BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-K
March 11, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2010

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2010 was approximately $18,862,089 based on the closing sale price of the company s common stock on such date of $2.31 per share, as reported by the NASDAQ

Capital Market.

As of March 7, 2011, there were 24,062,369 shares of company common stock issued and 24,046,878 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2010

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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 si 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 Annual Report on Form 10-K, including the documents referred to or incorporated by reference in this Report or statements of our management referring to our summarizing the contents of this Report, includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results may differ materially or perhaps significantly 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 similar expressions. In addition, any statements that refer to expectations or 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 and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including (i) the timing, status and results of our filings with the U.S. Food and Drug Administration, (ii) the timing, status and results of non-clinical work and clinical studies and (ii) heavily regulated industry in which we operate our business generally;

- 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;

- our expectations about the potential market sizes and market participation potential for our approved or proposed products;

- the protection and control afforded by our patents and any interest in licensed patents, or our ability to enforce our rights under such patents or licenses;

- litigation or other claims or disputes relating to our technologies, products or processes;

- 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;

- the ability of our manufacturing partners to supply us or our commercial parties with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner;

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 matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. 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 or articulate all risks we face, 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 above and throughout this Report.

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PART I

Item 1. Description of Business.

Overview

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

We utilize two novel drug delivery technologies:

- *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 U.S. Food and Drug Administration, or FDA, approved product, ONSOLIS® (fentanyl buccal soluble film), as well as our pipeline of products candidates, predominately utilize our BEMA® technology.

Our current development strategy focuses primarily on our ability to utilize the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into our drug delivery 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 FDA approval approaches.

On July 16, 2009, we announced the U.S. approval of our first product, ONSOLIS®. In 2010, regulatory approvals were granted for Canada (May 2010), and most recently in the European Union (referred to herein as E.U.) (October 2010) where it will be marketed under the trade-name BREAKYL . The FDA approval of ONSOLIS®, together with our satisfactory preparation of launch supplies of ONSOLIS®, triggered the payment to us by our commercial partner, Meda AB, a leading international specialty pharmaceutical company based in Sweden (referred to herein as Meda), of approval milestones aggregating $26.8 million. The first national approval of BREAKYL in the E.U. will result in a milestone payment of $2.5 million from Meda. A second milestone payment of $2.5 million will be realized at the time of first commercial sale in the E.U. We began receiving royalties from Meda on net sales of ONSOLIS® following launch and anticipate additional royalty sales following launches in Canada and the E.U. in 2011, although our royalty revenue from this product remains below original projections due to certain regulatory conditions in the U.S. discussed below.

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Meda s U.S. subsidiary, Meda Pharmaceuticals, based in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets and sells branded prescription therapeutics. Meda has an experienced, 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 successfully commercializing products. Meda has secured access to additional markets through acquisition of European businesses from Valeant Pharmaceuticals International, Inc., which we refer to herein as Valeant, and a joint venture with Valeant covering Australia, Mexico and Canada.

In 2010, we secured commercialization rights for ONSOLIS® for the remaining worldwide territories through execution of licensing agreements with Kunwha Pharmaceutical Ltd. for South Korea and TTY Biopharm Ltd. for Taiwan, each resulting in upfront payments to us of $300,000.

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Summary of Regulatory and Commercial Status of ONSOLIS®/BREAKYL

Region	Partner	Regulatory Status	Commercial Status
U.S.	Meda Pharmaceuticals	Approved	Launched October 2009
Canada	Meda Valeant Pharma Canada Inc.	Approved	Launch anticipated 2Q 2011
E.U.	Meda	Approved	Launch anticipated 3Q 2011 following approvals in individual member states
Australia	Meda Valeant Pharma Canada Inc.	Filed	
Taiwan	TTY Biopharm Ltd.	Pre-registration	
South Korea	Kunwha Pharmaceutical Co. Ltd.	Pre-registration	

Our next planned product utilizing the BEMA® technology is BEMA® Buprenorphine, a potential treatment for moderate to severe chronic pain. In December 2009, we announced that the primary efficacy endpoint was achieved in a Phase 2 clinical study evaluating the safety and efficacy of a range of doses of BEMA® Buprenorphine. 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. Completion of this Phase 2 study led to the initiation of a Phase 3 double-blind, randomized, placebo-controlled clinical study which was initiated in the fourth quarter of 2010. Study results are anticipated to be available in the third quarter of 2011, and if positive, will potentially lead to an NDA filing in the first half of 2012.

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 specifically for the treatment of opioid dependence. The product will combine a high dose of buprenorphine along with an abuse deterrent agent, naloxone. Preliminary pharmacokinetic studies have demonstrated the ability of the BEMA® technology to deliver the high doses of buprenorphine necessary for the treatment of opioid dependence. A BEMA® Buprenorphine/Naloxone product would provide us with an opportunity to compete in a rapidly growing opioid dependence market which, according to Wolters Kluwer, currently exceeds $1 billion in annual sales in the U.S. In March 2011, we announced the positive outcome of a pre-Investigational New Drug (pre-IND) meeting with the FDA on the development program for BEMA® Buprenorphine/Naloxone. We confirmed that the 505(b)(2) regulatory pathway will be pursued for the clinical development of BEMA® Buprenorphine/Naloxone.

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. We believe that this product candidate and other 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. However, although we continue to hold and prosecute our rights to the Bioral® technology, we are dedicating the vast majority of our resources to our BEMA® platform and related products and product candidates.

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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 multiple factors, including a highly restrictive Risk Evaluation and Mitigation Strategy (REMS) imposed by the FDA. The lack of approved REMS programs for our direct competitors has resulted in an unlevel playing field, which has created an unfavorable selling environment for ONSOLIS®. Furthermore, increasing pressure from payers and the availability of generic competitors have further impacted the market.

In December of 2010, Meda submitted a new REMS program for review and approval by the FDA which provides for potential broader access to ONSOLIS® through retail pharmacies and reduces some of the administrative burdens placed on prescribers. We anticipate approval and implementation of this retail REMS in mid-2011. This new REMS program follows the guidelines provided by FDA in November, 2010 to all companies that are or will be marketing fast acting fentanyl products in the future, thereby providing for a more level playing field in the marketplace. We anticipate all fast-acting fentanyl products that are currently in the marketplace without a REMS will come into compliance with the new FDA mandated program during 2011.

Since inception, we have recorded accumulated losses totaling approximately $72.2 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:

- commercialization of ONSOLIS® and other of our candidate 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 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®, BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone or any other product candidates discussed below and elsewhere in this Report are merely estimates and subject to many factors, many of which may be beyond our control, which will likely cause us to revise such estimates. Readers are also advised that our projected sales figures do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our management s reasonable judgments given the information available and their previous experiences, although such estimates may not prove to be accurate.

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

- Adhere to mucosa in seconds and dissolve in minutes;
- Permit absorption without patients being required to move the product around in the mouth for absorption, thus avoiding patient intervariability;
- 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, and the possibility for diversion or disposal of partially used product.

We previously licensed the BEMA® drug delivery technology in the United States on an exclusive basis from Atrix Laboratories (now known as QLT USA, Inc., which we refer to herein as QLT.) For a description of our agreements with QLT, see Key Collaborative and Supply Agreements below.

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 BEMA® Product Candidates

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

Product/Formulation	Indication	Development Status	Commercial Status
BEMA® Fentanyl ONSOLIS® /BREAKYL (U.S./EU trade names)	Breakthrough cancer Pain in opioid tolerant patients	Approval: U.S. in July 2009; Canada in May 2010; E.U. in October 2010	Partnered worldwide
BEMA® Buprenorphine	Moderate to severe chronic pain	Phase 2 results announced December 2009; Phase 3 initiated in 4Q10; NDA filing anticipated 1H 2012	Primary care rights expected to be partnered
BEMA® Buprenorphine/Naloxone	Treatment of opioid dependency	Pivotal bioequivalence studies planned for 2011; NDA filing anticipated 1H 2012	In-house commercialization or partnership.
BEMA® Granisetron	Prevention of nausea and vomiting associated with cancer therapies	IND filing February 2011; Pivotal bioequivalence trial planned for 2011	In-house commercialization for specialty indications possible; primary care rights expected to be partnered

While continuing to work closely with Meda on ONSOLIS® and related regulatory approvals in the E.U. and other worldwide jurisdictions (except for Taiwan where we are working with TTY and in South Korea where we are working with Kunwha), we are presently dedicating much of our corporate resources toward progressing our pipeline of BEMA® products, particularly BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone 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 BioAmphotericin B® or other opportunities that we may identify.

BEMA® Formulated Products

ONSOLIS®

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

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Under our agreements with Meda, we receive a double digit royalty on the net sales of ONSOLIS® and also have the potential to receive milestone payments based on achieving certain predetermined sales targets. In May 2010, ONSOLIS® was approved by the Canadian regulatory authorities. Upon launch, ONSOLIS® will be marketed in Canada by Meda Valeant Pharma Canada, Inc., a joint venture between Meda and Valeant Canada Limited. Approval was also obtained in the E.U. in October 2010, where the product will be marketed by Meda under the tradename BREAKYL Additional licensing deals completed in 2010 will provide the opportunity for ONSOLIS®/BREAKYL to be commercialized in all regions globally. In May 2010, we announced a commercialization and supply agreement with Kunwha Pharmaceutial Co. Ltd., for BEMA® Fentanyl in South Korea, and in October 2010, a licensing agreement was secured with TTY Biopharm Co. Ltd., for exclusive rights to develop and commercialize the product in Taiwan.

In 2009, the leading fast-acting 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 Covidien and Watson Pharmaceuticals. Cephalon introduced a second fast dissolving fentanyl product, Fentora® in late 2006. The reported combined retail sales of these products in 2010 was $375 million. We believe that ONSOLIS® may offer advantages over the marketed and pipeline fentanyl products in terms of ease of use and other attributes. In the E.U., sales of transmucosal fentanyl products for the treatment of breakthrough cancer pain exceed $135 million. We attribute much of the growth to the availability of new agents such as Abstral and Instanyl, both which were approved and launched in 2010.

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We may pursue an expanded indication that would permit promotion of ONSOLIS® for breakthrough pain in non-cancer patients in partnership with Meda. If obtained, we expect that an expanded claim for use in non-cancer breakthrough pain would increase our sales for ONSOLIS®.

BEMA® Buprenorphine (chronic pain)

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

In the fourth quarter of 2010, we initiated our Phase 3 clinical study evaluating the safety and efficacy of BEMA® Buprenorphine in chronic pain. A double-blind, randomized, placebo-controlled study is being conducted in patients with moderate to severe chronic low back pain. This study, along with a safety study to be initiated in the first quarter of 2011, will constitute the basis for an NDA filing. We expect to have top line Phase 3 data from this study in the third quarter of 2011. Assuming positive efficacy results, we expect the filing of an NDA to take place in the first half of 2012.

BEMA® Buprenorphine 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 similar 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;

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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 Wolters Klewer, the U.S. opioid market surpassed $10 billion in sales in 2010. 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/Naloxone (opioid dependence)

We are also investigating a higher dose formulation of BEMA® Buprenorphine combined with the abuse deterrent naloxone 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 simultaneously maintaining pain control. Currently in the U.S. there are two buprenorphine products approved for this indication with 2010 total retail sales in excess of $1 billion. We believe BEMA® Buprenorphine/Naloxone 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 over $300 million in annual peak sales. We expect to finalize our formulation and complete a pivotal bioequivalence study in 2011 to support a possible NDA filing in mid-2012.

We anticipate securing a commercial distribution partnership, similar in structure to our agreement with Meda for ONSOLIS®, for one or both indications of BEMA® Buprenorphine by the end of 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 is approximately $2.3 billion. We filed an Investigational New Drug (IND) application for BEMA® Granisetron in early 2011. We believe that, in the presence of nausea and vomiting, BEMA® Granisetron would have the potential for better tolerance than oral formulations, as well as potential for better and more consistent absorption. We expect to progress the development of BEMA® Granisetron in 2011 based on the program agreed upon during the 2010 FDA pre IND meeting. Based on the results of the studies performed this could lead to an NDA submission sometime in 2012.

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.

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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 licensor 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 could potentially be developed by applying our Bioral® drug delivery technology to select established pharmaceuticals. Any intended Bioral® product (i.e., drug encapsulated with our drug delivery technology) would require separate FDA regulatory approval, and accordingly, would be subject to the uncertainty, time and expense generally associated with the FDA regulatory process, and any product developed would face hurdles, regulatory requirements and uncertainty before market introduction.

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 assessing a Bioral® formulation of Amphotericin B for treatment of fungal infections. If this product can be clinically developed and gain regulatory approval, it could become the first oral Amphotericin B product available in the world to treat systemic fungal infections.

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

Our corporate focus is in the area of specialty pharmaceuticals applying our delivery technologies to existing therapeutics to create our own proprietary formulations, for which we then seek proprietary protection, 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. Our corporate focus came to initial fruition with the FDA s approval of ONSOLIS® (fentanyl buccal soluble film) in 2009. It is our goal to replicate the development, regulatory approval and commercialization pathways utilized for ONSOLIS® for 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 FDA s previous findings of safety and effectiveness for approved pharmaceuticals, including clinical and nonclinical 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 7, 14, or 28-day multiple dose toxicity study in a single species,

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thorough pharmacokineticevaluation 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 effective 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.

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 drugs 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.

Meda Licensing Agreements for ONSOLIS®

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

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

A $30.0 million milestone payment (received in 2007).

A $29.8 million milestone payment for the approval of ONSOLIS® by the FDA, and provision of commercial supplies of ONSOLIS® in the U.S.,(received in 2009) a double digit royalty on net sales of ONSOLIS® in the covered territories, subject to certain third party royalty payment costs and adjustments, as well as other adjustments in the event of certain specific supply disruptions. The license agreement provides for certain guaranteed minimum annual royalties to us during the second through seventh years following the product s first commercial sale, which occurred in the fourth quarter of 2009.

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Sales milestones equaling an aggregate of $30 million will be 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, such as additional indications for ONSOLIS®, that do not involve studies in support of the NDA.

By its terms, our North American license agreement with Meda 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 a 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 2006, we announced collaboration with Meda to develop and commercialize BEMA® Fentanyl (to be marketed as BREAKYL in Europe. Under terms of the agreement, we granted Meda rights to the European development and commercialization of BREAKYL , in exchange for an upfront fee of $2.5 million and a $2.5 million milestone payment in 2008 for completion of Phase 3 clinical trials. We will receive a double digit royalty on net sales and additional milestone payments of up to $5 million for first country approval and launch. Meda has managed the regulatory submission in Europe that led to approval in October 2010. Meda will exclusively commercialize BREAKYL in Europe.

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

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 a 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.

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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 paid for formulation development, commercial quantity scale-up work and the manufacture of clinical and commercial supplies of ONSOLIS®, based on Aveva s fully-burdened cost of manufacturing, 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 vested based on the occurrence of specified milestones) at a price equal to $3.50 per share. Of the original 75,000 warrant issuance, Aveva exercised a warrant to purchase 25,000 shares of our common stock in June 2009. We also extended a warrant to purchase 25,000 shares of our common stock which was revalued at an exercise price of $5.87 in July 2009, which expired July 2010 and a final warrant of 25,000 shares of common stock expired in January 2011.

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. During the year ending December 31, 2010 we paid Aveva $0.5 million directly related to ONSOLIS® cost of goods sold and also paid Aveva $0.3 million for various other projects and tasks.

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.

The term of our February 2008 agreement with LTS lasts 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.

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QLT. On May 27, 2004, prior to our acquisition of our Arius Pharmaceuticals subsidiary, Arius entered into a worldwide, exclusive royalty-bearing license agreement with QLT to develop, manufacture, market, and sell products incorporating what was then QLT s BEMA® technology, including but not limited to 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, was 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 and other assets. The aggregate purchase price for the non-U.S. portion of the BEMA® technology was $3 million, consisting of $1 million in cash paid at closing and a promissory note of $2 million to be paid over time as follows: (i) $1 million by the end of first quarter 2007 (which was paid March 30, 2007) and (ii) $1 million to be paid within 30 days of regulatory approval of the first non-U.S. BEMA® product. On June 18, 2010, in conjunction with BEMA® approval in Canada, we paid $0.75 million of the $1 million to QLT. We and QLT agreed that the remaining $0.25 million will be due upon delivery of certain patent obligations owed to us by QLT. As part of the transaction, and 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 for the non-U.S. BEMA® rights. In addition, we were granted the option to purchase the U.S. BEMA®-related assets for $7 million dollars.

In September 2007, we purchased all North American (U.S., Canada and Mexico) assets related to the BEMA® drug delivery technology from QLT for $7 million, consisting of $3 million in cash and a promissory note of $4 million, $2 million of which was paid in July 2009 following approval of ONSOLIS® in the U.S., and $2 million of which is due within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA®-based products reach $30 million. As part of the transaction, no further milestone payments or ongoing royalties will be due to QLT for the North American territory. To secure our obligation to pay the remaining $2 million amount when due, QLT was granted a security interest in the North American BEMA® assets, subject to a license of those assets from QLT to us for North America that would be granted to us on the original license terms upon any exercise of rights under such security interest.

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 would work with DNDi in determining the efficacy of Bioral® Amphotericin B for the above mentioned diseases. Preliminary research by DNDi did not provide sufficient evidence to progress Bioral® Amphotericin B for the intended diseases. Thus, the agreement was terminated and no further work is planned with DNDi.

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

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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. The royalty term expires upon the latter of expiration of the patent or generic entry into a particular country. 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 and also expires on July 16, 2011. 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).

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.

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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.

We are presently in discussions with CDC and an assignee of CDC s royalty rights relating to the interpretation of a provision of the CDLA calling for adjustments to the royalty owed to CDC based on the pricing of competitive products to ONSOLIS®. Based on our ongoing discussions, we anticipate a fair and reasonable resolution of this matter in the foreseeable future.

Research and Development

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

Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct and third party development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to non-clinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. For the years ended December 31, 2010, 2009 and 2008, we spent approximately $10.6 million, $10.4 million and $10.9 million, respectively, on research and development expenses, and such expenses represented approximately 56%, 50% and 60%, respectively, of our total operating expenses for such fiscal years. Meda has reimbursed approximately $0.7 million, $2.8 million and $2.7 million of our research and development expenses for the years ended December 31, 2010, 2009 and 2008, respectively. These reimbursements represent approximately 7%, 27% and 25% of our total research and development costs for such fiscal years. During the year ended December 31, 2010, a relatively small portion of our research and development expense is related to BREAKYL , which is reimbursed by Meda. Most of our research and development expense is related to BEMA® Buprenorphine.

Competition

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

Below are some examples of companies seeking to develop potentially competitive technologies, though 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 product candidates that we are currently developing or may be able to develop. Additionally, our competitive position may be materially affected by our ability to develop or successfully commercialize our drugs and technologies before any such competitor. Other external factors may also impact the ability of our products to meet expectations or effectively compete, including pricing pressures, healthcare reform, and other government interventions.

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There have been a growing number of companies developing products utilizing various thin film drug delivery technologies. While numerous over-the-counter pharmaceutical products have been brought to market in thin film formulations, few containing prescription products have been introduced in the U.S. The first such products to receive FDA approval were ONSOLIS® (BDSI/Meda) and Zuplenz (MonosolRx/Strativa). Leading companies in the development and manufacture of thin film technologies include LTS Lohmann Therapie-Systeme AG, ARx LLC and MonoSol Rx though each has been focused on oral dissolvable thin films, and not mucoadhesive films, which are designed to facilitate more rapid transmucosal drug delivery. Included among the companies which we believe are developing potentially competitive thin-film technologies to BEMA® or BEMA® products include: Auxillium (NASDAQ:AUXL), a specialty pharmaceutical company, who through a licensing agreement with PharmaForm is developing products for the management of acute and chronic pain using their transmucosal film technology; MonoSol Rx, a specialty pharmaceutical company developing and commercializing thin-film pharmaceutical and over-the-counter products using its PharmFilm® technology; and ULURU Inc. (AMEX:ULU), which utilizes their OraDisc mucoadhesive film technology to deliver drugs transmucosally.

In addition, a number of companies are developing improved versions of existing products using oral dissolving, nasal spray, inhaled and other drug delivery technologies. We believe that potential competitors are seeking to develop and commercialize technologies for buccal, sublingual or mucosal delivery of various therapeutics or groups of therapeutics. While our information concerning these competitors and their development strategy is limited, we believe our technology can be differentiated because the BEMA® technology provides for a rapid and consistent delivery of each dose based on how the BEMA® technology adheres to the buccal membrane and dissolves 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 $375 million in the U.S. The transmucosal fentanyl class has faced significant 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. In December of 2010, Meda submitted to FDA a new REMS program which provides broader access to ONSOLIS® through retail pharmacies and reduces some of the burdens placed on prescribers. We anticipate approval and implementation of this retail REMS in mid-2011. This new REMS program follows the guidelines provided by FDA in November, 2010, to all companies that are or will be marketing fast acting fentanyl products in the future, thereby providing for a level playing field. We anticipate all fast-acting fentanyl products that are currently in the marketplace without a REMS will come into compliance with the new FDA mandated program during 2011.

Cephalon s first product for the breakthrough cancer pain indication was Actiq® (oral transmucosal fentanyl citrate) which generated $49 million in sales in 2010. Total sales for generic versions of Actiq®, available from Covidien and Watson Pharmaceuticals, totaled $172 million over the same period. Fentora® utilizes an effervescent tablet which is administered buccally. Fentora® was approved and launched in late 2006 and generated $153 million in sales in 2010.

In December 2008, Prostrakan Group plc (LSE: PSK) announced receipt of marketing authorization from the German regulatory authorities for their fentanyl sublingual tablet (under the brand name Abstral®) which was subsequently launched in a number of countries. Abstral was licensed from Orexo AB. Prostrakan announced in July 2008, that its licensing agreement with Orexo would be extended to include North America. Prostrakan is a specialty pharmaceutical company headquartered in Scotland and employees approximately 300 people in its operations. Prostrakan entered the U.S. market in 2008 following the approval of Sancuso®, a transdermal patch for the prevention of chemotherapy-induced nausea and vomiting. Sancuso® was launched with a newly created U.S. sales force of approximately 70 representatives established in collaboration with NovaQuest (partnering group of Quintiles). In the U.S., Abstral® was submitted to FDA for review in August 2009, and in January 2010, Abstral was approved by the U.S. FDA. Prostrakan expects to launch Abstral® under a Risk Evaluation and Mitigation Strategy (REMS) in the first quarter of 2011.

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In the U.S., additional products are under development or FDA review utilizing other delivery technologies to administer fentanyl. These products include intranasal (PecFent®, Archimedes), a fentanyl sublingual spray formulation from INSYS Therapeutics, a dry inhaled powder formulation of fentanyl (Fentanyl TAIFUN, Akela) and an orally dissolving film referred to as Fastanix from NAL Pharmaceuticals. Other potent pain products are also in development, including AcelRx Pharmaceuticals with a nano-tab drug/device delivery system containing sufentanil for the treatment of breakthrough pain. This product, ARX-02, is in Phase 2 clinical 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 tolerability issues and 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 lozenge	Marketed (generics available)
Fentora® (fentanyl buccal tablet)	Cephalon	Effervescent buccal tablet	Marketed
Abstral® (fentanyl sublingual tablet)	Prostrakan	Sublingual tablet	Approved (U.S., E.U.)
PecFent®	Archimedes	Nasal spray	Approved (E.U.); Pending approval (U.S.)
Fentanyl SL Spray	INSYS Therapeutics	Sublingual spray	Phase 3 (U.S.)
Fentanyl TAIFUN®	Akela/Janssen (EU)/ Teikoku Seiyaku (Japan)	Dry powder Inhaler	Phase 3 (U.S., Japan)
Fastanix/NAL 1239	NAL Pharmaceuticals	Orally dissolving film	Phase 2 (U.S.)
ARX-02	AcelRx Pharmaceuticals	Nanotab containing sufentanil	Phase 2 (U.S.)

In Europe, the total market for transmucosal fentanyl products continues to grow with the availability of new formulations. Multiple formulations of fentanyl have recently been approved and launched in Europe for the treatment of breakthrough cancer pain, including Abstral, Effentora, and Instanyl (intranasal fentanyl spray). Sales of transmucosal fentanyl products grew 37% to a total of $137 million in the twelve month period ending September 2010. More recently, PecFent (fentanyl nasal spray) and BREAKYL (fentanyl buccal film) received marketing authorization from E.U. regulatory authorities.

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 (including reimbursement and third party payment) in the U.S. and other regions are likely to have increasing influence on the pharmaceutical market, including pain products. 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.

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A number of products may be competitors to BEMA® Buprenorphine that we are developing for the treatment of chronic pain. A potential focus will be to position BEMA® Buprenorphine as a step up from NSAIDs instead of or prior to Schedule II narcotics. Indications for such use include pain associated with lower back and severe arthritis conditions. Marketed competitors for these indications include Tramadol (Ultram® ER from PriCara and Ryzolt® from Purdue) and the potent opioids such as Opana® from Endo, OxyContin® from Purdue, Avinza® from King Pharmaceuticals, Kadian® from Actavis 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. We also believe that other companies may be exploring the use of buprenorphine in other delivery technologies, though we believe such products lag significantly behind BEMA® Buprenorphine.

Additionally, abuse deterrent formulations of pain products are currently being marketed, in clinical development or under FDA review. These formulations, such as Embeda®, Remoxy® and Acurox® (King Pharmaceuticals) use a variety of technologies to try and minimize abuse. The first abuse deterrent 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 nasal or transmucosal delivery systems. Should these products make it to market, they may potentially compete with BEMA® Buprenorphine.

The first buprenorphine formulation for the treatment of chronic pain was approved in 2010. Purdue Pharmaceuticals received FDA approval for Butrans (buprenorphine transdermal system) in July. Butrans is indicated for the management of moderate to severe chronic pain and delivers buprenorphine transdermally (through the skin) over a period of seven days. The approval of Butrans signaled the interest and approvability of new formulations of buprenorphine and will help to establish the value of the molecule prior to the availability of a BEMA® formulation. It is our view that the flexibility of dosing with a BEMA® formulation and ease of use will make it a preferred formulation for a significant number of patients with chronic pain conditions. Butrans was launched in early 2011. While limited information is available, other formulations of buprenorphine may also be in early stages of development for the treatment of pain.

A higher dose version of BEMA® Buprenophine combined with naloxone is being developed for the treatment of opioid addiction. The main competitor is Suboxone, a sublingual tablet and film formulation of buprenorphine combined with the abuse deterrent agent naloxone. Sales of Suboxone, and a formulation without the abuse deterrent agent naloxone (Subutex), achieved sales in excess of $1 billion in the U.S. in 2010, and sales continue to grow steadily. The sublingual film formulation of Suboxone was approved in August 2010, and at the end of 2010, the market volume share was 25%, which we believe is suggestive of the market interest in alternative formulation of buprenorphine/naloxone. A BEMA® formulation of buprenorphine/naloxone has significant appeal given its enhanced delivery (i.e. greater drug absorption) of buprenorphine, improved convenience secondary to faster dissolution time in the oral cavity and lack of taste issues. While limited information is available, other formulations of buprenorphine may also be in early stages of development for the treatment of opioid dependence, including a subcutaneous depot delivery system from Titan Pharmaceuticals, a transmucosal formulation from Orexo, an oral capsule from Nanotherapeutics, and outside the U.S., a sublingual tablet from Aoxing Pharmaceutical Company.

Numerous products are marketed for the prevention of nausea and vomiting associated with chemotherapy and radiation, with the 5-HT3 receptor antagonists accounting for approximately three-quarters of antiemetic sales. There are several marketed 5-HT3 receptor antagonists available, including Zofran (ondansetron), Kytril (granisetron), Anzemet (dolasetron) and Aloxi (palenosetron). In July 2010, the first thin film formulation of an antiemetic was approved. Zuplenz contains ondansetron in an oral soluble film formulation and is licensed to Strativa Pharmaceuticals. Zuplenz dissolves on the tongue without the need for water. Additional formulations of ondansetron are currently in various stages of clinical development including a sublingual dissolvable film (BA-030, Labtec/BioAlliance) and an extended release oral formulation (EUR-1025, Eurand). The first transdermal formulation of an antiemetic, Sancuso (granisetron), was approved in 2008 and is marketed by ProStrakan. In addition, there are several alternative formulations of granisetron currently in clinical development, including subcutaneous (APF-530, AP Pharma), sublingual spray (Zensana, Hana BioSciences/Strativa) and intranasal (Archimedes).

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Bioral® Technology

While many development activities are conducted within private companies, 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 Astellas and Abelcet® from Sigma Tau Pharmaceuticals Inc. 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. Previously, iCo Therapeutics announced results of an animal study showing plasma levels of amphotericin B following oral administration of iCo-009. In 2009, iCo Therapeutics published the results of a study showing inhibition of the parasite responsible for Visceral Leishmaniasis, and in September 2010 the product was granted orphan drug status for that indication.

A potential differentiating factor is that we believe that our technology may have cell-targeted delivery attributes as well. 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 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.

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 portfolio of patents, trademarks, license agreements, trade secrets, proprietary rights and any 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.

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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, dominated by, or infringing any external patents, and we do not believe that we require licenses under external patents for our BEMA® based products in the United States. It is possible, however, that a court of law in the United States or elsewhere might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our products or technologies. We may be unable to obtain such licenses from the patent holders. If we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products. This potentiality exists in our present litigation with MonoSol Rx. MonoSol Rx claims that the confidential and trade secret manufacturing process for ONSOLIS® infringes their patented manufacturing process for thin films. We strongly deny their claims. In addition, we believe that the manufacturing processes for our product candidates, including BEMA® Buprenophine, do not infringe MonoSol s patents, at least because they do not meet the limitations of the claims of MonolSol s patents.

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

On March 1, 2011, we were granted a patent extending the exclusivity of the BEMA® drug delivery technology in Canada to 2027. The Canadian Patent No. 2,658,585 provides additional patent protection for ONSOLIS® and BEMA® Buprenorphine.

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

We maintain our manufacturing processes for our BEMA® products and product candidates as trade secrets. In terms of patents relating to manufacturing of mucoadhesive erodible drug delivery devices, we are aware of a number of patents held by MonoSol Rx, including the asserted US Patent No. 7,824,588 and recently granted US Patent No. 7,897,080. Based on our examination of these patents, we do not believe our manufacturing processes infringe MonoSol s patents.

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.

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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 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® and BREAKYL™ are registered trademarks 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. In the second half of 2010, certain equipment and regulatory issues at Aveva led to the temporary stoppage of manufacturing of all products at that site, including ONSOLIS®. This temporary stoppage has delayed the Canadian launch of ONSOLIS®. Full production of ONSOLIS® resumed in November 2010 and presently we anticipate that launch stocks of ONSOLIS® should be available for market release in Canada in late March or April of 2011. As of the date of this Report, the issues at Aveva are not expected to have an impact on the U.S. supply of ONSOLIS®, but any additional unanticipated interruptions, coupled with potential expirations of existing stock, could impact U.S. supply of ONSOLIS®.

Effective December 15, 2006, we entered into a Process Development Agreement with LTS Lohmann Therapie-Systeme AG (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. Under the terms of this agreement, LTS is the exclusive manufacturer of BEMA® Buprenorphine. In the event that the parties cannot agree on terms of a supply agreement, the exclusive manufacturing right shall terminate. 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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For our other product candidates currently in development, 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 are also routinely seeking back up manufacturers to our current agreements.

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 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, 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®/ BREAKYL with our licensing agreements with Meda (world-wide except Taiwan and South Korea), Kunwha Pharmaceutical Co., Ltd. (South Korea) and TTY Biopharm Co., Ltd. (Taiwan). 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 such as through pain specialists and oncologists, while leaving promotional responsibilities for the large primary care audiences with partners.

European Union

In September 2006, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for BEMA® Fentanyl in the European Union. Under the terms of the agreement, we granted Meda rights to the European development and commercialization of BEMA® Fentanyl (which will be marketed in Europe under the tradename BREAKYL), in exchange for an upfront fee paid to us, certain milestone payments and double-digit royalties to be received by us on product sales. Payments included a $2.5 million payment upon execution of the agreement and a $2.5 million payment upon completion of clinical requirements for a European marketing application, both of which have been achieved. Additional milestones include a $2.5 million payment upon the first national marketing authorization and an additional $2.5 million at the time of the first commercial sale. Both are anticipated to occur in 2011. Meda manages the clinical development and regulatory process in Europe and will exclusively market BREAKYL .

BREAKYL received marketing authorization from the European regulatory authorities in October 2010. Progress continues toward preparations for the launch of BREAKYL in Europe, which will follow national marketing authorization approvals and will enable commercial sales in each of the twenty-five individual E.U. countries. Meda has focused activities in the E.U. on gaining thoughtleader 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.

North America

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.

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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. A specialty sales force consisting of 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 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®.

Meda is also responsible for the management of a Risk Evaluation and Mitigation Strategy, or REMS, program for ONSOLIS®. FDA has mandated that a 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. As a result, there remains an unlevel competitive environment which has impeded sales and marketing efforts in support of ONSOLIS®.

In December of 2010, Meda submitted a new REMS program which provides broader access to ONSOLIS® through retail pharmacies and reduces some of the administrative burdens placed on prescribers. We anticipate approval and implementation of this retail REMS by mid-2011. This new REMS program follows the guidelines provided by FDA in November, 2010, to all companies that are or will be marketing fast acting fentanyl products in the future thereby providing for a level playing field. We anticipate all fast-acting fentanyl products that are currently in the marketplace without a REMS will come into compliance with the new FDA mandated program during 2011.

ONSOLIS® was approved by the Canadian regulatory authorities in May 2010, and is the first product approved in Canada for the management of breakthrough cancer pain. ONSOLIS® will be marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between Meda and Valeant Canada Limited. ONSOLIS® is expected to be launched in Canada in the second quarter of 2011.

Additional Territories

On January 2, 2009, we entered into amendments to our agreements with Meda to grant Meda worldwide commercialization rights for ONSOLIS®/BREAKYL with the exception of Taiwan and South Korea. The sales royalties to be received by us will be the same for all territories as agreed to for Europe. In 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.

In 2010, licensing agreements were secured in Taiwan and South Korea providing the opportunity for commercialization in all territories globally. In May 2010, we announced a commercial partnership with Kunwha Pharmaceutical Co., Ltd., for the exclusive rights to develop and commercialize ONSOLIS® in the Republic of Korea. The agreement results in potential milestone payments of up to $1.275 million, which included the upfront payment of $0.3 million and royalties based on net sales. In October 2010, a commercial partnership with TTY Biopharm Co., Ltd., was announced, providing commercialization rights for Taiwan. This agreement results in potential milestone payments of up to $1.3 million along with royalties based on sales and included an upfront payment of $0.3 million.

We believe that utilizing a commercial partner with a strong U.S. and E.U. presence, along with a global reach, is allowing us to competitively launch ONSOLIS®/BREAKYL 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 partnerships with Meda and others will allow internal efforts to be focused on the development of our pipeline of products.

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Government Regulation

The nonclinical and clinical development, manufacturing and marketing of any product which we formulate with our licensed Bioral® or BEMA® technology as well as our related research and development activities, are subject to significant 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 and 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. Small scale manufacturing of the agent and laboratory and nonclinical tests for safety;

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

3. Larger scale manufacturing of the agent and 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.

Nonclinical Trials

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

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

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Clinical Trials

Clinical trials involve 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 and not all phases may be necessary when developing investigational products that will utilize the FDA s 505(b)(2) approval process. In Phase 1, the initial introduction of the investigational 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 the clinical efficacy and safety profile of the product within a larger population at geographically dispersed clinical study sites. Phase 3 frequently involves randomized controlled trials and, whenever possible, studies are conducted in a manner so that neither the patient nor the investigator knows what treatment is being administered. We, or the FDA, may suspend clinical trials at any time if it is believed that the individuals participating in such trials are being exposed to unacceptable health risks.

We 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. For BEMA® Buprenorphine, one human pharmacokinetic study was conducted in 2006, a second in 2008, a Phase 2 efficacy/safety study was performed in 2009, and two human pharmacokinetic studies were conducted and a Phase 3 efficacy/safety study was initiated in 2010. We expect that additional clinical studies in healthy subjects and patients will be performed with BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone and BEMA® Granisetron in 2011.

New Drug Application and FDA Approval Process

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

The NDA review process involves FDA investigation into the details of the manufacturing process, as well as the design and analysis of each of the nonclinical and clinical studies. This review includes inspection of the manufacturing facility, the data recording process for the clinical studies, the record keeping at a sample of clinical trial sites, and a thorough review of the data collected and analyzed for each nonclinical and clinical study. Through this investigation, FDA reaches a decision about the risk-benefit profile of a product candidate. If the benefit outweighs 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 approval of 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 quality control and quality assurance to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by other federal, state or local agencies. Additionally, in the event of non-compliance, 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 oral transmucosal fentanyl products, Fentora® and Actiq®, that a REMS requirement should 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. The goals of the ONSOLIS® REMS Program are to help ensure proper patient selection; avoid 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 REMS requires dispensing of a Medication Guide with each prescription, healthcare provider and pharmacy education, and a patient/physician registry. The REMS program remains an integral part of ONSOLIS® commercialization. In December of 2010, a new REMS program was submitted to FDA which provides broader access to ONSOLIS® through retail pharmacies and reduces some of the administrative burdens placed on prescribers by the original REMS program. We anticipate approval and implementation of this retail REMS by mid-2011. This new REMS program follows the guidelines provided by FDA in November, 2010 to all companies that are or will be marketing fast acting fentanyl products.

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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 of the Universities 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, 2010, 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 of the Universities 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 October 2010, we made royalty payments to both UMDNJ and Albany Medical College in the amount of $0.06 million each, which were related to a 2004 licensing arrangement. No further royalty payments are owed to either of the Universities at this time.

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. To date, we have not concluded an agreement in this regard with Dr. Mannino and discussions have not progressed relating to any such agreement.

Employees

As of March 7, 2011, we have 20 full-time employees and 1 part-time employee. Fourteen are involved in our clinical development program and operations and seven handle our administration, accounting and information technology. Advanced degrees and certifications of our staff include four Ph.Ds, two Pharm.Ds and three 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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Available Information

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

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Item 1A. RISK FACTORS

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

Risks Relating to Our Business

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

From our inception in January 1997 and through December 31, 2010, we have recorded significant losses. Our accumulated deficit at December 31, 2010 is approximately $72.2 million. As of December 31, 2010, we had negative working capital of approximately $3.1 million, including non-refundable deferred revenue of $12.5 million. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates and product concepts, obtain the required regulatory approvals and manufacture, market and sell our proposed products. We may be unable to achieve any or all of these goals.

Although we have generated licensing-related and other revenue to date, we have only recently begun to generate revenue from the commercial sales of an approved product ONSOLIS® and such revenue has been minimal to date due to the fact that ONSOLIS® has been adversely affected by a REMS program that has yet to be approved for the competitor products.

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

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

As a result of our current lack of financial liquidity, our auditors report for our 2010 financial statements, which are included as part of this Report, contains a statement concerning our ability to continue as a going concern. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a going concern is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include engaging in offerings of securities, negotiating up-front and milestone payments on pipeline products under development and royalties from sales of our products (like ONSOLIS®) which secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. However, we may be unable to achieve these goals and therefore may be unable to continue as a going concern.

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Until we have a larger royalty revenue stream from ONSOLIS® and milestone payments from a partnership around BEMA® Buprenorphine, and perhaps even thereafter, we will likely need to raise additional capital to continue our operations from time to time, and our failure to do so would significantly impair our ability to fund our operations, develop our technologies and product candidates, attract commercial partners, retain key personnel or promote our products.

Our operations have been funded almost entirely by external financing. Such financing has historically come primarily from license and royalty fees, the sale of common and preferred stock and convertible debt to third parties, related party loans and, to a lesser degree, from grants and bank loans. At December 31, 2010, we had cash of approximately $18.2 million. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) that our current working capital will be sufficient to satisfy our contemplated cash requirements through the third quarter of 2011, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements.

Depending on the timing of our certain potential commercial partnerships or financings, and given our anticipated cash usage and lack of significant revenues, we will likely need to raise additional capital in the future to fund our anticipated operating expenses and progress our business plans. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make the raising of capital more difficult or impossible and may also result in a lower price for our shares.

We may have difficulty raising any needed additional capital.

We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of material revenues from sales, as well as the inherent business risks associated with our company and present and future market conditions. Our business currently only generates a small amount of revenue from product sales, and such current sources of revenue will likely not be sufficient to meet our present and future capital requirements. Therefore, at least until we have a second product approved and have a second commercial partnership in place, given we plan to continue to expend substantial funds in the research, development and non-clinical and clinical testing of our drug delivery technologies and product candidates as well as on other strategic initiatives, we will likely require additional funds to conduct research and development, establish and conduct non-clinical and clinical trials, secure clinical and commercial-scale manufacturing arrangements and provide for marketing and distribution. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs, product launches or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are subject to numerous risks.

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

- the number of potential formulations, products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with non-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;

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costs of developing sales, marketing and distribution channels and our ability to sell our drug formulations or products;

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

competing technological and market developments;

market acceptance of our drug formulations or products;

costs for recruiting and retaining employees and consultants;

costs for training physicians; and

legal, accounting, insurance and other professional and business related costs.

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

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

The additional financings which we have undertaken and which we will likely in the future require, have and may be obtained through one or more transactions that have diluted or will dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 45 million shares of common stock and 5 million shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

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

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

Moreover, as of the date of this Report, two products which compete directly with ONSOLIS®, namely Actiq® and Fentora® (each of which are marketed by Cephalon, Inc.), are currently being marketed without the requirement of compliance with a REMS. Instead, these products are currently marketed under a less onerous risk management plan that was in place prior to enactment of the 2007 legislation that granted FDA with REMS authorities. This condition currently puts ONSOLIS® at a material competitive disadvantage with these products, which may impact sales of ONSOLIS®. Additionally, two generic forms of Actiq® have been approved by the FDA and were commercially launched in 2010. We are not aware that the marketing of either of these products would be a subject to a REMS until such time that a REMS has been implemented and is in effect for Actiq®. This condition would also put ONSOLIS® at a potential material competitive disadvantage, which could impact Meda s ability to sell ONSOLIS®.

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

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

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

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

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

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

Use of our products and, if approved, our product candidates will require physicians to be informed regarding the intended benefits of our products and product candidates. The time and cost of such an educational process may be substantial. Inability to carry out this physician education process may adversely affect market acceptance of our proposed formulations or products. We may be unable to timely educate physicians regarding our intended pharmaceutical formulations or products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our formulations or products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our products or product candidates are created, if at all.

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

In conducting our research and development activities, we currently rely, and expect to continue to rely, on numerous collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements is our U.S. and European commercialization agreements with Meda and our manufacturing development and supply agreements with Aveva or LTS relating to ONSOLIS® and with LTS relating to BREAKYL (the brand name for ONSOLIS® in Europe) and BEMA® Buprenorphine. The loss of, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials and commercial sales. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation. This is particularly true with regard to our relationship with Meda, who is our worldwide (outside of Taiwan and South Korea) commercialization partner for our one approved product ONSOLIS®.

This risks associated with reliance on key third parties was demonstrated in 2010 when Aveva experienced certain adverse equipment and regulatory issues leading to the temporary stoppage of manufacturing of all products at that site, which left us exposed to delays in our and our partners commercial plans. Any future manufacturing interruptions or related supply issues could have a material adverse effect on our company.

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

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

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

We currently have a general liability/product liability policy which includes coverage for our clinical trials. Annual aggregate limits include $7 million with a $6 million limit per occurrence for general liability and $3 million with a $3 million limit per occurrence for product liability. Under, our agreements, Meda is required to carry comprehensive general product liability and tort liability insurance, each in amounts not less than $2 million per incident and US $10 million annual aggregate and to name us as an additional insured thereon. However, we or our commercial partners may be unable to obtain or maintain adequate product liability insurance on acceptable terms, if at all, and there is a risk that our insurance will not provide adequate coverage against our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us or our partners could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

- incur significant costs in legal expenses for defending against an intellectual property infringement suit;
- cease selling, making, importing, incorporating or using one or more or all of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our formulations or products, which would be costly and time-consuming.

With respect to our BEMA® delivery technology, the mucoadhesive erodible drug delivery device technology space is congested. There is a risk that a court of law in the United States or elsewhere could determine that ONSOLIS® or another of our BEMA® based products is in conflict with or covered by external patents. This risk presently exists in our litigation with MonoSol Rx, which was filed by MonoSol in November 2010, wherein MonoSol claims that our and our partners trade secreted manufacturing process for ONSOLIS® is infringing upon MonoSol s patented manufacturing process. If the court in that case were to rule against us and our partners in that case, we could be forced to license technology from MonoSol or otherwise incur liability for damages, which could have a material adverse effect on our company.

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

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

If a lawsuit were to be filed against us for patent infringement, we would incur significant legal costs to defend ourselves. Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our BEMA® and/or Bioral® products (including, without limitation, ONSOLIS®). We may be unable to obtain such licenses from the patent holders.

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

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

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

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

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

In addition, we may have to resort to costly and time consuming litigation to protect or enforce our rights under certain intellectual property, or to determine their scope, validity or enforceability. Enforcing or defending our rights will be expensive, could cause significant diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technologies to develop or sell competing products.

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

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

- potential delays associated with research and development and non-clinical and clinical trials due to an inability to timely obtain a single or limited source component;
- our potential inability to timely obtain an adequate supply of required components; and

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the potential for reduced control over pricing, quality and timely delivery.

Except for our agreements with Aveva and LTS, we do not have long-term agreements with most of our suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. As it is the primary manufacturer of our only approved product, ONSOLIS®, our relationship with Aveva is particularly important to us, and any loss of or material diminution of Aveva s capabilities due to factors such as regulatory issues, accidents, acts of God or any other factor would have a material adverse effect on our Company. We do not carry interruption insurance for any such loss. Any loss of or interruption in the supply of components from Aveva or other third party suppliers would require us to seek alternative sources of supply or require us to manufacture these components internally, which we are currently not able to do. If the supply of any components is lost or interrupted, product or components from alternative suppliers may not be available in sufficient quality or in volumes within required time frames, if at all, to meet our or our partners needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing; or cause us to lose sales, force us into breach of other agreements, incur additional costs, delay new product introductions or harm our reputation. Furthermore, product or components from a new supplier may not be identical to those provided by the original supplier. Such differences could have material effects on our overall business plan and timing, could fall outside of regulatory requirements, affect product formulations or the safety and effectiveness of our products that are being developed.

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

Our management s expertise is primarily in the research and development, formulation development and non-clinical and clinical trial phases of pharmaceutical product development. Our management s experience in the manufacturing of pharmaceutical products is more limited and we have limited equipment and no facilities of our own from which these activities could be performed. Therefore, we are dependent on third parties for our formulation development, manufacturing and the packaging of our products. This is particularly true with respect to Aveva, the primary manufacturer of our only approved product, ONSOLIS®. This reliance exposes us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to formulate sufficient product to conduct clinical trials and, subsequently, to launch and maintain the marketing of our products.

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

This risks associated with reliance on key third manufacturers was demonstrated in 2010 when Aveva experienced certain adverse equipment and regulatory issues leading to the temporary stoppage of manufacturing of all products at that site, which impacted our and our partners commercial plans. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including loss of sales and royalty revenue and claims by or against us or our partners for breach of contract.

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

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

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

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

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

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

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

Risks Related to Our Products in Development and Regulation

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

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

Moreover, although we received FDA approval for one product, ONSOLIS®, we may not receive regulatory approval of our other proposed products and formulations. We may be unable to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and viability.

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

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

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

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

the establishment of a viable Good Manufacturing Process capable of potential scale-up.

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

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

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

Moreover, it is our stated intention to seek to avail ourselves of the FDA s 505(b)(2) approval procedure where it is appropriate to do so. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

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

Data already obtained, or in the future obtained, from non-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later non-clinical studies and clinical trials. Moreover, non-clinical and clinical data is susceptible to multiple and varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including those involved in competing drug delivery technologies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the product candidate, resulting in delays to commercialization, and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

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We depend on technology owned or licensed to us by third parties, and the loss of access to this technology would terminate or delay the further development of our products, injure our reputation or force us to pay higher royalties.

We rely, in large part, on drug delivery technologies that we have purchased from third parties such as QLT with respect to our BEMA® technology, and the University of Medicine and Dentistry of New Jersey with respect to our Bioral® technology. Although we have purchased the BEMA® technology from QLT, we may be unable to fulfill our remaining payment obligations under such agreement. The loss of our key technologies would seriously impair our business and future viability, and could result in delays in developing, introducing or maintaining our products and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the technology we license could prevent the implementation or impair the functionality of our products or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

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

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

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

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

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

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

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

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

Risks Related to Our Industry

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

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

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

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

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

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

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

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

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. All of our clinical trials have been, and all of our proposed clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have a general liability/product liability policy that includes coverage for our clinical trials, with an annual aggregate limit of $2 million with a $2 million limit per occurrence. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products and product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products. In addition, although third party partners like Meda are required to provide insurance in connection with specific products like ONSOLIS®, such partners may face similar insurance related risks.

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

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

Risks Related to Our Management and Affiliate Transactions

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

Our ability to achieve our corporate objectives will depend to a significant degree upon the continued services of key management, technical and scientific personnel. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain key person life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Executive officers, directors and entities affiliated with them have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders.

As of the date of this Report, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 29.29% of our outstanding common stock. These figures do not reflect any future potential exercise of common stock purchase warrants (including those issued to Laurus Master Fund, Ltd., CDC and others) into shares of common stock.

The interests of our current officers, directors and affiliated stockholders may differ from the interests of other stockholders. As a result, these current officers, directors and affiliated stockholders could have the ability to exercise significant control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

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

issuance of blank check preferred stock.

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

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

Risks Related to Our Common Stock

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

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

Our stock price is subject to market factors, and your investment in our securities could decline in value.

Since our initial public offering in June 2002, there has only been a relatively limited public market for our securities and there is a risk that an active trading market in our securities may not be adequately maintained. In addition, the overall market for securities in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies. In particular, the market prices of securities of biotechnology and pharmaceutical companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our securities, which could cause a decline in the value of your securities. These fluctuations, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

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

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

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

We are authorized to issue 45 million shares of our common stock. As of March 7, 2011, there are 24,062,369 shares of common stock issued and 24,046,878 shares of common stock outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of outstanding options or warrants. To the extent such options (including options under our stock incentive plan) or warrants are exercised, the holders of our common stock may experience further dilution.

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors would experience additional dilution. Moreover, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5 million authorized but undesignated shares of preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

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

We have a material number of shares of common stock underlying securities of our company, the future sale of which could depress the price of our publicly-traded stock. As of March 7, 2011: (i) 4,576,465 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.65 per share, and (ii) 5,273,921 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $4.13 per share. If and when these securities are exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

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

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

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

- providing for a staggered board of directors, which impairs the ability of our stockholders to remove our directors at annual or special meetings of stockholders;
- authorizing the issuance of blank check preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent;

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establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;

requiring a super-majority vote of our stockholders to remove directors of our company; and

providing that our stockholders may only remove our directors for cause (as defined in our bylaws).

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

There are no unresolved written comments that were received from the SEC staff 180 days or more before the end of our fiscal year relating to our periodic or current reports under the Exchange Act.

Item 2. Description of Property.

Our executive offices are located in Raleigh, North Carolina. The lease, which commenced November 2007, for this approximately 5,500 square foot space has a term of approximately 63 months and base rent for this term is $589,454. Rent is payable in monthly installments, and is subject to yearly price increases and increases for our share of common area maintenance costs. The landlord for this space is HRLP Raleigh, L.P.. We believe this space is adequate as our principal executive office location.

Our finance and accounting offices are located in Tampa, Florida. We share this office space with Accentia and pay $2,848 on a monthly basis for approximately 981 square feet of office space occupied by our four full-time employees in this office.

Item 3. Legal Proceedings.

On November 5, 2010, we received notice of a possible legal action against us for alleged patent infringement involving a third-party patent. The aforementioned legal action was filed by MonoSol Rx, LLC (MonoSol) in the Federal District Court of New Jersey on November 2, 2010, and we were formally served on January 19, 2011. MonoSol claims that our manufacturing process for ONSOLIS®, which has never been disclosed publicly and which we and our partners maintain as a trade secret, infringes its patent (United States Patent No. 7,824,588). MonoSol also has made a claim of false marking as part of its compliant. Of note, the BEMA® technology itself is not at issue in the case, but rather only the

manner in which ONSOLIS®, which incorporates the BEMA® technology, is manufactured.

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We refute as without merit MonoSol s assertion of patent infringement, which relates to our confidential, proprietary manufacturing process for ONSOLIS®. We further refute MonoSol s claim of false marking.

On February 23, 2011, we filed our initial answer in this case. In our answer, we stated that our position that our products, methods and/or components do not infringe MonSol s patent because they do not meet the limitations of any valid claim of MonoSol s patent.

Moreover, in our answer, we stated our position that MonoSol s patent which is the subject of the case is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law.

For these and other reasons, we intend to defend this case vigorously, and we are very confident that MonoSol s claims will be rejected.

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PART II

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

Our common stock is listed for quotation on the NASDAQ Capital Market under the symbol BDSI . The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2010 and 2009, as reported by the NASDAQ Capital Market, is set forth below.

Quarterly Common Stock Price Ranges

Fiscal Year 2010, Quarter Ended:	High	Low
March 31, 2010	$ 4.31	$ 3.34
June 30, 2010	$ 4.21	$ 2.13
September 30, 2010	$ 3.00	$ 2.20
December 31, 2010	$ 3.70	$ 2.67

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

As of March 7, 2011, we had approximately 153 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain earnings for further business development and do not expect to pay cash dividends in the foreseeable future .

Securities Authorized for Issuance Under Equity Compensation Plans

The following table indicates shares of common stock authorized for issuance under our Amended and Restated 2001 Incentive Plan as of December 31, 2010:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders	4,311,539	$ 3.65	898,058
Equity compensation plans not approved by security holders			
Total	4,311,539	$ 3.65	898,058

As our Amended and Restated 2001 Incentive Plan is set to expire in 2011, we plan to present a new incentive plan for approval by our stockholders at our 2011 annual meeting of stockholders.

Stock Performance

The following graph shows a comparison of the five year total cumulative returns of an investment of $100 in cash on December 31, 2005 in (i) our common stock (ii) the Nasdaq Composite Index (iii) the Nasdaq Biotechnology Index and (iv) the Nasdaq Pharmaceutical Index. All

values assume reinvestment of the full amount of all dividends (to date, we have not declared any dividends).

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This stock performance graph shall not be deemed filed with the SEC or subject to Section 18 of the Securities Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended (the Securities Act).

Comparison of cumulative total return on investment since December 31, 2005:

	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010
BioDelivery Sciences Int l, Inc.	$ 100.00	$ 128.63	$ 118.15	$ 116.94	$ 158.47	$ 143.15
Nasdaq Composite (U.S. Companies)	100.00	109.52	120.27	71.51	102.89	120.29
Nasdaq Biotechnology	100.00	101.02	105.65	92.31	106.74	122.76
Nasdaq Pharmaceutical	100.00	107.83	105.79	85.27	96.63	95.59

Item 6. Selected Financial Data.

The data presented below as of and for the fiscal years ended December 31, 2010 and 2009 and for the fiscal year ended December 31, 2008 is derived from our audited consolidated financial statements included elsewhere in this report. The financial data as of December 31, 2008 and as of and for the fiscal years ended December 31, 2007 and 2006 is derived from our audited financial statements which are not included in this report. The information set forth below should be read in conjunction with the Company s consolidated financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 of this report and our consolidated financial statements and related notes beginning on page F-1 and other financial information included in this Report.

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	Fiscal Year				
	2010	2009	2008	2007	2006
	(Dollars in thousands, except per share data)				
Statements of Operations Data:					
Total revenue	$ 3,405	$ 62,815	$ 263	$ 202	$ 276
Operating (loss) income	(16,319)	40,129	(17,964)	(21,660)	(14,812)
Net (loss) income	(13,033)	33,047	(17,233)	(25,187)	(22,395)
Diluted net (loss) income per share	(0.56)	1.54	(0.90)	(1.64)	(1.67)
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 18,209	$ 23,873	$ 906	$ 16,597	$ 2,172
Total assets	33,580	39,678	13,337	27,988	9,842
Accumulated deficit	(72,246)	(59,214)	(92,260)	(75,027)	(45,970)
Total stockholders equity (deficit)	9,786	14,458	(33,582)	(18,788)	(8,714)
Statements of Cash Flows Data:					
Net cash flows from operating activities	$ (11,682)	$ 18,190	$ (9,816)	$ 12,217	$ (9,681)

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 upon closing, a $30 million milestone payment on September 14, 2007 and an additional $29.8 million milestone payment associated with approval of ONSOLIS® by the FDA and providing product 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 2011 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.

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We have a very limited history of commercial operations, having focused the vast majority of our corporate effort on research and development activities. We have since our founding received revenue in the form of: (i) 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 and subsequently, a substantial amount was 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, including research revenues in 2010 from TTY Biopharm Co., LTD. (TTY) and Kunwha Pharmaceutical Co., Ltd. (Kunwha) and (v) minimal royalty revenue from a license with Accentia. Most of these types of revenue are generally not repeating or predicable. Therefore, 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.

Critical Accounting Policies and Estimates

Impairment Testing

Our goodwill impairment testing is calculated at the reporting unit level. We performed an evaluation and determined that there is only one reporting unit. 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 is subject to significant changes from period to period. No goodwill impairment charges have resulted from this analysis for 2010, 2009 or 2008.

In accordance with Generally Accepted Accounting Principles (referred to herein as 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 flow 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 undiscounted future cash flow related to the intangible asset.

In making this impairment assessment, we predominately use an undiscounted cash flow model derived from internal forecasts. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In the event that our management determines that the value of intangible assets have become impaired using this approach, we will record an accounting charge for the amount of the impairment. No impairment charges have been recorded for other amortizing intangibles in 2009 or 2008. We did, however, record a $0.2 million impairment charge during the twelve months ended December 31, 2010. The impairment charge removed the remaining intangible asset related to Bioral®. The Company determined not to pursue Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis (see note 12 to the financial statements).

Fair market value accounting (derivative liability)

The most significant estimate that could have a material effect on net (loss) gain for the last three years is the fair market value accounting for our derivative liability. Our derivative liability consists of free standing warrants that are recorded as liabilities due to the registration rights agreements and the requirement for continued effectiveness of the warrants. As a result, the warrants must be recorded at fair value. The changes in fair value are posted to the derivative gain (loss) in other income (loss). We utilize the Black Scholes method to estimate the fair value of our warrants. The most significant factor in the Black Scholes calculation is our stock price. An increase in the stock price consequently increases the value of our liability and causes a loss. The opposite occurs with a decrease in our stock price.

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During the year ending December 31, 2010, a $0.38 decline in the value of our stock was the primary cause of the $3.1 million derivative gain. The relationship between the gain or loss and our stock price will change from year-to-year based on other Black Scholes factors, including the remaining warrant term and volatility of our stock.

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 Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our common stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

We use the Black-Scholes option pricing model to determine the fair value of stock option and warrant grants. In applying the Black-Scholes option pricing model during 2010, we assumed no dividend yield, risk-free interest rates ranging from 1.17% to 2.36%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor ranging from 73.41% to 79.02% and option exercise prices ranging from $2.26 to $3.95.

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.

Significant Valuation and Qualifying Accounts

We have no significant or material contra-asset allowances or reserves. The only material liability accrual is for the payment of bonuses in 2011 that are based upon meeting performance objectives in 2010. These incentive payments were formally approved by our board of directors in February 2011 and are partially contingent upon a retrospective review to take place later in 2011. We estimated the bonus payment to be approximately $0.6 million. This was split almost evenly within General and Administrative and Research and Development expenses for the year ended December 31, 2010.

Revenue Recognition

Meda License, Development and Supply Agreements

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.

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.

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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, $59.8 million of the aggregate milestones and services revenue were recognized. Upon first commercial sale in a European country, an estimated $18 million will be recognized, which includes an additional $5.0 million in milestones and approximately $0.5 million in research and development services. At December 31, 2010, there was remaining deferred revenue of $14.1 million, of which $12.5 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 $0.1 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided through expiration of the license terms, as defined above.

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.

Other License Arrangements

In October 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Updated No. 2009-13 (ASU 2009-13), which addressed the accounting for multiple-deliverable arrangements. The Company chose early adoption of this standard, which is in effect for the year ended December 31, 2010.

ASU-2009-13 has been applied to two similar transactions in 2010. In May 2010, we entered into a License and Supply Agreement with Kunwha to develop, manufacture, sell and distribute BEMA® Fentanyl in the Republic of Korea. The upfront payment from Kunwha of $0.3 million (net of taxes, approximating $0.25 million) received in June 2010 is recorded as contract revenue in the accompanying consolidated statements of operations.

In October 2010, we entered into a License and Supply Agreement with TTY to develop, manufacture, sell and distribute BEMA® Fentanyl product in Taiwan. The upfront payment from TTY of $0.3 million received in October 2010 is recorded as contract revenue in the accompanying consolidated statements of operations.

The principal change upon the adoption of ASU-2009-13 is the upfront recognition of $0.3 million in revenue upon signing each of the two agreements. The upfront signing milestone qualifies as a separate unit of accounting and was determined to have a standalone basis. Both milestone payments are non-refundable. We are responsible for supplying ONSOLIS® to both TTY and Kunwha. We will receive a royalty payment for such supply. The adoption of ASU-2009-13 is not expected to have a material impact after this initial adoption. Under previous guidance, these two upfront payments would have been deferred and only recognized upon first sale, which is not expected until 2012 or 2013.

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Product Royalty Revenues

Product royalty revenue amounts are based on a percentage of net sales revenue of the ONSOLIS® product under our license agreement with Meda. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. This is shown as product royalty revenues on the accompanying consolidated statements of operations. Meda has the right to reject products that do not comply with product, packaging, or regulatory specifications. Defective product must be identified by Meda within 10 days after inspection at Meda s distribution site. We bill Meda immediately upon receipt by Meda of product (FOB manufacturer). On a quarterly basis, a reconciliation is prepared that reflects the difference between actual net sales by Meda multiplied by the royalty percentage, and the actual royalty payments made during the quarter (which is based on a transfer price at the time we invoice Meda). The parties true-up the differences within 45 days of each quarter-end.

Product Royalties, Related Party

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

Research Revenues

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

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.

Contract Revenue

The Meda up-front and milestone payments related to ONSOLIS® of $30.0 million in 2007 was initially recorded as deferred revenue. Upon FDA approval of ONSOLIS® in July 2009, and the subsequent product launch in October 2009, $29.8 million was received from Meda and was released as revenue, along with the initial $30 million received. In 2010, we recognized $0.5 million that was received upon signing licensing contracts for ONSOLIS® in South Korea and Taiwan.

Cost of Product Royalties

The cost of product royalties includes the direct costs attributable to the production of ONSOLIS®. 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.

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Cost of Product Royalties 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 product royalties. 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, and an established profit margin as outlined in the supply agreement. This is shown as cost of product royalties on the accompanying consolidated statements of operations. Cost of product royalties also includes royalty expenses owed to third parties. These royalty expenses are directly related to the products sold during the period.

For the Year Ended December 31, 2010 Compared to the Year Ended December 31, 2009

Product Royalty Revenues. We recognized $1.9 million and $2.8 million in product royalty revenue during the years ended 2010 and 2009, respectively, under our license agreement with Meda.

Product Royalties, Related Party. We recognized $0.02 million in product royalties, related party, during the year ended 2009 under our license agreement with Accentia relating to CRS. There were no product royalties, related party in 2010.

Research Revenues. We recognized $0.7 million and $0.2 million of revenue related to a research and development agreement with Meda during the years ended 2010 and 2009, respectively.

Sponsored Research Revenues. We recognized $0.2 million in sponsored research revenue from the U.S. Government s Qualifying Therapeutic Discovery Project during the year ended 2010. There was no sponsored research revenue received in 2009.

Contract Revenues. We recognized $0.5 million in contract revenue during the year ended 2010 which related to license agreements with TTY and Kunwha. Contract revenue of $59.8 million during the year ended 2009 was related to previously deferred revenue under our license agreement with Meda.

Cost of Product Royalties . We recognized $0.8 million and $2.0 million in cost of product royalties during the years ended 2010 and 2009, respectively, related to direct costs attributable to the production of our product ONSOLIS®.

Research and Development Expenses. During the years ended December 31, 2010 and 2009, research and development expenses totaled $10.6 million and $10.4 million, respectively. Our scientific staff continued to work toward increased development and application of our BEMA® technologies, but particularly with respect to BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone and ONSOLIS®. Funding of this research in 2010 and 2009 was obtained through deferred license revenue, shelf financing, 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 our drug delivery technologies.

General and Administrative Expenses. During the years ended December 31, 2010 and 2009, general and administrative expenses totaled $8 million and $10.3 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. The decrease in general and administrative expenses in 2010 relates principally to a dispute settlement of $1.9 million and the legal costs associated with the settlement between us and Accentia that were recorded in 2009. This amount is shown in related party, general and administrative.

Impairment of intangible license. During the year ended December 31, 2010 we had an impairment of intangible license and associated charge of $0.2 million. This represented 100% of the remaining unamortized carrying value, related to the Bioral® drug delivery technology. There was no impairment charge during the year ended December 31, 2009.

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Interest Income, Net. During the year ended December 31, 2010 we had interest income of $133,613 compared to $35,596 for the corresponding period in 2009. The Company had a higher average cash balance during the year ended December 31, 2010 as compared to 2009. During the first half of 2009, the Company averaged only $3 million in cash until the receipt of $26.8 million from Meda upon FDA approval of ONSOLIS® and delivery of product to support the product launch. We maintained a $22 million average cash balance during 2010, allowing higher dividends and interest to be earned.

Derivative Gain (loss). Derivative gain (loss) in 2010 and 2009 is related to the adjustment of derivative liabilities to fair value as of December 31, 2010 and December 31, 2009. Derivatives are primarily free-standing warrants. The warrants are measured using Black Scholes calculations. A major component of the calculation is the Company stock price. During 2009, the Company stock rose by over $1 per share. This increased our warrant liability, and correspondingly caused the Derivative loss. During 2010, the opposite situation occurred. The Company stock declined by .38 per share, which was the prime cause of the 2010 Derivative gain.

Income Tax Benefit and tax net operating loss carryforwards. We had federal and state net operating loss carryforwards (NOL) of approximately $27 million and $21.1 million at December 31, 2010 as compared to federal and state NOLs of $20.3 million and $14.3 million as of December 31, 2009. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 for state purposes. In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, we recorded a valuation allowance with respect to all of our deferred tax assets. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a loss corporation (as defined in the Internal Revenue Code), there are annual limitations on the amount of the net operating loss and other deductions which are available to us.

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

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

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

Research Revenues. We recognized $0.2 million of revenue related to research and development agreement with Meda during the years ended 2009 and 2008, respectively.

Sponsored Research Revenues. There was no sponsored research revenue received in 2009 or 2008.

Contract Revenues. We recognized $59.8 million in previously deferred license revenue in 2009 under our license agreement with Meda. There was no contract revenue recognized in 2008.

Cost of Product Royalties . We recognized $2.0 million in cost of product royalties in 2009 related to direct costs attributable to the production of our product ONSOLIS®. There was no cost of product royalties 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® 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® 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.

Impairment of intangible license. There was no impairment charge during the years ended December 31, 2009 or 2008.

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 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. 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.

Major Research and Development Projects

In 2010, we continued to dedicate a significant amount of our corporate resources to the E.U. regulatory review and manufacturing of ONSOLIS®, and in addition, expanded the clinical development of BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone, and BEMA® Granisetron. Substantial expenditures were devoted to manufacturing efforts (in conjunction with our manufacturing partners) required to support ONSOLIS® and the non-clinical and clinical development of our product candidates. Clinical research expenses in 2010 were primarily dedicated to two Phase 1 studies and the start of the Phase 3 program for BEMA® Buprenorphine for the treatment of chronic pain. Additional investments were made in formulation development work for BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone and BEMA® Granisetron, and the performance of a 7-day toxicology study with BEMA® Granisetron. Further clinical development of ONSOLIS® is the responsibility of Meda both in the U.S. and Europe. In addition, we continue to evaluate new product and technology opportunities that would fit into our commercial strategy.

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

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

BEMA® Buprenorphine. BEMA® Buprenorphine is our second analgesic product using the BEMA® technology. We submitted an IND that was accepted by the FDA for BEMA® Buprenorphine in December 2005. We have conducted multiple Phase 1 studies with BEMA® Buprenorphine, one Phase 2 study in acute pain, and have started the Phase 3 program for the treatment of moderate to severe chronic pain. The program is schedule to complete in the second half of 2011 with NDA submission in the first half of 2012.

Due to the ability of BEMA® Buprenorphine to participate in the key chronic pain market, we believe that BEMA® Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion dollar U.S. market for opioid analgesics; this would translate to over $500 million in peak annual sales. We do not expect to generate any royalty revenue from sales of BEMA® Buprenorphine, if ever, until at least 2013. We initiated partnering discussions for BEMA® Buprenorphine in 2010.