BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-K/A
November 19, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Amendment No. 1)

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 ¨

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.

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EXPLANATORY NOTE

BioDelivery Sciences International, Inc. (the **Company**) is filing this Amendment No. 1 (the **Amendment**) to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (the **Original 10-K**), which was originally filed with the Securities and Exchange Commission (the **SEC**) on March 19, 2010 (the **Original Filing Date**), in order to amend certain disclosures in the Original 10-K in response to written comments provided by the SEC.

Specifically, the Company is only amending the following portions of the Original 10-K: (i) Part I, Item 1 of the Original 10-K to add disclosure regarding the duration of its agreement with Aveva Drug Delivery Systems, Inc.; and (ii) Part II, Item 7 of the Original 10-K, under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations, to augment the Company s disclosure of its revenue recognition policies.

Except for the amendments described above, this Amendment does not modify or update other disclosures in, or exhibits to, the Original 10-K, and, accordingly, this Amendment should be read in conjunction with the Original 10-K.

Readers are cautioned that information contained in this Amendment is only current as of the Original Filing Date; therefore, to obtain more current information regarding the Company, readers are advised to review the Company s subsequent filings with the SEC.

As a result of the Amendment, the certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as filed as exhibits to the Original 10-K, have been re-executed and re-filed as of the date of this Amendment.

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BioDelivery Sciences International, Inc.

Annual Report on Form 10-K/A

(Amendment No. 1)

For the fiscal year ended December 31, 2009

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

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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.

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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 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.

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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;
- 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

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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;
- 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.

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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
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.

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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.

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.

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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;
- 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 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

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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® 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.

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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.

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

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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,
- 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.

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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®.

By its terms, our North American license agreement with Meda generally lasts for the duration of the subject patents and expires only on termination of the agreement. Either we or Meda may terminate the agreement for cause (including bankruptcy-like proceedings and uncured breaches of the agreement). We may terminate the agreement: (i) upon Meda s failure to pay the upfront license fee, (ii) on a country-by-country basis if Meda fails to cure a loss of a license to sell narcotics, (iii) upon Meda s uncured breach of our fentanyl supply agreement with Meda, (iv) upon Meda s uncured failure to pay certain sums to us under the agreement or such supply agreement, or (v) upon an material misrepresentation in any royalty statement the result of willful misconduct, gross negligence or bad faith. Meda may terminate the North American license agreement at any time after a specified notice to us.

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.

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.

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By its terms, our European license agreement with Meda generally lasts for the duration of the subject patents and expires only on termination of the agreement. Either we or Meda may terminate the agreement for cause (including bankruptcy-like proceedings and uncured breaches of the agreement). We may terminate the agreement: (i) upon Meda s failure to pay the upfront license fee, (ii) on a country-by-country basis if Meda fails to cure a loss of a license to sell narcotics, (iii) upon Meda s uncured breach of our fentanyl supply agreement with Meda, (iv) upon Meda s uncured failure to pay certain sums to us under the agreement or such supply agreement, or (v) upon an material misrepresentation in any royalty statement the result of willful misconduct, gross negligence or bad faith. Either we or Meda may terminate at any time after a specified notice to the other upon the occurrence of certain events, including expiration of patent rights.

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.

Our supply agreement with Aveva runs for a term of four years from the first commercial sale of ONSOLIS® and can be renewed for subsequent two year terms. Either we or Aveva can terminate the agreement on advanced written notice. Aveva may terminate the agreement on our bankruptcy or an uncured breach of the agreement by us, and we may terminate on the bankruptcy of Aveva, an uncured breach by Aveva or upon the occurrence of any failure by Aveva to properly supply stocks of ONSOLIS® on a timely basis under specified circumstances.

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.

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.

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The term of our February 2008 agreement with LTS lasts is until BEMA® Buprenorphine has been approved for sale. Either we or LTS may terminate the agreement upon any bankruptcy-like proceeding of the other, uncured breach of the agreement, for medical safety or irreconcilable differences between the management teams. LTS may terminate the agreement if we refuse to comply with LTS suggestions, advices and guidelines and therefore, in LTS judgment, the purpose of this agreement cannot be achieved and continuation is inappropriate, impractical or inadvisable (provided that the parties have first attempted to resolve the disagreement through good faith discussions). We may terminate the agreement, following a workout period, if we believe that the essential purpose of the agreement is unattainable.

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.

The term of our agreement with DNDi continues until the expiration of the last patent forming part of the intellectual property that is the subject of the agreement. DNDi may terminate the agreement on 30 days notice during the evaluation period for Bioral® Amphotericin B, and either we or DNDi may terminate after notice upon uncured breach.

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 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.

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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 mid-single digit royalty based on net sales of ONSOLIS® (including minimum royalties of $375,000 per quarter beginning in the second full year following commercial launch). 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.

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

During 2006 and 2007, we were a party to disputes with CDC. On September 5, 2007, in connection with CDC s consent to the Meda North American licensing transaction, we and CDC entered into a Dispute Resolution Agreement (DRA) pursuant to which we and CDC agreed to waive and dismiss with prejudice all current disputes between us and CDC. As a condition to CDC s entry into the DRA and its consent to the Meda North American licensing transaction, we and CDC entered into a Royalty Purchase and Amendment Agreement, dated September 5, 2007 (the RPAA) pursuant to which: (i) we granted CDC a right of first refusal on our financings, which replaced a right of first negotiation on financings previously held by CDC (the ROFR) and (ii) we granted CDC a 1% royalty on sales of the next BEMA® product, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval (the Next BEMA® Product).

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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.

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.

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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 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

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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 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

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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 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.

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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.

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.

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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.

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.

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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.

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.

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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.

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.

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.

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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.

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.

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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.

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®.

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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 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.

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PART II

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 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.

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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.

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.

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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.

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	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	

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Contractual Rights and Obligations	Milestone Payments	Notes	Cash flows received and revenue deferred December 31, 2009	December 31, 2008
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
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

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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. At December 31, 2009, there was remaining deferred revenue of $13.4 million, of which $11.7 million is related to the EU Meda arrangement milestones and EU Meda research and development services. We have estimated the amount of time (based on expected man-days) and associated dollars (based on comparable services provided by outside third parties), as further noted below. As time progresses, we continue to estimate the time required for ongoing obligations, and adjust the remaining deferral accordingly on a quarterly basis.

Upon delivery of the license to Meda, we have determined that each of the undelivered obligations have stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. We have also obtained third-party evidence of fair value for the 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 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.

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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.

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. Meda has the right to reject products that do not comply with product, packaging, or regulatory specifications. Defective product must be identified by Meda within 10 days after inspection at Meda s distribution site. We bill Meda immediately upon receipt by Meda of product (FOB manufacturer). On a quarterly basis, a reconciliation is prepared that reflects the difference between actual net sales by Meda multiplied by the royalty percentage, and the actual royalty payments made during the quarter (which is based on a transfer price at the time we invoice Meda). The parties true-up the differences within 45 days of each quarter-end.

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.

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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. The Company does not take ownership of the subject product (i.e., it has no inventory) as such product is transferred to Meda immediately in accordance with terms of the Company s contractual arrangements with Meda and its commercial supplier, Aveva. While Aveva manufactures the product for the Company, and Meda s royalty payments to the Company include an amount related to cost of goods, ownership and title to the product, including insurance risk, belong to Aveva from raw material through completion and inventory of the subject product, and then to Meda upon shipment of such subject product. This is in accordance with the Company s contracts with Aveva and Meda, which identify the subject product as FOB manufacturer.

It includes all costs related to creating the products at our contract manufacturer, which can include stability costs directly related to the product sold. The stability of a product may be defined as the extent to which a product retains, within specified limits, throughout its period of storage and use, the same properties and characteristics possessed at the time of its packaging. Stability testing provides evidence on how the quality of a drug substance or drug product varies with time. 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.

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.

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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.

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.

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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 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.

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

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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.

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

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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 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

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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;
- 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.

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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.

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Item 15. Exhibits.

Number	Description
31.1	Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302
31.2	Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302
32.1	Certification Pursuant To 18 U.S.C. Section 1350 (*)
32.2	Certification Pursuant To 18 U.S.C. Section 1350 (*)

* 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.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this amended report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: November 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	November 19, 2010
/s/ Mark A. Sirgo **Mark A. Sirgo**	President, Chief Executive Officer and Director	November 19, 2010
/s/ William B. Stone **William B. Stone**	Lead Director	November 19, 2010
/s/ John J. Shea **John J. Shea**	Director	November 19, 2010
/s/ William S. Poole **William S. Poole**	Director	November 19, 2010