BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-K
March 19, 2012
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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, 2011

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

For the transition period from to

Commission file number 001-31361

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

801 Corporate Center Drive, Suite #210

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

Issuer s telephone number: 919-582-9050

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

Title of each class	**Name of exchange on which registered**
Common stock, par value $.0001	Nasdaq Capital Market

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

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

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 x No ¨

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2011 was approximately $78,773,615 based on the closing sale price of the company s common stock on such date of $3.23 per share, as reported by the NASDAQ Capital Market.

As of March 13, 2012, there were 29,577,146 shares of company common stock issued and 29,561,655 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, 2011

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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 c 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 our BEMA® drug delivery technology platform and any proposed products, product candidates or marketed products, including our sole approved and marketed product, ONSOLIS®, and our partnered product candidate, BEMA® Buprenorphine;

- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including (i) the timing, status and results of our or our commercial partners filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies and (ii) the heavily regulated industry in which we operate our business generally;

- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates;

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

- our ability to generate commercially viable products and the market acceptance of our BEMA® technology platform and our proposed products and product candidates;

- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;

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

- the protection and control afforded by our patents or other intellectual property, and any interest patents or other intellectual property that we license, or our or our partners ability to enforce our rights under such owned or licensed patents or other intellectual property;

- the outcome of ongoing or potential future litigation or other claims or disputes relating to our business, technologies, products or processes;

our expected revenues (including sales, milestone payment and royalty revenues) from our products or product candidates and any related commercial agreements of ours;

the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to address any regulatory issues that have arisen or may in the future arise;

our ability to retain members of our management team and our employees; and

competition existing today or that will likely arise in the future.

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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.

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

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we may seek to acquire or license additional drug delivery technologies. Should we gain access to such technologies, we would seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through commercial partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace.

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

ONSOLIS®

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

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

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Meda s U.S. subsidiary, Meda Pharmaceuticals, based in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets and sells branded prescription therapeutics. Meda has an experienced, 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.

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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.

The following is a summary of the current regulatory and commercial Status of ONSOLIS®/BREAKYL .

Region	Partner	Regulatory Status	Commercial Status
U.S.	Meda Pharmaceuticals	Approved	Launched October 2009
Canada	Meda Valeant Pharma Canada Inc.	Approved	Launched 3Q 2011
E.U.	Meda	Approved	Launch anticipated in 2012
Australia	Meda Valeant Pharma Canada Inc.	Filed	
Taiwan	TTY Biopharm Ltd.	Filed	
South Korea	Kunwha Pharmaceutical Co. Ltd.	Pre-registration	

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 and certain manufacturing and formulation issues described below. The lack of approved REMS programs for our direct competitors resulted in an unlevel playing field, which 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 to the FDA a new REMS program which was to provide broader access to ONSOLIS® through retail pharmacies and reduce some of the burdens placed on prescribers. This REMS program followed the guidelines provided by the FDA in November 2010, to all companies that were or would be marketing transmucosal fentanyl products, thereby providing for a level playing field. However, the FDA abandoned individual REMS programs through the creation of a consortium consisting of all manufacturers of transmucosal fentanyl products, including both us and our commercial partner Meda. The goal of the group was to develop one single REMS program covering all products in the class.

On December 29, 2011, the FDA approved a class-wide REMS program covering all transmucosal fentanyl products under a single risk management program. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all marketed transmucosal fentanyl products under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program also ends the disparity in prescribing requirements for ONSOLIS® compared to similar products and provides ONSOLIS® with both retail and inpatient facility access. Healthcare professionals and patients enrolled in the prior ONSOLIS® REMS will be automatically transferred into the new TIRF REMS Program. Additionally, prescribers and patients enrolled in other individuals REMS programs will also automatically be transferred into the program. In addition to consistency in educational materials, technological advances will simplify the process of participation and verification of program participation. The full program is expected to be implemented in March 2012. At that point, it is anticipated that ONSOLIS® will be in a better position to compete on its own merits.

On March 12, 2012, we announced the postponement of the U.S. relaunch of ONSOLIS® until the product formulation can be modified to address two appearance issues raised by FDA following a recent inspection of the manufacturing facility of our North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. (which we refer to herein as Aveva). Specifically, the FDA identified the formation of microscopic crystals and a slight fading of the color during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity or safety, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specification before additional product can be manufactured and distributed. Therefore, the U.S. relaunch and additional manufacturing of ONSOLIS® has been postponed until such product appearance issues have been resolved.

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BEMA® Buprenorphine

Our next product, currently in development, 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. Completion of this Phase 2 study led to the initiation of a Phase 3 double-blind, randomized, placebo-controlled clinical study which was initiated in the fourth quarter of 2010. On September 28, 2011, we announced the preliminary findings of our randomized, placebo-controlled, Phase 3 clinical study of BEMA® Buprenorphine for the treatment of moderate to severe chronic pain in a mixed opioid naïve and opioid experienced population. The primary endpoint of the study, overall pain intensity difference between BEMA® Buprenorphine and placebo, was not achieved. Following full analysis of the data, we concluded that we encountered a high placebo response in the opioid naïve segment of the patient population, particularly at our starting dose, which we believe accounted for the lack of statistically significant efficacy that was observed in the trial overall. This is an occurrence typical of many pain trials, and we feel this can be addressed in future studies with adjustments to our patient population, study criteria, starting dose and sample size. We believe the totality of the study results favor BEMA® Buprenorphine, including a near statistically significant difference between BEMA® Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). In addition, when eliminating the group of patients that did not titrate beyond the starting dose, a statistically significant difference between BEMA® Buprenorphine and placebo (p=0.025) was identified. Neither of these subgroups was sufficiently large enough to be powered to show a statistical difference; however, the robust results in these subgroups resulted in near statistical significance in the opioid experienced patients and statistical significance in the opioid experienced patients titrating beyond the starting dose. Overall, the trial, though not successful, has provided a wealth of knowledge that will assist us in the final design of what we believe will be successful future clinical studies.

We believe that our outlook on BEMA® Buprenorphine was validated when, in January 2012, we announced the signing of a worldwide licensing and development agreement for BEMA® Buprenorphine with Endo Pharmaceuticals, Inc. (which we refer to herein as Endo) under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BEMA® Buprenorphine for the treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront payment, which we received in January 2012; (ii) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events; (iii) $55 million in potential sales milestones upon achievement of designated sales levels; and (iv) a tiered, mid- to upper-teen royalty on net sales of BEMA® Buprenorphine in the United States and a mid- to high-single digit royalty on net sales of BEMA® Buprenorphine outside the United States. We expect to use portions of our Endo milestone payments to fund our development obligations under the Endo agreement with respect to BEMA® Buprenorphine.

One of the key intellectual property milestones under our Endo agreement was achieved when, in February 2012, the U.S. Patent and Trademark Office (or USPTO) issued a Notice of Allowance regarding one of our patent applications (No. 13/184306) which, once the patent is granted, will extend the exclusivity of the BEMA® drug delivery technology for BEMA® Buprenorphine (as well as BEMA® Buprenorphine/Naloxone, discussed below) from 2020 to 2027. As a result, we will be entitled to a milestone payment in the amount of $15 million upon the final granting of this patent and an additional milestone payment of $20 million at the time of approval of a New Drug Application (or NDA) by the FDA for BEMA® Buprenorphine for the treatment of chronic pain.

Endo is one of the premier companies in the area of pain management and has demonstrated significant achievements in the pain space, particularly with the development, launch and commercialization of a portfolio of pain therapeutics including opioids. Endo currently has approximately 650 sales representatives covering pain specialty and primary care physicians. Endo s current branded pain portfolio exceeds $2 billion in annual sales and includes products such as Opana ER, Lidoderm and Voltaren Gel. Endo has strong sales and marketing capability in pain therapeutics, and a managed care organization that has established solid formulary positioning for the company s products. We believe BEMA® Buprenorphine is an excellent fit to Endo s pain portfolio and will, if approved, add a Schedule III opioid to their branded pain franchise. BEMA® Buprenorphine would complement Endo s pain therapeutics portfolio providing the company with an opportunity to offer a ladder of pain products, aligned with pain severity and opioid scheduling. In particular, BEMA® Buprenorphine would potentially be aligned with the needs of pain specialists and primary care physicians who seek an alternative to Schedule II opioids for the treatment of moderate to severe chronic pain that is not adequately controlled with commonly prescribed first-line therapies (e.g., NSAIDs).

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BEMA® Buprenorphine/Naloxone

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. 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 $1.4 billion in annual sales in the U.S.

Pharmacokinetic studies have demonstrated the ability of the BEMA® technology to deliver the high doses of buprenorphine necessary for the treatment of opioid dependence. 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, at which we confirmed that the 505(b)(2) regulatory pathway will be pursued for the clinical development of this product. In September 2011, we announced positive preliminary results from a study assessing the pharmacokinetics of a BEMA® Buprenorphine/Naloxone combination. The study assessed buprenorphine and naloxone absorption profiles compared to the FDA approved and currently marketed opioid dependence product, Suboxone. Results of the study demonstrated the ability of the BEMA® formulation to meet the key pharmacokinetic goal of delivering plasma concentrations of buprenorphine in the range needed to treat opioid dependence while minimizing the exposure of naloxone. In December 2011, we announced positive results of a second pharmacokinetic study and plans to meet with FDA to confirm the development plan and regulatory strategy going forward. A meeting was held with FDA in early February 2012, and following the meeting, we announced that we had reached an agreement with the FDA on the development plan for BEMA® Buprenorphine/Naloxone, which includes a pivotal pharmacokinetic study comparing BEMA® Buprenorphine/Naloxone to Suboxone in normal volunteers and a supporting safety study in opioid dependent patients. The FDA concurred with our strategy while requesting one additional, non-comparative pharmacokinetic study examining the effects of multiple films administered concurrently. A similar study was requested and completed as part of the NDA for ONSOLIS®. We plan to initiate a pivotal bioequivalence study and safety study by mid-2012. Based on current timelines, we believe we may be in a position to submit a NDA in the first half of 2013.

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.

Additional Overview Information

From our inception through December 31, 2011, we have recorded accumulated losses totaling approximately $95.6 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for our product candidates, our goal will be to augment our current sources of revenue and, as applicable, deferred revenue (principally licensing fees), with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

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

- commercializing ONSOLIS® and other of our candidate products;
- partnering with other pharmaceutical companies such as Meda and Endo 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
- securing proceeds from public and private financings and other strategic transactions.

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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.

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;
- provide a reproducible delivery rate, not susceptible to varying or intermittent contact with oral membranes; and
- dissolve completely, leaving no residual product or waste and avoiding patient removal, and the possibility for diversion or disposal of partially used product.

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

Bioral® Technology

We have previously engaged in development efforts with another drug delivery technology, known as the Bioral® technology, although we are not presently (and did not in 2011) dedicate any time or resources to the development of this technology or any related products. The Bioral® technology seeks to encapsulate 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. The 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 with Meda AB
BEMA® Buprenorphine	Moderate to severe chronic pain	Phase 3 results announced September 2011	Partnered worldwide with Endo Pharmaceuticals
BEMA® Buprenorphine/Naloxone	Treatment of opioid dependency	Pivotal studies planned for 2012; NDA filing anticipated first half 2013	In-house commercialization or partnership.
BEMA® Granisetron	Prevention of nausea and vomiting associated with cancer therapies	IND filing February 2011	In-house commercialization for specialty indications possible; primary care rights expected to be partnered

While continuing to work closely with Meda on ONSOLIS® (including on regulatory approvals in 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 to developing our pipeline of BEMA® products, particularly BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone. 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® Granisetron or other opportunities that we may identify.

BEMA® Formulated Products and Product Candidates

ONSOLIS®

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

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

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In 2011, the leading company in the fast-acting fentanyl market was Teva Pharmaceuticals (NASDAQ:TEVA), which completed an acquisition of Cephalon, Inc. in October 2011. Teva markets both the branded (Actiq®) and generic formulations of fentanyl transmucosal lozenge. Additional generic manufacturers include Covidien and Watson Pharmaceuticals. Teva introduced a second transmucosal fentanyl product, Fentora® in late 2006. The reported combined retail sales of these products in 2011 was $346 million. In 2011, additional transmucosal formulations of fentanyl were launched and/or approved, including, Abstral®, a sublingual tablet, which was launched in early 2011 by Prostrakan, a nasal spray formulation from Archimedes sold under the trade name Lazanda® and a sublingual spray from Insys, known as Subsys was approved in January 2012. We believe that ONSOLIS® may offer advantages over the marketed and pipeline fentanyl products in terms of ease of use and other attributes; however, we recognize the substantial increase in competition in the category.

We may at some point 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 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, for fear of addiction, reluctant to prescribe narcotics, particularly on a chronic basis. Also, since buprenorphine is a Schedule III controlled substance, physicians will be able to phone, fax or otherwise electronically deliver the prescription to the pharmacy with refills permitted for up to 6 months, thus making chronic therapy easier for both the patient and the physician. Refills are not permitted for Schedule II controlled substances, requiring the patient to obtain a new prescription from the doctor s office and take such prescription to the pharmacy each time the medication is required.

We announced the preliminary findings in September 2011 of our randomized, placebo-controlled, Phase 3 clinical study for the treatment of moderate to severe chronic pain in a mixed opioid naïve and opioid experienced population. The primary endpoint of the study, overall pain intensity difference between BEMA® Buprenorphine and placebo, was not achieved. Following full analysis of the data, we witnessed a high placebo response in the opioid naïve segment of the patient population, particularly at our starting dose, which accounted for the overall lack of efficacy that was observed in the trial overall. We believe the totality of the study results favor BEMA® Buprenorphine, including a near statistically significant difference between BEMA® Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). In addition, when eliminating the group of patients that did not titrate beyond the starting dose, a statistically significant difference between BEMA® Buprenorphine and placebo (p=0.025) was identified. Neither of these subgroups was sufficiently large enough to be powered to show a statistical difference; however, the robust results in these subgroups resulted in near statistical significance in the opioid experienced patients and statistical significance in the opioid experienced patients titrating beyond the starting dose. We expect to model our future clinical trials for this product with the knowledge gained from our initial Phase 3 study.

In January 2012, we announced the signing of a worldwide licensing and development agreement for BEMA® Buprenorphine with Endo. Under terms of the agreement, Endo will be responsible for the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. Endo will commercialize BEMA® Buprenorphine outside the U.S. through its own efforts or through regional partnerships. Both companies will collaborate on the planning and finalization of the Phase 3 clinical development program and regulatory strategy for BEMA® Buprenorphine for chronic pain. We will maintain responsibility for the conduct of planned clinical studies leading up to the submission of the New Drug Application (NDA). Endo will have the responsibility of submitting the NDA and managing the interactions with the FDA. We plan to initiate two Phase 3 clinical studies, one in opioid naïve and one in opioid experienced patients by the middle 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. Such regulatory designation indicates it is less prone to abuse and addiction and more convenient for physicians to prescribe (with prescription refills possible), pharmacists to dispense, and patients to obtain;

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

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

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

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

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

The pain market is well established, with many pharmaceutical companies marketing innovative products as well as generic versions of older, non-patent protected products. According to Wolters Kluwer, the U.S. opioid market exceeded $10 billion in sales in 2011. 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 2011 total retail sales in excess of $1.4 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 $250 million in annual peak sales. We expect to finalize our formulation and complete a pivotal bioequivalence study in 2012 to support a possible NDA filing in the first half of 2013.

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 exceeds $2 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.

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, for current and future product candidates, the development, regulatory approval and commercialization pathways utilized for ONSOLIS®

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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,

pharmacokinetic evaluation of the new dosage form in humans,

stability of drug substance,

description of drug product components,

description of manufacturing process,

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

depending on the drug product, may include:
(i) at least one placebo controlled clinical study in humans,

(ii) a second clinical study to establish the safety of the product in the intended patient population.

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 incorporating novel formulations of established pharmaceuticals into our delivery technologies, we believe that we will more quickly and efficiently navigate the FDA approval process, and, if such approval is obtained, more effectively 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®, BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone, most of the drug candidates we target will have been through the regulatory process and therefore the safety and efficacy of the drug will have been established. Consequently, we believe that our clinical trials would primarily need to show that our products will deliver the drug without changing the clinical attributes of the drug or causing unintended safety or tolerability concerns for the patient.

Endo Licensing Agreement for BEMA® Buprenorphine

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

In aggregate, the agreement is worth up to $180 million to us if all milestones are met, which includes an upfront non-refundable payment of $30 million (received January 2012), as well as intellectual property, development, regulatory and commercial milestone payments. Additionally, we will receive a tiered mid to upper teen royalty on U.S. net sales of BEMA® Buprenorphine and an upper single-digit royalty on sales outside the U.S. One of the key intellectual property milestones under our Endo agreement was achieved when, in February 2012, the U.S. Patent and Trademark Office (or USPTO) issued a Notice of Allowance regarding one of our patent applications (No. 13/184306) which, once the patent is granted, will extend the exclusivity of the BEMA® drug delivery technology for BEMA® Buprenorphine (as well as BEMA® Buprenorphine/Naloxone, discussed below) from 2020 to 2027. As a result, we will be entitled to a milestone payment in the amount of $15 million upon the final granting of this patent and an additional milestone payment of $20 million at the time of approval of an NDA by the FDA for BEMA® Buprenorphine for the treatment of chronic pain.

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Meda Licensing Agreements for ONSOLIS®

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

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

- a $30.0 million milestone payment (received in 2007).
- a $29.8 million milestone payment for the approval of ONSOLIS® by the FDA and provision of commercial supplies of ONSOLIS® in the U.S.(received in 2009).
- a double digit royalty on net sales of ONSOLIS® in the covered territories, subject to certain third party royalty payment costs and adjustments, as well as other adjustments in the event of certain specific supply disruptions. The license agreement provides for certain guaranteed minimum annual royalties to us during the second through seventh years following the product s first commercial sale, which occurred in the fourth quarter of 2009.
- sales milestones equaling an aggregate of $30 million will be payable at:
  - $10.0 million when and if annual sales 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. In addition, Meda is subject to certain minimum sales representative calls and advertising and promotional expenditure requirements under the North American license agreement and has agreed to support all future costs of clinical development, such as additional indications for ONSOLIS® that do not involve studies in support of the NDA.

European Agreement. In 2006, we announced collaboration with Meda to develop and commercialize BEMA® Fentanyl (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 (received in 2008) for completion of Phase 3 clinical trials. We will receive a double digit royalty on net sales and additional milestone payments of $5 million upon approval and launch in the first country in the European territory. Meda has managed the regulatory submission in Europe that led to approval in October 2010. Meda will exclusively commercialize BREAKYL in Europe.

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

Key Collaborative and Supply Relationships

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

Endo Pharmaceuticals. We believe that our agreement with Endo is currently one of our most important third party agreements. For a description of our agreements with Endo, please see Endo Pharmaceutical Licensing Agreement above.

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Meda. We believe that our agreements with Meda are currently one of our most important third party agreements. For a description of our agreements with Meda, please see Meda Licensing Agreements for ONSOLIS® above.

Aveva Drug Delivery Systems. Effective October 17, 2005, we entered into an agreement with Aveva Drug Delivery Systems, Inc. pursuant to which Aveva acts as our North American supplier of ONSOLIS® for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of ONSOLIS® for the United States, Mexico and Canada. Our supply agreement with Aveva runs for a term of four years from the first commercial sale of ONSOLIS® (October 2009) and can be renewed for subsequent two year terms. Either we or Aveva can terminate the agreement on advanced written notice.

On March 12, 2012, we announced the postponement of the U.S. relaunch of ONSOLIS® until the product formulation can be modified to address two appearance issues raised by FDA following a recent inspection of the Aveva manufacturing facility where ONSOLIS® is produced. Specifically, the FDA identified the formation of microscopic crystals and a slight fading of the color during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity or safety, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specification before additional product can be manufactured and distributed. Therefore, the U.S. relaunch and additional manufacturing of our ONSOLIS® product has been postponed until such product formulation regarding the appearance issues has been resolved.

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 BREAKYL to us for European clinical trials. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BREAKYL for clinical trials as well as commercial distribution supplies within the European Union. Further, under the agreement LTS has granted us a license under European Patent No. 0 949 925, in regard to BREAKYL in the European Union.

Tolmar. On May 27, 2004, prior to our acquisition of our Arius Pharmaceuticals subsidiary, Arius entered into a worldwide, exclusive royalty-bearing license agreement with Tolmar to develop, manufacture, market, and sell products incorporating what was then Tolmar 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 Tolmar license agreement. In August 2006, we purchased from Tolmar 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 Tolmar. We paid the remaining $0.25 million in December 2011 upon delivery of certain patent obligations. As part of the transaction, and solely with respect to the non-U.S. portion of the former license with Tolmar, no further milestone payments or ongoing royalties will be due to Tolmar 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 Tolmar for $7 million, consisting of $3 million in cash and a promissory note of $4 million, $2 million of which was paid in July 2009 following approval of ONSOLIS® in the U.S., and $2 million of which is due within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA®-based products reach $30 million. As part of the transaction, no further milestone payments or ongoing royalties will be due to Tolmar for the North American territory. To secure our obligation to pay the remaining $2 million amount when due, Tolmar was granted a security interest in the North American BEMA® assets, subject to a license of those assets from Tolmar to us for North America that would be granted to us on the original license terms upon any exercise of rights under such security interest.

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In January 2012, we executed a letter agreement with Tolmar and its parent company, TOLMAR Holding, Inc., whereby the parties agreed that, if we paid Tolmar $1.05 million by February 28, 2012, Tolmar would accept such payment as satisfaction in full of the remaining $2 million outstanding under the aforementioned Tolmar note. Further, upon receipt of such payment (i) the related security agreements, security interests, liens, guaranties and payment obligations with respect to such note and the assets securing its repayment would terminate, (ii) Tolmar would execute a corresponding release and (iii) we do not have any further payment obligations to Tolmar under the note or BEMA® acquisition documents, except with respect to certain indemnification obligations. We paid the $1.05 million contemplated by the letter agreement on January 6, 2012, fully satisfying the outstanding balance of the note, and Tolmar subsequently executed its final release of the related security interests contemplated by the letter agreement. As a result, we now fully own the BEMA® technology, subject to the interests therein held by our licensees.

We also have relationships with third party contract research organizations that assist us with the management of our clinical trials. Further, have collaboration agreements with entities (including Accentia Biopharmaceuticals, Inc. (which we refer to herein as 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 Endo and Meda are examples of these types of relationships, and we will continue to seek other similar arrangements.

Relationship with CDC IV, LLC

On July 14, 2005, we entered into a Clinical Development and License Agreement, 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®.

Under the CDLA, as amended, CDC is entitled to receive a low-double digit royalty based on net sales of ONSOLIS®. The CDLA includes minimum royalties of $375,000 per quarter beginning in the second full year following commercial launch. The minimum provision came into effect in 2011. The royalty term and minimum payments end upon the latter of expiration of the patent or generic entry into any particular country. In addition, we granted CDC a warrant exercisable for up to 601,120 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 was exercised on June 24, 2011. 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 was exercisable at $3.00 per share which expired on July 16, 2011. We previously issued to CDC in March 2007 a warrant to purchase 1 million shares of our common stock in connection with financing. Such warrant was exercisable at $3.80 per share and expired on March 12, 2012. 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.

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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.

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.

On May 12, 2011, we entered into an Amendment to Clinical Development and License Agreement (the CDLA Amendment) by and among CDC and NB Athyrium LLC (Athyrium). We are a party to a Clinical Development and License Agreement, dated as of July 14, 2005 (as amended, the CDLA), with a predecessor to CDC pursuant to which CDC provided funding for the development of our ONSOLIS® product. Athyrium holds certain rights, acquired from CDC, to receive royalties on sales of ONSOLIS®.

Under the terms of the CDLA Amendment, among other matters, the parties agreed to increase the royalty rate to be received by CDC/Athyrium retroactively to the initial launch date of ONSOLIS® and, accordingly, we have recorded $0.3 million as additional cost of product royalties for the year ended December 31, 2011. In addition, certain terms of the CLDA were amended and restated to clarify that royalty payments by us under the CDLA will be calculated based on Meda s sales of ONSOLIS®, whereas previous royalty payments by us to CDC were calculated based on sales of ONSOLIS® by us to Meda.

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The difference between these two calculations resulted in a $1.1 million overpayment by us which was recorded as a prepayment. As a result, we did not pay any of the 2011 quarterly royalty payments due to CDC/Athyrium and will not be required to pay another royalty payment until the December 31, 2011 royalty calculation, which is due during the first quarter of 2012.

Research and Development

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

Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct and third party development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to non-clinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. For the years ended December 31, 2011, 2010 and 2009, we spent approximately $20.8 million, $10.6 million and $10.4 million, respectively, on research and development expenses, and such expenses represented approximately 72%, 56% and 50%, respectively, of our total operating expenses for such fiscal years. Meda has reimbursed approximately $0.8 million, $0.7 million and $2.8 million of our research and development expenses for the years ended December 31, 2011, 2010 and 2009, respectively. These reimbursements represent approximately 4%, 7% and 27% of our total research and development costs for such fiscal years. 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 BEMA® technology, our marketed products and any proposed drug products and formulations under development noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

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

There have been a growing number of companies developing products utilizing various thin film drug delivery technologies. While numerous over-the-counter pharmaceutical products have been brought to market in thin film formulations, few containing prescription products have been introduced in the U.S. Among 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 and consistent transmucosal drug delivery. Included among the companies which we believe are developing potentially competitive thin-film technologies to BEMA® or BEMA® products include: MonoSol Rx, a specialty pharmaceutical company developing and commercializing thin-film pharmaceutical and over-the-counter products using its PharmFilm® technology; IntelGenX Corporation, a drug delivery company focusing on the development of oral controlled release and rapidly disintegrating products and delivery systems such as VersaFilm; and ULURU Inc. (AMEX:ULU), which utilizes their OraDisc mucoadhesive film technology to deliver drugs transmucosally.

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In addition, a number of companies are developing improved versions of existing products using oral dissolving, nasal spray, aerosol, sustained release injection and other drug delivery technologies. We believe that potential competitors are seeking to develop and commercialize technologies for buccal, sublingual or mucosal delivery of various therapeutics or groups of therapeutics. While our information concerning these competitors and their development strategy is limited, we believe our technology can be differentiated because the BEMA® technology provides for a rapid and consistent delivery of each dose based on how the BEMA® technology adheres to the buccal membrane and dissolves at a predetermined rate. Our clinical trials have demonstrated that the BEMA® technology is an effective means of drug delivery that is well tolerated and offers convenience to patients.

ONSOLIS®

For ONSOLIS®, in the breakthrough cancer pain area, the principal competitor is Teva Pharmaceuticals (NASDAQ:TEVA), which completed its acquisition of Cephalon in October 2011. Teva markets both a lozenge (Actiq) and effervescent buccal tablet (Fentora) formulation of fentanyl. Additional competitors include ProStrakan with a sublingual tablet formulation of fentanyl (Abstral), Archimedes with a nasal spray formulation (Lazanda) and Insys with a sublingual spray formulation (Subsys). In addition, generic formulations of Actiq are currently available.

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 imposed a requirement 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 the FDA and put in place prior to launch. In October 2009, ONSOLIS® was launched in the U.S. with an accompanying REMS program known as the FOCUS Program.

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

In December of 2010, Meda submitted to the FDA a new REMS program which was to provide broader access to ONSOLIS® through retail pharmacies and reduce some of the burdens placed on prescribers. This REMS program followed the guidelines provided by the FDA in November, 2010, to all companies that were or would be marketing fast acting fentanyl products in the future, thereby providing for a level playing field. However, the FDA abandoned individual REMS programs through the creation of a consortium consisting of all manufacturers of transmucosal fentanyl products. The goal of the group was to develop one single REMS program covering all products in the class. On December 29, 2011, the FDA approved a REMS program covering all transmucosal fentanyl products. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all marketed transmucosal fentanyl products under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program also ends the disparity in prescribing requirements for ONSOLIS® compared to similar products. Healthcare professionals and patients enrolled in the prior ONSOLIS® REMS would be automatically transferred into the new TIRF REMS Program. Additionally, prescribers and patients enrolled in other individuals REMS programs would also automatically be transferred into the program. In addition to consistency in educational materials, technological advances will simplify the process of participation and verification of program participation. The full program is expected to be implemented in March 2012, and the U.S. relaunch of ONSOLIS® is expected to occur under the new classwide REMS upon availability of product supplies. At that point, it is anticipated that ONSOLIS® will be in a better position to compete on its own merits.

In 2011, the overall market for transmucosal fentanyl products for breakthrough pain according to Wolters Kluwer, totaled $346 million in the U.S. The first approved product for the management of breakthrough cancer pain was Actiq® (oral transmucosal fentanyl citrate) which, according to Wolters Kluwer, generated $38 million in sales in 2011. Total sales for generic versions of Actiq®, available from multiple manufacturers including Covidien, Teva and Watson Pharmaceuticals, according to Wolters Kluwer totaled $146 million over the same period. Fentora® utilizes an effervescent tablet which is administered buccally. Fentora® was approved and launched in late 2006 and according to Wolters Kluwer, generated $160 million in sales in 2011.

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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 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 January 2010, Abstral® was approved in the U.S. by the FDA. Prostrakan launched Abstral® in the second quarter of 2011.

In the U.S., additional products were approved by the FDA utilizing other delivery technologies to administer fentanyl. These products include intranasal Lazanda® from Archimedes, which was approved in June 2011, and a fentanyl sublingual spray formulation from Insys known as Subsys, which received FDA approval in January 2012. Additional products using alternative delivery technologies remain in clinical development including 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 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)	Teva/Generics	Fentanyl lozenge	Marketed (generics available)
Fentora® (fentanyl buccal tablet)	Teva	Effervescent buccal tablet	Marketed
Abstral® (fentanyl sublingual tablet)	Prostrakan	Sublingual tablet	Marketed
Lazanda® (fentanyl nasal spray)	Archimedes	Nasal spray	Marketed
Subsys (fentanyl sublingual spray)	INSYS Therapeutics	Sublingual spray	Approved
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.)

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

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 43% to a total of $163 million in the twelve month period ending June 2011.

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.

BEMA® Buprenorphine (chronic pain)

A number of products may be competitors to BEMA® Buprenorphine for the treatment of chronic pain. A potential focus will be to position BEMA® Buprenorphine as a step up from NSAIDs instead of, or prior to, prescribing more addictive Schedule II narcotics. Indications for such use include pain associated with lower back and severe arthritis conditions. Marketed competitors for these indications include Tramadol (Ultram® ER from PriCara and Ryzolt® from Purdue) and the potent opioids such as Opana® ER from Endo, OxyContin® from Purdue, Avinza® from Pfizer, 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® and Remoxy® (Pfizer) 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.

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. Sales of Butrans in 2011 totaled approximately $58 million and continue to steadily grow. While limited information is available, other formulations of buprenorphine may also be in early stages of development for the treatment of pain.

BEMA® Buprenorphine/Naloxone

We are also developing a higher dose version of BEMA® Buprenorphine combined with naloxone, an abuse deterrent, which has been developed for the treatment of opioid addiction. The product currently marketed for this indication 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 $1.4 billion in the U.S. in 2011, and sales continue to grow steadily. The sublingual film formulation of Suboxone was approved in August 2010, and at the end of 2011, the market volume share was approximately 54%, which we believe is suggestive of the market interest in alternative formulation of buprenorphine/naloxone. We believe a BEMA® formulation of buprenorphine/naloxone has significant appeal given its enhanced delivery (i.e. greater drug absorption) of buprenorphine, improved convenience, faster dissolution time in the oral cavity and lack of taste issues.

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In terms of competition, in addition to Suboxone, in 2011, Phase 3 trials were completed for Probuphine, a subcutaneous depot delivery system containing buprenorphine from Titan Pharmaceuticals. Results of clinical studies demonstrated efficacy and safety, and Probuphine is expected to be submitted for FDA review in mid-2012. Probuphine is anticipated to address the needs of the subset of patients undergoing treatment for opioid dependence who are unable to maintain compliance with alternative formulations or those who may be at high risk for diversion. 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 sublingual tablet formulation from Orexo and an oral capsule from Nanotherapeutics. The potential also exists for a future generic of Suboxone, though no product has been made available since patent expiration in October 2009. It is believed that most generic manufacturers have abandoned plans for generic versions of Suboxone given the challenges in developing a bioequivalent formulation of a product with both an active component and an abuse deterrent. This is an issue believed to be addressed through the BEMA® technology and its dual layers, as well as the 505(b)(2) development pathway being pursued.

BEMA® Granisetron

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. The first transdermal formulation of an antiemetic, Sancuso (granisetron), was approved in 2008 and is marketed by ProStrakan. In addition, there are alternative formulations of granisetron currently in clinical development, including subcutaneous (APF-530, AP Pharma), sublingual spray (Zensana, NovaDel) and intranasal (Almac).

Licenses, Intellectual Property and Proprietary Information

Our intellectual property strategy is intended to maximize protection to our proprietary technologies and know-how and to further expand targeted opportunities by extension of our patents, trademarks, license agreements and trade secrets portfolio. In addition, our intellectual property strategic focus allows the trigger of specific royalty payment obligations by our partner company which is business critical.

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

BEMA® Technology

The drug delivery 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.

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This potential exists in our present litigation with MonoSol Rx, LLC (Monsol). MonoSol claimed in a litigation initiated in late 2010 that our confidential and trade secret manufacturing process for ONSOLIS® infringes their patented manufacturing process for thin films. We do not believe that we have infringed these claims. Moreover, we believe that the claims in MonoSol patents 588, 292 and 891 are invalid, and, in connection with ex parte proceedings we have brought before the USPTO, the USPTO has rejected all claims each of the 588, 292 and 891 patents. We also 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 maintain our manufacturing processes for our BEMA® products and product candidates as trade secrets. Based on our examination of these patents, we do not believe our manufacturing processes infringe MonoSol s patents. As of March 7, 2012, the USPTO rejected every claim in the patents asserted by MonoSol against us, and the court conducted a status conference at which the court granted our motion to stay the case pending outcome of the reexamination proceedings in the USPTO.

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

On March 1, 2011, we were granted a patent extending the exclusivity of the BEMA® drug delivery technology in Canada to 2027. The Canadian Patent No. 2,658,585 provides additional patent protection for ONSOLIS® and BEMA® Buprenorphine. In February 2012, the USPTO issued a Notice of Allowance of our patent application (No. 13/184306) that, once formally granted, will extend the exclusivity of the BEMA® drug delivery technology for BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone in the United States from 2020 to 2027.

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.

With respect to trademarks, BDSI®, BEMA® and Bio® al are registered trademarks of BioDelivery Sciences International, Inc. ONSOLIS® and BREAKYL™ are registered trademarks of Meda Pharmaceuticals, Inc.

Manufacturing

We rely and plan to rely on third-party manufacturers to produce our products for research purposes as well as for commercial distribution. 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.

We have experienced certain supply issues with Aveva in the past. On November 9, 2010, we announced that due to a temporary stoppage of manufacturing at Aveva (which stoppage ended shortly after such announcement), we estimated that launch stocks of ONSOLIS® for shipment in the Canadian market would be available in late March or April of 2011. We reported in May 2011 that all product necessary to supply the Canadian launch of ONSOLIS® and to continue to resupply the United States had been manufactured at Aveva. In August 2011, ONSOLIS® product was released for distribution in both Canada and the United States.

However, on March 12, 2012, we announced the postponement of the U.S. relaunch of ONSOLIS® until the product formulation can be modified to address two appearance issues raised by FDA following a recent inspection of the Aveva manufacturing facility where ONSOLIS® is produced. Specifically, the FDA identified the formation of microscopic crystals and a slight fading of the color during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity or safety, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specification before additional product can be manufactured and distributed. Therefore, the U.S. relaunch and additional manufacturing of ONSOLIS® has been postponed until such product appearance issues have been resolved.

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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 BREAKYL to us for clinical trials in Europe. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BREAKYL 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 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 BREAKYL in the European Union.

For our other product candidates currently in development, we intend to outsource manufacturing to third-party manufacturers, in compliance with the 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 (TTY Biopharm Co., Ltd.) and South Korea (Kunwha Pharmaceutical Co., Ltd.) and our more recent worldwide license and development agreement with Endo for BEMA® Buprenorphine for chronic pain. In the longer-term, we will consider the possibility of becoming a fully-integrated pharmaceutical company capable of selling our own products in specialty pharmaceutical markets while leaving promotional responsibilities for the large primary care audiences with partners.

ONSOLIS® /BREAKYL

European Union

In September 2006, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for BEMA® Fentanyl in the European Union. This product will be marketed in Europe under the trade name BREAKYL . The agreement between us and Meda outlines specific marketing minimum expenditures and sales call volumes in addition to minimum royalty payments beginning during the first five years after launch. Additionally, Meda is responsible for all post-approval clinical studies and label expansion trials. BREAKYL received marketing authorization from the European regulatory authorities in October 2010. Progress continues toward preparations for the launch of BREAKYL in Europe, which will follow national marketing authorization and pricing approvals and will enable commercial sales in each of the twenty-five individual E.U. countries.

North America

In September 2007, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for ONSOLIS®, under which Meda is responsible for the sales, marketing and distribution of ONSOLIS® in the U.S., Canada and Mexico. The agreement 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.

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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®. The 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 the FDA and put in place prior to launch. Despite this requirement, the FDA did not reached agreement with Cephalon on a REMS program for Fentora® or Actiq® until July 21, 2011, nearly two years after the approval of ONSOLIS®. The absence of a REMS program for competing fentanyl products during this time period resulted in an un-level competitive environment and a highly unfavorable selling environment for ONSOLIS®.

On December 29, 2011, the FDA approved a REMS program covering all transmucosal fentanyl products. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all marketed transmucosal fentanyl products under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program also ends the disparity in prescribing requirements for ONSOLIS® compared to similar products. The full program is expected to be implemented in March 2012. At that point, it is anticipated that ONSOLIS® will be in a better position to compete on its own merits.

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® is marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between Meda and Valeant Canada Limited. ONSOLIS® was launched in Canada in the third quarter of 2011.

On March 12, 2012, we announced the postponement of the U.S. relaunch of ONSOLIS® until the product formulation can be modified to address two appearance issues raised by FDA following a recent inspection of the Aveva manufacturing facility where ONSOLIS® is produced. Specifically, the FDA identified the formation of microscopic crystals and a slight fading of the color during the 24-month shelf life of the product. While these changes do not affect the product s underlying integrity or safety, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and product specification before additional product can be manufactured and distributed. Therefore, the U.S. relaunch and additional manufacturing of ONSOLIS® has been postponed until such product appearance issues have been resolved.

Additional Territories

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

In 2010, licensing agreements were secured in Taiwan and South Korea providing the opportunity for commercialization in all territories globally. In May 2010, we announced a commercial partnership with Kunwha 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 commercial partners to market and sell ONSOLIS®/BREAKYL relieves us of the burden associated with a significant increase in expenditures or headcount otherwise associated with a commercial launch of a first product. Additionally, we believe our commercial partnerships for ONSOLIS®/BREAKYL will allow internal efforts to be focused on the development of our pipeline of products.

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BEMA® Buprenorphine

We announced the signing of a world-wide licensing and development agreement for BEMA® Buprenorphine with Endo in January 2012. Under terms of the agreement, Endo will be responsible for the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis.

Endo is one of the premier companies in the area of pain management and has demonstrated significant success in the pain space particularly with the development, launch and commercialization of a portfolio of pain therapeutics including Opana ER, Lidoderm and Voltaren Gel. Endo s long experience in pain includes a very strong sales and marketing capability, with sales representatives that are well established in the offices of high value Healthcare Practitioners who are high prescribers of opioids and other pain products. Endo currently has approximately 650 sales representatives covering pain specialty and primary care physicians. Endo also has a managed care organization that has established solid formulary positioning for the company s products.

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

Government Regulation

The nonclinical and clinical development, manufacturing and marketing of any product which we formulate 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 to market our products is granted.

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

1. small scale manufacturing of the product;

2. laboratory and nonclinical tests for safety of the product;

3. submission to the FDA of an IND for the product which must become effective before human clinical trials can commence;

4. larger scale manufacturing of the product;

5. clinical trials to characterize the efficacy and safety of the product in the intended patient population;

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

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7. FDA approval of the NDA or Biologic License Application.

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.

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 FDA protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy and the planned evaluation of results. Each protocol must be submitted to the FDA prior to its conduct. Further, each clinical study must be conducted under the auspices of an independent, institutional review board. The institutional review board will consider, among other things, ethical factors, the safety of the human subjects intended for the study and the possible liability of the participating 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 product 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 have in the past and will continue to rely upon third party contractors to advise and assist us in the preparation of our INDs and the conduct of clinical trials that will be conducted under the INDs.

New Drug Application and FDA Approval Process

The results of the pharmaceutical and manufacturing development work, nonclinical studies and clinical studies are submitted to the FDA in the form of 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.

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

The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Consequently, there is a risk that approval may not be granted on a timely basis, if at all. The FDA may deny 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 its safety and efficacy. Moreover, if regulatory approval of a product 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, the FDA may issue warning letters and/or seek criminal and civil penalties, enjoin manufacture, seize product or revoke approval.

Risk Evaluation and Mitigation Strategy

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

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

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

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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 Bioral® 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 these agreements, as amended, each of the Universities was issued an equity interest 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.

We have not spent any resources in recent years in developing the Bioral® cochleate technology or any related products. In September 2009, we vacated our Newark research facility located at UMDNJ and terminated our relationship with Dr. Raphael Mannino, our former Chief Scientific Officer and the inventor of many of the patents directed to the Bioral® 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 13, 2012, we have 17 full-time employees and 1 part-time employee. Eleven 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 three Ph.Ds, two Pharm.Ds, three CPAs and one MBA. 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.

Available Information

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

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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, 2011, we have recorded significant losses. Our accumulated deficit at December 31, 2011 is approximately $95.6 million. As of December 31, 2011, we had negative working capital of approximately $6.8 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: (i) the lack of a uniform REMS program, and (ii) certain manufacturing and post-FDA approval appearance issues associated with ONSOLIS®.

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

As a result of our historical lack of liquidity, our auditors have previously issued opinions, on our 2010 and 2009 financial statements which are included as part of this Report, which expressed substantial doubt with respect to our ability to continue as a going concern. As a result of our cash position at December 31, 2011, the receipt of an upfront milestone from Endo on our BEMA® Buprenorphine product, and our anticipated receipt of an additional $15 million milestone by the second quarter of 2012 upon the final grant of the patent related to such product which are to be used on clinical trials for and development of this product and not for general working capital, we believe that we will be able to fund planned operations and product development through the first quarter of 2013. Additionally, we believe that the timing of certain planned expenditures is discretionary and such expenditures could be deferred if needed.

Our auditors have included an emphasis of a matter paragraph in their report to the accompanying audited financial statements to highlight our current liquidity position and operating plans and, the fact that we will need, absent improvements in revenues from the sales of our products, to obtain additional capital before or during the first quarter of 2013 to fund our operations through the end of 2013 and into 2014. If we are unable to obtain such funding, we may be required to scale back operations (perhaps significantly), which could have a material adverse effect on our business and results of operations.

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Until we have a larger royalty revenue stream from Meda on ONSOLIS® and reach the NDA approval milestone payment under the Endo licensing agreement for BEMA® Buprenorphine for chronic pain, 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, 2011, we had cash of approximately $10.8 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 2012, although this excludes the additional capital that will be required for additional clinical trials of BEMA® Buprenorphine for chronic pain and further assumes that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements.

Depending on the timing and receipt of milestone payments from our commercial partnership with Meda and Endo, and given our anticipated cash usage and lack of significant revenues, we will likely need to raise additional capital in the future to fund our anticipated operating expenses and progress our business plans. This may include the potential need to fund additional Phase 3 clinical trials for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain, which are required because, as announced in late September 2011, our initial Phase 3 trial for this product failed to meet its primary endpoint. As a result, the further development of BEMA® Buprenorphine will require significant additional capital to complete. It is anticipated that the majority of these costs will come from certain predetermined milestone payments that are part of the Endo agreement. And although we received an up-front milestone payment of $30 million in January 2012 from Endo on our BEMA® Buprenorphine product, these funds are to be used primarily on clinical trials and to develop the product, and not for general working capital. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make raising additional capital more difficult or impossible and may also result in a lower price for our shares.

We may have difficulty raising any needed additional capital.

We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of material revenues from sales, as well as the inherent business risks associated with our company and present and future market conditions. Our business currently only generates a small amount of revenue from product sales, and 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, 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;
- progress and cost of our research and development programs;
- progress with non-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) clearance and addressing regulatory and other issues that may arise post-approval (such as we have experienced with ONSOLIS®);

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costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;

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

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

competing technological and market developments;

market acceptance of our drug formulations or products;

costs for recruiting and retaining employees and consultants;

costs for training physicians; and

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

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

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

The additional financings which we have undertaken and which we will likely in the future require, have and may be obtained through one or more transactions that have diluted or will dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 75 million shares of common stock and 5 million shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders. In particular, we have on file with the SEC a universal shelf registration statement that allows us (subject to certain limitations) to issue up to $40 million of our common stock, preferred stock, notes, warrants and other securities of our company.

The Risk Evaluation and Mitigation Strategy (REMS) that the FDA required for ONSOLIS® and the subsequent classwide REMS for all transmucosal fentanyl products may continue slow sales and marketing efforts for ONSOLIS®, which could impact our royalty 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 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, until recently, two products which compete directly with ONSOLIS®, namely Actiq® and Fentora® (each of which are marketed by Teva), were being marketed without the requirement of compliance with a REMS. This condition put ONSOLIS® at a material competitive disadvantage with these products, which likely impacted sales of ONSOLIS®.

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On December 29, 2011, FDA approved a REMS program covering all transmucosal fentanyl products. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all marketed transmucosal fentanyl products under a single program and is expected to be implemented in March 2012. There is a risk that healthcare providers may respond negatively to the new classwide REMS program in a manner similar to the original ONSOLIS® REMS program. Should this occur, Meda s ability to generate revenue from sales of ONSOLIS® could be materially compromised, which would result in low royalty payments to us.

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:

- regulatory clearance of marketing claims for the uses that we are developing;
- 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;
- 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
- ability to timely and effectively manufacture and market our products.

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

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 are our commercialization agreements with Meda and Endo as well as our manufacturing development and supply agreements with Aveva and LTS relating to ONSOLIS® and with LTS relating to BREAKYL . 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®.

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

Under our collaborative agreements with Meda, we are responsible for paying certain costs relating to ONSOLIS®. In addition, our licensing and development agreement with Endo requires us to support the clinical development of BEMA® Buprenorphine for pain. Our inability to adequately project or control such costs could have a material adverse effect on our potential profits from such agreements.

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

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

We currently have a general liability/product liability policy which includes coverage for our clinical trials. Annual aggregate limits include $7 million with a $6 million limit per occurrence for general liability and $5 million with a $5 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 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 which was filed by MonoSol in November 2010, wherein MonoSol claims that our and our partner s 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 partner in that case, we could be forced to license technology from MonoSol or otherwise incur liability for damages, which could have a material adverse effect on our company. For an update to this litigation, refer to Item 3, Legal Proceedings .

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.

Our lawsuit with MonSol has caused us incur significant legal costs to defend ourselves, and we would be subject to similar costs if we are a party to similar lawsuits in the future. Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our BEMA® products (including, without limitation, ONSOLIS®). We may be unable to obtain such licenses from the patent holders, which could materially and adversely impact our business.

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

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

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

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

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

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

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

Except for our agreements with Aveva and LTS, we do not have long-term agreements with most of our suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. As it is the primary manufacturer of our only approved product, ONSOLIS®, our relationship with Aveva is particularly important to us, and any loss of or material diminution of Aveva s capabilities due to factors such as regulatory issues, accidents, acts of God or any other factor would have a material adverse effect on our company. Such risks were demonstrated when certain manufacturing issues were experienced at Aveva in 2010-2011 and when, subsequently and separately, the FDA identified certain product appearance issues with ONSOLIS®, which resulted in the March 2012 postponement of the U.S. relaunch of the product until such issues are resolved. We do not carry interruption insurance for any such loss. Any loss of or interruption in the supply of components from Aveva or other third party suppliers would require us to seek alternative sources of supply or require us to manufacture these components internally, which we are currently not able to do.

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

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

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

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our formulations or products;
- 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 or with respect to our BEMA® Buprenorphine product under our agreements with Endo, 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.

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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.

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

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

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

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

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

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.

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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.

Moreover, there is a risk that our clinical trials will fail to meet their primary endpoints, which would make them unacceptable in having the subject product approved by the FDA. In September 2011, we announced that our Phase 3 clinical trial for BEMA® Buprenorphine did not meet its primary endpoint and therefore we will be required to conduct one or more new trials. In our licensing and development agreement with Endo, we are responsible for the conduct of planned clinical studies leading up to the submission of a NDA for BEMA® Buprenorphine. Conducting a new clinical trial in accordance with the FDA requirements will require significant additional capital, and we will not be able to commercialize and sell our BEMA® Buprenorphine product until we are able to meet our primary endpoint and obtain subsequent FDA approval. Additionally, even if our clinical trial meets their primary endpoint, FDA approval may be withheld, which would materially and adversely impact our business.

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

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

Finally, if any of our clinical trials do not meet their primary endpoints, we would need to redo such clinical trials in order to progress development of the subject product. These additional trials would be costly and divert resources from other projects.

The foregoing risks were evidenced by the failure of our Phase 3 trial for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain to meet its primary endpoint, which we announced September 2011.

We 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 Tolmar with respect to our BEMA® technology. 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.

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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 the FDA required for ONSOLIS®. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. Any such current or new regulations may be difficult and expensive for us and our manufacturing and commercial partners to comply with, may delay the introduction of our products, may adversely affect our net sales, if any, and may have a material adverse effect on our results of operations.

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

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in our 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 a procurement quota in order to obtain these substances. The DEA may not establish a procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides for public comment on the labeling, promotion, risk management plan and other documents associated with such product. A DEA review of such materials may result in potentially significant delays in obtaining procurement quota for controlled substances, a reduction in the quota issued to us or an elimination of our quota entirely. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or sales of products, which could have a material adverse effect on our business and results of operations.

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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.

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

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

The ability of Meda to sell ONSOLIS® 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.

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

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. All of our clinical trials have been, and all of our proposed clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have a product liability policy that includes coverage for our clinical trials, with an annual aggregate limit of $5 million with a $5 million limit per occurrence. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products and product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products. In addition, although third party partners like Meda are required to provide insurance in connection with specific products like ONSOLIS®, such partners may face similar insurance related risks.

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

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

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.

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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 25.10% of our outstanding common stock. These figures do not reflect any future potential exercise of outstanding common stock purchase warrants into shares of common stock.

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

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

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.

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

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

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

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

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

As of December 31, 2011, there are 29,577,146 shares of common stock issued and 29,561,655 shares of common stock outstanding. On July 21, 2011, at our 2011 Annual Meeting of Stockholders, our stockholders approved an amendment to our certificate of incorporation to increase the number of authorized shares of common stock, par value $.001, of our common stock from 45,000,000 to 75,000,000 shares. This increase in our authorized shares of common stock provides us with the flexibility to issue more shares in the future, which might cause dilution to our stockholders. In addition, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of outstanding options or warrants. To the extent such options (including options under our stock incentive plan) or warrants are exercised, the holders of our common stock may experience further dilution.

Moreover, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors would experience additional dilution. Finally, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5 million 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 13, 2012: (i) 5,035,609 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.49 per share, and (ii) 2,291,301 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.80 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.

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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;
- limiting the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;
- requiring a super-majority vote of our stockholders to remove directors of our company; and
- providing that our stockholders may only remove our directors for cause (as defined in our bylaws).

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

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

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from 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.

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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 2, 2010, MonoSol Rx, LLC (MonoSol) filed an action against us and our ONSOLIS® commercial partners in the Federal District Court of New Jersey (DNJ) for alleged patent infringement. We were formally served in this matter on January 19, 2011. MonoSol claims that our manufacturing process for ONSOLIS®, which has never been disclosed publicly and which we and our partners maintain as a trade secret, infringes its patent (United States Patent No. 7,824,588). MonoSol also has made a claim of false marking as part of its complaint. 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. Pursuant to its compliant, MonoSol is seeking an unspecified amount of damages, attorney s fees and an injunction preventing future infringement of MonoSol s patents.

We strongly refute as without merit MonoSol s assertion of patent infringement, which relates to our confidential, proprietary manufacturing process for ONSOLIS®. On February 23, 2011, we filed our initial answer in this case. In our answer, we stated our position that our products, methods and/or components do not infringe MonoSol s 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 anticipate that MonoSol s claims will be rejected.

We have engaged in voluntary and court mandated settlement discussions with MonoSol, but to date have been unable to reach any settlement with them. These discussions are part of the normal course of such an action but does not alter our view of non-infringement and invalidity of the subject patents.

On July 13, 2011, a case management conference was held and a mandatory settlement conference before the magistrate judge was held on September 8, 2011. On September 12, 2011, we filed a request for inter partes re examination in the United States Patent and Trademark Office (USPTO) of MonoSol s US patent No 7,824,588 demonstrating that all claims of the patent were anticipated by or obvious in the light of prior art references, including several prior art references not previously considered by the USPTO. On September 16, 2011, we filed in court a motion for stay pending the outcome of the re examination proceedings.

On September 26, 2011, MonoSol filed a second amended complaint, which added two additional patents not previously asserted and on October 4, 2011 MonoSol filed an opposition to the motion for stay. We filed an answer to the second amended complaint denying infringement and asserting challenges to the validity of the two newly-asserted patents. The court conducted a status conference on October 25, 2011, at which it denied the motion to stay without prejudice. On November 18, 2011, MonoSol served its supplemental initial disclosures and its

infringement contentions pursuant to the DNJ Local Patent Rules. By letter dated December 14, 2011, we notified the Court that the USPTO had issued an office action in the reexamination proceedings rejecting all 191 claims of the MonoSol U.S. patent No. 7,824,588.

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On January 3, 2012, we served our non infringement and invalidity contentions. On January 5, 2012, the Court conducted a status conference and invited the re-filing of our motion for stay pending the outcome of reexamination proceedings in the USPTO. On January 20, 2012, we filed requests for reexamination of MonoSol s US patent No 7,357,891, and No 7,425, 292, demonstrating that all claims of those two patents were anticipated by or obvious in the light of prior art references, including prior art references not previously considered by the USPTO. We then filed our renewed motion for stay pending the outcome of the re-examination proceedings on January 23, 2012.

The USPTO has recently granted the requests for reexamination we filed with respect to the 292 and 891 patents. In its initial office action in each, the USPTO has rejected every claim in each patent. Thus the USPTO has now rejected every claim in the three patents asserted by MonoSol against us. The court conducted a status conference on March 7, 2012, at which it granted our motion to stay the case pending outcome of the reexamination proceedings in the USPTO.

Item 4. Mine Safety Disclosures.

Not applicable.

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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 2011 and 2010, as reported by the NASDAQ Capital Market, is set forth below.

Quarterly Common Stock Price Ranges

Fiscal Year 2011, Quarter Ended:	High	Low
March 31, 2011	$ 3.82	$ 3.22
June 30, 2011	$ 3.89	$ 3.23
September 30, 2011	$ 3.99	$ 1.09
December 31, 2011	$ 1.13	$ 0.78

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

As of March 13, 2012, we had approximately 136 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain earnings for further business development and do not expect to pay cash dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)[1]	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance (c)
Equity compensation plans approved by security holders	4,553,251	$ 3.66	3,127,346
Equity compensation plans not approved by security holders			
Total	4,553,251	$ 3.66	3,127,346

(1) Includes 4,400,888 shares of common stock underlying options previously granted under our Amended and Restated 2001 Incentive Plan which are still exercisable despite the fact that such plan expired July 2011. Also includes 152,363 shares of common stock underlying options granted under our 2011 Equity Incentive Plan granted in 2011, which plan was approved by our stockholders at our 2011 annual meeting.

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, 2006 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, 2006:

	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011
BioDelivery Sciences Int l, Inc.	$ 100.00	$ 91.85	$ 90.91	$ 123.20	$ 111.29	$ 25.39
Nasdaq Composite (U.S. Companies)	100.00	109.81	65.29	93.95	109.84	107.86
Nasdaq Biotechnology	100.00	104.85	91.38	105.66	121.52	135.86
Nasdaq Pharmaceutical	100.00	98.10	79.07	89.61	88.65	96.49

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Item 6. Selected Financial Data.

The statements of operations data and statements of cash flows data for the years ended December 31, 2011, 2010 and 2009 and the balance sheet data as of December 31, 2011 and 2010 have been derived from our audited consolidated financial statements included elsewhere in this annual report. The statements of operations data and statements of cash flows data for the years ended December 31, 2008 and 2007 and the balance sheet data as of December 31, 2009, 2008 and 2007 have been derived from our audited consolidated financial statements not included in this annual report. The following selected financial data should be read in conjunction with our Management s Discussion and Analysis of Financial Condition and Results of Operations and consolidated financial statements and related notes beginning on page F-1 and other financial information included in this Report.

	Fiscal Year				
	2011	2010	2009	2008	2007
	(Dollars in thousands, except per share data)				
Statements of Operations Data:					
Total revenue	$ 3,263	$ 3,405	$ 62,815	$ 263	$ 202
Operating (loss) income	(26,988)	(16,319)	40,129	(17,964)	(21,660)
Net (loss) income	(23,325)	(13,033)	33,047	(17,233)	(25,187)
Diluted net (loss) income per share	(0.82)	(0.56)	1.54	(0.90)	(1.64)
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 10,750	$ 18,209	$ 23,873	$ 906	$ 16,597
Total assets	23,645	33,580	39,678	13,337	27,988
Accumulated deficit	(95,572)	(72,246)	(59,214)	(92,260)	(75,027)
Total stockholders equity (deficit)	4,120	9,786	14,458	(33,582)	(18,788)
Statements of Cash Flows Data:					
Net cash flows from operating activities	$ (23,275)	$ (11,682)	$ 18,190	$ (9,816)	$ 12,217

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 2004.

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. In January 2012, we entered into a definitive License and Development Agreement with Endo for BEMA® Buprenorphine and to complete U.S. development of the product for purposes of seeking FDA approval.

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 and Endo agreements) in 2012 are expected to be nominal. We anticipate that funding for the next several years will come primarily from milestone payments and royalties from Meda and Endo, 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) contract revenue from Endo related to an upfront signing milestone on our BEMA® Buprenorphine product in 2012, (ii) royalty revenue from Meda from sales of ONSOLIS®; (iii) up-front non-refundable license and milestone payments from Meda 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), (iv) revenue from the sale of a royalty stream in 2004, (v) research and collaboration revenues, including research revenues in 2010 from TTY Biopharm Co., LTD. (TTY) and Kunwha Pharmaceutical Co., Ltd. (Kunwha) and (vi) minimal royalty revenue from a license with Accentia. Most of these types of revenue are generally not repeating or predictable. Therefore, we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future. 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 must also maintain our relationships with our key commercial partners and address regulatory, legal and/or commercial issues and risks that relate our business from time to time, many of which could impact, perhaps negatively, our planned operations. We may not be able to appropriately address these risks and difficulties.

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 2011, 2010 or 2009.

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 2011. 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®. We have previously determined not to pursue Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis (see note 12 to the accompanying financial statements).

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Fair market value accounting (derivative liability)

The most significant estimate that could have a material effect on net (loss) gain is the fair market value accounting for our derivative liability. Our derivative liability consists of free standing warrants that are recorded as liabilities due to the registration rights agreements and the requirement for continued effectiveness of the warrants. As a result, the warrants must be recorded 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.

During the year ending December 31, 2011, a $2.74 decline in the value of our stock was the primary cause of the $3.5 million derivative gain. Our stock price is a major component of the valuation of our free standing warrant liabilities. A stock price decline lowers the derivative liability, resulting in a 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 Financial Accounting Standards Board Accounting Standards Codification (FASB)(ASC) FASB ASC Topic 718 Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our common stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

We use the Black-Scholes option pricing model to determine the fair value of stock option and warrant grants. In applying the Black-Scholes option pricing model during 2011, we assumed no dividend yield, risk-free interest rates ranging from 0.90% to 1.99%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor ranging from 69.05% to 77.75% and option exercise prices ranging from $1.38 to $3.55.

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

Revenue Recognition

Meda License, Development and Supply Agreements

In August 2006 and September 2007, we entered into 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, $59.7 million of the aggregate milestones and services revenue were recognized. Upon first commercial sale in a European country, an estimated $17.6 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, 2011, there was remaining deferred revenue of $14.2 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 as the milestone requirements are achieved and revenue recognition is permitted under GAAP.

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 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 upfront payments of $0.3 million in October 2010 and an additional $0.3 million in November 2011 were both 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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In addition, ASU 2009-13 has influenced the accounting treatment of our Endo contract, which was signed in January 2012. As a milestone revenue recognition arrangement, the Endo contract includes a $30 million upfront signing payment. We received the payment in January 2012; therefore, it will be recorded immediately as contract revenue in 2012.

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 (2009) relating to chronic rhinosinusitis (referred to herein a CRS). This is shown as product royalties, 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.

Results of Operations

For the Year Ended December 31, 2011 Compared to the Year Ended December 31, 2010

Product Royalty Revenues. We recognized $2.7 million and $1.9 million in product royalty revenue during the years ended 2011 and 2010, respectively, under our license agreement with Meda. The increase in product royalty revenues can be attributed to the commercial launch of ONSOLIS® in Canada.

Research Revenues. We recognized $0.2 million and $0.7 million of revenue related to a research and development agreement with Meda during the years ended 2011 and 2010, 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 2011.

Contract Revenues. We recognized $0.3 million in contract revenue during the year ended 2011 which related to our license agreement with TTY. During 2010, we recognized $0.5 million in contract revenue related to our license agreements with TTY and Kunwha.

Cost of Product Royalties. We recognized $1.8 million and $0.8 million in cost of product royalties during the years ended 2011 and 2010, respectively, related to direct costs attributable to the production of ONSOLIS®. This includes both manufacturing costs and royalties owed to CDC and Athyrium. We are required to pay royalties to CDC and Athyrium under a Clinical Development and License Agreement entered into in 2005, and most recently amended in May 2011.

Research and Development Expenses. During the years ended December 31, 2011 and 2010, research and development expenses totaled $20.8 million and $10.6 million, respectively. The increase in research and development expenses can be attributed to the BEMA® Buprenorphine clinical trial in 2011. 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 2011 and 2010 was obtained through deferred license revenue, sponsored research revenue, exercise of options by employees and directors and sales of securities. Research and development expenses g