009, we announced our receipt of a $1.3 million grant from the Walter Reed Army Institute of Research to support the clinical study of Bioral® Amphotericin B in the treatment of Cutaneous Leishmaniasis, a skin infection typically found in third world countries.

On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia Biopharmaceuticals, Inc., a related party that we refer to herein as Accentia. Accentia is commercializing technology licensed from Mayo Foundation for Medical Education and Research, or the Mayo Foundation, for the treatment of chronic rhinosinusitis (CRS) and asthma on a worldwide basis. The technology consists of using a low-dose topical antifungal to control the debilitating symptoms of CRS and asthma.

Other Potential Bioral® Candidates

We also believe our Bioral® technology has the potential to be delivered to other types of pharmaceutical actives, and also to other therapeutics such as small interfering RNA, or siRNA, and although we have not dedicated material corporate resources to these opportunities in recent years, we may seek to out-license these opportunities.

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

From our inception though 2004, we focused primarily on research and development of our licensed Bioral® encochleation technology and the application of such technology to specific drugs. In 2004, however, as a result of our acquisition of Arius Pharmaceuticals and the BEMA® technology, we began (and continue) to shift our corporate focus to what we call the area of specialty pharmaceuticals : applying our licensed technologies to existing therapeutics to create our own proprietary formulations, for which we then seek proprietary protection, to obtain FDA approval and subsequently commercialize. We believe that focusing our drug delivery technologies for use with existing FDA approved drugs to be less risky than attempting to discover new drugs, sometimes called new chemical entities, or NCEs. This transition in corporate focus has continued and came to initial fruition with the FDA s approval of ONSOLIS® in 2009. It is our goal to replicate the development, regulatory approval and commercialization achievements we made with ONSOLIS® with our current and future product candidates.

An important part of our strategy is to attempt to capitalize on the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of our formulations of previously approved therapeutics. Under the 505(b)(2) approval process, we are able to seek FDA approval of a new dosage form, dosage regimen or new indication of a pharmaceutical that has previously been approved by the FDA. This regulation enables us to partially rely on the findings of third parties which the FDA has published on approved pharmaceuticals, including clinical and non-clinical testing, thereby reducing, though not eliminating, the need to engage in these costly and time consuming activities. A typical development program for a 505(b)(2) submission will include:

- a single genotoxicity study with the drug substance,

Table of Contents

a 14 or 28-day multiple dose toxicity study in a single species,

thorough pharmacokinetic evaluation of the new dosage form in humans,

at least one placebo controlled clinical study in humans,

a second clinical study to establish the safety of the product in the intended patient population,

stability of drug substance,

full description of drug product manufacturing process,

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

special studies specific to the formulation.

This drug development approval program is designed to be less extensive and lengthy and, as a result, we believe, more cost efficient than attempting to gain approval of an NCE. By utilizing this regulatory process and focusing on creating novel formulations of established pharmaceuticals that could potentially benefit from incorporation into our delivery technologies, we believe that we will more quickly and efficiently navigate the FDA approval process, and, if such approval is obtained, move our product candidates to market.

As part of our strategy, however, we will also continue on a more limited basis to seek partners to whom we can license our delivery technologies so that they may be applied to the proprietary products of such partners. Drug delivery technologies can provide pharmaceutical and biotechnology companies with an avenue for developing new drug delivery formulations, as well as extending the exclusivity of products in the marketplace. Companies, such as ours, can also apply their technologies to drugs no longer patent protected. Pharmaceutical and biotechnology companies view new and improved delivery technology as a way to gain competitive advantage through enhanced safety, efficacy, convenience and patient compliance of their drugs, and we will continue to attempt to leverage this need for improved delivery systems.

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 our technologies, we believe health care providers will be familiar with the drug and accustomed to prescribing them. As with ONSOLIS® and BEMA® Buprenorphine, most of the drug candidates we target will have been through the regulatory process and therefore the safety and efficacy of the drug has been established. Consequently, we believe that our clinical trials would primarily need to show that our BEMA® or Bioral® based products will deliver the drug without causing unintended safety or tolerability concerns for the patient or changing the clinical attributes of the drug. Focusing on drug delivery as compared to drug discovery should allow us to also potentially form a number of collaborations to deliver a wide variety of medicines without limiting rights to utilize our proprietary technology with additional drug opportunities.

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 manufacture, market, sell, and, following regulatory approval, continue development of ONSOLIS® in the United States, Mexico and Canada.

Pursuant to such license agreement, we did or will receive:

- A $30.0 million milestone payment upon closing, which was received on September 14, 2007.
- An additional $29.8 million milestone for the approval of ONSOLIS® by the FDA, and in conjunction with commercial supplies of ONSOLIS®, sufficient for commercial launch of ONSOLIS® in the U.S. Of this amount, $3.0 million was advanced in January 2009. The remaining $26.8 million was received on July 21, 2009.
- A significant 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 payable at:
  - $10.0 million when and if annual sales exceed $75.0 million;
  - $10.0 million when and if annual sales exceed $125.0 million; and
  - $10.0 million when and if annual sales 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. Per our agreement with Meda, this financial support, if we elect to co-promote, will not begin for a period of time following FDA approval of ONSOLIS®. 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 that do not involve studies in support of the NDA such as additional indications for ONSOLIS®.

European Agreement. In August 2006, we announced collaboration with Meda to develop and commercialize ONSOLIS® in Europe. Under terms of the agreement, we granted Meda rights to the European development and commercialization of ONSOLIS®, in exchange for an upfront fee paid to us, certain milestone payments and double digit royalties to be received by us on net product sales. Payments already received include a $2.5 million payment upon execution of the agreement and a $3.0 million payment upon completion of Phase 3 clinical trials in January 2008. Additional milestones would, if achieved, provide us with up to an aggregate of $5 million in revenue. Meda will manage the clinical development and regulatory submissions in Europe. Upon regulatory approval, Meda will exclusively commercialize ONSOLIS® in Europe.

Table of Contents

On January 2, 2009, we entered into an amendment to the European agreements with Meda pursuant to which we received $3.0 million in consideration of the following changes made to such European agreements: Meda was granted worldwide commercialization rights to ONSOLIS®, with the exception of Taiwan and South Korea (the rights to which shall be retained by us). The sales royalties to be received by us will be the same for all territories as that 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. We and Meda have also modified several terms of the related ONSOLIS® Supply Agreement between the parties, dated September 5, 2007, to reflect the changes in the territorial scope of the expanded territory.

Key Collaborative and Supply Relationships

We are 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 in our 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:

Meda. We believe that our agreements with Meda are currently 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. (which we refer to herein as Aveva) pursuant to which Aveva will supply ONSOLIS® product 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, Mexico and Canada. We will pay for formulation development, commercial quantity scale-up work and the manufacture of clinical supplies, as well as for the cost of commercial supplies of ONSOLIS® based on Aveva s fully-burdened cost of manufacturing such supplies plus an established profit margin. The agreement has an initial term which is subject to automatic renewal for additional terms unless either party provides notice of termination in advance of such renewal. In connection with this agreement, we issued Aveva a warrant to purchase up to 75,000 shares of our common stock (which shares vest based on the occurrence of specified milestones) at a price equal to $3.50 per share, which warrant expired in June 2009. In July 2009, to replace such expired warrant, we issued Aveva a warrant to purchase up to 25,000 shares of our common stock at a price equal to $5.87, which warrant expires in July 2010.

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 and scale-up activities and supply ONSOLIS® product to us for European clinical trials. Under the terms of this agreement, LTS is anticipated to be the sole supplier of ONSOLIS® for clinical trials and commercial distribution within the European Union. Further, under the agreement LTS has granted us a license under European Patent No. 0 949 925, in regard to our ONSOLIS® product in the European Union.

Table of Contents

Effective February 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 product to us for clinical trials. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BEMA® Buprenorphine for clinical trials and commercial distribution throughout the world.

Drugs for Neglected Diseases initiative. On January 20, 2009, we entered in to a research collaboration and license agreement with the Drugs for Neglected Diseases initiative (DNDi) to allow the development of Bioral® Amphotericin B for African Human Trypanosomiasis also known as African sleeping sickness, Chagas Disease and visceral and cutaneous leishmaniasis. Under the terms of the agreement we will work with DNDi in determining the efficacy of Bioral® Amphotericin B for the above mentioned diseases. Should efficacy be shown, DNDi will then be financially responsible for clinical trials and regulatory approvals of Bioral® Amphotericin B in all countries of the World excluding Japan, Australia, New Zealand, Russia, CIS countries, China, and all countries in North America and any country in, or that joins the European Union. We will be responsible for providing the necessary clinical trial supplies of Bioral® Amphotericin B at cost, and if DNDi is successful in obtaining approval of the product, we will supply DNDi commercial quantities of Bioral® Amphotericin B at an agreed upon profit. DNDi, under the agreement, will be only be able to distribute Bioral® Amphotericin B through public sector and not for profit agencies for the above described diseases, in the above described counties, but excluding any military organization.

QLT. On May 27, 2004, prior to our acquisition of Arius Pharmaceuticals, Arius entered into a worldwide, exclusive royalty-bearing license agreement with Atrix Laboratories (now a subsidiary of QLT) to develop, market, and sell products incorporating QLT s BEMA® technology, including the use of fentanyl in the BEMA® technology, and to use the BEMA® trademark in conjunction therewith. All research and development related to the BEMA® technology, including three existing INDs that were transferred to Arius in accordance with the QLT license agreement.

In August 2006, we purchased from QLT all of the non-U.S. rights to the BEMA® drug delivery technology, including all patent rights and related intellectual property. The aggregate purchase price for the non-U.S. portion of the BEMA® technology is $3 million, to be paid over time as follows: (i) $1 million was paid at closing, (ii) $1 million by the end of first quarter 2007 (which was paid March 30, 2007) and, (iii) $1 million to be paid within 30 days of regulatory approval of the first non-U.S. BEMA® product. As part of the transaction solely with respect to the non-U.S. portion of the former license with QLT, no further milestone payments or ongoing royalties will be due to QLT. In addition, we were granted the option to purchase the remaining U.S. asset for $7 million dollars.

In September 2007, we exercised such option and purchased from QLT the BEMA® drug delivery technology and intellectual property assets specifically related to the development and commercialization of BEMA® in the United States. In consideration for such rights, we paid QLT $7 million, consisting of $3 million in cash and a promissory note, secured by the purchased assets, in the principal amount of $4 million. Payments under such note are due as follows: (i) $2 million within ten (10) business days of FDA approval of a product based on the BEMA® technology which was paid July

Table of Contents

2009 and (ii) $2 million within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA®-based products reach $30 million. We used the proceeds of a $3 million secured loan from Southwest Bank of St. Louis to fund the initial payment to QLT in early September 2007. Such loan was subsequently repaid in full on September 14, 2007, concurrently with the closing of the Meda U.S. licensing transaction.

Premier Research International. In February and March 2009, we entered into a Master Clinical Development Agreement and related proposal with Premier Research International LLC (Premier) for research and development services related to BEMA® Buprenorphine product. The services provided cost approximately $1.3 million and were performed over eleven months. As of February 2010, the services from Premier have been completed.

We also have collaboration agreements with entities (including Accentia) that are affiliated with and partially-owned by members of our board of directors and management to conduct research and license certain proposed drugs. See Certain Relationships and Related Transactions for a description of these affiliated party transactions.

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 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, or CDLA, with 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 royalty based on net sales of ONSOLIS® (including minimum royalties). In addition, we granted CDC a warrant exercisable for up to 500,000 shares of our common stock at an exercise price of $3.50 per share. As a result of the anti-dilution provisions of the CDC warrant and the pricing of our October 2005 public offering, the conversion price of the CDC warrant is now $2.91. The warrant expires after the earlier of: (i) 5:00 p.m. Eastern Time on the second anniversary of the approval by the FDA of the first NDA relating to ONSOLIS® (which will be July 16, 2011); (ii) the closing of a sale of all or substantially all of our assets or the acquisition of our company by another entity by means of merger or other transaction as a result of which our stockholders immediately prior to such acquisition possess a minority of the voting power of the acquiring entity immediately following such acquisition, or (iii) any liquidation or winding up of our company. We also issued to CDC a warrant to purchase 904,000 shares of our common stock in connection with the May 2006 amendment to the CDLA. Such warrant is exercisable at $3.00 per share. All of the shares of common stock issued to CDC (as well as the shares underlying CDC s warrants) as described above have been registered with the SEC.

During 2006 and 2007, we were a party to disputes with CDC. On September 5, 2007, in

Table of Contents

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).

Pursuant to the ROFR, if we desire to enter into a transaction with any third party to offer and sell our debt and/or equity securities for cash other than in connection with: (i) a bona fide commercial partnering transaction relating to ONSOLIS® product or (ii) any debt financing from a federal or state accredited bank, provided the annualized interest rate thereunder will not exceed 18% (a Financing Transaction), we shall first provide CDC a written notice containing all of the terms and conditions pursuant to which we would enter the Financing Transaction (the Definitive Terms). For a period of ten (10) days following CDC s receipt of the Definitive Terms (the Acceptance Period), CDC shall have the right, but not the obligation (the Acceptance Right), to elect in writing to engage in the Financing Transaction on the Definitive Terms. If, during the Acceptance Period, CDC elects to exercise its Acceptance Right, we and CDC agree to then exclusively negotiate definitive documentation relating to the Financing Transaction for a period not to exceed thirty (30) days from the date of CDC s exercise of its Acceptance Right. The definitive documentation shall be based upon, and shall be consistent in all material respects with, the Definitive Terms, without modification. If, during the Acceptance Period, CDC does not elect to exercise its Acceptance Right, or, in the event the Acceptance Right is exercised but a closing of the Financing Transaction does not occur within the thirty (30) day period referred to above, then we shall have sixty (60) days in which to consummate a Financing Transaction with any third party with no further action or approval required by the CDC; provided, however, that the terms and conditions of such transaction shall be not less favorable to us than the terms and conditions set forth in the Definitive Terms.

The ROFR will cease at any time we maintain a volume weighted average stock price of $9.00 per share (as adjusted for stock splits, reverse stock splits, stock dividends and such similar transactions) 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 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.

Research and Development

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

Table of Contents

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, 2009 and 2008, we spent approximately $10.4 million and $10.9 million, respectively, on research and development expenses, and such expenses represented approximately 50% and 60%, respectively, of our total operating expenses for such fiscal years. Meda has reimbursed approximately $2.8 million and $2.7 million of our research and development expenses for the years ended December 31, 2009 and 2008, respectively. These reimbursements represent approximately 27% and 25% of our total research and development costs for such fiscal years.

Competition

The pharmaceutical industry is highly competitive and subject to rapid and substantial regulatory and technological changes. Developments by others may render our proposed BEMA® or Bioral® technologies and 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, although the examples are not exhaustive. 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 drugs which 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.

BEMA®

Included among the companies which we believe are developing potentially competitive technologies to BEMA® are: MonoSol Rx, a drug delivery company specializing in the development and commercialization of thin-film pharmaceutical and over-the-counter products; Transcept Pharmaceuticals, Inc. (NASDAQ:TSPT), a specialty pharmaceutical company utilizing transmucosal delivery for central nervous system (CNS) drugs; ULURU Inc. (AMEX:ULU), which utilizes a mucoadhesive polymer disc to deliver drugs transmucosally, and Orexo AB, Inc. the company responsible for the sublingual tablet delivery system used for the transmucosal fentanyl product Abstral.

In addition, a number of companies are developing improved versions of existing products using nasal spray and inhaled technologies. We believe that potential competitors are seeking to develop and commercialize technologies for the buccal, sublingual or mucosal delivery for 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

Table of Contents

provides for a rapid and consistent delivery of each dose based on how the BEMA® technology adheres to the buccal membrane and dissolves over 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.

For ONSOLIS®, in the breakthrough cancer pain area, the principal competitor remains Cephalon, Inc. (NASDAQ:CEPH). In 2009, the overall market for transmucosal fentanyl products for breakthrough pain totaled $633 million. The transmucosal fentanyl class has faced challenges following safety issues stemming from inappropriate use of Cephalon s Fentora® and the subsequent Dear Doctor letter (Cephalon Press Release, September 2007), a significant decline in sales promotion activity, and the FDA s rejection of an expanded indication for Fentora®. Furthermore, the FDA has required that a Risk Evaluation and Mitigation Strategy, or REMS, be required for all transmucosal fentanyl products. The 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 FDA and put in place prior to launch. Despite this requirement, as of the date of this Report, the FDA has not reached agreement with Cephalon on a REMS program for Fentora® or Actiq®, which had an October 2009 action date.

Cephalon s first product for the breakthrough cancer pain indication was Actiq® (oral transmucosal fentanyl citrate) which generated $84 million in sales in 2009. Cephalon licensed a generic of this product to Barr Laboratories upon approval of Fentora®. Total sales for generic versions of Actiq®, available from Barr Laboratories and Watson Pharmaceuticals, totaled $370 million over the same period. Additional generic versions of Actiq® are anticipated to reach the market in early 2010. Fentora® utilizes an effervescent tablet which is administered buccally. Fentora® was approved and launched in late 2006 and generated $179 million in sales in 2009.

Endo Pharmaceuticals, who originally licensed Abstral , a polymer formulated sublingual fentanyl tablet currently under review by FDA for breakthrough cancer pain, from Orexo AB, returned all rights to Orexo in 2008 following its own internal strategy changes. Prostrakan Group plc (LSE: PSK) announced in July 2008, that its licensing agreement with Orexo would be extended to include North America. Prostrakan is a specialty pharmaceutical company headquartered in Scotland and employees approximately 300 people in its operations. Prostrakan entered the U.S. market in 2008 following the approval of Sancuso , a transdermal patch for the prevention of chemotherapy-induced nausea and vomiting. Sancuso was launched with a newly created U.S. sales force of approximately 70 representatives established in collaboration with NovaQuest (partnering group of Quintiles). In December 2008, Prostrakan announced receipt of marketing authorization from the German regulatory authorities for their fentanyl sublingual tablet (under the brand name Abstral®) and was subsequently launched in a number of countries. In the U.S., Abstral® was submitted to FDA for review in August 2009. Prostrakan expects to launch Abstral® in the second-half of 2010. It is anticipated that Abstral® will be required to obtain approval on a REMS program with the same goals required of ONSOLIS®.

Additional products are under development utilizing intranasal delivery of fentanyl include Nasalfent® (Archimedes) and an intranasal fentanyl spray from Nycomed, while other companies are focusing on delivery using sublingual spray formulations. YM Biosciences, Akela Pharma/Janssen and Alexza are developing inhaled formulations of fentanyl for administration across the alveoli in the lungs. Alexza/Endo reported termination of their agreement to develop Staccato Fentanyl. No additional information suggesting the continued development of Staccato Fentanyl is available. Other potent pain products are also in development, including Javelin Pharmaceuticals, Inc. (AMEX: JAV) who is developing an intranasal morphine and AcelRx Pharmaceuticals with a nano-tab drug/device delivery system containing sufentanil for the treatment of breakthrough pain. This product, ARX-02, has

Table of Contents

completed initial Phase 1 trials. 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 potentially have a higher level of 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)	Cephalon/Generics	Fentanyl lollipop	Marketed (generics available)
Fentora® (fentanyl buccal tablet)	Cephalon	Effervescent buccal tablet	Marketed
Abstral® (fentanyl sublingual tablet)	Prostrakan	Sublingual tablet	NDA submitted to FDA in August 2009; Marketed in E.U. following June 2008 approval
Instanyl®	Nycomed	Nasal spray	Approved in E.U. in July 2009
Nasalfent®	Archimedes	Fentanyl nasal spray	NDA submitted to FDA in August 2009; E.U. filing in April 2009.
Fentanyl SL Spray	INSYS Therapeutics	Fentanyl sublingual spray	Phase 3, Efficacy trial completed
AD923	Pharmasol (rights assigned from Sosei in 2009)	Sublingual Spray	Phase 3 in E.U.
Fentanyl TAIFUN®	Akela/Janssen (EU)/ Teikoku Seiyaku (Japan)	Dry powder Inhaler	Phase 3 in E.U. Phase 2 in Japan
ARX-02	AcelRx Pharmaceuticals	Nano-tab drug/device delivery system containing sufentanil	Phase 2
AZ003-Stacatto Fentanyl	Alexza	Aerosolized fentanyl for inhalation	Phase 1

In addition to direct competitors, there are other factors that impact the market for transmucosal fentanyl products and pain products in general. The significant pricing pressures and the prospect of healthcare reform in the U.S. are likely to have increasing influence on the pharmaceutical market, including pain products, since the cost of such products heavily rely on reimbursement and third party

Table of Contents

payers. Additionally, the increasing number of FDA imposed REMS programs results in added barriers for branded products but may also make the availability of generics less appealing since most REMS, including that required for ONSOLIS®, will require additional expenses and resources to implement effectively. We expect that REMS programs are likely to play a widespread role in the area of pain management.

A number of products may be competitors to our BEMA® Buprenorphine product candidate. A potential focus will be to position BEMA® Buprenorphine as a step up from NSAIDs and instead of or prior to Schedule II narcotics. Indications for such use include pain associated with severe arthritis and lower back conditions. Marketed competitors for these indications include Tramadol (Ultram® ER from PriCara and Ryzolt® from Purdue) and the potent opioids such as Opana from Endo, OxyContin® from Purdue, Avinza® and Kadian® from King Pharmaceuticals and Duragesic® from Johnson & Johnson. Other competition includes multiple new chemical entities in clinical development with different mechanisms of action as well as various combination formulations. Additionally, abuse deterrent formulations of pain products are currently being marketed, in clinical development or are under FDA review. These formulations, such as Remoxy and Embeda (King Pharmaceuticals) use a variety of technologies to try and minimize abuse. These products have recently been approved and 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. Other products using buprenorphine are under clinical investigation and utilize transdermal, nasal, and subcutaneous depot delivery systems. Should these products make it to market, they may potentially compete with BEMA® Buprenorphine.

Bioral® Technology

While many development activities are private, and therefore we cannot know what research or progress has actually been made, we are not aware of any other drug delivery technology that, like our Bioral® technology, uses a naturally occurring drug delivery vehicle or carrier that can be used to simultaneously address two important clinical goals: oral delivery of drugs that normally require injection and targeted cell delivery once the drug is in the body.

Included among the companies which we believe are developing potentially competitive technologies are Emisphere Technologies, Inc. (NASDAQ:EMIS), Nektar (NASDAQ:NKTR) and CyDex Pharmaceuticals, a privately-held company. We believe that these potential competitors are seeking to develop and commercialize technologies for the oral delivery of drugs which may require customization for 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 our cochleate technology is seeking to deliver a potential broad base of water soluble and water insoluble (fat or lipid soluble) compounds with limited customization for each specific drug.

Specific to Bioral® Amphotericin B, competitors may include currently marketed liposomal amphotericin B products, such as AmBisome from Gilead Sciences, Inc. (NASDAQ:GILD) and Abelcet from Enzon Pharmaceuticals Inc. (NASDAQ:ENZN). Sales of liposomal Amphotericin B products were in excess of $200 million in 2009. However, neither formulation is available in a dosing form that allows for oral administration. iCo Therapeutics Inc. is evaluating an oral formulation of amphotericin B, referred to as iCo-009, under an exclusive option from the University of British Columbia. This product is a lipid-based reformulation of amphotericin B for oral administration. In 2009, iCo Therapeutics published the results of a study showing inhibition of the parasite responsible for Visceral Leishmaniasis. Previously, iCo Therapeutics announced results of an animal study showing plasma levels of amphotericin B following oral administration of iCo-009.

Table of Contents

A potential differentiating factor is that we believe that our technology may have cell-targeted delivery attributes as well. Additional companies which are developing potentially competitive technologies in this area may include Enzon and Flamel Technologies S.A. (NASDAQ:FLML) which we believe may be seeking to develop technologies for cell-targeted delivery of drugs. 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, we seek to use our cochleate to encapsulate the therapeutic to achieve drug delivery into the interior of the cells such as inflammatory cells.

Although the competitors mentioned above are developing drug delivery techniques conceptually similar to ours with respect to encapsulation, or more specifically nano-encapsulation, we believe that our approach is different, proprietary and protected under our licensed and patented technology. One primary way we can be differentiated from our competitors is in our approach of using naturally occurring substances to form a cochleate which encapsulates the drug in a scroll-like multilayered delivery vehicle.

Licenses, Intellectual Property and Proprietary Information

Our intellectual property strategy is intended to maximize the protection afforded to our proprietary information, technologies and to expand our patent portfolio, license agreements, proprietary rights and any future licensing opportunities we might pursue. However, our interest in our intellectual property is subject to and burdened by various royalty payment obligations and by other material contractual or license obligations.

In general, the patent position of biotechnology and pharmaceutical organizations is considered to be uncertain and involves complex legal and technical issues. There is considerable uncertainty regarding the breadth of claims in patent cases and the degree of protection thus afforded. While we believe that our intellectual property position is sound and that we can continue developing our drug delivery technologies, it may be that our pending patent applications will not be granted or that our current or future intellectual property will not afford us protection against competitors. It is possible that our intellectual property positions will be successfully challenged or that patents issued to others 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 dominate our patent position.

BEMA® Technology

The mucoadhesive erodible drug delivery device technology space is congested, although we do not believe that our BEMA® products are in conflict, with or dominated by or infringing any external patents and we do not believe that we require licenses under these 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.

We have been granted non-exclusive license rights, under certain conditions, to European Patent No. 0 949 925, controlled by LTS to market the 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 remain ongoing. We have not conducted freedom to operate searches and analyses for our other proposed products.

Table of Contents

We own various patents and patent applications relating to the BEMA® technology. US 6,159,498 (expiration date October 2016), US 7,579,019 (expiration date January 2019) 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. Should we prevail in this case, the patent expiration date of US 7,579,019 would be extended from January 31, 2019 to January 22, 2020.

Cochleate Technology and Products

We believe that our rights to the cochleate intellectual property will enable us to continue to develop this drug delivery technology for Amphotericin B, as well as potentially for other therapeutics. We continue to prudently and strategically augment our existing cochleate patent portfolio and seek patent protection for not only our delivery technology, but also potentially for methods of using our cochleate delivery technology and the combination of our delivery technology with various drugs no longer under patent protection.

We are currently aware of United States patent 5,616,334 dealing with lipid formulations of Amphotericin B products. We do not believe that our Bioral® products infringe or are in conflict with this patent, although it is possible that a court of law in the United States might determine otherwise. Accordingly, we do not believe that we require a license under this patent. Although, if a court were to determine that we were infringing this or other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B. However, we may be unable to obtain such licenses from the patent holders, and 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.

Certain portions of the development of our cochleate technology were supported by funding from the United States government. This support provides the United States government certain rights in technologies developed solely by government employees. We believe to the extent the United States government would have rights in technologies developed under our agreements we may need to obtain a license, likely royalty bearing, relating to the United States government s rights in the technology. Rights to negotiate a license to any United States government rights are provided for in our agreements.

We own various patents and patent applications relating to the Bioral® technology. US 5,994,318 (expiration November 2015) and EP 0 812 209 (expiration February 2016) are of particular value to our business and technology platform relating to the Bioral® delivery technology.

In addition, to help protect our proprietary know-how and inventions for which patents may be filed in the future, or for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection, confidentiality agreements and intellectual property assignment agreements with all of our employees.

With respect to trademarks, BDSI®, BEMA® and Bioral® are registered trademarks of BioDelivery Sciences International, Inc. ONSOLIS® is a registered trademark of Meda Pharmaceuticals, Inc.

Table of Contents

Manufacturing

During drug development and the regulatory approval process, we plan to rely on third-party manufacturers to produce our compounds for research purposes and for non-clinical and clinical trials. We are currently parties to the following manufacturing arrangements and, except as described below, we do not presently have manufacturing arrangements with respect to our intended 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.

Effective December 15, 2006, we entered into a Process Development Agreement with LTS pursuant to which LTS will undertake process development and scale-up activities and supply ONSOLIS® to us for clinical trials in Europe. Under the terms of this agreement, LTS is anticipated to be the sole supplier of ONSOLIS® for clinical trials and commercial distribution within the European Union.

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 product to us for clinical trials and commercial distribution throughout the world. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BEMA® Buprenorphine commercial product throughout the world. Further, under the agreement LTS has granted a license to European Patent No. 0 949 925 in regard to ONSOLIS® in the European Union.

If our other intended product candidates near market introduction, we intend to outsource manufacturing to third-party manufacturers, in compliance with FDA and other international regulatory agencies applicable Good Manufacturing Practices. We are currently seeking manufacturing partners for certain of our products and formulations and believe that such commercial manufacturing arrangements are likely to be available to us.

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

Sales and Marketing

Following, and assuming, completion of our clinical development and regulatory approval for each proposed product, we will pursue one of several approaches (or a combination thereof) for marketing and selling our products. These include licensing the products to appropriate partners so that they can market and distribute the products for us, co-promotions where we would share in the sales promotion, or use of contract sales organizations, or use of our own yet-to be constituted sales organization. We have already implemented this strategy with regard to our lead product, ONSOLIS®, with our licensing agreement with Meda, which was expanded in 2009 to include the rest of world (with the exception of Taiwan and South Korea). 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, while leaving promotional responsibilities for the large primary care audiences with a partner.

Table of Contents

In September 2006, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for ONSOLIS® in the European Union. Under the terms of the agreement, we granted Meda rights to the European development and commercialization of ONSOLIS® (which will be marketed in Europe under the trade name BREAKYL), in exchange for an upfront fee to be paid to us, certain milestone payments and double digit royalties to be received by us on product sales. Payments include a $2.5 million payment upon execution of the agreement, a $2.5 million payment upon completion of clinical requirements for a European marketing application and additional milestones that would, if achieved, provide us with up to an additional aggregate of $5.0 million in revenue. Meda will manage the clinical development and regulatory submissions in Europe. Upon regulatory approval, Meda will exclusively commercialize ONSOLIS® in Europe.

ONSOLIS® is currently under review by the European regulatory authorities. Progress continues toward preparations for the approval and launch of ONSOLIS® in Europe for later 2010. Meda has focused activities in Europe on gaining thought leader input and building support through the use of advisory boards and other medical meetings. Data has also been presented at some of the important European medical conferences.

In September 2007, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for ONSOLIS® covering the United States, Canada and Mexico. Under the terms of the September 2007 agreement, Meda is responsible for the sales, marketing and distribution of ONSOLIS® in the U.S., Canada and Mexico. The agreement between us and Meda outlines specific marketing minimum expenditures and sales call volumes in addition to minimum royalty payments beginning in the second full year of sales. 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, including the clinical development activity for ONSOLIS® in patients with breakthrough pain associated with other non-cancer related conditions such as back pain and osteoarthritis.

On January 2, 2009, we entered into amendments to our agreements with Meda to grant Meda worldwide commercialization rights for ONSOLIS®, with the exception of Taiwan and South Korea, (the rights to which shall be retained by us). The sales royalties to be received by us will be the same for all territories as that agreed to for Europe. In addition, various terms of our European Union agreement with Meda have been modified to reflect the rights and obligations of both us and Meda in recognition of the expansion of the scope of such agreement. We and Meda have also modified several terms of the related ONSOLIS® Supply Agreement, dated September 5, 2007, to reflect the changes in the territorial scope of the expanded territory definition of the European Union agreement.

ONSOLIS® was commercially launched in the United States in mid-October 2009 following approval by the FDA in July 2009. ONSOLIS® commercial efforts are being supported by a therapeutic specialty sales force assembled by Meda Pharmaceuticals to target Oncologists and Pain Management Specialists treating cancer breakthrough pain. Approximately fifty highly-experienced and well-trained sales representatives promote ONSOLIS® to target healthcare providers. These individuals are supported by several internal functions at Meda including Marketing, Medical Affairs and Managed Care personnel. Sales efforts are supported through extensive marketing activities, which include journal advertising in select oncology and pain management medical journals, trade show exhibits, medical education, symposia, webcasts and peer selling programs. A strategy is also in place to include electronic and internet promotional activities. Sales representatives have numerous materials available for healthcare providers and their patients to support education on breakthrough cancer pain and the use of ONSOLIS®. The ONSOLIS® promotion is anticipated to be of the same relative size and scope of promotion from our primary competitors, which at this time includes only Cephalon.

Table of Contents

We believe that utilizing a commercial partner with a strong U.S. and E.U. presence, along with a global reach, will allow us to competitively launch ONSOLIS® without 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 partnership with Meda will allow internal efforts to be focused on the development of additional product opportunities. Our agreements with Meda provide additional benefit by leveraging a single commercial partner for a global launch of ONSOLIS®.

Government Regulation

The manufacturing and marketing of any drug which we formulate with our licensed Bioral® or BEMA® technologies as well as our related research and development activities, are subject to regulation for safety, efficacy and quality by governmental authorities in the United States and other countries. We anticipate that these regulations will apply separately to each drug product with our drug delivery technologies. We believe that complying with these regulations will involve a considerable level of 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 is granted allowing us to market our products.

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

1. Laboratory and non-clinical tests for safety and small scale manufacturing of the agent;

2. The submission to the FDA of an IND which must become effective before human clinical trials can commence;

3. Clinical trials to characterize the efficacy and safety of the product in the intended patient population;

4. The submission of an NDA or Biologic License Application to the FDA; and

5. FDA approval of the NDA or Biologic License Application prior to any commercial sale or shipment of the product.

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 for products, drugs and devices.

Table of Contents

Non-clinical Trials

Non-clinical testing includes laboratory evaluation of chemistry and formulation, as well as tissue culture and animal studies to assess the safety and potential efficacy of the product. Non-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices. Non-clinical testing is inherently risky and the results can be unpredictable or difficult to interpret. The results of non-clinical 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 objects to 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 non-clinical trials.

Clinical Trials

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. 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. The institutional review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. 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. In Phase 1, the initial introduction of the product into healthy human subjects, the drug is tested for safety (adverse side effects), absorption, metabolism, bio-distribution, excretion, food and drug interactions, abuse potential as well as limited measures of pharmacologic effect. Phase 2 is the proof of principle stage and involves studies in a limited patient population in order to:

- assess the potential efficacy of the product for specific, targeted indications;
- identify the range of doses 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 and confirm the clinical efficacy and establish the 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 intend 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. Multiple non-clinical studies were conducted with Bioral® Amphotericin B and one clinical study was done in 2008. One human pharmacokinetic study was conducted with BEMA® Buprenorphine in 2006, a second in 2008 and a Phase 2 efficacy study was performed in 2009. We expect that additional studies in normal volunteers and patients will be performed with BEMA® Buprenorphine, BEMA® Granisetron and Bioral® Amphotericin B in 2010.

Table of Contents

New Drug Application and FDA Approval Process

The results of the manufacturing process development work, non-clinical studies and clinical studies are submitted to the FDA in the form of a New Drug Application (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 non-clinical and clinical testing, the NDA applicant must submit detailed information about chemistry, manufacturing and controls that will describe how the product is made 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 non-clinical 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 data collected and analyzed for each non-clinical and clinical study. Through this investigation, FDA reaches a decision about the risk-benefit profile of a product candidate. If the benefit is worth the risk, FDA begins negotiation with the company on the content of an acceptable package insert and associated REMS plan if required.

The approval 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 an NDA if applicable regulatory criteria are not satisfied, 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 the safety and efficacy of the drug. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which it may be marketed. 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 drug and quality control 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, 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 FDA s authority over drug safety and directs FDA to develop systems aimed at managing the risk-benefit ratio of a drug, with a particular focus on post-approval safety. FDAAA authorized FDA to require and enforce a Risk Evaluation and Mitigation Strategy, or REMS, if the Agency determines that it is necessary to ensure that the benefits of a drug outweigh the potential risks. The legislation also provides FDA with increased authority to require REMS at any point in a drug product s lifecycle based on new safety information.

Table of Contents

A REMS is defined by FDA as a strategy to manage a known or potential serious risk associated with a drug or biological product. 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. FDA may impose civil monetary penalties, the drug or biological product can be deemed misbranded, and/or FDA may obtain injunctive relief against further distribution of the product.

In the case of ONSOLIS®, FDA determined that based on risks associated with existing transmucosal fentanyl products, Fentora® and Actiq®, that a REMS requirement be imposed on the category. Notice of this need was first communicated to us in a Complete Response letter in August 2008. ONSOLIS® was approved with a REMS Program in July 2009, and this particular program is referred to as the FOCUS (Full Ongoing Commitment to Patient Safety) Program. The goals of the FOCUS Program are to help assure proper patient selection and avoidance of use of ONSOLIS® in opioid non-tolerant patients, reduce the risk of exposure to ONSOLIS® in persons for whom it was not prescribed, and to train prescribers, pharmacists, and patients about proper dosing and administration. The FOCUS Program requires dispensing of a Medication Guide with each prescription, healthcare provider and pharmacy education, and a patient/physician registry. The FOCUS Program was and remains an integral part of the launch of ONSOLIS®.

International Approval

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

Other Regulation

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

Historical Relationship with UMDNJ and Albany Medical College

In September 1995, our predecessor company entered into a license agreement with UMDNJ and Albany Medical College to be the exclusive worldwide developer and co-licensor of the cochleate

Table of Contents

technology, in conjunction with the Universities right to permit the use of the technology by non-profit organizations for research purposes on a non-commercial basis. Under the license agreement, we and the Universities have also jointly patented certain aspects of the cochleate technology. Pursuant to the license agreement, we agreed that each University would be issued an equity interest in our capital stock, originally equal to 2% of our outstanding capital stock. These arrangements were subsequently revised in December 2002. On December 16, 2002, we amended our license agreement with the Universities to provide for a decrease in the royalty payments to be paid to the Universities on sublicenses in consideration of an increase in the royalty on product sales and the issuance to the Universities of options to purchase shares of our common stock. As of December 31, 2009, UMDNJ owned 139,522 shares (which include shares issued under a research agreement) and Albany Medical College owned 2,222 shares of our common stock. There are no further requirements to provide either University any additional equity interests in our company. The license agreement grants us an exclusive license to the cochleate technology owned by these Universities and obligates us to pay a royalty fee on net sales of cochleate products.

In September 2009 we vacated our Newark research facility located at UMDNJ and terminated our relationship with Dr. Raphael Mannino, our former Chief Scientific Officer and the inventor of many of the patents directed to the cochleate technology. At that time, we also announced that we were in discussions with Dr. Mannino to potentially sublicense the Bioral® technology to Dr. Mannino or his affiliates for a specific and limited application of the Bioral® technology to develop certain therapeutics. As of the date of this Report, these discussions have not progressed.

Employees

As of March 12, 2010, we have 16 full-time employees and 1 part-time employee. Eleven are involved in our clinical and program development and operations and six handle our administration, accounting and information technology. Advanced degrees and certifications of our staff include three Ph.Ds, two Pharm.Ds, one J.D/LL.M, and two CPAs. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our engineering and support our 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.

Table of Contents

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

Since we have incurred significant losses since inception and have only generated minimal revenues from 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, 2008, we have recorded significant losses. Our accumulated deficit at December 31, 2009 is approximately $59.2 million. As of December 31, 2009, we had working capital of only approximately $1.8 million. 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 proposed products. 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 was only recently launched. 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 commercialization activities, mostly relating to ONSOLIS®. 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.

As a result of our current lack of financial liquidity, our auditors have expressed substantial doubt regarding our ability to continue as a going concern.

As a result of our current lack of financial liquidity, our auditors report for our 2009 financial statements, which are included as part of this Report, contains a statement concerning our ability to continue as a going concern. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a going concern is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include engaging in offerings of

Table of Contents

securities, negotiating up-front and milestone payments on pipeline products under development and royalties from sales of our products (like ONSOLIS®) which secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. However, we may be unable to achieve these goals and therefore may be unable to continue as a going concern.

We will likely need to raise additional capital to continue our operations, 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, 2009, we had cash of approximately $23.9 million. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) and our July 2009 receipt of milestone payments from Meda in connection with the FDA approval of ONSOLIS®, that our current working capital will be sufficient to satisfy our contemplated cash requirements through the first quarter of 2011, assuming 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.

Given our cash burn and lack of significant revenues, we will likely need to raise additional capital in the future to fund our anticipated operating expenses and progress our business plans. 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 the raising of capital more difficult or impossible and may also result in a lower price for our shares.

We may have difficulty raising any needed additional capital.

We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of material revenues from sales, as well as the inherent business risks associated with our company and present and future market conditions. Our business currently only generates a small amount of revenue from products sales, and such current sources of revenue will likely not be sufficient to meet our present and future capital requirements. Therefore, at least until we have a second product approved and have a second commercial partnerships in place, given we plan to continue to expend substantial funds in the research, development and non-clinical and clinical testing of our drug delivery technologies and product candidates as well as on other strategic initiatives, we will likely require additional funds to conduct research and development, establish and conduct non-clinical and clinical trials, secure clinical and commercial-scale manufacturing arrangements and provide for marketing and distribution. 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 formulations, products and technologies in development;

Table of Contents

continued 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;

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 drug formulations or products;

costs involved in establishing manufacturing capabilities for commercial quantities of our drug formulations or products;

competing technological and market developments;

market acceptance of our drug formulations or 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 45 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

The Risk Evaluation and Mitigation Strategy (REMS) that the FDA required for ONSOLIS® may have the effect of slowing sales and marketing efforts, which could impact our revenue from the product.

Because it contains the potent narcotic fentanyl, as part of its approval of ONSOLIS®, the FDA required that we and Meda put in place a detailed REMS. The REMS sets forth detailed procedures that seek to mitigate the risk of ONSOLIS® overdose, abuse, addiction and serious complications due to medication errors. These procedures have and will continue to place administrative burdens on our commercial partner Meda and potential prescribers of ONSOLIS®, which burdens could make it more difficult for Meda to market and sell ONSOLIS®. Meda s compliance with the REMS could lead to lower than expected revenue generation and could make it more difficult for us to achieve our annual peak sales projections for ONSOLIS®, which projections may take longer than expected to achieve or may not be achieved at all. Since our royalty revenue from Meda is dependent on sales by Meda of ONSOLIS®, Meda s inability to generate sales of this product would have a material adverse effect on our results of operations.

Moreover, as of the date of this Report, two products which compete directly with ONSOLIS®, namely Actiq® and Fentora® (each of which are marketed by Cephalon, Inc.), are currently being marketed without the requirement of compliance with a REMS. Instead, these products are currently marketed under a less onerous risk management plan that was in place prior to enactment of the 2007 legislation that granted FDA with REMS authorities. This condition currently puts ONSOLIS® at a material competitive disadvantage with these products, which may impact sales of ONSOLIS®. Additionally, two generic forms of Actiq® have been approved by the FDA. We are not aware that these products have been launched, but upon launch, we are not aware that the marketing of either of these products would be a subject to a REMS until such time that a REMS has been implemented and is in effect for Actiq®. This condition would also put ONSOLIS® at a potential material competitive disadvantage, which could impact Meda s ability to sell ONSOLIS®.

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. This is especially true for our one existing approved product, ONSOLIS®.

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

- receipt of regulatory clearance of marketing claims for the uses that we are developing;
- establishment and demonstration of the advantages, safety and efficacy of our formulations, 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;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our proposed formulations or products;

Table of Contents

regulatory programs such as the REMS for ONSOLIS® or market (including competitive) forces that may make it more difficult for us to penetrate a particular market segment; and

our, or our partners , 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 or 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.

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 of our product candidates, which exposes 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, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements is our U.S. and European commercialization agreements with Meda and our manufacturing development and supply agreement with Aveva Drug Delivery Systems, Inc., or Aveva, and LTS Lohmann Therapie-Systeme AG, or LTS, relating to ONSOLIS® and with LTS relating to BREAKYL (the brand name for ONSOLIS® in Europe) and BEMA® Buprenorphine. The loss of, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under any applicable agreements or arrangements, 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 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®.

In addition, under our collaborative agreements with Meda, we are responsible for paying certain costs relating to ONSOLIS®. Our inability to adequately project or control such costs would have a material adverse effect on our potential profits from such agreements.

Table of Contents

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 likely 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, with an annual aggregate limit of $2 million with a $2 million limit per occurrence. 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 may be sued by third parties who claim that our products, and formulations, methods of manufacture or methods of use infringe on their intellectual property rights.

We may be exposed to future 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;

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;

Table of Contents

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 mucoadhesive erodible drug delivery device technology space is congested. 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. We have a 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 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.

With respect to our Bioral® technology, we are currently aware of United States patent 5,616,334 dealing with lipid formulations of Amphotericin B products. We do not believe that our Bioral® products are covered by or in conflict with this patent, although there is a risk that a court of law in the United States might determine otherwise. Accordingly, we do not believe that we require a license under this patent. If a court were, however, to determine that we were infringing this or other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B. We may be unable to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, there would be a material adverse effect upon our business plan to commercialize these products.

If a lawsuit were to be filed against us for patent infringement, we would incur significant legal costs to defend ourselves. 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® and/or Bioral® products (including, without limitation, ONSOLIS®). We may be unable to obtain such licenses from the patent holders.

In addition, certain portions of the development of our cochleate technology were supported by funding from the United States government. This support provides the United States government certain rights in technologies developed solely by government employees. We believe to the extent the United States government would have rights in technologies developed under our agreements we may need to obtain a license, likely royalty bearing, relating to the United States government s rights in the technology. Rights to negotiate a license to any United States government rights are provided for in our agreements.

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 any, 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.

Table of Contents

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 us 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.

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:

- potential 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;
- our potential inability to timely obtain an adequate supply of required components; and
- the potential for 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

Table of Contents

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. 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 non-clinical 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. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to commercialize our products.

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) to engage in sales, marketing and distribution efforts around our products and product candidates. 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;

Table of Contents

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.

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

If we choose at some point 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, 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.

Risks Related to Our Products in Development and Regulation

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 proposed formulations and products 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®, we may not receive regulatory approval of our other proposed products and formulations. 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.

Table of Contents

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:

a demonstration of the benefit from delivery of each specific drug through our drug delivery technologies;

a demonstration, through non-clinical and clinical trials, that our drug delivery technologies are safe and effective; and

the 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. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators did not follow the FDA s requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are permanently halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell any drug or medical device for human consumption or use without FDA approval.

Moreover, 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. 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.

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

Data already obtained, or in the future obtained, 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 is 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. 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.

Table of Contents

We depend on technology owned or licensed to us by third parties, 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 royalties.

We rely, in large part, on drug delivery technologies that we license from third parties such as QLT, with respect to our BEMA® technology, and the University of Medicine and Dentistry of New Jersey with respect to our Bioral® technology. Although we have purchased the BEMA® technology from QLT, we may be unable to fulfill our obligations under such agreement. The loss of our key technologies 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 technology we license could prevent the implementation or impair the functionality of our products or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

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 sought and may seek to develop and market mucosal adhesive, encapsulation or other drug delivery technologies and related pharmaceutical products which may compete with our technologies and products. Competitors may develop similar or different technologies or products which may become more accepted by the marketplace or which may supplant our technology entirely. In addition, these competitors may be larger and better financed than we are, thus giving them a significant advantage over us.

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 marketed product and lead product candidate 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 our lead product candidate, BEMA® Buprenorphine, 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 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.

Table of Contents

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 marketed product ONSOLIS® and in our lead product candidate BEMA® Buprenorphine (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 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 procurement quota in order to obtain these substances. The DEA may not establish 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 (including, without limitation, the significant healthcare reform legislation advocated by President Obama that is being worked on by Congress as of the date of this Report) will be adopted, the announcement or adoption of such proposals and related laws, rules and regulations could materially harm our business, financial condition results of operations or stock price.

The ability of Meda to sell ONSOLIS® 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 medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

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

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. All of our clinical trials have been, and all of our proposed clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have a general liability/product liability policy that includes coverage for our clinical trials, with an annual aggregate limit of $2 million with a $2 million limit per occurrence. 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

Table of Contents

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.

In connection with our or our partners research and development activities and 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 development 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.

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. 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 substantial 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 31% of our outstanding common stock. These figures do not reflect any future potential exercise of common stock purchase warrants (including those issued to Laurus Master Fund, Ltd., CDC and others) into shares of common stock.

Table of Contents

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 significant control 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.

Certain of our management team have relationships which may potentially result in conflicts of interests.

Dr. Frank O Donnell, who is the Chairman of our board of directors and also is a substantial beneficial owner of our securities through Hopkins Capital Group II, LLC, has a financial interest in a number of other companies which have business relationships with us. These companies include Accentia, RetinaPharma Technologies, Inc. and Biotechnology Specialty Partners, Inc. We have entered into license agreements with Accentia and RetinaPharma International, Inc. with regard to proposed products incorporating our Bioral® technology. We have entered into a non-exclusive distribution agreement with Biotechnology Specialty Partners, Inc. In addition, William Poole, a director of our company, is also a director of Accentia, and James A. McNulty, our Chief Financial Officer, is employed on a part-time basis by Accentia. These relationships and agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and such members of our management. The risks associated with potential conflicts of interests were evidenced recently in a settlement, announced in late December 2009, of a potential dispute between us and Accentia relating to the development of Emezine.

Our business arrangement with Accentia may be impaired as a result of Accentia s bankruptcy filing.

We have commercial ties to Accentia, a related party, through our license agreement with them and the sharing of certain corporate resources. On November 10, 2008, Accentia and its subsidiaries, including Biovest International, Inc. filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. As such, there is a risk that projects on which we are working with Accentia may not progress in the future and that we may not receive royalty payments which we are due from Accentia. In addition, certain payments due by us to Accentia under our December 2009 settlement of a potential dispute between us and Accentia relating to the development of Emezine will be triggered upon Accentia s exit from bankruptcy, including payments on the sale or licensing of our BEMA® Granisetron product candidate.

Table of Contents

Risks Related to Our Common Stock

CDC s right of first refusal on future financings of ours could impede our ability to raise capital.

Under our May 2006 Securities Purchase Agreement with CDC, as amended, until such time as our public share price reaches $9 for certain time periods, in the event that we seek to raise money through the offer and sale of debt or equity securities, we must first offer CDC an opportunity to provide financing to us. If CDC elects to exercise its right to such opportunity, we must negotiate exclusively with CDC the terms of a financing for 30 days which must match the terms of the financing we present to them. If no terms are agreed to, we may pursue a financing with a third party for 60 days, but only on terms and conditions no less favorable to us than the terms and conditions presented to CDC. CDC has exercised similar rights to our detriment in the past, and it is possible that CDC will seek to exercise this right again in the future. The existence or alleged existence of CDC s right of first refusal, or CDC s exercise thereof or claims related thereto, has and may in the future deter potential investors from providing us needed financing, which would have a material adverse effect on our operations and viability as a company.

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 listing maintenance requirements of the NASDAQ Capital Market and NASDAQ rules, which require, among other things, maintaining a minimum bid price per share, 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. If we are unable to satisfy the NASDAQ criteria for maintaining listing, 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.

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

We are authorized to issue 45 million shares of our common stock. As of the date of this Report, there are 21,200,254 shares of common stock issued and 21,184,763 shares of common stock outstanding. However, 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.

Table of Contents

In addition, 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. Moreover, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5 million authorized but undesignated shares of preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

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

We have a material number of shares of common stock underlying securities of our company, the future sale of which could depress the price of our publicly-traded stock. As of the date of this Report: (i) 3,853,976 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.81 per share, and (ii) 3,886,491 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.95 per share. 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.

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

Our certificate of incorporation, our bylaws 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;

eliminating the ability of stockholders to call special meetings of stockholders;

permitting stockholder action by written consent; and

Table of Contents

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.

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 than those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this Report should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

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

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

Item 2. Description of Property.

Our executive offices are located in Raleigh, North Carolina. The lease for this approximately 5,500 square foot space has a term of approximately 63 months and base rent for this term is $589,454, payable in monthly installments, and 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 Accentia and pay $2,848 on a monthly basis for approximately 981 square feet of office space occupied by our four full-time employees in this office.

Item 3. Legal Proceedings.

Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Table of Contents

PART II

Item 5. Market for Common Equity and Related Stockholder Matters.

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 2009 and 2008, as reported by the NASDAQ Capital Market, is set forth below.

Quarterly Common Stock Price Ranges

Fiscal Year 2009, Quarter Ended:	High	Low
March 31, 2009	$ 3.86	$ 2.42
June 30, 2009	$ 8.29	$ 3.29
September 30, 2009	$ 7.25	$ 4.23
December 31, 2009	$ 5.25	$ 3.82

Fiscal Year 2008, Quarter Ended:	High	Low
March 31, 2008	$ 3.10	$ 2.21
June 30, 2008	$ 3.12	$ 1.57
September 30, 2008	$ 4.74	$ 1.93
December 31, 2008	$ 2.90	$ 2.08

As of March 12, 2010, we had approximately 156 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain any earnings for further business development.

We have never declared or paid any cash dividend on our common stock. We currently intend to retain any potential future earnings and do not expect to pay any 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 Amended and Restate 2001 Incentive plan as of December 31, 2009:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	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	3,662,133	$ 3.78	1,579,197
Equity compensation plans not approved by security holders			
Total	3,662,133	$ 3.78	1,579,197

Table of Contents

Item 6. Selected Financial Data.

We are a smaller reporting company as defined by Regulation S-K and as such, are not required to provide the information contained in this item pursuant to Regulation S-K.

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 utilizing licensed and owned proprietary drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, significant new formulations of proven therapeutics. From the founding of our predecessor in 1995 through 2002, we were a development stage company. Our first license agreement, which was in relation to our Bioral® cochleate technology, was funded in 2003 in the amount of $2.0 million. In 2004, we sold a royalty stream asset utilizing the same technology to Accentia for $2.5 million and separately acquired the BEMA® drug delivery technology upon our acquisition of Arius Pharmaceuticals.

In July 2006, we licensed commercialization rights in Europe for our lead product, the BEMA® based ONSOLIS®, to Meda and received an up-front, non-refundable payment of $2.5 million. In September 2007, we entered into a definitive License and Development Agreement with Meda for ONSOLIS® in the U.S., Canada and Mexico. Pursuant to such license agreement, we received a $30 million milestone payment upon closing, which was received on September 14, 2007 and an additional $29.8 million milestone payment for the approval of ONSOLIS® by the FDA, and in conjunction with commercial supplies of ONSOLIS® sufficient for commercial launch of ONSOLIS® in the U.S. Of this amount, $3.0 million was advanced in January 2009. The remaining $26.8 million was received on July 21, 2009.

We expect to continue research and development of our drug delivery technologies, some of which will be funded by Meda under specific programs as described below. We will continue to seek additional license agreements, which may include up-front payments. For all other programs and products under development, revenues and payments (other than milestone payments under our Meda agreements) in 2010 are expected to be nominal. We anticipate that funding for the next several years will come primarily from milestone payments and royalties from Meda, 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 history on research and development activities. While we have received revenues to date in the form of: (i) initial royalty revenue from sales of ONSOLIS®; (ii) up-front non-refundable license and milestone payments in 2007, 2008 and 2009 (which were initially classified as deferred revenue but portions of which have subsequently been reclassified as recognized revenue under prevailing revenue recognition rules), (iii), revenue from the sale of a royalty stream in 2004, (iv) research and collaboration revenues and (v) minimal royalty revenue from a license with Accentia, our revenues are not repeating or predicable, so we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future. Readers are cautioned that period-to-period comparisons of our operating results

Table of Contents

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 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 may not be able to appropriately address these risks and difficulties.

Critical Accounting Policies and Estimates

Valuation of Goodwill and Intangible Assets

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for in accordance with accounting principles generally accepted in the United States of America, which we refer to herein as GAAP. As described below, goodwill is not amortized but is tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Our carrying value of goodwill at December 31, 2009 was $2.72 million.

We amortize intangible assets with limited useful lives using the straight-line method over their estimated period of benefit. Such period ranges from ten to twelve years. A number of factors are considered for these estimations, including the longevity of our license agreements. Our carrying value of other amortizing intangible assets at December 31, 2009 was $7.13 million, net of accumulated amortization of $2.3 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test has two steps. The 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 and the second step is not necessary. If the carrying value exceeds the fair value, the second step calculates the possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded. The determination of goodwill impairment is highly subjective. It considers many factors both internal and external and subject to significant changes from period to period. No goodwill impairment charges have resulted from this analysis for 2009 or 2008.

In accordance with GAAP related to impairment of long-lived assets other than goodwill (our other amortizing intangibles), impairment exists if the sum of the future estimated undiscounted cash flows related to the asset is less than the carrying amount of the intangible asset or to its related group of assets. In that circumstance, then an impairment charge is recorded for the excess of the carrying amount of the intangible over the estimated discounted future cash flows related to the asset.

In making this assessment, we predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our impairment testing. 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 addition, selection of a risk-adjusted discount rate on the estimated undiscounted cash flows is susceptible to future changes in market conditions, and when unfavorable, can adversely affect our original estimates of fair values. 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 to other amortizing intangible in either 2009 or 2008.

Table of Contents

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

We account for stock-based awards to employees and non-employees using FASB ASC Topic 718 (formerly called the accounting provisions of SFAS 123R) 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 options-pricing model to determine the fair value of stock option and warrant grants. In applying the Black-Scholes options-pricing model during 2009, we assumed no dividend yield, risk-free interest rates ranging from 0.51% to 2.71%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor range between 57.88% to 90.24% and option exercise prices ranging from $3.05 to $5.40.

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 as discussed in the previous paragraph.

Revenue Recognition

Meda License, Development and Supply Agreements:

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 6 to the accompanying financial statements.

Based on our assessment of each arrangement, all deliverables of 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 have been recorded as deferred revenue.

Upon delivery of the license rights to Meda (date of first commercial sale in each territory), we have 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 delivered to Meda. A portion of the upfront payments has been attributed to our 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.

Table of Contents

Research and development services revenue associated with the non-cancer indication and further development of the first indication for treatment of breakthrough cancer pain of the ONSOLIS® product which have been performed prior to the commencement of the license term has been deferred and will be recognized upon delivery of the license rights to Meda. Services provided subsequent to commencement of the license term will be recognized when the services are performed, if all other revenue recognition criteria are met. Based on the guidance of GAAP, we have determined that we are acting as a principal under the Meda Agreements and, as such, will record these amounts on a gross basis as research and development services revenue.

Revenue associated with product sold to Meda prior to the commencement of the license term was deferred and then subsequently recognized upon delivery of the license rights to Meda. Subsequent to the commencement of the license term, we will recognize revenue for product supplied to Meda when title and risk of loss have passed to Meda and the remaining criteria have been met. Based on the guidance of GAAP, we have determined that we are acting as a principal as it relates to these activities under the product supply agreements and, as such, will record the amounts on a gross basis as product supply revenue.

Product royalty revenue is based on third-party sales of the ONSOLIS® product. We will recognize product royalty revenues from Meda on the accrual basis in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met.

Accounting for Meda License, Development and Supply Agreements:

Contractual Rights and Obligations	Milestone Payments	Notes	Cash flows received and revenue deferred December 31, 2009	Cash flows received and revenue deferred December 31, 2008
North America				
License rights to ONSOLIS® (BEMA® Fentanyl) patents and trademarks	$ 30,000,000		$ 30,000,000	$ 30,000,000
Milestones:				
FDA approval	$ 15,000,000	less a $200,000 discount	$ 14,800,000	
Earlier of date of first commercial sale or availability of launch supply product	$ 15,000,000		$ 15,000,000	
Research and Development Services for:				
Non-Cancer subsequent indication of product and further development of initial product		Contract Hourly Rates	$ 1,541,570	$ 1,135,412
Total North America Agreement Milestones	$ 60,000,000		$ 61,341,570	$ 31,135,412
Europe and Rest of World				
License rights to BREAKYL (BEMA® Fentanyl) patents and trademarks	$ 5,500,000		$ 5,500,000	$ 2,500,000
Milestones:				
Completion of Phase 3 clinical trials	$ 2,500,000		$ 2,500,000	$ 2,500,000
Governmental Approval in an EU country	$ 2,500,000			
Date of first sale in an EU country	$ 2,500,000			

Table of Contents

Research and Development Services for:				
BREAKYL product through governmental approval in a EU country		Contract Hourly Rates	$ 3,744,674	$ 1,553,627
Total Europe and Rest of World Milestones	$ 13,000,000		$ 11,744,674	$ 6,553,627
Total All Milestones	**$ 73,000,000**		**$ 73,086,244**	**$ 37,689,039**
Release of Milestones upon first sale			$ (59,727,633)	$
Remaining Deferred Revenue			$ 13,358,611	$ 37,689,039

In August 2006 and September 2007, we entered into the Meda Agreements with Meda to develop and commercialize the ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered through a patented transmucosal drug delivery technology, BEMA® (applied to the inner cheek mucosa) in the United States, Mexico and Canada (such agreements, the Meda U.S. Agreements) and in certain countries in Europe (such agreements, the Meda EU Agreements). These arrangements have license terms which 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 January 2017.

Our rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

We have, in accordance with GAAP, assessed the multiple deliverables associated with these arrangements to determine which are considered separate units of accounting, both at the inception of the arrangement and upon delivery of the items required in the arrangements. The assessment requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

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 standalone 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 are 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 were recognized. Upon first commercial sale in a European country, an estimated $17.4 million will be recognized, which includes an additional $5.0 million in milestones and approximately $0.7 million in research and development services.

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 non-cancer and other research and development services and other service obligations, based on hourly rates billed by unrelated third-party

Table of Contents

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 non-cancer indication and further research and development of the first indication of 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 $1.6 million (under the Meda U.S. Agreements) and $0.2 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.

In accordance with GAAP, 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.

We will earn royalties based on a percentage of net sales revenue of the ONSOLIS® marketed product. Product royalty revenues are computed on a quarterly basis when Meda s third-party sales revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met.

License Arrangements

License arrangements may consist of non-refundable upfront license fees, data transfer fees, exclusive licensed rights to manufacture patented or patent pending products, technology access fees, various performance or sales milestones and future product royalty payments.

Non-refundable, upfront fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue over the established or estimated term of the license when the license arrangement commences and the licensed data, technology and/or product or supplies to manufacture the product is delivered. Such deliverables may include physical quantities of products, supplies, or design of the products, the conceptual framework and mechanism of actions taken by a third party, and rights to the patents or patents pending for such products.

We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology, know-how, rights, products or services conveyed in conjunction with the non-refundable fees have no utility to the licensee that could be considered separate and independent of our performance under other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such upfront fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in research and development arrangements are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process. This includes the acceptance by the customer; no requirement by us for continued performance of future research and development services related to the milestone; the milestone payments are non-refundable, and substantive effort is involved in achieving the milestone. If any of these conditions are not met, we defer the milestone payments and recognize them as revenue over the estimated period of performance under the contract as we complete our performance obligations.

Table of Contents

Payment related to sales targets, whether or not referred to as milestones, specified in underlying sales and manufacturing agreements are recognized upon achievement of those targets as a performance bonus.

Royalties, Related Party

Royalty revenue amounts are recognized as revenue on a monthly basis based on net sales under our license agreement with Accentia relating to chronic rhinosinusitis. This is shown as royalty revenue, related party on the accompanying consolidated statements of operations.

Royalties, Other

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 royalty revenue, other on the accompanying consolidated statements of operations.

Contract Revenue

In accordance with GAAP and our revenue recognition policy, the Meda up-front and milestone payments related to ONSOLIS® of $30.0 million in 2007, the $6.0 million received in January 2009 and the $29.8 million received in July 2009 were initially recorded as deferred revenue, and are recognized in accordance with our revenue recognition policy once commercialization revenues begin. We also have revenues from Meda in connection with services performed prior to approval of ONSOLIS®, which were also deferred until approval. Upon FDA approval of ONSOLIS® in July 2009, and the subsequent launch in October 2009, we recognized contract revenue of $59.7 million.

Sponsored Research

Sponsored research amounts are recognized as revenue when the research underlying such funding has been performed or when the grant funds have otherwise been properly utilized. Grant revenue is recognized to the extent provided for under the related grant or collaborative research agreement. This is shown as sponsored research revenue on the accompanying consolidated statements of operations.

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.

Cost of Royalty Revenues, Other

The cost of royalty revenue, other, includes the direct costs attributable to the production of our product. It includes all costs related to creating the products at our contract manufacturer, which can include stability costs directly related to the product sold. Only costs that are tied to the production of the products are considered cost of royalty revenue. Our contract manufacturer for ONSOLIS®, Aveva, bills us for the material cost used in creating the product along with direct labor costs, and certain overhead costs as outlined in the supply agreement. This is shown as cost of royalty revenues on the accompanying consolidated statements of operations. Cost of royalty revenues, other also includes royalty expenses owed to third parties. These royalty expenses are directly related to the products sold during the period.

Table of Contents

For the Year Ended December 31, 2009 Compared to the Year Ended December 31, 2008

Royalties related party. We recognized $0.02 million and $0.05 million in royalty revenue during the years ended 2009 and 2008, respectively, under our license agreement with Accentia relating to CRS.

Royalty Revenues, Other. We recognized $2.8 million in royalty revenue, other during the year ended 2009 under our license agreement with Meda. There was no royalty revenue, other in 2008.

Research Revenues. We recognized $0.2 million of revenue related to various contractor agreements during the years ended 2009 and 2008, respectively.

Sponsored Research Revenues. We recognized $0.05 million in sponsored research revenue during the year ended 2009. There was no sponsored research revenue received in 2008.

Contract Revenues. We recognized $59.7 million in previously deferred license revenue in 2009 under our license agreement with Meda. There was no contract revenue recognized in 2008.

Cost of Royalty Revenues, Other. We recognized $2.0 million in cost of royalty revenue in 2009 related to direct costs attributable to the production of our product ONSOLIS®. There was no cost of royalty revenues, other, recognized in 2008.

Research and Development Expenses. During the years ended December 31, 2009 and 2008, research and development expenses totaled $10.4 million and $10.9 million, respectively. Our scientific staff continued to work toward increased development and application of our BEMA® and Bioral® cochleate technologies, but particularly with respect to ONSOLIS®. Funding of this research in 2009 and 2008 was obtained through deferred license revenue, sponsored research revenue, exercise of options by employees and directors and sales of securities. Research and development expenses generally include compensation for scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA® and Bioral® drug delivery technologies.

General and Administrative Expenses. During the years ended December 31, 2009 and 2008, general and administrative expenses totaled $10.3 million and $7.3 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 in 2009 relates principally to a dispute settlement of $1.9 million and the legal costs associated with the settlement between us and Accentia. This amount is shown in related party, general and administrative. Other lesser contributors to the increase include bonuses paid and stock-based compensation in 2009.

Interest Income (Expense), Net. During the year ended December 31, 2009 we had no interest expense, compared to $0.48 million for the corresponding period in 2008. The decrease in net interest expense is due to amortization of interest on the CDC note in 2008. Interest income was $0.04 million and $0.17 million for the years 2009 and 2008 respectively.

Derivative Gain (loss). Derivative gain (loss) in 2009 and 2008 is related to the adjustment of derivative liabilities to fair value as of December 31, 2009 and December 31, 2008. Fair value adjustments in 2009 include amounts associated with 1.7 million Laurus warrants that were exercised throughout 2009.

Table of Contents

Income Tax Benefit and tax net operating loss carryforwards. We had positive cash flow from operations of $18.1 million in 2009 as a result of $32.8 million in milestones and $2.8 million in royalty revenues received from Meda. We had federal and state net operating loss carryforwards (NOL) of approximately $35.1 million and $28 million at December 31, 2008. The remaining federal and state carryforwards at December 31, 2009 are $20.3 million and $14.3 million, respectively. 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. We have a federal net operating loss of approximately $20.3 million as of December 31, 2009. 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. Some of these losses may be subject to these limitations. Our state NOLS are approximately $14.3 million as of December 31, 2009.

Major Research and Development Projects

In 2009, we continued to dedicate a significant amount of our corporate resources to the U.S. and E.U. filing and regulatory review of ONSOLIS®, and also dedicated resources on the clinical development of BEMA® Buprenorphine and, to a lesser extent, on Bioral® Amphotericin B and BEMA® Granisetron. Substantial expenditures were devoted to manufacturing efforts (in conjunction with our manufacturing partners) required to support the commercial launch of ONSOLIS® and the non-clinical and clinical development of our product candidates. Clinical research expenses in 2009 were dedicated to an initial study with Bioral® Amphotericin B and the Phase 2 development of BEMA® Buprenorphine. Further clinical development of ONSOLIS® is the responsibility of Meda both in the U.S. and Europe.

We believe that other non-core projects which we have previously identified as being in our pipeline (such as BEMA® Zolpedim (for insomnia) and Bioral® siRNA therapeutics) represent promising opportunities. However, we are consistently evaluating such opportunities as to whether and how to actively pursue them and looking for creative ways to finance them. Currently, we are only pursuing opportunities for the Bioral® siRNA therapeutics as part of collaborations with other companies. Other projects previously identified as part of our pipeline have been either funded via external means or have been discontinued.

The projected dates for filing INDs or approval of NDAs, our estimates of development costs and our projected sales associated with each of our products and formulations 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, which could cause delays and or cost overruns or otherwise 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 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:

ONSOLIS®. We licensed the U.S. rights to the BEMA® drug delivery technology from QLT. We acquired this license when we acquired Arius in August 2004. In August 2006, we purchased the non-U.S. rights to the technology from QLT for a total of $3.0 million; $1.0 million was paid in August 2006, and a note for $1.0 million due in March 2007 was paid. The final $1.0 million is due upon European

Table of Contents

approval of a BEMA® product. The agreement included an option to buy the U.S. rights within 12 months of the non-U.S. purchase. We exercised our option in September 2007 with a payment to QLT of $3.0 million, a note for $2.0 million which was due upon FDA approval of ONSOLIS® (paid in July 2009) and a final $2.0 million due when net sales reach $30.0 million. As a result of these transactions, and subject to making final payments to QLT, we now own the BEMA® technology and will have no royalty obligations to QLT.

Our lead BEMA® product ONSOLIS® is a formulation of the narcotic analgesic medication fentanyl. In 2005, we announced that we received confirmation from the FDA that we could utilize the FDA s 505(b)(2) process for submission of the NDA for ONSOLIS®. As a result of this guidance, we began our preparations for Phase 3 clinical studies in the fourth quarter of 2005. In early 2006, we began enrollment on the Phase 3 clinical studies. We projected that due to the nature of treating patients with breakthrough cancer pain, our patient recruitment process for the ONSOLIS® clinical program would take anywhere from 6 to 18 months. Subsequently, we completed enrollment in our efficacy study (FEN 201) and reported our findings in April 2007. The data demonstrated that our primary efficacy endpoint of the Summary of the Pain Intensity Difference at 30 minutes (SPID 30) was statistically significantly different from placebo (p value less than 0.0004). We completed the analysis and documentation of the results from our FEN 201 study as well as our FEN 202 safety study and submitted them as part of our NDA for ONSOLIS® on October 31, 2007. The FDA subsequently accepted our NDA for filing on December 31, 2007, and provided us with a PDUFA date (i.e., the date by which FDA expects to provide a decision on the approvability of an NDA) of August 31, 2008. In August 2008, we received a Complete Response Letter from FDA citing a new requirement for approval, the preparation and submission of an acceptable Risk Evaluation and Mitigation Strategy (REMS). Submission of this document was made in December of 2008 and FDA had a 6 month period prior to the action date. ONSOLIS® was approved by the FDA on July 16, 2009.

We believe that ONSOLIS® may have the potential to capture a significant share of the breakthrough cancer pain market in the U.S., which we estimate could result in annual projected peak sales of over $200 million, on which we will pay a royalty to CDC.

In January 2008, we announced the expansion of our clinical development program for ONSOLIS® to assess the efficacy and safety of the product for the treatment of breakthrough pain associated with other chronic pain conditions beyond cancer. Initial non-clinical studies to support long term toxicology testing were performed in 2008 with the full toxicology program scheduled to start, following FDA agreement. Meda, under our North America license development and supply agreements will be fully responsible for funding the expanded development program in non-cancer breakthrough pain.

The risks to our company associated with the ONSOLIS® project include: (i) delays in reaching agreement with regulatory authorities outside the U.S.; (ii) barriers to physician prescribing and patient access in conjunction with a REMS program; (iii) competition from larger, more established companies, including companies not presently operating with a REMS; (iv) inability of our contract manufacturer to make commercial supplies or meet our commercial supply requirements; (v) the development of unexpected safety issues with the product; and (vi) reliance on our commercial partner Meda, including failure of Meda to launch outside the U.S. and sell the product both in and out of the U.S. The failure of the ONSOLIS® project for these or any other reason, or a failure of the product to meet commercial forecasts, would seriously impair our viability, including revenues, investor confidence and potentially our public stock price as ONSOLIS® is our first FDA approved product.

Table of Contents

BEMA® Buprenorphine. BEMA® Buprenorphine will be our second BEMA® analgesic product. This product is not covered under any commercial marketing agreements. We submitted an IND that was accepted by the FDA for BEMA® Buprenorphine in December 2005. We conducted an initial Phase 1 single dose pharmacokinetic trial in normal volunteers during 2006 which demonstrated that therapeutic blood concentrations of the active ingredient could be achieved in these healthy volunteers. In 2008, additional clinical trial supplies were manufactured at LTS in Germany and a second single dose study in normal healthy volunteers was started in November 2008. The preliminary results of this study, announced in March 2009, were favorable, and as a result, we began our Phase 2 program to evaluate its effectiveness in a dental pain model in June 2009. Results of the study, announced in December 2009, with secondary data announced in February 2010, were positive based on achievement of the primary endpoint, and suggest the efficacy of the product in the treatment of chronic pain.

We plan to initiate BEMA® Buprenorphine into a Phase 3 program during the first quarter of 2011, under which we will be treating patients who have acute moderate to severe postoperative pain with the doses identified from our Phase 2 program. The BEMA® Buprenorphine Phase 3 program for an acute pain indication may take up to 24 months to complete from the time Phase 2 is started. After completing the Phase 3 program, it will likely take approximately 3 to 6 months to compile and submit our NDA to the FDA. After submission, the FDA will then have up to 10 months from the date the submission is accepted to render a decision on the approvability of our NDA. If the FDA approves our NDA, we would anticipate launching the product within 3 months of that approval.

Due to the ability of BEMA® Buprenorphine to participate in the key pain markets (chronic pain, acute pain, post-operative pain), we believe that BEMA® Buprenorphine has the potential to achieve up to a 5% share of the $10 billion dollar U.S. market for the opioid narcotics. This would translate into 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 2012. We have begun partnering discussions for BEMA® Buprenorphine in 2010.

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; (iv) product safety issues; (v) failure of or delay by the FDA to approve our NDA; (vi) failure to secure a commercial partner for the product or to develop our own internal commercial capability; (vii) failure of a commercial partner or us to effectively launch and sell the product; and (viii) 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.

Bioral® Amphotericin B. We license the encochleation drug delivery technology which we use in our Amphotericin B formulation from the Universities. We filed the IND on this oral formulation of Amphotericin, for the treatment of fungal infections including esophageal candidiasis in the fourth quarter 2006. The IND was accepted by the FDA. We began Phase 1 studies in normal volunteers in the second half of 2008. These studies assessed the oral absorption and safety of Amphotericin B from our cochleate formulation in normal volunteers. Preliminary results were announced in December 2008. Following completion of Phase 1 trials, we anticipate moving into a Phase 2 study in patients in 2010. Based on the outcome of our Phase 2 program our Phase 3 program could start sometime in 2011. A Phase 3 program, should it be initiated, would run approximately 18-24 months after which we would spend approximately 3-6 months compiling and submitting the NDA. If the FDA accepts the NDA for filing, they will then have up to 10 months from the date the submission is accepted to decide whether the application is approvable. If we receive approval within this timeframe we would be prepared for a product launch within 3 months from this time. We may be unable to complete any clinical phase of clinical trials.

Table of Contents

Our market research indicates that as a treatment for esophageal candidiasis, Bioral® Amphotericin B formulation may be able to achieve projected peak sales of approximately $400 million annually, on which we will pay a royalty to UMDNJ. We do not anticipate generating any revenue for Bioral® Amphotericin B, if ever, until at least late 2013.

The risks to our company associated with the Bioral Amphotericin B project include: (i) inability of a contract manufacturer to produce clinical supplies; (ii) clinical studies not showing significant oral absorption of product; (iii) failure of subsequent clinical trials; (iv) product safety issues; (v) lack of corporate funding to progress the program; and (vi) failure to effectively commercialize the product.

Of the major programs to which we are currently dedicating resources, we believe this program has the highest risk because of the early-stage and more complex nature of the Bioral® technology (as opposed to BEMA®). However, due to the large market for anti-fungal projects, we believe the potential of Bioral® Amphotericin B from a commercial perspective may be significant to us. The failure of this program or a failure of the product to meet commercial forecasts could have a material adverse effect on long term corporate revenue, and would also negatively affect investor confidence in our company and potentially our public stock price. Progress with or ultimate commercialization of Bioral® Amphotericin B would, as it is our lead Bioral® product, likely validate the broader encochleation concept.

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, the sale of a royalty stream asset, sponsored research, funded research arrangements and from various strategic and licensing agreements, including the CDLA and commercialization agreements with Meda relating to ONSOLIS®. We intend to finance our research and development and commercialization efforts and our working capital needs from existing cash, royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

In July, 2009, we announced the FDA s approval of ONSOLIS®. The FDA approval, together with our satisfactory preparation of launch supplies of ONSOLIS®, triggered a milestone payment by Meda of $26.8 million. Prior to FDA approval, we received from Meda in January 2009 an advance of $3 million on the approval milestone and in September 2007, an up-front non-refundable payment of $30 million. This represents, since inception through December 31, 2009, a total of $59.8 million received as license and milestone payments associated with our Meda license, development and supply agreements for North America. Such agreements also include the receipt of an additional $30 million if certain sales targets for ONSOLIS® are met.

We also anticipate the approval of ONSOLIS® in Europe (which will be marketed as BREAKYL). In August 2006 we received a $2.5 million up-front non-refundable payment in connection with execution of the Meda Europe license, development and supply agreements. In March 2008 we received a milestone payment of $2.5 million in connection with our Meda Europe Agreement. We received from Meda in January 2009 a payment of $3 million to expand the Meda Europe agreement to the rest of the world (except for Taiwan and South Korea). All payments received associated with the aforementioned agreements total $8 million since inception through December 31, 2009. Further, the Meda Europe agreements include an additional $2.5 million, respectively, in milestone payments that are due upon product approval and the first sale in Europe.

The Meda Agreements require all pre-launch marketing and commercialization costs for ONSOLIS® to be paid by Meda, as well as all required clinical costs associated with ONSOLIS® after

Table of Contents

FDA approval. Meda will pay for costs of Phase 3-b and Phase 4 studies which, although not required as part of our ONSOLIS® NDA, may be done to support the program with additional market data. In addition, Meda is paying for the development costs for ONSOLIS® in non-cancer breakthrough pain.

In January 2009, we completed a universal shelf registration for up to $50 million of our securities which can potentially be drawn over a three year period based on certain terms and conditions to be determined if and when we decide to utilize the shelf registration.

On October 6, 2009, we announced we had received a $1.3 million grant from the Walter Reed Army Institute of Research to support the clinical study of our Bioral Amphotericin B product candidate for the treatment of Cutaneous Leishmaniasis.

At December 31, 2009, we had cash and cash equivalents of approximately $23.9 million. We generated $18.2 million of cash from operations in the year ended December 31, 2009, principally reflecting receipt of $32.8 million in milestone payments from Meda offset partially by cash outflows required to support 2009 operations.

As of December 31, 2009, we had stockholders equity of $14.5 million, versus a stockholders deficit of $33.6 million at December 31, 2008, attributable to our positive cash flow from operations in 2009, and the recognition of deferred revenue as described above.

We anticipate that cash used in operations and our investment in our facilities will continue beyond our ONSOLIS® agreements with Meda as we research, develop, and potentially, manufacture and commercialize additional drug formulations with our BEMA® and Bioral® technologies. While we believe further application of our BEMA® and Bioral® cochleate technologies to other drugs will result in license agreements with additional pharmaceutical manufacturers, our plan of operations for the foreseeable future will be to develop additional products with our BEMA® technology and further develop our Bioral® cochleate technology for use in a limited number of applications. Our near term focus will not be on the marketing, production or sale of FDA approved products, although we may seek to develop these capabilities in the future as part of our longer term strategic plan.

The recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues, fluctuates or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when we require additional financial investment. If we are unable to attract additional funds it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned basic operations (minimal research and development activities beyond those covered under our Meda and other related agreements), debt repayment obligations and capital expenditures through the first quarter of 2011.

However, additional capital will be required in order to proceed with our support of the commercial launch of ONSOLIS®, clinical development programs for other products in our pipeline, such as BEMA® Buprenorphine and Bioral® Amphotericin B (the scale of which is dependent in part on the success of ONSOLIS® and on the results from our clinical studies for each of these products), and for 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. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

public equity markets;

Table of Contents

private equity financings;

collaborative arrangements;

grants and new license revenues;

bank loans;

equipment financing;

public or private debt; and

exercise of existing warrants.

Readers are cautioned that additional capital 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 2009 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 contractual obligations as of December 31, 2009 are as follows:

	Payments Due by Period			
	Less than 1 year	1-3 years	3-5 years	More than 5 years
Leases	$ 121,794	$ 265,271		
Employment agreements	$ 887,776	43,579		
Minimum royalty expenses*	$ 1,500,000	3,000,000	3,000,000	7,875,000
Total contractual cash obligations	$ 2,509,570	$ 3,308,850	$ 3,000,000	$ 7,875,000

* Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC regardless of actual sales.

Off Balance Sheet Arrangements

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

Table of Contents

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

We are a smaller reporting company as defined by Regulation S-K and as such, are not required to provide the information contained in this item pursuant to Regulation S-K.

Item 8. Financial Statements.

Our Consolidated Financial Statements and Notes thereto and the report of Cherry, Bekaert & Holland, L.L.P., our independent registered public accounting firm, are set forth on pages F-1 through F-27 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 Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, at December 31, 2009, 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 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.

Table of Contents

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth fiscal quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

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

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with 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 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, 2008. 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, 2009.

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of March 12, 2010 are as follows:

Name	Age	Position(s) Held
Francis E. O Donnell, Jr., M.D.	60	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	56	President, Chief Executive Officer and Director
James A. McNulty	59	Chief Financial Officer, Secretary and Treasurer
Andrew L. Finn, Pharm.D.	60	Executive Vice President of Product Development
William B. Stone	66	Lead Director
John J. Shea	83	Director
William S. Poole	62	Director

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

Francis E. O Donnell, Jr., M.D., age 60, has been of our Chairman of the Board and a Director since March 29, 2002. 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 managing director 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. He is a co-founder and chairman of RetinaPharma Technologies, Inc. He serves as Chairman and CEO of Accentia and its majority owned subsidiary, Biovest International, Inc., a holding company with commercialization assets representing a vertically-integrated platform for specialty pharmaceuticals and biologics. 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 also a trustee of St. Louis University.

Mark A. Sirgo, Pharm.D., age 56, has been our President and Chief Executive Officer since July 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 more than 25 years of experience in the pharmaceutical industry, including 16 years in clinical drug development, 7 years in marketing, sales, and business development and 5 years in executive management. 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. (NASDAQ:PPDI), a leading contract service provider to the pharmaceutical industry. Dr. Sirgo serves on the Board of Directors of Salix Pharmaceuticals, Inc. (NASDAQ:SLXP), a specialty pharmaceutical company specializing in gastrointestinal products. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

Table of Contents

James A. McNulty, age 59, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis since October 2000 until January 1, 2008 when his position became full-time. Mr. McNulty has, since May 2000, also served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture activities. Hopkins Capital Group is owned and controlled by Dr. Francis E. O Donnell, Jr. Mr. McNulty also serves part-time as the Treasurer and Corporate Secretary of Accentia, a holding company with commercialization assets in specialty pharmaceuticals and biologics, and through December 31, 2007 as Chief Financial Officer for Biovest International, a majority-owned subsidiary of Accentia. Mr. McNulty is a Director of RetinaPharma Technologies, Inc., an affiliate of Hopkins Capital Group. 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 served as CFO of Star Scientific, Inc. from October 1998 to May 2000. From June 2000 through January 2002 he served as CFO/COO of American Prescription Providers, Inc. 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, and is a member of the American and Florida Institutes of CPA s.

Andrew L. Finn, Pharm.D., age 60, 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 more than 25 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 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 U.S. Clinical Research 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 received his BS in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

William B. Stone, age 66, has been a member of our board of directors since October 2001 and is our Lead Director and Chairman of the Audit Committee of our board of directors. For thirty years, until his retirement in October 2000, Mr. Stone was employed with Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and Chief Information Officer for 16 years and 4 years, respectively. During his tenure at Mallinckrodt, Mr. Stone was responsible for global accounting and reporting, financial organization, staffing and development, and systems of internal accounting control. In this capacity, he was responsible for Mallinckrodt s SEC and other financial filings, for internal management performance reports, for 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 accountants 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

Table of Contents

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 information systems, 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 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 83, 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 of 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 earned a B.S. in Chemistry at Bethany College.

William S. Poole, age 62, has been a member of our board of directors since April 2005 and services as Chairman of the Compensation Committee of our board of directors. 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 2007-08. In addition, Mr. Poole is a member of the board of directors of Accentia.

Key Employees

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

Niraj Vasisht, Ph.D. has been our Senior Vice President of Product Development and Chief Technology Officer since October 2008. He joined the company in February 2005 as the Vice President of Product Development with over 14 years of experience in pharmaceutical development. Dr. Vasisht s heads our pharmaceutical development, technology development, manufacturing and supply chain functions for our product candidates, providing technical and strategic leadership to the business development function. In his position, he evaluates suitability of drug candidates into the delivery platform, creates technologies for the company s intellectual property and product pipeline extension, and oversees contract manufacturing operations. He directs and oversees the product design, formulation development, quality control, process engineering, validation and stability testing of the drug product, and

Table of Contents

is responsible for the chemistry, manufacturing and controls (CMC) section in IND, IMPD, NDA and MAA filings. 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 Masters 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 nearly 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.

Charles E. Dadswell, Esq. joined our company in January 2008 as General Counsel. He is responsible for overseeing all activities pertaining to our intellectual property portfolio and contract activities. Mr. Dadswell has over 20 years of pharmaceutical industry experience, including 16 years in intellectual property, four years in sales and marketing, and six years in executive management. Mr. Dadswell previously held numerous positions at Glaxo, Glaxo Wellcome and most recently, at GlaxoSmithKline as the Vice President of U.S. Intellectual Property, where he was responsible for managing GSK s Research Triangle Park, North Carolina Patent group.

Director Independence

We believe that William B. Stone, John J. Shea and William S. Poole 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.

Board Committees

Our board of directors has established three standing committees-Audit, Compensation, and Nominating and Corporate Governance. 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, John J. Shea and William S. Poole, 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

Table of Contents

as defined in Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee met four times during 2009. Each member of the Audit Committee was present at all 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 auditors, and engages such independent auditors;
- approves the plan and fees for the annual audit, performs a review of quarterly reports, tax and other audit-related services, and approves in advance any non-audit service to be provided by the independent auditors;
- monitors the independence of the independent auditors and the rotation of partners of the independent auditors on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and our quarterly financial statements;
- oversees all aspects our systems of internal accounting control and corporate governance functions on behalf of the board;
- provides oversight assistance in connection with legal, ethical and risk management compliance programs established by management and the board, including Sarbanes-Oxley implementation, and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our board of directors has a Nominating and Corporate Governance Committee composed of William S. Poole, John J. Shea and William B. Stone. 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 was formed in May of 2004 and met two times in 2009. The Nominating and Corporate Governance Committee 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 James A McNulty, BioDelivery Sciences International, Inc, 324 South Hyde Park Avenue, Suite 350, Tampa FL 33606. 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 2009, we did not pay any fees to any third parties to assist in the identification of nominees. During 2009, we did not receive any director nominee suggestions from stockholders.

Table of Contents

Compensation Committees

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. The Compensation Committee has a charter (which is reviewed annually) and is comprised of three members: John J. Shea, William B. Stone and William S. Poole, who acts as chairman of this committee. The compensation committee met five times during 2009.

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 2009, 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 $10,250 in 2009.

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 to 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 2009, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, except that options granted to each member of our board of directors (Francis E. O Donnell, Jr., Mark A. Sirgo, William B. Stone, John J. Shea and William S. Poole) on July 22, 2009 were reported on Form 4s filed on July 31, 2009.

Code of Ethics

We have adopted a code of ethics that applies to all employees, as well as each member of our Board of Directors. Our code of ethics is posted on our website, and we intend to satisfy any disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of ethics by posting such information on our website, www.bdsi.com.

Table of Contents

Item 11. Executive Compensation.

The following table sets forth all annualized compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2009 and 2008. 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, 2009.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(18)	Non-Equity Incentive Plan Compensation ($)(18)	All Other Compensation ($)	Total ($)
Mark A. Sirgo, Pharm.D. President, Chief Executive Officer and Director	2009	$ 470,463[1]	$ 220,378[2]		$ 321,760	$ 88,883[3]	$ 43,602[4]	$ 1,145,086
	2008	$ 301,920	$ 150,000		$ 119,288	$ 30,516[5]	$ 22,871[6]	$ 624,595
James A. McNulty, CPA Chief Financial Officer, Secretary and Treasurer	2009	$ 290,377	$ 120,196[7]		$ 326,860		$ 32,164[8]	$ 769,597
	2008	$ 202,252	$ 100,000		$ 69,696		$ 26,475[9]	$ 398,423
Andrew L. Finn, Pharm.D. Executive VP of Product Development	2009	$ 244,800	$ 144,480[10]		$ 12,239		$ 21,945[11]	$ 423,464
	2008	$ 244,800	$ 120,000		$ 96,720		$ 18,259[12]	$ 479,779
Raphael J. Mannino, Ph.D* Former Executive Vice President and Chief Scientific Officer	2009	$ 168,262[13]	$ 33,415[14]		$ 21,840		$ 312,898[15]	$ 536,415
	2008	$ 222,768[16]			$ 43,681		$ 20,529[17]	$ 286,978

* In September 2009, we terminated our relationship with Dr. Mannino.

(1) The compensation disclosed in this item includes $99,944 of salary paid in 2009, which relates to services performed in 2008, but was contingent upon the FDA approval of ONSOLIS®, which occurred July 2009.

(2) The bonus disclosed in this item of $220,378 is related to 2008, but was contingent upon the FDA approval of ONSOLIS®, which occurred July 2009.

(3) The compensation disclosed in this item is composed of 25,000 stock options granted as compensation for serving as a director.

(4) Includes: Vacation payout of $20,902, $10,450 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2009.

(5) The compensation disclosed in this item is composed of 30,000 stock options granted as compensation for serving as a director.

(7) The bonus disclosed in this item of $120,196 is related to 2008, but was contingent upon the FDA approval of ONSOLIS®, which occurred July 2009.

(8) Includes: $19,914 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2009.

Table of Contents

(9) Includes: Vacation payout of $2,640, $12,335 of health insurance premiums paid and 401(k) matching of $11,500 paid in 2008.
(10) The bonus disclosed in this item of $144,480 is related to 2008, but was contingent upon the FDA approval of ONSOLIS®, which occurred July 2009.
(11) Includes: $12,318 of health insurance premiums paid and 401(k) matching of $9,627 paid in 2009.
(12) Includes: $6,759 of health insurance premiums paid and 401(k) matching of $11,500 paid in 2008.
(13) Includes: $90,000, which funds were accrued or reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2009 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.
(14) The bonus disclosed in this item of $33,415 is related to 2008, but was contingent upon the FDA approval of ONSOLIS®, which occurred July 2009.
(15) Includes: Vacation payout of $1,976, $11,855 of health insurance premiums paid, car allowance of $5,000, 401(k) matching of $4,163 and a severance payment of $289,904 pursuant to an employment agreement, which employment was terminated September 1, 2009.
(16) Includes: $120,000, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2008 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.
(17) Includes: $8,566 of health insurance premiums paid, car allowance of $6,500 and 401(k) matching of $5,463.
(18) 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 non-compete agreements with us.

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

Mark A. Sirgo, Pharm.D., President and Chief Executive Officer On August 24, 2004, Dr. Sirgo executed a three-year employment agreement to be our Senior Vice President of Commercial and Corporate Development and the President of Arius at an annual salary of $175,000. Dr. Sirgo also received a signing bonus in the amount of $31,177 at the signing of this agreement. He was subsequently promoted three times and now holds the position of President and Chief Executive Officer of our company.

On February 22, 2007, Dr. Sirgo s employment agreement was amended to: (i) make it renewable for consecutive one year terms after August 24, 2007 unless written notice is given by either party at least 30 days prior to the end of the applicable term and (ii) increase Dr. Sirgo s annual salary to $260,000, which will be adjusted to $296,000 per annum at such time as we engage in any asset sale, royalty sale, bank loan, joint venture/partnering funding, or debt and or equity financing which yields gross proceeds of $5 million or greater. Such adjustment occurred in May 2007. Dr. Sirgo is eligible for a discretionary annual bonus of up to 50% of his base salary.

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

Table of Contents

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).

James A. McNulty, CPA, Chief Financial Officer, Secretary and Treasurer Through December 31, 2007 he served as part-time CFO , devoting approximately 50% of his time to our company. Beginning January 1, 2008, Mr. McNulty devotes substantially all of his time to our company. He has an employment agreement with us (which was amended on August 31, 2002, and subsequently amended again in June 2003) for a base salary of $185,000, reduced to $110,000 in June 2003 and then increased to $114,400 in February 2007 concurrently with Mr. McNulty s entry into his new employment agreement described below. Mr. McNulty s employment agreement, dated February 22, 2007, is for a term of ending on February 22, 2008 and is subject at the end of that term 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. Mr. McNulty is also employed part-time as Secretary/Treasurer of Accentia. Under the terms of the his agreement, Mr. McNulty received base salary in 2008 of $198,000 per year and a target bonus of up to 50% of his base salary.

We may terminate Mr. McNulty s employment agreement without cause and Mr. McNulty may resign upon 30 days advance written notice to the other party. 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).

Table of Contents

Andrew L. Finn, Pharm.D., Executive Vice President of Product Development On August 24, 2004, Dr. Finn executed a three-year employment agreement to be our Senior Vice President of Product Development and the Senior Vice President and Chief Operating Officer of Arius at an annual salary of $175,000. He was subsequently promoted and now holds the position of Executive Vice President of Product Development of our company. Dr. Finn also received a signing bonus in the amount of $28,092 at the signing of this agreement.

On February 22, 2007, Dr. Finn s employment agreement was amended to: (i) make it renewable for consecutive one year terms after August 24, 2007 unless written notice is given by either party at least 30 days prior to the end of the applicable term and (ii) increase Dr. Finn s annual salary to $228,800, which will be adjusted to $240,000 per annum at such time as we engage in any asset sale, royalty sale, bank loan, joint venture/partnering funding, or debt and or equity financing which yields gross proceeds of $5 million or greater. Such adjustment occurred in May 2007. Dr. Finn is eligible for a discretionary annual bonus of up to 50% of his base salary.

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).

Dr. Raphael Mannino, Ph.D., Former Executive Vice President and Chief Scientific Officer On October 21, 2009, Dr. Mannino executed a separation agreement with us pursuant to a Notice of Termination, dated September 1, 2009, which terminated Dr. Mannino s employment with us.

In consideration of the execution of this Agreement by Dr. Mannino, we made a cash severance payment in the amount of $289,904., paid as a single one-time cash payment subject to required withholding, paid in accordance with provisions set forth in the employment agreement dated February 22, 2007, between Dr. Mannino and us. We also paid to Dr. Mannino accrued, but unused vacation benefits as of September 30, 2009 (less applicable federal, state and other withholdings).

Niraj Vasisht, Ph.D., Senior Vice President Product Development On October 1, 2008, Dr. Vasisht executed a one-year employment agreement to be our Senior Vice President and Chief Technical Officer at an annual salary of $190,300. Dr Vasisht is eligible for a discretionary annual bonus of up to 50% of his base salary.

Table of Contents

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

Dr. Vasisht s employment agreement also includes a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement, except that if Dr. Vasisht 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, 2009.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Prices ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not vested (#)
Mark A. Sirgo, Pharm.D.	25,000			$ 5.40	7/22/19				
			100,000[1]	$ 4.83	4/30/19				
			9,175[2]	$ 3.05	1/22/19				
	43,662		27,323[3]	$ 2.01	7/24/18				
	16,150		32,298[4]	$ 2.85	1/31/18				
	20,000			$ 4.13	7/25/17				
	305,917		128,083[5]	$ 6.63	4/13/17				
	45,891			$ 2.42	1/26/17				
	17,730			$ 2.05	7/27/16				

Table of Contents

	49,000		$ 3.03	12/1/15
	20,000		$ 2.94	8/22/15
	8,929		$ 2.94	7/28/15
	5,147		$ 3.40	10/21/14
James A. McNulty, CPA		100,000[1]	$ 4.83	4/30/19
		12,275[2]	$ 3.05	1/22/19
	6,093	12,184[3]	$ 2.01	7/24/18
	10,803	21,605[4]	$ 2.85	1/31/18
	66,667	33,333[5]	$ 6.63	4/13/17
	34,109		$ 2.42	1/26/17
	15,603		$ 2.05	7/27/16
	10,000		$ 3.03	12/1/15
	26,189		$ 2.94	7/28/15
	3,235		$ 3.40	10/21/14
	18,616		$ 3.83	8/14/13
Andrew L. Finn, Pharm.D.		7,439[2]	$ 3.05	1/22/19
	11,077	22,154[3]	$ 2.01	7/24/18
	13,094	26,188[4]	$ 2.85	1/31/18
	66,667	33,333[5]	$ 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
Raphael J. Mannino, Ph.D (6)				

(1) Of the unvested stock options, one third of the unvested stock options will vest on April 30, 2010, another third will vest on April 30, 2011 and the remaining third will vest on April 30, 2012.
(2) Of the unvested stock options, one third of the unvested stock options will vest on January 22, 2010, another third will vest on January 22, 2011 and the remaining third will vest on January 22, 2012.
(3) Of the unvested stock options, half of the unvested stock options will vest on July 24, 2010 and another half will vest on July 24, 2011.
(4) Of the unvested stock options, half of the unvested stock options will vest on January 31, 2010 and another half will vest on January 31, 2011.
(5) These unvested stock options will vest on April 13, 2010.
(6) Pursuant to termination effective September 1, 2009, any vested unexercised options were forfeited as of December 31, 2009.

Outstanding Equity Awards Narrative Disclosure

Amended and Restated 2001 Incentive Plan

The purpose of the Amended and Restated 2001 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

Table of Contents

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.

Under our original 2001 Incentive Plan, we reserved 572,082 shares. The plan was approved by our stockholders at our 2001 annual meeting. Our board of directors, with stockholder approval, has subsequently voted to amend and restate the plan on three occasions to increase the number of shares reserved for issuance thereunder, most recently at the July 2009 Annual Meeting whereby the number of shares reserved for issuance increased to 6,000,000. Options to purchase 3,662,133 shares of common stock are outstanding as of December 31, 2009 under the Amended and Restated 2001 Incentive Plan.

All options were issued under our Amended and Restated 2001 Incentive Plan. 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.

Directors are eligible to participate in our Amended and Restated 2001 Incentive Plan. The plan provides for an initial grant of an option to purchase up to 25,000 shares (prorated based on months to be served in the fiscal year in which they join) of common stock to each director upon first joining our board of directors and subsequent grants of options to purchase 25,000 shares upon each anniversary of such director s appointment and an additional 15,000 option grant for serving as Lead Director. The board chairman is also granted 7,500 additional options. Such options are granted at an exercise price equal to the fair market value of the common stock on the grant date and immediately vest.

Options and warrants to purchase 7,548,624 shares of our common stock at prices ranging from $2.01 to $6.63 are outstanding at December 31, 2009. None of our options have been granted at less than the fair market value at the time of grant. Options issued during 2009 to employees and directors totaled 557,005 shares, at exercise prices ranging from $2.90 and $5.87.

Compensation of Directors Summary Table

DIRECTOR COMPENSATION

Name (a)	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Francis E. O Donnell, Jr.[1]	$ 42,500			$ 115,548			$ 158,048
William B. Stone [2]	$ 41,500			$ 142,213			$ 183,713
John J. Shea [3]	$ 37,500			$ 88,883			$ 126,383
William S. Poole [4]	$ 37,500			$ 88,883			$ 126,383

(1) As of December 31, 2009, the outstanding stock options held by Dr. O Donnell total 215,000, all of which have vested.
(2) As of December 31, 2009, the outstanding stock options held by Mr. Stone total 320,000, all of which have vested.

Table of Contents

(3) As of December 31, 2009, the outstanding stock options held by Mr. Shea total 233,700, all of which have vested.
(4) As of December 31, 2009, the outstanding stock options held by Mr. Poole total 195,000, all of which have vested.

Narrative to Director Compensation

In July, 2009, the Compensation Committee of our board of directors adopted a new Director Remuneration Policy, which revised the compensation our directors earn for serving on our board of directors and individual committees. The new policy is the following;

$20,000 annual cash retainer to each board member, paid quarterly in arrears.

$10,000 annual cash retainer to the Chairman of the Board, paid quarterly in arrears.

$8,000 annual cash retainer annual to the Chairman of the Audit Committee, paid quarterly in arrears.

$4,000 annual cash retainer to the Chairman of the Compensation Committee, paid quarterly in arrears.

$4,000 cash retainer annual to the Chairman of the Nominating & Corporate Governance Committee, paid quarterly in arrears.

$2,000 cash retainer annual to each committee member, paid quarterly in arrears.

$3,000 cash payment for each board meeting attended in person.

$2,000 cash payment for each committee meeting attended in person.

$500 cash payment for each board meeting attended telephonically.

$300 cash payment for each committee meeting attended telephonically.

25,000 options to purchase shares of our Common Stock per year, to each director.

7,500 additional options to purchase shares of our Common Stock per year to the Chairman of the Board.

15,000 additional options to purchase shares 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 option awards.

79

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 12, 2010, 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	Number of Shares of Common Stock Owned[1]	Percentage of Class as of March 12, 2010
Hopkins Capital Group II, LLC [2]	3,527,052	16.45%
Francis E. O Donnell, Jr., M.D.[3]	3,925,717	18.13%
The Francis E. O Donnell, Jr. Irrevocable Trust #1[4]	3,813,302	17.69%
CDC IV, LLC [5]	2,505,120	10.57%
Mark A. Sirgo, Pharm.D. [6]	1,384,809	6.36%
James A. McNulty [7]	247,869	1.16%
Andrew L. Finn, Pharm.D. [8]	969,713	4.53%
William B. Stone [9]	355,000	1.65%
John J. Shea [10]	260,000	1.21%
William S. Poole [11]	203,190	*
All Directors and Officers as a group (7 persons)	7,346,298	31.39%

* Less than 1%

(1) Based on 21,184,763 shares of common stock outstanding as of March 12, 2010.

(2) Includes 400,402 shares of our common stock which were converted from Series B Convertible Preferred Stock in January 2007. Includes a warrant held in the name of Hopkins Capital Group II, LLC to purchase 251,562 shares of our common stock with an exercise price of $5.55, which warrant was acquired September 2007. The address for Hopkins Capital Group II, LLC is 324 S Hyde Park, Suite 350, Tampa, FL 33609.

(3) Dr. O Donnell is our Chairman of the Board and a Director. Includes the shares and warrant owned by Hopkins Capital Group II, LLC, as to which Dr. O Donnell disclaims beneficial interest (see Note 2). Excludes 167,500 shares owned by The Francis E. O Donnell, Jr. Irrevocable Trust #1, of which Dr. O Donnell s sister, Kathleen O Donnell, is trustee, and as to which Dr. O Donnell disclaims beneficial interest (see Note 4). Includes 21,400 shares owned by The Jonnie R. Williams Trust, of which Dr. O Donnell is trustee, and as to which Dr. O Donnell disclaims beneficial interest of. The remaining 4,576 shares of common stock are owned by Dr. O Donnell s sister. In addition, this number includes 157,689 shares owned personally by Dr. O Donnell and options to purchase 215,000 shares of our common stock, all of which is currently exercisable. Dr. O Donnell s address is 865 Longboat Club Road, Longboat Key FL 34228.

(4) Includes the shares and warrant owned by Hopkins Capital Group II, LLC (see Note 3). The remaining 167,500 shares of common stock are held directly by this trust. Includes a warrant beneficially owned to purchase 251,562 shares of our common stock with an exercise price of $5.55, which warrant was acquired September 2007. Also includes a warrant owned to purchase 118,750 shares of our common stock with an exercise price of $5.55, which warrant was acquired June 2009. The address for The Francis E. O Donnell, Jr. Irrevocable Trust #1 is c/o Kathleen M O Donnell, McCabe O Donnell, a Professional Association, 3101 North Central Avenue, Suite 700, Phoenix, AZ 85012.

Table of Contents

(5) Includes an aggregate of 2,505,120 shares of common stock underlying warrants held by CDC, IV, LLC. The address for CDC IV, LLC is 47 Hullfish Street, Suite 310, Princeton, NJ. 08542.

(6) Includes 808,175 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Includes options to purchase 576,634 shares of common stock, all of which are currently exercisable. Excludes options to purchase 315,019 shares of common stock which are not currently exercisable. Dr. Sirgo s address is 1203 Clematis Street, Knightdale, North Carolina 27545.

(7) Mr. McNulty is our Chief Financial Officer, Secretary and Treasurer. Includes 41,659 shares owned by Mr. McNulty. Includes options to purchase 206,210 shares of our common stock, all of which are currently exercisable. Includes 2,288 shares owned by his wife, as to which he disclaims beneficial interest of. Excludes options to purchase 191,582 shares of common stock which are not currently exercisable. Mr. McNulty s address is 4419 W. Sevilla Street, Tampa, FL 33629.

(8) Dr. Finn is our Executive Vice President of Clinical Development and Regulatory Affairs. Includes 752,413 shares owned by Dr. Finn. Includes options to purchase 217,300 shares of common stock, all of which are currently exercisable. Excludes options to purchase 96,291 shares of common stock which are not currently exercisable. Dr. Finn s address is 3104 Raymond Street, Raleigh, NC 27607.

(9) Mr. Stone is a Director. Includes 35,000 shares owned and options to purchase 320,000 shares of our common stock, all of which are currently exercisable. Mr. Stone s address is 11120 Geyer Downs Lane, Frontenac MO 63131.

(10) Mr. Shea is a Director. Includes 26,300 shares owned and options to purchase 233,700 shares of our common stock, all of which are currently exercisable. Mr. Shea s address is 290 Wax Myrtle Trail, Southern Shores, NC 27949.

(11) Mr. Poole is a Director. Includes 8,190 shares owned and options to purchase 195,000 shares of our common stock, all of which are currently exercisable. Mr. Poole s address is 7813 Hardwick Drive, Raleigh, NC 27615.

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:

HCG II, Accentia and affiliates

We also have several business relationships with Accentia and its affiliates. Hopkins Capital Group II, LLC, or HCG II, which is controlled by Dr. Frank O Donnell, Jr., our Chairman of the Board and which owns a significant percentage of our common stock as of the date of this Report, is a significant stockholder of Accentia. In addition, Dr. O Donnell is also the Chairman and CEO of Accentia and of Biovest International, Inc. (Pink Sheets:BVTI.PK), a subsidiary of Accentia. In addition, William S. Poole, a director of our company, is also a director of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, is also Secretary and Treasurer of Accentia and Chief Financial Officer of HCG II.

Table of Contents

On November 10, 2008, Accentia and its subsidiaries, including Biovest International, Inc. filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. As such, readers are advised that projects which we are working on with Accentia may not progress in the future and that we may not receive royalty payments which we are due from Accentia.

Amphotericin B License. On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from the Mayo Foundation for Medical Education and Research for the treatment of CRS and asthma on a worldwide basis. Under our license agreement with Accentia as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales in the U.S. of its CRS products and other products in the designated field. On September 8, 2004, we entered into a definitive Asset Purchase Agreement with Accentia pursuant to which we sold to Accentia an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of $2.5 million. The royalty revenue stream sold was a fifty percent (50%) interest in the future royalties earnable by us on sales by Accentia for products utilizing our topical formulation of our encochleated Amphotericin B for the treatment of CRS, thus effectively reducing our royalty on the sales of such CRS products by 50%. We agreed with Accentia, however, that the future royalty stream sold shall not include royalty payments that are payable by Accentia based on the sale of encochleated products exclusively intended to treat asthma, and the rights to such royalty payments, as originally set forth in the license agreement, shall remain with us. The license agreement was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

Arius/TEAMM Distribution Agreement. On March 12, 2004, our Arius subsidiary (then a separate company) entered into a Distribution Agreement pursuant to which it granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc. with respect to the Emezine® product for the treatment of nausea and vomiting. TEAMM was renamed Accentia Pharmaceuticals, Inc. in 2007 and is a wholly-owned subsidiary of Accentia. As part of this agreement, TEAMM agreed to pay for the development costs of Emezine We received development cost reimbursements of $1.0 million in 2004 from Accentia in connection with this agreement and an additional $300,000 in 2005 upon the acceptance of the Emezine NDA for filing. On December 17 2008, in conjunction with the Reckitt Benckiser Healthcare (UK) Limited (Reckitt) termination of the Emezine® agreement, the Arius TEAMM Distribution Agreement was terminated.

Emezine Settlement Agreement. On December 30, 2009, we entered into a Settlement Agreement with Accentia, Arius and TEAMM. The purpose of such agreement was to memorialize the terms and conditions of a settlement between us and Accentia of claims by TEAMM relating to the Distribution Agreement between Arius and TEAMM. At the time the Distribution Agreement was entered into, Arius was not affiliated with us. Arius was acquired by us in August 2004. We do not believe that Accentia s claims have merit, but we also believe that the alternative of a protracted dispute would be distracting, time consuming and costly at a time when we are focusing our efforts on the commercial launch of ONSOLIS®, our first approved product, and on the development of our product pipeline including BEMA® Buprenorphine. As such, we have elected to enter into the Agreement.

The Agreement provides that we and Accentia mutually release all claims that either may have against each other and, in connection therewith, we will (a) pay $2.5 million to Accentia (paid to escrow in February 2010) and (b) grant the following royalty rights (the Product Rights) to Accentia with respect to our BEMA® Granisetron product candidate (BEMA® Granisetron) (or in the event it is not

Table of Contents

BEMA® Granisetron, our third product candidate (excluding BEMA® Buprenorphine) as to which we file an NDA, which, together with BEMA® Granisetron, shall be referred to hereinafter as the Product): (i) 70/30 split between our company and Accentia, respectively) of royalty received if a third party sells the Product and 85/15 split on net sales if we sell the Product; and (ii) we will, from the sale of the Product, fully recover amounts equal to (1) all internal and external worldwide development costs of the Product (Costs) plus interest (measured on weighted average prime interest rate from first dollar spent until Product launch) and (2) the $2.5 Million Payment plus interest (measured on weighted average prime interest rate from the time of payment until Product launch) before Accentia begins to receive its split as described in (b) (i) above. In addition, pursuant to the Agreement, we have received a warrant to purchase 2 million shares of Accentia s majority-owned subsidiary, Biovest, from Accentia, with a strike price equal to 120% of the closing bid price of Biovest s common stock as of the date the Bankruptcy Court enters a final order authorizing Accentia to carry out the Agreement, with the issuance of the Warrant to occur upon the $2.5 Million Payment by us. The Warrant will be exercisable immediately and for a period of seven 7 years from the date of issuance. During the initial two 2 year exercise period, any exercise of the Warrant by us will be subject to approval by Biovest.

Other

On July 19, 2002, we issued Ellenoff Grossman & Schole LLP, our outside legal counsel, 25,000 options to purchase shares of our common stock at $7.00 per share. On December 30, 2003, we issued Ellenoff Grossman & Schole LLP 19,607 options to purchase shares of our common stock at $2.55 per share. In 2004, we issued Ellenoff Grossman & Schole LLP 44,509 shares of our common stock as compensation for services rendered. Ellenoff Grossman & Schole LLP is also counsel to our subsidiary, Bioral Nutrient Delivery, LLC. During 2003, Bioral Nutrient Delivery, LLC issued 37,500 Class B Shares of BND to Ellenoff Grossman & Schole LLP. These Class B Shares were issued at the inception of Bioral Nutrient Delivery, LLC at nominal value.

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 three independent directors which constitute a majority as required by NASDAQ Stock Market rules. We believe that William B. Stone, John J. Shea and William S. Poole 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.

Table of Contents

Item 14. Principal Accountant Fees and Services.

Audit Fees. The aggregate fees billed by Cherry, Bekaert & Holland, L.L.P. 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, 2009 and 2008 totaled $114,200 and $155,745, respectively. The above amounts include interim procedures as audit fees as well as attendance at audit committee meetings.

Audit-Related Fees. The aggregate fees billed by Cherry, Bekaert & Holland, L.L.P. for audit-related fees for the years ended December 31, 2009 and 2008 were $67,412 and $11,539, respectively.

Tax Fees. The aggregate fees billed by Cherry, Bekaert & Holland, LLP. for professional services rendered for tax compliance, for the years ended December 31, 2009 and 2008 were $26,003 and $58,501, 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 & Holland, L.L.P. in 2009. 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 & Holland, L.L.P.

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated August 10, 2004, by and among the Company, Arius Acquisition Corp., Arius, Dr. Mark Sirgo and Dr. Andrew Finn (9)
2.2	Asset Purchase Agreement, dated September 8, 2004, by and between the Company and Accentia, Inc. (11)
3.1	Articles of Incorporation of the Company (3)
3.2	Bylaws of the Company (3)
3.3	Secretary s Certificate regarding amendments to Company s Bylaws, dated August 23, 2005 (17)
3.4	Certificate of Amendment to the Company s Certificate of Incorporation creating a staggered board of directors, dated July 25, 2008 (31)
3.5	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 (34)
4.1	Common Stock Purchase Warrant, dated July 15, 2005, by the Company in favor of Clinical Care Development, LLC (16)
4.2	Warrant, dated May 16, 2006, made by the Company in favor of CDC IV, LLC (19)
4.3	Common Stock Purchase Warrant, dated March 12, 2007, by the Company in favor of CDC IV, LLC (27)
4.4	Common Stock Purchase Warrant, dated April 10, 2007, issued by the Company in favor of Laurus Master Fund, Ltd. (28)
4.5	Common Stock Purchase warrant (475,000 shares), dated September 5, 2007, by the Company in favor of HCG II (29)
10.1	Research Agreement with the University of Medicine and Dentistry of New Jersey (1)
10.2	Licensing Agreement with the University of Medicine and Dentistry of New Jersey (2)
10.3	Licensing Agreement with Albany Medical College (2)
10.4	License Agreement with Tatton Technologies, LLC (3)
10.5	Addendum to License Agreement with Tatton Technologies, LLC (5)
10.6	License Agreement with RetinaPharma, Inc. (13)
10.7	Addendum to License Agreement with RetinaPharma, Inc. (4)
10.8	License Agreement with Biotech Specialty Partners, LLC (3)
10.9	Sub-License Agreement, effective as of December 31, 2002, by and between the Company and Pharmaceutical Product Development, Inc. (6)+
10.10	Amended and Restated 2001 Incentive Plan (7)
10.11	License Agreement, dated effective April 12, 2004, between the Company and Accentia, Inc. (8)
10.12	Amendment to License Agreement, dated effective June 1, 2004, between the Company and Accentia, Inc. (8)
10.13	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (10)
10.14	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (10)
10.15	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (10)

85

Table of Contents

10.16	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (10)
10.17	Common Stock Purchase Agreement, dated January 20, 2005, between the Company and Sigma Tau Finanziaria S.p.A. (12)+
10.18	Licensing Agreement, dated January 20, 2005, between the Company and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (12)+
10.19	Letter Amendment to License Agreement, dated March 28, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (13)
10.20	Letter Amendment to License Agreement, dated April 25, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (13)
10.21	Registration Rights Agreement, dated May 31, 2005, by and between the Company and Laurus Master Fund, Ltd. (14)
10.22	Letter Amendment to License Agreement, dated June 6, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (15)
10.23	Clinical Development and License Agreement, dated as of July 14, 2005, among Clinical Development Capital LLC, the Company and Arius Pharmaceuticals, Inc. (16)+
10.24	Supply Agreement, dated October 17, 2005, by and between Aveva Drug Delivery Systems, Inc., Arius Pharmaceuticals, Inc. and the Company (18)
10.25	Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC IV, LLC (19)
10.26	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 (19)
10.27	Amended and Restated Registration Rights Agreement, dated as of May 16, 2006, by and between the Company and CDC IV, LLC (19)
10.28	Amendment No. 1 to Amended and Restated 2001 Incentive Plan (20)
10.29	Registration Rights Agreement, dated July 31, 2006, between the Company and Laurus Master Fund, Ltd. (21)
10.30	Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT USA, Inc. and Arius Two, Inc. (22)+
10.31	Secured Promissory Note dated August 2, 2006, by Arius Two, Inc. in favor of QLT USA, Inc. (22)+
10.32	Security Agreement, dated August 2, 2006, between Arius Two, Inc. and QLT USA, Inc. (22)
10.33	Patent and Trademark Security Agreement, dated August 2, 2006, between Arius Two, Inc. and QLT USA, Inc. (22)
10.34	Guaranty, dated August 2, 2006, by the Company in favor of QLT USA, Inc. (22)
10.35	Assignment of Patents and Trademarks, dated August 2, 2006, by QLT USA, Inc. in favor of Arius Two, Inc. (22)
10.36	BEMA Acquisition Consent, Amendment, and Waiver, dated August 2, 2006, by and between Arius Pharmaceuticals, Inc., Arius Two, Inc. and CDC IV, LLC. (22)
10.37	Letter agreement, dated August 2, 2006 between the Company, Arius Pharmaceuticals, Inc. and Arius Two, Inc. (22)
10.38	Consent and Waiver Agreement, dated August 2, 2006, by and among Laurus Master Fund, the Company, Arius Pharmaceuticals, Inc. and Arius Two, Inc. (22)
10.39	Second Amendment Agreement, dated August 2, 2006, between QLT USA, Inc. and Arius Pharmaceuticals, Inc. (22)+
10.40	BEMA License Agreement, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (22)+
10.41	First Amendment Agreement, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (22)+

Table of Contents

10.42	License and Development Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (22)+
10.43	BEMA Fentanyl Supply Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (22)+
10.44	Sublicensing Consent, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (22)+
10.45	Sublicensing Consent and Amendment, dated August 2, 2006, by the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC (22)+
10.46	Letter agreement, dated August 2, 2006, between Meda AB, Arius Pharmaceuticals, Inc, Arius Two, Inc. and the Company (22)
10.47	Notice of Breach and Demand for Dispute Resolution, sent August 30, 2006, from the Company to CDC IV, LLC (23)
10.48	Notice of Breach and Termination, received August 30, 2006, from CDC IV, LLC to the Company (24)
10.49	Amended and Restated Registration Rights Agreement, dated December 28, 2006, between the Company and Laurus Master Fund, Ltd. (25)
10.50	Process Development Agreement, effective December 15, 2006, between LTS Lohmann Therapie-Systeme AG and the Company (28)+
10.51	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Mark A. Sirgo (26)
10.52	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Andrew L. Finn (26)
10.53	Employment Agreement, dated February 22, 2007, between the Company and James A. McNulty (26)
10.54	Dispute Resolution Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (27)
10.55	Amendment to Clinical Development and License Agreement, dated March 9, 2007, between the Company and CDC IV, LLC (27)
10.56	Promissory Note, dated March 12, 2007, by the Company in favor of CDC IV, LLC (27)
10.57	Registration Rights Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (27)
10.58	Subscription Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (27)
10.59	Cooperative Research and Development Agreement, dated June 7, 2006 between the Company and Walter Reed Army Institute of Research (28)
10.60	Second Amended and Restated Registration Rights Agreement, dated April 10, 2007, between the Company and Laurus Master Fund, Ltd. (34)
10.61	Registration Rights Agreement, dated September 5, 2007, by and among the Company and HCG II (28)
10.62	License and Development Agreement, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc. and Meda AB (29)+
10.63	BEMA Fentanyl Supply Agreement, dated September 5, 2007, between the Company and Meda AB (29)+
10.64	Sublicensing Consent dated September 5, 2007, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (29)+
10.65	License Agreement dated, September 5, 2007, by and between Arius Two, Inc., and Arius Pharmaceuticals, Inc. (29)+

Table of Contents

10.66	Intellectual Property Assignment Agreement dated, September 5, 2007 by and between QLT USA, Inc. and Arius Two. (29)+
10.67	Amended and Restated Patent and Trademark Agreement, dated as of September 5, 2007, by and between Arius Two, Inc., and QLT USA, Inc. (29)
10.68	Amended and Restated Patent and Trademark Security Agreement, dated as of September 5, 2007, made between Arius Two, Inc., and QLT USA, Inc. (29)
10.69	Assignment of Patent and Trademarks, dated September 5, 2007. (29)
10.70	Patent and Trademark Security Agreement, dated as of September 5, 2007, between Arius Two, Inc., and QLT USA, Inc. (29)
10.71	Security Agreement, dated as of September 5, 2007, between Arius Two, Inc., and QLT USA, Inc. (29)
10.72	Second Amendment Agreement dated September 5, 2007, by Arius Two, Inc. and Arius Pharmaceuticals, Inc. (29)
10.73	Secured Promissory Note, dated September 5, 2007, between Arius Two, Inc. and QLT USA, Inc. (29)+
10.74	Guaranty, dated as of September 5, 2007, made between BioDelivery Sciences International, Inc. and in favor of QLT USA, Inc. (29)
10.75	Bema Acquisition Consent, amendment and waiver, dated September 5, 2007, between the Company and CDC IV, LLC (29)
10.76	Sublicensing Consent and Amendment, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc., CDC IV, LLC and Meda AB. (29)+
10.77	Royalty Purchase and Amendment Agreement, dated as of September 5, 2007 between BioDelivery Sciences International, Inc., and CDC IV, LLC (29)+
10.78	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. (29)+
10.79	Dispute Resolution Agreement, dated September 5, 2007 by and between the Company and CDC IV, LLC (29)
10.80	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 (29)
10.81	Side Letter Agreement, dated September 5, 2007, between CDC IV, LLC and QLT USA, Inc. (29)
10.82	Side Letter Agreement, dated September 5, 2007, between CDC IV, LLC, the Company, Arius Pharmaceuticals, Inc., and Arius Two, Inc. (29)
10.83	Side Letter Agreement, dated September 5, 2007, between MEDA AB and QLT USA, Inc. (29)
10.84	Allonge, effective date, September 5, 2007, between the Company and CDC IV, LLC (29)
10.85	Promissory Note, dated September 11, 2007, by the Company in favor of Meda AB (30)
10.86	Letter Amendment, effective January 2, 2009, between the Company, Arius Pharmaceuticals, Inc. and Meda AB relating to European commercialization rights for ONSOLIS® (32)+
10.87	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® (32)+
10.88	Amendment Consent (EU), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (32)
10.89	Amendment Consent (NA), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (32)

Table of Contents

10.90	Research Collaboration and License Agreement, dated January 20, 2009, between the Company and The Drugs for Neglected Diseases Initiative (33)+
10.91	Process Development Agreement, dated February 8, 2008, between the Company and LTS (35)+
10.92	Amendment to Amended and Restated 2001 Incentive Plan of the Company, dated November 19, 2008 (35)
10.93	Termination Letter Agreement, dated December 17, 2008, between Arius Pharmaceuticals, Inc. and Reckitt Benckiser Healthcare (UK) Limited (35)
10.95	Separation Agreement and General Claims release, effective September 1, 2009, between the Company and Dr. Raphael J. Mannino (36)
10.96	Emezine Settlement Agreement, dated December 30, 2009, between the Company, Accentia, Arius Pharmaceuticals, Inc. and TEAMM (37)
10.97	Form of Warrant for the Company to purchase 2,000,000 shares of Biovest International, Inc. from Accentia (37)
10.98	Escrow Agreement, dated December 30, 2009, the Company, Accentia, Arius, TEAMM and American Stock Transfer & Trust Company, LLC, as escrow agent (37)
21.1	Subsidiaries of the Registrant *
23.1	Consent of Cherry, Bekaert & Holland, L.L.P.*
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.*#

* 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 10-QSB, August 20, 2001.
(2) Previously filed with Form 10-KSB, August 15, 2001.
(3) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(4) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.
(5) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.
(6) Previously filed with Form 8-K, January 7, 2003.
(7) Previously filed with Form 10-QSB/A, September 2, 2003.
(8) Previously filed with Form 8-K, June 4, 2004.
(9) Previously filed with Form 8-K, August 12, 2004.
(10) Previously filed with Form 8-K, August 26, 2004.
(11) Previously filed with Form 8-K, September 8, 2004.
(12) Previously filed with Form 8-K, January 24, 2005.
(13) Previously filed with Form 10-KSB/A, April 29, 2005.
(14) Previously filed with Form 8-K, June 3, 2005.
(15) Previously filed with Form 10-KSB/A, June 10, 2005.

Table of Contents

(16) Previously filed with Form 8-K, July 21, 2005.
(17) Previously filed with Form 8-K, August 24, 2005.
(18) Previously filed with Form 10-QSB, November 10, 2005.
(19) Previously filed with Form 8-K, May 22, 2006.
(20) Previously filed as Annex A to Schedule 14A, June 27, 2006.
(21) Previously filed with Form 8-K, August 4, 2006.
(22) Previously filed with Form 8-K, August 9, 2006.
(23) Previously filed with Form 8-K, August 31, 2006.
(24) Previously filed with Form 8-K, August 31, 2006.
(25) Previously filed with Form 8-K, December 28, 2006.
(26) Previously filed with Form 8-K, February 22, 2007.
(27) Previously filed with Form 8-K, March 16, 2007.
(28) Previously filed with Form 10-K, March 7, 2008.
(29) Previously filed with Form 8-K, September 10, 2007.
(30) Previously filed with Form 8-K, September 12, 2007.
(31) Previously filed with Form 8-K, July 28, 2008.
(32) Previously filed with Form 8-K, January 6, 2009.
(33) Previously filed with Form 8-K, January 23, 2009.
(34) Previously filed with Form 8-K, February 13, 2009.
(35) Previously filed with Form 10-K, March 20, 2009.
(36) Previously filed with Form 10-Q, November 3, 2009.
(37) Previously filed with Form 8-K, December 31, 2009.

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 as of December 31, 2009 and 2008, and the related consolidated statements of operations and stockholders equity (deficit) and cash flows for each of the years in the two-year period ended December 31, 2009. We also have audited the Company s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management s Report on Internal Control over Financial Reporting included in Item 9A Controls and Procedures in the Company s 2009 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. as of December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the years in the two year period ended December 31, 2009 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, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Table of Contents

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, during 2009, the Company recognized net income of approximately $33 million, principally due to the recognition of approximately $58 million of previously deferred revenue. Further, the Company had a net loss of approximately $17.2 million in 2008 and at December 31, 2009 had incurred cumulative net losses of approximately $59.2 million. These conditions raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are described in Note 2. The consolidated financial statements do not include any adjustments with respect to the possibly future effects of recoverability and classification of assets nor the amounts and classification of liabilities that might arise from the outcome of this uncertainty.

/s/ Cherry, Bekaert & Holland, L.L.P.

Tampa, Florida

March 17, 2010

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2009 AND 2008

	2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,873,403	$ 905,720
Accounts receivable	1,268,712	468,987
Prepaid expenses and other current assets	287,978	184,007
Total current assets	25,430,093	1,558,714
Equipment, net	3,743,011	126,734
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	542,171	542,171
Acquired product rights	8,900,000	6,900,000
Accumulated amortization	(2,312,964)	(1,615,263)
Total other intangible assets	7,129,207	5,826,908
Due from related party, warrant receivable	638,600	
Deposits on equipment		2,954,460
Other assets	21,976	11,571
Restricted cash		144,000
Total assets	$ 39,677,887	$ 13,337,387
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Notes payable	$	$ 76,666
Accounts payable and accrued liabilities, other	3,172,406	2,684,015
Accounts payable and accrued liabilities, related party	2,723,844	260,614
Clinical trial payables and accrued liabilities, other	674,343	857,996
Income taxes payable	312,128	
Deferred revenue, current	11,758,732	36,060,500
Derivative liabilities (note 8)	4,978,256	5,350,829
Total current liabilities	23,619,709	45,290,620
Deferred revenue, long-term	1,599,879	1,628,539
Total liabilities	25,219,588	46,919,159
Commitments and contingencies (Notes 6, 7 and 12)		
Stockholders equity (deficit):		
Common Stock, $.001 par value; 45,000,000 shares authorized, 21,181,854 and 19,179,029 shares issued; 21,166,363 and 19,163,538 shares outstanding in 2009 and 2008, respectively	21,182	19,179

Additional paid-in capital	73,697,818	58,706,499
Treasury stock, at cost, 15,491 shares, 2009 and 2008	(47,183)	(47,183)
Accumulated deficit	(59,213,518)	(92,260,267)
Total stockholders equity (deficit)	14,458,299	(33,581,772)
Total liabilities and stockholders equity (deficit)	$ 39,677,887	$ 13,337,387

See notes to consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2009 AND 2008

	2009	2008
Revenues:		
Royalty revenue, related party	$ 15,411	$ 50,821
Royalty revenue, other	2,844,415	
Sponsored research	50,000	
Research fees	177,373	212,359
Contract revenue	59,727,633	
Total revenues	62,814,832	263,180
Cost of royalty revenue, other	2,043,693	
Expenses:		
Research and development	10,177,644	10,282,244
Related party research and development	143,065	641,511
General and administrative	8,399,812	7,242,191
Related party general and administrative	1,921,400	61,400
Total expenses	20,641,921	18,227,346
Income (loss) from operations	40,129,218	(17,964,166)
Interest income (expense), net	35,596	(461,577)
Derivative (loss) gain	(6,790,827)	1,192,742
Other expenses, net	(15,110)	
	(6,770,341)	731,165
Income (loss) before taxes	33,358,877	(17,233,001)
Income tax expense	(312,128)	
Net Income (loss)	$ 33,046,749	($ 17,233,001)
Net income (loss) attributable to common stockholders	$ 33,046,749	($ 17,233,001)
Basic:		
Weighted average common stock shares outstanding	20,224,706	19,202,029
Basic earnings per share	$ 1.63	($ 0.90)
Diluted:		
Diluted weighted average common stock shares outstanding	21,499,083	19,202,029

Diluted earnings per share	$	1.54	($	0.90)

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, 2009 AND 2008

	Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders (Deficit)
	Shares	Amount	Capital	Stock	Deficit	Equity
Balances, January 1, 2008	19,101,037	$ 19,101	$ 56,267,563	($ 47,183)	($ 75,027,266)	($ 18,787,785)
Stock-based compensation			2,330,951			2,330,951
Stock option exercises	65,000	65	107,985			108,050
Warrant exercises for cash	12,992	13				13
Net loss					(17,233,001)	(17,233,001)
Balances, December 31, 2008	19,179,029	19,179	58,706,499	(47,183)	(92,260,267)	(33,581,772)
Stock-based compensation			2,003,031			2,003,031
Stock option exercises	265,551	266	663,105			663,371
Warrant issuance			55,452			55,452
Warrants exercised for cash	1,737,274	1,737	5,106,332			5,108,069
Reclassification of derivative liability to equity			7,163,399			7,163,399
Net income					33,046,749	33,046,749
Balances, December 31, 2009	21,181,854	$ 21,182	$ 73,697,818	($ 47,183)	($ 59,213,518)	$ 14,458,299

See notes to consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2009 AND 2008

	2009	2008
Operating activities:		
Net income (loss)	$ 33,046,749	($ 17,233,001)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:		
Depreciation	176,405	124,727
Amortization of intangible assets	697,701	641,055
Derivative (loss) gain	6,790,827	(1,192,742)
Accretion of debt discount		603,836
Stock-based compensation expense	2,003,031	2,330,951
Warrant issuance expense	55,452	
Loss on disposal of Equipment	2,401	
Changes in assets and liabilities:		
Accounts receivable	(809,724)	(163,490)
Prepaid expenses and other assets	29,328	172,446
Accounts payable and accrued liabilities	216,162	(136,184)
Income taxes payable	312,128	
Deferred revenue	(24,330,426)	5,036,463
Net cash flows from operating activities	18,190,034	(9,815,939)
Investing activities:		
Purchase of equipment	(749,983)	(28,364)
Purchase of investments		(375,044)
Sale of investments		375,044
Proceeds from (purchase of) certificate of deposit		2,800,000
Deposits on equipment		(2,041,162)
Purchase of intangible assets	(2,000,000)	
Net cash flows from investing activities	(2,749,983)	730,474
Financing activities:		
Proceeds from exercise of stock options	663,371	108,050
Payment on notes payable, related parties		(1,900,000)
Payment on notes payable, other	(76,665)	(205,831)
Proceeds from exercise of common stock warrants	5,108,069	13
(Repayment of) proceeds from related party advances, net	1,832,857	(1,808,140)
Net cash flows from financing activities	7,527,632	(3,805,908)
Net change in cash and cash equivalents	22,967,683	(12,891,373)
Cash and cash equivalents at beginning of year	905,720	13,797,093
Cash and cash equivalents at end of year	$ 23,873,403	$ 905,720

See notes to consolidated financial statements

Table of Contents

SUPPLEMENTAL CASH FLOW INFORMATION

Non-cash Financing and Investing activities

The Company reclassified deposits on equipment totaling $3,747,095 to Equipment due to the completion of the equipment and being placed in production during the twelve months ended December 31, 2009.

The Company financed an insurance policy through the issuance of a note payable in the amount of $191,664 during the twelve months ended December 31, 2008.

The Company reclassified derivative liabilities of $7,163,399 to equity during the twelve months ended December 31, 2009 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, 2009 AND 2008

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 are collectively referred herein to as the Company. The Company is a specialty pharmaceutical company that is leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. The 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. The Company s drug delivery technologies include: (i) the patented BioErodible MucoAdhesive (BEMA®) technology drug delivery technology and (ii) the patented Bioral® cochleate drug delivery technology, designed for the potential oral delivery of a broad base of products otherwise administered intravenously. 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 and its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. (Arius One) and Arius Two, Inc. (Arius Two) and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND). BND is currently 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 places its cash and cash equivalents with financial institutions in the United States. In October and November 2008 the Federal Deposit Insurance Corporation (FDIC) temporarily increased coverage to $250,000 for substantially all depository accounts and temporarily provides unlimited coverage (through June 30, 2010) for certain qualifying and participating non-interest bearing transaction accounts. The increased coverage for depository accounts is scheduled to expire on December 31, 2013, at which time it is anticipated that amounts insured by the FDIC will return to $100,000. As of year end the Company had approximately $22.5 million that exceeds current FDIC insured limits.

Revenue recognition:

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 lead product, ONSOLIS® (formerly known as BEMA® Fentanyl), 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 recognizes revenue associated with the Meda Agreements in accordance with Generally Accepted Accounting Principles in the United States (GAAP) related to revenue

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. Basis of presentation (continued):

Significant accounting policies (continued):

Revenue recognition (continued):

Meda License, Development and Supply Agreement (continued):

arrangements with multiple deliverables. 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 7.

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 U.S. FDA and other governmental approval. A portion of the upfront payments will be 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.

Reimbursement of direct out-of-pocket costs:

The Company pays fees to regulatory agencies and other out-of-pocket costs for which it is reimbursed at cost, without mark-up or profit. The gross amount of these reimbursed research and development costs are reported in accordance with GAAP as research and development services revenue in the consolidated statements of operations. Criteria for qualifying as such are transactions where 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. The actual expenses creating the reimbursements are reflected as research and development expense.

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 pursuant to the Meda Agreements.

Royalty Revenue, Other

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. 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.

Cost of Royalty Revenues, Other

The cost of royalty revenue, other, includes the direct costs attributable to the production of the Company s product. It includes all costs related to creating the products at the Company s contract manufacturer, which can include stability costs directly related to the product sold. Only costs that are tied to the production of the products are considered cost of royalty revenue. The Company s contract manufacturer, Aveva, bills the Company for the material cost used in creating the product along with

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. Basis of presentation (continued):

Significant Accounting Policies (continued):

Certain Risks, Concentrations and Uncertainties:

direct labor costs, and certain overhead costs as outlined in the supply agreement. Cost of royalty revenues, other also includes royalty expenses owed to third parties. These royalty expenses are directly related to the products sold during the period.

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 Meda accounted for 100% of the Company s accounts receivable at December 31, 2009 and 2008. Deferred revenue balances relate to the Meda Agreements as of December 31, 2009 and 2008. The Company depends significantly upon the collaboration with Meda, and its activities may be impacted if this relationship is disrupted.

Key components used in the manufacture of ONSOLIS® are currently provided by sole or a limited numbers of suppliers. This limitation 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.

Equipment and deposits:

Office and Manufacturing equipment are carried at cost less accumulated depreciation, which is computed on a straight-line basis over their estimated useful lives, generally 5 years. Accelerated depreciation methods are utilized for income tax purposes.

The Company periodically reviews intangible assets with finite lives 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 were no impairment charges recognized on finite lived intangibles in 2009 or 2008.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. Basis of presentation (continued):

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

	Estimated Useful Lives
Licenses	14 years
U.S. Product right	10-12 years
EU Product rights	11 years

The Company incurred amortization expense on other intangible assets of approximately $.7 million and $.6 million for the years ended December 31, 2009 and 2008, 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,	
2010	$ 797,447
2011	797,447
2012	797.447
2013	797,447
2014	797,447
Thereafter	3,141,972
	$ 7,129,207

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. The 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 values) 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 2009 or 2008.

Use of estimates in financial statements:

The preparation of the accompanying consolidated financial statements conforms with GAAP and 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 Income (loss) 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, 2009 and 2008.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. Basis of presentation (continued):

	December 31, 2009	2008
Basic:		
Net income (loss) attributable to common stockholders	33,046,749	(17,233,001)
Weighted average common shares outstanding	20,224,706	19,202,029
Basic earnings per common share	1.63	(0.90)
Diluted:		
Weighted average common shares outstanding	20,224,706	19,202,029
Effect of dilutive securities:		
Stock options and warrants	1,274,377	
Diluted weighted average common shares outstanding	21,499,083	19,202,029
Diluted earnings per common share	1.54	(0.90)

Basic earnings per common share is calculated using the weighted average common shares 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 their effect of inclusion would be antidilutive. During the years ended December 31, 2009 and 2008, 4,084,789 and 9,352,232 outstanding stock options and warrants, 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.

The following is the total outstanding options and warrants for the years ended December 31, 2009 and 2008, respectively.

	2009	2008
Options and warrants to purchase Common Stock	7,548,624	9,352,232

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 award 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 volatilities are based on historical volatility of the Company s stock and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

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

	2009	2008
Expected price volatility	57.88%-90.24%	54.41-87.13%
Risk-free interest rate	.51%-2.71%	2.67%-3.88%
Weighted average expected life in years	5-6 years	5-6 years
Dividend yield	0	0

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. Basis of presentation (continued):

Fair Value of Financial Assets and Liabilities

The Company measures the fair value of financial assets and liabilities in accordance with GAAP which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

Effective January 1, 2008, the Company adopted provisions in accordance with GAAP related to financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis. The adoption of the provisions did not materially impact the Company s consolidated financial position and results of operations.

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)

The following table summarizes assets and liabilities measured at fair value on a recurring basis at December 31, 2009 and December 31, 2008, respectively:

	2009				2008			
Fair Value Measurements Using:	**Level 1**	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets								
Due from related party (warrant receivable)	$	$ 638,600	$	$ 638,600	$	$	$	$
Liabilities								
Derivative liabilities	$	$ 4,978,256	$	$ 4,978,256	$	$ 5,350,829	$	$ 5,350,829

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 financials.

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,

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. Basis of presentation (continued):

estimated terms and risk free rates) necessary to fair 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:

The Financial Accounting Standards Board (FASB) issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (SFAS No. 168), on June 29, 2009 and, in doing so, authorized the Codification as the sole source for authoritative U.S. GAAP. SFAS No. 168 was effective for financial statements issued for reporting periods that ended after September 15, 2009. Upon effectiveness, it superseded all prior accounting standards in U.S. GAAP, aside from those issued by the SEC.

In June 2009, the FASB issued Accounting Standards Update No. 2009-01 (ASU 2009-01), which establishes the FASB Accounting Standards Codification as the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The Company adopted ASU 2009-01 during the three months ended September 30, 2009 and its adoption did not have any impact on the Company s consolidated financial statements.

In August 2009, the FASB issued Accounting Standards Update No. 2009-05 (ASU 2009-05), which clarified how to measure the fair value of liabilities in circumstances when a quoted price in an active market for the identical liability is not available. ASU 2009-05 is effective for the first reporting period beginning after the issuance of this standard. The Company has adopted ASU 2009-05 during the three months ended December 31, 2009 and determined there to be no impact on its consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update No. 2009-13 (ASU 2009-13), which

addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified beginning in fiscal years on or after June 15, 2010. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements, if any.

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 agreements with MEDA regarding ONSOLIS®. 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 financing, 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 (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

2. Liquidity and management s plans (continued):

Significant financing and revenue in 2009 consisted of:

- $26.8 million payment received in July 2009 for the approval milestone for ONSOLIS®, related to agreements between the Company, Arius One and Meda.
- $6.0 million payment received in January 2009 which included a $3.0 million advance against the $15 million approval milestone for ONSOLIS® and $3.0 million related to amendments to the material agreements between the Company, Arius One and Meda for the expansion of the territory covered by the Company s European agreement with Meda.
- Approximately $5.1 million from the exercise of warrants and approximately $0.7 million from the exercise of Common Stock options; and
- Approximately $2.8 million received in royalty revenues during 2009 related to ONSOLIS® sales in the U.S.
- $1.3 million grant received in October 2009 from the Walter Reed Army Institute of Research.

Significant financing in 2008 consisted of:

- Approximately $0.11 million from the exercise of Common Stock options; and
- $2.5 million non-refundable milestone payment received in March 2008, under the European agreements with Meda relating to the licensing rights for the ONSOLIS® product in Europe (see Note 7).

Company management believes that the Company s existing cash and cash equivalents are sufficient to finance planned basic operations (minimal research and development activities beyond those covered under the Company s Meda and related agreements) through the first quarter of 2011.

In addition, in January 2009, the Company completed a universal shelf registration for up to $50 million of the Company s securities which can potentially be drawn over a three year period based on certain terms and conditions to be determined at the time the Company decides if and when to utilize the shelf registration.

The Company believes that it will be able to secure outside funding or loans at levels sufficient to support planned operations. However, there can be no assurance that additional capital or loans will be available on favorable terms, if at all. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned operations or to obtain funds through arrangements that may

require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company s financial condition and viability.

The recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues, fluctuates or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when the Company requires additional financial investment. If the Company is unable to attract additional funds it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on the Company s business, results of operations, financial condition and stock price.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

3. Research and development arrangements and related party transactions:

The Company had a collaborative research agreement with the University of Medicine and Dentistry of New Jersey (UMDNJ), an entity that is also a Company stockholder, under which the Company paid salary for a UMDNJ employee, laboratory supplies and employee parking costs. The agreement expired at the end of 2005. The Company also leased its Newark, New Jersey facility from UMDNJ under an operating lease agreement which expired on December 31, 2005 and was converted to a month-to-month lease. In September 2009, the Company shutdown, vacated and eliminated all activities performed at the Newark facility. The Company incurred approximately $0.1 million of research expense in connection with this agreement in each of the years ended December 31, 2009 and 2008. Amounts due to UMDNJ at December 31, 2008 were approximately $0.1 million. There are zero amounts due to UMDNJ at December 31, 2009. The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia Biopharmaceuticals, Inc., a related party (Accentia), and shares two employees, with personnel costs paid based on the approximate time spent on Company activities. Rent payments to Accentia were $0.06 million for years 2009 and 2008, respectively, and are included in general and administrative costs, related party. There were no rent amounts due to Accentia at December 31, 2009 and 2008.

On December 30, 2009, the Company entered into an Emezine Settlement Agreement (the Settlement Agreement) with Accentia, Arius One and Accentia Pharmaceuticals, Inc. f/k/a TEAMM Pharmaceuticals Inc., a subsidiary of Accentia (TEAMM) The purpose of such agreement was to memorialize the terms and conditions of a settlement between the Company and Accentia of claims by TEAMM relating to the Distribution Agreement between Arius One and TEAMM. At the time the Distribution Agreement was entered into, Arius One was not affiliated with the Company. Arius One was acquired by the Company in August 2004. The Company did not believe that Accentia s claims had merit, but the Company also believed that the alternative of a protracted dispute would be distracting, time consuming and costly.

The Settlement Agreement provides that the Company and Accentia mutually release all claims that either may have against each other and, in connection therewith, the Company will (a) pay $2.5 million to Accentia (paid to escrow in February 2010) and (b) grant the following royalty rights (the Product Rights) to Accentia with respect to the Company s BEMA® Granisetron product candidate (BEMA® Granisetron) (or in the event it is not BEMA® Granisetron, the third Company product candidate (excluding BEMA® Buprenorphine) as to which the Company files an NDA, which, together with BEMA Granisetron, shall be referred to hereinafter as the Product): (i) 70/30 split (Company/Accentia) of royalty received if a third party sells the Product and 85/15 split on net sales if the Company sells the Product; and (ii) the Company will, from the sale of the Product, fully recover amounts equal to (1) all internal and external worldwide development costs of the Product (Costs) plus interest (measured on weighted average prime interest rate from first dollar spent until Product launch) and (2) the $2.5 Million Payment plus interest (measured on weighted average prime interest rate from the time of payment until Product launch) before Accentia begins to receive its split as described in (b) (i) above.

In addition, pursuant to the Settlement Agreement, the Company has received a warrant to purchase 2 million shares of Accentia s majority-owned subsidiary, Biovest, from Accentia, with a strike price equal to 120% of the closing bid price of Biovest s common stock as of the date the Bankruptcy Court enters a final order authorizing Accentia to carry out the Settlement Agreement, with the issuance of the Warrant to occur upon the $2.5 Million Payment by the Company. The Warrant will be exercisable immediately and for a period of seven 7 years from the date of issuance. During the initial two 2 year exercise period, any exercise of the Warrant by the Company will be subject to approval by Biovest.

The $1.9 million settlement ($2.5 million less the $0.6 million value of the warrant calculated using Black-Scholes) is shown as related party, general and administrative, in the accompanying consolidated statements of operations.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

4. Equipment:

Equipment consists of the following:

	December 31, 2009	2008
Office, laboratory and manufacturing equipment	$ 5,014,433	$ 2,039,838
Less accumulated depreciation	(1,271,422)	(1,913,104)
	$ 3,743,011	$ 126,734

Depreciation expense for years ended December 31, 2009 and 2008 was approximately $176,000 and $125,000, respectively.

5. Notes payable:

There were zero notes payable at December 31, 2009. Notes payable at December 31, 2008, consisted of insurance premium financing. The short-term financing from First Insurance Funding Corp., at 5.95% per annum was payable monthly through April, 2009.

6. Meda License, Development and Supply Agreements:

In August 2006 and September 2007, the Company entered into the Meda Agreements with Meda to develop and commercialize the ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered through a patented transmucosal drug delivery technology, BEMA® (applied to the inner cheek mucosa) in the United States, Mexico and Canada (such agreements, the Meda U.S. Agreements) and in certain countries in Europe (such agreements, the Meda EU Agreements). These arrangements have 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 January 2017.

The Company s rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

Contractual Rights and Obligations	Milestone Payments	Notes	Cash flows received and revenue deferred December 31, 2009	December 31, 2008
North America				
License rights to ONSOLIS® (BEMA® Fentanyl) patents and trademarks				
	$ 30,000,000		$ 30,000,000	$ 30,000,000
Milestones:				
FDA approval	$ 15,000,000	less a $200,000 discount	$ 14,800,000	
Earlier of date of first commercial sale or availability of launch supply product	$ 15,000,000		$ 15,000,000	
Research and Development Services for:				
Non-Cancer subsequent indication of product and further development of initial product		Contract Hourly Rates	$ 1,541,570	$ 1,135,412

Total North America Agreement Milestones	$ 60,000,000		$ 61,341,570	$ 31,135,412
Europe and Rest of World				
License rights to BREAKYL (BEMA® Fentanyl) patents and trademarks	$ 5,500,000		$ 5,500,000	$ 2,500,000
Milestones:				
Completion of Phase 3 clinical trials	$ 2,500,000		$ 2,500,000	$ 2,500,000
Governmental Approval in an EU country	$ 2,500,000			
Date of first sale in an EU country	$ 2,500,000			
Research and Development Services for:				
BREAKYL product through governmental approval in a EU country		Contract Hourly Rates	$ 3,744,674	$ 1,553,627

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

6. Meda License, Development and Supply Arrangements (continued):

Contractual Rights and Obligations	Milestone Payments	Notes	Cash flows received and revenue deferred December 31, 2009	Cash flows received and revenue deferred December 31, 2008
Total Europe and Rest of World Milestones	$ 13,000,000		$ 11,744,674	$ 6,553,627
Total All Milestones	**$ 73,000,000**		**$ 73,086,244**	**$ 37,689,039**
Release of Milestones upon first sale			$ (59,727,633)	$
Remaining Deferred Revenue			$ 13,358,611	$ 37,689,039

The Company has, in accordance with GAAP, assessed these arrangements and their deliverables to determine if such deliverables are considered separate units of accounting at the inception or upon delivery of the items required in the arrangements. The assessment requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable and, if so, to determine the fair value to be allocated to each unit of accounting.

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 standalone value apart from the license. As such, all cash payments from Meda that were related to these deliverables 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 deliverables associated with research and development services will be 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 were recognized. Upon first commercial sale in a European country, an estimated $17.4 million will be recognized, which includes an additional $5.0 million in milestones and approximately $0.7 million in research and development services.

In connection with delivery of the license to Meda, the Company has 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. Further, the Company obtained third-party evidence of fair value for the non-cancer and 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 also obtained third-party evidence of fair value of the product supply deliverable based on the outsourced

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

6. Meda License, Development and Supply Arrangements (continued):

contract manufacturing cost charged 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 will be accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication of 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 $1.6 million (under the Meda U.S. Agreements) and $0.2 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.

In accordance with GAAP, 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.

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. 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. The Company has earned royalty revenue of approximately $2.8 million for the year ended December 31, 2009. The Company has incurred cost of royalty revenue, other of approximately $2.0 million related to this royalty revenue.

7. Acquired product rights and license agreements:

On August 2, 2006, Arius Two, a newly formed, wholly-owned subsidiary of the Company, entered into an Intellectual Property Assignment Agreement and related agreements with QLT U.S.A, Inc. (QLT) pursuant to which Arius Two purchased intellectual property rights owned by QLT related to its BEMA® technology for territories located outside of the United States. The Company, through its Arius One subsidiary, previously licensed exclusive rights to the BEMA® technology for such territories. Arius Two paid $3.0 million for the acquired intellectual property rights, consisting of $1.0 million in cash and a promissory note, secured by the purchased assets, for $2.0 million. Payments under such note are due as follows: (i) $1.0 million on March 31, 2007, (payment made on March 30, 2007) and (ii) $1.0 million within 10 business days of initial non-U.S. approval of any BEMA® product. Management deems the last $1.0 million payment a contingent liability and therefore will not record the $1.0 million as a liability or intangible asset until the conditions occur which would trigger the requirement to make this payment.

On September 5, 2007, the Company purchased from QLT the BEMA® drug delivery technology and intellectual property assets specifically related to the development and commercialization of the BEMA® technology in the United States (the BEMA® U.S. Rights) for a purchase price of $7.0 million, consisting of $3.0 million in cash and a $4.0 million promissory note, secured by the purchased assets. Payments under such note are due as follows: (i) $2.0 million within ten (10) business days of FDA approval of a product based on the BEMA® technology, (payment made July 31, 2009) and (ii) $2.0 million within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA®-based products reach $30.0 million.

Management deems the remaining $2 million balance a contingent liability and, therefore, will not record the $2 million (or parts thereof) as a liability or intangible asset until such time as the conditions which trigger the payment obligation have been satisfied. On the date of this transaction, the Company will assign the remaining license amounts to BEMA® to acquired product rights. The Company had previously licensed the BEMA® rights from QLT.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

8. Derivative Financial Instruments:

The following tabular presentation reflects the components of derivative financial instruments as of December 31,

	2009	2008
Free standing warrants	$ 4,978,256	$ 5,350,829

	2009	2008
Shares into which derivative liabilities can be settled:		
Free standing warrants	2,909,991	4,622,265

	2009	2008
Derivative (expense) income in the accompanying statements of operations is related to the individual derivatives as follows:		
Free standing derivatives (warrants)	(6,790,827)	1,192,742

9. Income taxes:

The Company had income tax expense in 2009 of $0.3 million. The Company did not record income tax expense in 2008 as the Company had incurred net operating losses. The Company has recognized valuation allowances for all deferred tax assets for years ending 2009 and 2008. The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	Year Ended December 31,	
	2009	2008
Federal statutory income tax rate	34.00%	34.00%
State taxes, net of federal benefit	3.45	3.45
Permanent differences	7.00	(2.52)
Research and development (R&D) credit	(3.32)	7.42
Other	(0.66)	(0.41)
Valuation allowance	(39.53)	(41.94)
	0.94%	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)	2009	2008
Deferred revenue	$ 3,061,084	$ 12,228,901
Basis difference in equipment	(831,921)	(26,423)
Basis difference in intangibles	(1,004,670)	(1,073,793)
Accrued liabilities and other	80,537	444,786
loss on extinguishment	3,080,454	3,080,454
R&D Credit	3,876,140	2,767,494
Stock options	1,165,932	653,633
Derivative	(765,928)	(1,390,767)
AMT credit	312,128	
Net operating loss carry-forward (NOL)	7,406,919	12,884,154
	16,380,675	29,568,439
Less: valuation allowance	(16,380,675)	(29,568,439)
	$	$

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

9. Income taxes (continued):

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 of approximately $20.3 million as of December 31, 2009. 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 net operating loss and other deductions which are available to the Company. Some of these losses may be subject to these limitations. The Company s State NOLS are approximately $14.3 million as of December 31, 2009.

10. Stockholders equity:

Preferred stock:

The Company has authorized five million shares of $.001 par value preferred stock. At January 1, 2009, 2,588,236 shares were designated as follows: Series A Preferred Stock of 1,647,059 shares and Series B preferred Stock of 341,176 shares. On February 11, 2009, the Board of Directors of the Company approved, by unanimous written consent to action, an amendment to the Company s Certificate of Incorporation (the Certificate of Incorporation) by way of a Certificate of Elimination for the Company s Series A Non-Voting Convertible Preferred Stock, Series B Convertible Preferred Stock, and Series C Non-Voting Convertible Preferred Stock (the Certificate of Elimination). On February 12, 2009, the Company filed the Certificate of Elimination with the Secretary of State of the State of Delaware, which is the effective date of the amendment. The Company may reissue up to 5 million shares of Preferred Stock.

Stock options:

The Company has an Amended and Restated 2001 Incentive Plan, which covers a total of 6,000,000 shares of Common Stock (as amended). Options may be awarded during the ten-year term of the 2001 stock incentive plan to Company employees, directors, consultants and other affiliates.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

10. Stockholders equity (continued):

Stock option activity for the years ended December 31, 2009 and 2008 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2008	2,695,904	$ 3.95	
Granted in 2008:			
Officers and Directors	509,195	2.23	
Others	473,366	2.40	
Exercised	(65,000)	1.66	
Forfeitures	(109,998)	3.34	
Outstanding at December 31, 2008	3,503,467	$ 3.56	$ 1,044,112
Granted in 2009:			
Officers and Directors	389,663	$ 4.85	
Others	187,995	3.41	
Exercised	(265,552)	2.50	
Forfeitures	(153,440)	3.20	
Outstanding at December 31, 2009	3,662,133	$ 3.78	$ 2,982,195

Options outstanding at December 31, 2009 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	2,720,888	7.18	$ 2.92	
$ 5.01 10.00	941,245	7.72	$ 6.27	
	3,662,133			$ 2,982,195

Options exercisable at December 31, 2009 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	1,916,474	6.55	$ 2.80	
$ 5.01 10.00	689,914	7.78	$ 6.22	
	2,606,388			$ 2,206,847

The weighted average grant date fair value of options granted during 2009 and 2008 whose exercise price was equal to the market price of the stock at the grant date was $4.24 and $2.31, respectively. The weighted average grant date fair value of options granted during 2009 whose exercise price was greater than the market price of the stock at the grant date is $4.83. There were no options granted during 2008 whose exercise price is greater than the market price of the stock at the grant date.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

10. Stockholders equity (continued):

Nonvested stock options as of December 31, 2009, 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, 2009	1,360,212		
Granted	577,658		
Vested	(781,049)		
Forfeited	(101,076)		
Nonvested at December 31, 2009	1,055,745	$ 3.96	$ 775,348

As of December 31, 2009, there was approximately $1.3 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next three 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, 2009 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	2,552,620	3.08	$ 3.29	
$5.01 10.00	1,333,871	3.64	$ 5.21	
	3,886,491			$ 1,628,287

Reclassification of derivative liability to equity:

During the year ended December 31, 2009, Laurus exercised warrants to purchase 1,712,274 shares of Common Stock for $.001 to $3.05 per share. At 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.

11. 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 $0.1 million in 2009 and 2008.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

12. Commitments and contingencies:

Employment agreements:

The Company has employment agreements with certain employees, which extend for 36 months. These agreements provide for base levels of compensation and separation benefits. Future minimum payments under these employment agreements as of December 31, 2009 are $0.9 million and $0.05 million for the years ended December 31, 2010 and 2011, respectively.

Operating leases:

Since April 2001, the Company leased a facility from UMDNJ (a stockholder), under an operating lease which expired on December 31, 2005. The Company has since vacated that space in September 2009.

Since November 2007, the Company also leases space for their corporate offices which expires in January 2013. Lease expense for both locations was approximately $0.2 million for years ended December 31, 2009 and 2008, respectively.

The future minimum commitment on the remaining operating lease at December 31, 2009 is as follows:

Years ending December 31,	
2010	$ 121,794
2011	125,318
2012	128,949
2013	11,004
	$ 387,065

Royalty commitment:

Upon its formation, the Company originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, the Company issued shares of Common Stock and agreed to make future royalty payments to the universities upon (a) the licensing of rights to sub-licensees (up to 5% of fees as amended on December 16, 2002); (b) sales by sub-licensees (25% of Company proceeds); or (c) Company sales (3% of revenue). Amounts due to these universities at December 31, 2009 and 2008 for royalties are both approximately $.06 million. Royalty expense was $0.0 million for each of the years ended December 31, 2009 and 2008.

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, 2009 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

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

12. Commitments and contingencies (continued):

development of the Company s ONSOLIS® product. Pursuant to the CDLA, in February 2006 the Company entered into a Security Agreement (the Security Agreement) under which it granted CDC a security interest in the Company s assets related to ONSOLIS®. The Security Agreement terminated at the time of FDA approval of ONSOLIS®. As such, until the July 2009 approval, CDC retained the right to reclaim the ONSOLIS® related assets in the event of a default by the Company under the CDLA.

In September 2007, in connection with CDC s consent to the 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

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 19, 2010

By: /s/ Mark A. Sirgo
Name: **Mark A. Sirgo**
Title: **President and Chief Executive Officer (Principal Executive Officer)**

By: /s/ James A. McNulty
Name: **James A. McNulty**
Title: **Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)**

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/s/ Francis E. O Donnell, Jr. **Francis E. O Donnell, Jr.**	Chairman of the Board and Director	March 19, 2010
/s/ Mark A. Sirgo **Mark A. Sirgo**	President, Chief Executive Officer and Director	March 19, 2010
/s/ William B. Stone **William B. Stone**	Lead Director	March 19, 2010
/s/ John J. Shea **John J. Shea**	Director	March 19, 2010
/s/ William S. Poole **William S. Poole**	Director	March 19, 2010