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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) Yes ☒ No ☐

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

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

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

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

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.

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

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 other 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.

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.

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.

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.

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).

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.

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.

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.

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;

- 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®

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.

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.

- *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.

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.

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.

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.

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.

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.)

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.

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.

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 "Bioral®" 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.

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.

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.

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

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.

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.

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.

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.

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®);

- 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®.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

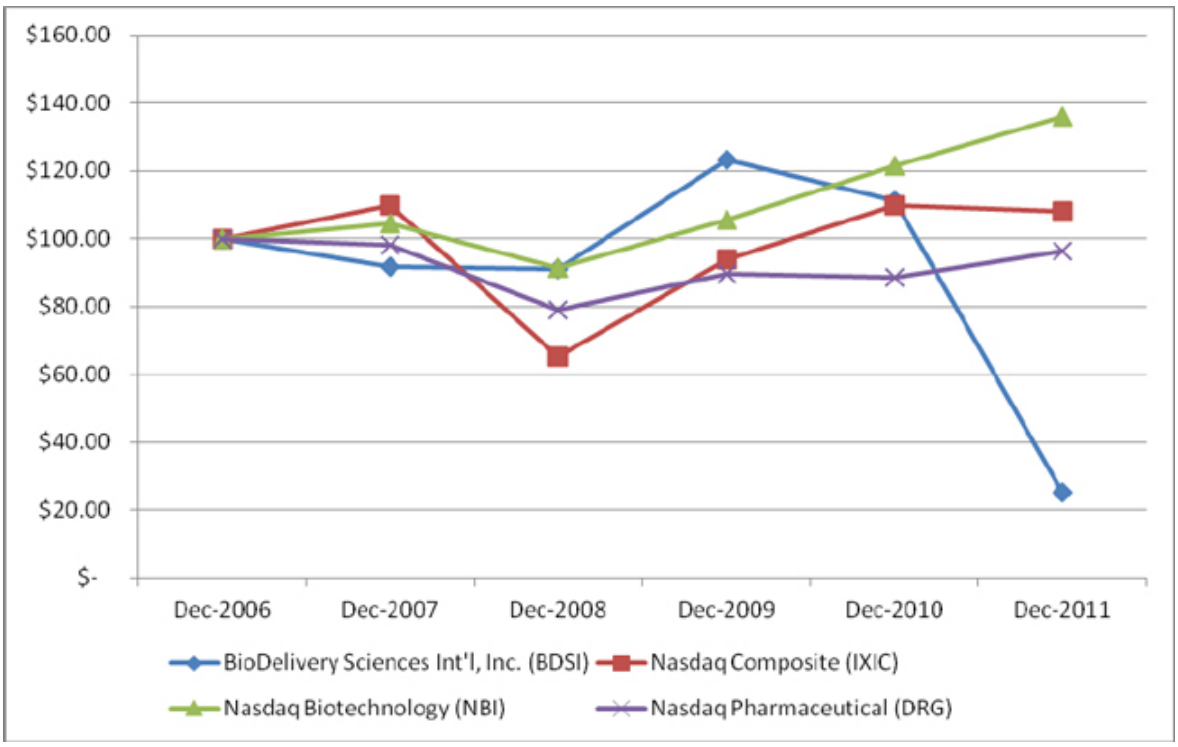
(1) Includes 4,400,888 shares of common stock underlying options previously granted under our Amended and Restated 2001 Incentive Plan which are still exercisable despite the fact that such plan expired July 2011. Also includes 152,363 shares of common stock underlying options granted under our 2011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

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

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.

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).

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.

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.

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.

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 generally include compensation for scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the our drug delivery technologies.

General and Administrative Expenses. During the years ended December 31, 2011 and 2010, general and administrative expenses totaled $7.7 million and $8 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. The decrease in general and administrative expenses can be attributed to a larger derivative gain in 2011, primarily due to a decline in the fair market value of our free standing warrants in Biovest International acquired in our settlement with Accentia in 2009. We also had general and administrative expenses associated with our registered direct offering in 2010.

Impairment of intangible license. During the year ended December 31, 2010 we had an impairment of intangible license and associated charge of $0.2 million. This represented 100% of the remaining unamortized carrying value, related to the Bioral® drug delivery technology. There was no impairment charge during the year ended December 31, 2011.

Interest Income, Net. During the year ended December 31, 2011 we had interest income of $0.19 million compared to $0.13 million for the corresponding period in 2010. We earned additional interest income in 2011 by relying less on U.S. treasuries. Instead, we allocated more cash to a short term tax-free municipal securities fund. The fund allowed us to maintain ready access to cash and provided a better yield than treasuries.

Derivative Gain. Derivative gain in 2011 and 2010 is related to the adjustment of derivative liabilities to fair value as of December 31, 2011 and 2010, respectively. Derivatives are primarily free-standing warrants. The warrants are measured using Black-Scholes calculations. A major component of the calculation is our stock price. During 2011, the Company stock fell by $2.74 per share. This decreased our warrant liability, and correspondingly caused the derivative gain. During 2010, our stock declined by $0.38 per share, which was the primary cause of the 2010 derivative gain.

Income Tax Benefit and tax net operating loss carryforwards. We had federal and state net operating loss carryforwards ("NOL") of approximately $51 million and $45.4 million at December 31, 2011 as compared to federal and state NOLs of $27 million and $21.1 million as of December 31, 2010. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 for state purposes. In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, we recorded a valuation allowance with respect to all of our deferred tax assets. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation" (as defined in the Internal Revenue Code), there are annual limitations on the amount of the net operating loss and other deductions which are available to us.

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

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

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

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

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

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

Cost of Product Royalties. We recognized $0.8 million and $2.0 million in cost of product royalties during the years ended 2010 and 2009, respectively, related to direct costs attributable to the production of our product ONSOLIS®. 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, 2010 and 2009, research and development expenses totaled $10.6 million and $10.4 million, respectively. Our scientific staff continued to work toward increased development and application of our BEMA® technologies, but particularly with respect to BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone and ONSOLIS®. Funding of this research in 2010 and 2009 was obtained through deferred license revenue, shelf financing, sponsored research revenue, exercise of options by employees and directors and sales of securities. Research and development expenses generally include compensation for scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the our drug delivery technologies.

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

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

Interest Income, Net. During the year ended December 31, 2010 we had interest income of $0.13 million compared to $0.04 million for the corresponding period in 2009. We had a higher average cash balance during the year ended December 31, 2010 as compared to 2009. During the first half of 2009, we averaged only $3 million in cash until the receipt of $26.8 million from Meda upon FDA approval of ONSOLIS® and delivery of product to support the product launch. We maintained a $22 million average cash balance during 2010, allowing higher dividends and interest to be earned.

Derivative Gain (loss). Derivative gain (loss) in 2010 and 2009 is related to the adjustment of derivative liabilities to fair value as of December 31, 2010 and 2009, respectively. Derivatives are primarily free-standing warrants. The warrants are measured using Black Scholes calculations. A major component of the calculation is our stock price. During 2009, our stock rose by over $1.00 per share. This increased our warrant liability, and correspondingly caused the Derivative loss. During 2010, the opposite situation occurred. Our stock declined by $0.38 per share, which was the prime cause of the 2010 Derivative gain.

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

Major Research and Development Projects

In 2011, we continued to dedicate our corporate resources to our portfolio of products utilizing the BEMA® technology. This included the Phase 3 clinical development of BEMA® Buprenorphine and pharmacokinetic studies and formulation development work for BEMA® Buprenorphine/Naloxone. Additional expenditures were devoted to manufacturing efforts (in conjunction with our manufacturing partners) required to support ONSOLIS® and BREAKYL™. Clinical research expenses in 2011 were primarily dedicated to the Phase 3 study for BEMA® Buprenorphine for the treatment of chronic pain. Additional investments were made in formulation development work and pharmacokinetic studies for BEMA® Buprenorphine/Naloxone. Further clinical development of ONSOLIS® is the responsibility of Meda both in the U.S. and Europe. In addition, we continue to evaluate new product and technology opportunities that would fit into our commercial strategy.

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

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

BEMA® Buprenorphine. BEMA® Buprenorphine is our second analgesic product using the BEMA® technology. We have conducted multiple Phase 1 studies with BEMA® Buprenorphine, one Phase 2 study in acute pain, and a Phase 3 study in a mixed population of opioid naïve and opioid experienced patients for the treatment of moderate to severe chronic pain.

Due to the ability of BEMA® Buprenorphine to participate in the key chronic pain market, we believe that BEMA® Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion dollar U.S. market for opioid analgesics, which would translate to over $500 million in peak annual sales. We do not expect to generate any royalty revenue from sales of BEMA® Buprenorphine, if ever, until at least 2014. A license and development agreement has been finalized with Endo for the worldwide rights to BEMA® Buprenorphine for chronic pain in January 2012.

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

BEMA® Buprenorphine/Naloxone. A higher dose formulation of BEMA® Buprenorphine combined with the abuse deterrent naloxone is being developed for the treatment of opioid dependence. Because of its lower propensity for abuse and addiction, BEMA® Buprenorphine, when given in a high dose, may serve as a treatment for opioid dependence by preventing opioid addicted patients' withdrawal symptoms while at the same time maintaining pain control. Pharmacokinetic studies conducted in 2011 demonstrated the ability of the BEMA® technology to effectively deliver high blood plasma concentrations of buprenorphine in the range required to treat opioid dependence while minimizing naloxone exposure. We expect to conduct a pivotal bioequivalence study and a safety study in 2012 to support a possible NDA filing in the first half of 2013.

BEMA® Granisetron. The BEMA® technology is being utilized 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. We submitted an IND application to the FDA for BEMA® Granisetron in February 2011. We believe that BEMA® Granisetron would have the potential for better tolerance than oral formulations in the presence of nausea and vomiting as well as potential for better and more consistent absorption in the presence of nausea and vomiting. Due to our focus on progressing our more advanced pipeline products, limited additional development activity on this product was conducted in 2011.

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, the sale of a royalty stream asset, sponsored research, funded research arrangements and from various strategic and licensing agreements, including a clinical development agreement with CDC IV, LLC and commercialization agreements with Meda relating to ONSOLIS® and, more recently, with our commercialization agreement with Endo for BEMA® Buprenorphine. We intend to finance our research and development programs, commercialization efforts and our working capital needs from existing cash, product royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

We have always been sensitive to the dilution caused by the sale of our equity in order to maintain business operations. As such, since our initial public offering in 2002 through the signing of the Endo agreement in January 2012, approximately two-thirds of all operational funding come from partnering dollars and royalty revenue. The other one-third has come from equity and debt offerings.

We began calendar year 2011 with $18.2 million in cash. A factor in this relatively high starting cash balance was a result of receiving significant 2009 milestone payments from Meda. The largest was a $29.8 million payment in July for the approval and launch of ONSOLIS® in the U.S. During 2010, significant sources of operating cash were $9.7 million in net proceeds from registered direct offering of common stock and warrants in April 2010. During 2011, significant sources of operating cash were $14 million in net proceeds from a private placement offering of common stock in March 2011. As a result, we used $23.3 million in operating cash to fund our operations including research and development activities, primarily for BEMA® Buprenorphine.

On March 11, 2011, we consummated a private placement offering to institutional investors of an aggregate of 4,807,693 shares of our common stock at a price equal to $3.12 per share, representing a 10% discount to an agreed upon volume weighted average price of our stock. Gross proceeds we received from the offering were $15 million (net proceeds approximating $14 million). No warrants were issued to investors in the offering. Proceeds from this offering have been used principally for the clinical development of our pipeline of products, particularly BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone.

In the third quarter of 2011, ONSOLIS® product was released for distribution in both Canada and the United States. This release of product provided the launching stocks for the commercial launch of ONSOLIS® in Canada, as well as provided for supply of ONSOLIS® in the U.S. ONSOLIS® is approved in the U.S., Canada, and the E.U. (where it will be marketed as BREAKYL™) for the management of breakthrough pain in opioid tolerant, adult patients with cancer. ONSOLIS® is marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between our commercial partner for ONSOLIS®, Meda, and Valeant Canada Limited. However, in March 2012, we announced that the FDA had noted certain appearance issues with ONSOLIS® that will require us to reformulate the product and which has led to a postponement of the U.S. and Canadian relaunch of ONSOLIS®.

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

At December 31, 2011, we had cash and cash equivalents of approximately $10.8 million. We used $23.3 million of cash in operations during the twelve months ended December 31, 2011. As of December 31, 2011, we had stockholders' equity of $4.1 million, versus $9.8 million at December 31, 2010. In January 2012, we received a $30 million, upfront non-refundable milestone payment related to our definitive license and development agreement with Endo to license, develop, manufacture, market and sell our BEMA® Buprenorphine product. In addition, we expect to receive an additional $15 million milestone payment from Endo due to our achievement of a certain intellectual property related milestone. However, this $45 million in cash is expected to primarily be used to fund our clinical research obligations under our agreement with Endo. As such, our existing cash, even with the aforementioned $45 million milestone payments, together with other expected cash inflows from other milestones and royalties, are anticipated by management to be sufficient to fully fund our operations through the first quarter of 2013 at the planned level. Included in this estimation are costs of between $0.6 million and $1.2 million that we expect will be incurred in connection with the reformulation of ONSOLIS®, but also savings in legal expenses that we expect due to the March 2012 stay of our litigation with MonoSol. Certain planned expenditures are discretionary and could be deferred if we are required to do so to fund critical operations.

Accordingly, additional capital will likely be required to support commercialization efforts for ONSOLIS® (including commercial launch in Europe which is expected in 2012), clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of our agreement with Endo) planned development of BEMA® Buprenorphine/Naloxone and general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

- public equity markets;

- private equity financings;
- collaborative arrangements;
- grants and new license revenues;
- bank loans;
- equipment financing;
- public or private debt; and
- exercise of existing warrants.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations in 2012 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

In addition, the worldwide financial and credit crisis that began in 2008 and has fluctuated to the present time has strained investor liquidity and contracted credit markets. During the year ending December 31, 2011, the financial and credit crisis did not directly nor materially impact our company. However, if this environment continues, fluctuates or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when we require additional financial investment. If we are unable to attract additional funds it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2011 are as follows:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 139,953	$ 128,949	$ 11,004	$ —	$ —
Employment agreements	769,477	769,477	—	—	—
Minimum royalty expenses*	11,962,000	1,462,000	3,000,000	3,000,000	4,500,000
Total contractual cash obligations**	$12,871,430	$2,360,426	$3,011,004	$3,000,000	$4,500,000

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

** We signed a commercialization agreement with Endo in January 2012. Endo will have worldwide rights to market our BEMA® Buprenorphine product. In return for milestone payments and royalties, we are required to conduct and pay for certain clinical trials as outlined in a mutually agreed development plan. These costs will depend on the size and scope of the required trials. The Endo agreement does not specify minimums in terms of the cost of the trials.

Off Balance Sheet Arrangements

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

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

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents include Ultra Short Term Government Funds. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. On November 9, 2010, the Federal Deposit Insurance Corporation ("FDIC") issued a Final Rule implementing Section 343 of the Dodd-Frank Wall Street Reform and Consumer Protection Act that provides for unlimited insurance coverage of noninterest-bearing transaction accounts. From December 31, 2010 through December 31, 2012, all non-interest bearing transaction accounts are fully insured, regardless of the balance of the account, at all FDIC-insured institutions. The unlimited insurance coverage is available to all depositors, including consumers, businesses and government entities. This unlimited coverage is separate from, and in addition to, the $250,000 insurance coverage provided to a depositor's other deposit accounts held at an FDIC-insured institution. As of December 31, 2011, we had approximately $8.5 million which exceed these insured limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Market indexed security risk

We hold a warrant to purchase 2 million shares of common stock of Biovest International and have issued warrants to various holders underlying shares of our common stock. These warrant investments are re-measured to their fair value at each reporting period with changes in their fair value recorded as derivative (loss) gain in the condensed consolidated statement of operations. We use the Black-Scholes model for valuation of the warrants.

Item 8. Financial Statements and Supplementary Data.

Our Consolidated Financial Statements and Notes thereto and the report of Cherry, Bekaert & Holland, L.L.P., our independent registered public accounting firm, are set forth on pages F-1 through F-32 of this Report.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, at December 31, 2011, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

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

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

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2011. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2011.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of March 13, 2012 are as follows:

Name	Age	Position(s) Held
Francis E. O'Donnell, Jr., M.D.	62	Executive Chairman and Director
Mark A. Sirgo, Pharm.D.	58	President, Chief Executive Officer and Director
James A. McNulty	61	Chief Financial Officer, Secretary and Treasurer
Andrew L. Finn, Pharm.D	62	Executive Vice President of Product Development
Benny Ward	48	Executive Vice President Strategic and Business Development
William B. Stone	68	Lead Director
John J. Shea	85	Director
William S. Poole	65	Director
Samuel P. Sears, Jr	68	Director

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

Francis E. O'Donnell, Jr., M.D., age 62, has been our Chairman of the Board and a Director since March 29, 2002 and was appointed as our Executive Chairman in January 2012. Dr. O'Donnell has previously served as our President and Chief Executive Officer. In January 2005, he relinquished the title of President and in August 2005 he relinquished the title of Chief Executive Officer. Since 1999, Dr. O'Donnell has served as Manager of The Hopkins Capital Group, an affiliation of limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare. He serves as Executive Chairman of Accentia, and its majority-owned subsidiary, Biovest. Dr. O'Donnell has published over 30 peer-reviewed scientific articles and has been awarded over 34 U.S. patents. He is the recipient of the 2000 Jules Stein Award from Retinitis Pigmentosa International. He is a Trustee for St. Louis University. Dr. O'Donnell is qualified to serve on our board of directors because of his extensive experience in specialty biopharmaceutical companies. Dr. O'Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O'Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine.

Mark A. Sirgo, Pharm.D., age 58, has been our President since January 2005 and Chief Executive Officer and Director since August 2005. He joined our company in August 2004 as Senior Vice President of Commercialization and Corporate Development upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder and Chief Executive Officer. He has also served as our Executive Vice President, Corporate and Commercial Development and our Chief Operating Officer. Dr. Sirgo has nearly 30 years of experience in the pharmaceutical industry, including 16 years in clinical drug development, 7 years in marketing, sales, and business development and 8 years in executive management positions. Prior to his involvement with Arius Pharmaceuticals from 2003 to 2004, he spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 while at Glaxo Wellcome, among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc. (NASDAQ:PPDI), a leading contract service provider to the pharmaceutical industry. Dr. Sirgo serves on the board of directors and as Chairman of the Compensation Committee of Salix Pharmaceuticals, Inc. (NASDAQ:SLXP), a specialty pharmaceutical company specializing in gastrointestinal products since 2008. Dr. Sirgo is qualified to serve on our board of directors because of his extensive experience in specialty biopharmaceutical companies. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

James A. McNulty, age 61, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis since October 2000 until January 1, 2008 when his position became full-time. Since May 2000, Mr. McNulty has also served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture investing activities. Hopkins Capital Group is owned and controlled by Dr. Francis E. O'Donnell, Jr.. Mr. McNulty also serves part-time as the Treasurer and Corporate Secretary of Accentia, a holding company with commercialization assets in specialty pharmaceuticals and biologics, and through December 31, 2007 as Chief Financial Officer for Biovest, a majority-owned subsidiary of Accentia. Mr. McNulty is a Director of RetinaPharma Technologies, Inc., an affiliate of Hopkins Capital Group. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, which became one of Florida's largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He served as CFO of Star Scientific, Inc. from October 1998 to May 2000. From June 2000 through January 2002 he served as CFO/COO of American Prescription Providers, Inc. He is, since 2011, a Director of Quantum Technology Sciences, Inc., a private company. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is qualified to serve on our management team because of his extensive experience in public and private accounting. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, a member of the American and Florida Institutes of CPA's and is a board member of the Central Florida chapter of Financial Executives International.

Andrew L. Finn, Pharm.D., age 62, has been our Executive Vice President of Product Development since January 2007. He joined the company in August 2004 upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder. Dr. Finn has previously served as our Senior Vice President of Product Development and Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn has nearly 30 years experience in pharmaceutical product development. Prior to his involvement with Arius, he was, from 2000 to 2003, Executive Vice President of Product Development at POZEN Inc. with responsibilities for formulation development, non-clinical development, clinical research and regulatory affairs. He participated in the POZEN activities leading up to the initial public offering and submitted marketing applications in Europe and the U.S. for two migraine products. From 1996 to 1999, Dr. Finn was Co-Founder and Chief Executive Officer of enVision Sciences, a regulatory and clinical service company. From 1991 to 1996, he was Vice President of Clinical Research and Biometrics for Solvay Pharmaceuticals, where he oversaw NDA submissions in the areas of inflammatory bowel disease, osteoporosis prevention and treatment of obsessive-compulsive disorder. Prior to this, he spent 10 years in positions of increasing responsibility at Glaxo Inc., where he oversaw a number of NDA submissions, including Zofran for chemotherapy induced nausea and vomiting. Dr. Finn is qualified to serve on our management team because of his extensive experience in specialty biopharmaceutical companies. Dr. Finn received his BS in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

Benny Ward, CPA., age 48, has been our Executive Vice-President of Business and Strategic Development since September 2010. Mr. Ward has more than 15 years of financial, operations and management experience, including 12 with life science companies. From 2006 to 2008, he served as Vice President of Finance and Chief Financial Officer of venture backed InnerPulse, Inc., a development stage cardiac rhythm management device company. Prior to joining InnerPulse, Mr. Ward was Vice President of Finance and Chief Financial Officer of Closure Medical Corporation, a world-leading, publicly traded developer and manufacturer of biomaterial-based medical adhesives that was acquired by Johnson & Johnson in June 2005. He joined Closure Medical in 1996 serving as a key member of the management team from the company's successful initial public offering through its 2005 sale to Johnson & Johnson. Before joining Closure Medical, he spent three years as an auditor for Price Waterhouse. Mr. Ward serves on the Advisory Board of the School of Business at East Carolina University and is a board member of the Children's Flight of Hope and Chesson Labs. Mr. Ward is qualified to serve on our management team because of his extensive experience in specialty biopharmaceutical companies. Mr. Ward received his Bachelor of Science degree in Accounting and Bachelor of Arts degree in Political Science from East Carolina University.

William B. Stone, age 68, has been a member of our board of directors since October 2001 and is our Lead Director and Chairman of the Audit Committee of our board of directors. For thirty years, until his retirement in October 2000, Mr. Stone was employed with Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and Chief Information Officer for 16 years and 4 years, respectively. During his tenure at Mallinckrodt, Mr. Stone was responsible for global accounting and reporting, financial organization, staffing and development, and systems of internal accounting control. In this capacity, he was responsible for Mallinckrodt's SEC and other financial filings, internal management performance reports, strategic and tactical financial planning and for evaluation of capital sources and investments. Mr. Stone presented financial analyses and special projects to Mallinckrodt's board of directors and audit committee, and reported to the audit committee regarding the conduct and effectiveness of the independent accountant's quarterly reviews and annual audit. In the capacity of Chief Information Officer, Mr. Stone was responsible for Mallinckrodt's worldwide computer information systems and organization, staffing and development. He assessed effectiveness and control for computer-assisted information systems and led a successful program for justification, selection and deployment of global standardized computer hardware and software. Further, Mr. Stone reported to the audit committee as leader of Mallinckrodt's successful global program to address Year 2000 implications associated with computer-assisted information, laboratory control and process control computer hardware and software. He also chaired Mallinckrodt's corporate employee benefits committee for over 8 years and has been a member of Financial Executives International since 1980. Mr. Stone is qualified to serve on our board of directors because of his extensive experience in accounting and with pharmaceutical companies. Mr. Stone is a graduate of the University of Missouri-Columbia where he earned BS and MA degrees in accounting, and is a Certified Public Accountant.

John J. Shea, age 85, has been a member of our board of directors since March 2002 and serves as Chairman of the Nominating and Corporate Governance Committee of our board of directors. He is currently the head of his own firm J. Shea Inc. and has also been a Quality Systems Adviser with Quintiles, a private consulting firm. Mr. Shea has also served in the capacity of Director of Quality Assurance and was responsible for the implementation of quality assurance procedures in a number of public companies. From 1987-1989, he served as Director of Quality Assurance at NeoRx Corporation. Mr. Shea was also the Director of Corporate Quality Assurance at Hexcel Corporation from 1980-1987. Mr. Shea has also served as the quality assurance person for other companies including, Teledyne Relays, Ortho Diagnostics, Inc. and Bio Reagents & Diagnostics, Inc. He is a member of the (North Carolina) Dare County Airport Authority and Audit Committee. Mr. Shea is qualified to serve on our board of directors because of his extensive business experience in the pharmaceutical industry. Mr. Shea earned a B.S. in Chemistry at Bethany College.

William S. Poole, age 65, has been a member of our board of directors since April 2005 and serves as Chairman of the Compensation Committee of our board of directors. He has extensive experience in the biopharmaceutical and medical device industries for over thirty years. From 1972 to early 1996, Mr. Poole worked for Lederle Laboratories, a Division of American Cyanamid Company. During his 24-year career at Cyanamid, Mr. Poole held positions of increasing responsibility and held the position of World-Wide Division President of the Medical Device Division when Wyeth acquired Cyanamid in 1995. He later served as President, North American Pharmaceuticals, of Novo Nordisk Pharmaceuticals, and also as President of Biovail Pharmaceuticals. In both of these companies, Mr. Poole was instrumental in aggressively growing revenue, building solid management teams and dramatically improving profitability. As President of these firms, Mr. Poole had total P&L responsibility and directly managed vice presidents in charge of each business department within the organizations. In recent years, Mr. Poole has acted as a private consultant and, until his appointment to the board, Mr. Poole served as a member of the Commercial Advisory Board of our subsidiary, Arius Pharmaceuticals. Mr. Poole was Acting President/CEO of Spherics, Inc., a biotechnology company focusing on unique delivery mechanisms of certain drugs for the treatment of CNS diseases during 2007 and 2008. Mr. Poole is also a member of the board of directors of Accentia. Mr. Poole is qualified to serve on our board of directors because of his extensive business experience in the pharmaceutical industry. Mr. Poole earned a B.A. in Psychology at Boston University.

Samuel P. Sears, Jr., age 68, was appointed as a member of our board of directors in October, 2011. Mr. Sears has extensive experience in the biopharmaceutical, nutraceutical and biotechnology industries. Since 2006, Mr. Sears has been a partner at the law firm of Cetrulo and Capone, PC, where he currently serves as managing partner, and from 2000 to 2006, he provided private consulting and legal advisory services to start-up and early stage development companies. Since 2000, Mr. Sears has served as Director, Chairman of the Audit Committee, Chairman of the Executive Committee, and Member of the Compensation Committee of Commonwealth Biotechnologies, Inc. (NASDAQ: CBTEQ), a research and development support services company. From 1998 to 2000, Mr. Sears served as Vice Chairman and treasurer of American Prescription Providers, Inc., a specialty pharmacy network offering prescriptions and nutraceuticals to patients with chronic diseases. From 1994 through May 1998, Mr. Sears was Chief Executive Officer and Chairman of Star Scientific, Inc. (NASDAQ: CIGX). From 1968 to 1993, Mr. Sears was in private law practice. Mr. Sears is qualified to serve on our board of directors because of his extensive legal and business experience, including in the pharmaceutical industry. Mr. Sears is a graduate of Harvard College and Boston College Law School.

Key Employees

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

Niraj Vasisht, Ph.D. has been our Senior Vice President of Product Development and Chief Technology Officer since October 2008. He joined the company in February 2005 as the Vice President of Product Development with over 14 years of experience in pharmaceutical development. Dr. Vasisht's heads our pharmaceutical development for our product candidates, technology assessment for potential candidates, and provides technical and strategic leadership to the business development function. In his position, he evaluates suitability of drug candidates into the delivery platform, creates technologies for the company's intellectual property and product pipeline extension, and oversees contract CTM manufacturing operations. He directs and oversees the product design, formulation development, quality control, process engineering, validation and stability testing of the drug product, and is responsible for the chemistry, manufacturing and controls (CMC) section in IND, IMPD, NDA and MAA filings. From 1994 to 2005, Dr. Vasisht held positions of increasing responsibility at Southwest Research Institute where he ultimately served as the Director of Microencapsulation, Pharmaceutical Development and Nanomaterials and was responsible for leading the group that provides research and development and product development services to pharmaceutical, consumer health, and nutraceutical companies. Dr. Vasisht is the inventor/co-inventor on multiple patents in drug delivery. Dr. Vasisht received a BTech degree in Chemical Engineering from the Indian Institute of Technology at Kanpur, a Master's of Science from the University of New Hampshire and a Doctorate in Chemical Engineering from Rensselaer Polytechnic Institute.

Albert J. Medwar, M.B.A. has been our Vice President of Marketing and Corporate Development since joining the company in April 2007, with over 20 years of experience in marketing, sales, and marketing research. Prior to joining the company, Mr. Medwar was the Head of Oncology Marketing at EMD Pharmaceuticals, the U.S. subsidiary of Merck KGaA, where he was responsible for developing the global market for a pipeline of oncology products. Mr. Medwar was also the Marketing Director for Triangle Pharmaceuticals, a start-up company focusing on the development and commercialization of compounds for HIV and hepatitis. Mr. Medwar's pharmaceutical career began in sales at Burroughs Wellcome, which later became Glaxo Wellcome. After six years of sales experience, he took on marketing research responsibilities, and then played an important role in the launch of a short acting opioid analgesic, remifentanil, and held increasing marketing responsibility for a number of products including a portfolio of anesthetic/analgesic agents, Zofran, and Wellbutrin SR. Mr. Medwar received a Bachelor of Science degree from Cornell University and a Masters of Business Administration from Bentley College.

Steven Dykstra was appointed our Senior Vice President of Manufacturing Operations in January 2011. He joined the company with over 30 years experience in the development and manufacture of pharmaceutical products. Steve is responsible for the execution of all manufacturing operations conducted by the organization to maintain adequate product supply for ONSOLIS® and to bring our product candidates successfully to market. Steve started his career with Baxter Travenol and assumed positions of increasing responsibility working for American Critical Care, Dupont Pharmaceuticals, DuPont Merck Pharmaceuticals, MGI Pharma, and finally IVX Animal Health/Teva where he was Vice President of Manufacturing Operations. He has also worked as a consultant in Manufacturing Operations. He has 14 years experience with outsourced development, manufacturing, and distribution while at MGI Pharma where he was Senior Director of Manufacturing Operations. Steve received a BS in Chemistry from Illinois State University. Steve was certified by the American Production and Inventory Control Society in Production and Inventory Management (APICS-CPIM) in 1998. He is the inventor of two patents related to healthcare and he has been published in the American Journal of Hospital Pharmacy.

Executive Chairman

On January 20, 2012, our board of directors, upon the recommendation of the Nominating and Corporate Governance Committee of the board, created the office of Executive Chairman of the Company and appointed Dr. Frank O'Donnell, then our Chairman of the Board, as Executive Chairman of our company. In taking such action, our board was intending to formally memorialize the role that Dr. O'Donnell has played with our company over the years.

As Executive Chairman of our company, Dr. O'Donnell acts as an officer and employee and, as such, performs his duties subject in all instances to the oversight of our board of directors and the power of our board of directors to approve all applicable corporation actions (which powers shall not be vested in the office of Executive Chairman).

Subject to such other roles, duties and projects as may (consistent with the terms and provisions of our Amended and Restated Bylaws and the resolutions of our board that formed the office of Executive Chairman) be assigned by our board to the Executive Chairman, the primary responsibilities of the Executive Chairman are as follows:

1. Chair annual and special board meetings and annual stockholder meetings and, subject to availability, attend meetings of the committees of the board;

2. Provide overall board leadership and establish guiding principles for the board;

3. Manage the affairs of the board and facilitate board action in such a way that strategic and policy decisions are fully discussed, debated and decided by the board;

4. In cooperation with the President and Chief Executive Officer, ensure that our strategic orientation is defined and communicated to the board for its approval and that all material issues are dealt with by the board during the year;

5. Ensure that the board has efficient communication channels regarding all material issues concerning the business and see to it that directors are informed about these issues;

6. Act as a representative of the board and consult with board members outside the regularly scheduled meetings of the board and of board committees;

7. Meet and confer as often as required with our President and Chief Executive Officer to ensure that there is efficient communication between the Executive Chairman, the President and Chief Executive Officer and board members;

8. Offer advice and consultation to the President and Chief Executive Officer on the overall management of the business and affairs of our company as well as specific matters upon the request of the President and Chief Executive Officer;

9. In consultation and partnership with the President and Chief Executive Officer, the Executive Chairman may act as our representative with business partners of our company; and

10. At the request of the board or the President and Chief Executive Officer, and in consultation and partnership with the President and Chief Executive Officer, the Executive Chairman may be placed in charge of special corporate strategic initiatives or projects.

The compensation of the Executive Chairman shall be determined from time to time by the Compensation Committee of the board in accordance with such committee's charter and practice. In March 2012, the Compensation Committee determined and approved that Dr. O'Donnell would receive compensation at a level equal to 50% of the President/CEO's salary, cash bonus and options. The salary portion would begin on January 1, 2012 and the cash bonus and option portion would be determined in the first quarter of 2013, when, under normal circumstances, the company 2012 objectives would be evaluated. Because of the change in his compensation, Dr. O'Donnell will no longer receive cash retainers or option awards under the existing board of director remuneration program for his role as a member of our board of directors.

Director Independence

We believe that William B. Stone, John J. Shea, William S. Poole and Samuel P. Sears, Jr. qualify as independent directors for NASDAQ Stock Market purposes. This means that our board of directors is composed of a majority of independent directors as required by NASDAQ Stock Market rules.

Meetings of the Board of Directors and Stockholders

Our board of directors met in person and telephonically 15 times during 2011 and also acted by unanimous written consent. Each member of our board of directors was present at eighty-seven (87%) percent or more of the board of directors meetings held. It is our policy that all directors must attend all stockholder meetings, barring extenuating circumstances. All directors were present at the 2011 Annual Meeting of Stockholders, with the exception of Samuel P. Sears, Jr., who did not become a member until after the aforementioned meeting.

Board Committees

Our board of directors has established three standing committees-Audit, Compensation, and Nominating and Corporate Governance. All standing committees (as well as our Lead Director) operate under a charter that has been approved by the board.

Audit Committee

Our board of directors has an Audit Committee, composed of William B. Stone, John J. Shea, William S. Poole and Samuel P. Sears, Jr. (who was appointed October 2011), all of whom are independent directors as defined in accordance with section 3(a)(58)(A) of the Exchange Act and the rules of NASDAQ. Mr. Stone serves as chairman of the committee. The board of directors has determined that Mr. Stone is an “audit committee financial expert” as defined in Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee met six times during 2011. Each member of the Audit Committee was present at one hundred (100%) percent of the Audit Committee meetings held during such director’s tenure as a member of the Audit Committee.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually) and performs several functions. The Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;
- oversees all aspects our systems of internal accounting control and corporate governance functions on behalf of the board; and
- provides oversight assistance in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our board of directors has a Nominating and Corporate Governance Committee composed of William S. Poole, John J. Shea, William B. Stone and Samuel P. Sears, Jr. (who was appointed October 2011). Mr. Shea serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The Nominating and Corporate Governance Committee met three times in 2011 and has a charter which is reviewed annually. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the NASDAQ Stock Market. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders. To recommend a nominee please write to the Nominating and Corporate Governance Committee c/o James A. McNulty, BioDelivery Sciences International, Inc, 324 South Hyde Park Avenue, Suite 350, Tampa FL 33606. The Nominating and Corporate Governance Committee has established nomination criteria by which board candidates are to be evaluated. The Nominating and Corporate Governance Committee will assess all director nominees using the same criteria. During 2011, we did not pay any fees to any third parties to assist in the identification of nominees. During 2011, we did not receive any director nominee suggestions from stockholders.

In 2010, the Nominating and Corporate Governance Committee adopted a set of criteria by which it will seek to evaluate candidates to serve on our board of directors. The evaluation methodology includes a scored system based on criteria including items such as experience in the biotechnology sector, experience with public companies, executive managerial experience, operations and commercial experience, fundraising experience and contacts in the investment banking industry, personal and skill set compatibility with current board members, industry reputation, knowledge of our company generally, independence and ethnic and gender diversity. While diversity is considered as a board qualification criteria, it would not be weighted any more or less in an evaluation process than any other criteria. The established criteria do not distinguish board candidates based on whether the candidate is recommended by a stockholder of our company.

In October 2011, Mr. Sears was appointed to our board of directors upon recommendation by the Nominating and Corporate Governance Committee. Mr. Sears' qualifications were analyzed in accordance with the criteria describe above.

Compensation Committee

Our board of directors also has a Compensation Committee, which reviews or recommends the compensation arrangements for our management and employees and also assists the board of directors in reviewing and approving matters such as company benefit and insurance plans, including monitoring the performance thereof. The Compensation Committee has a charter (which is reviewed annually) and is composed of three members: John J. Shea, William B. Stone, William S. Poole and Samuel P. Sears, Jr. (who was appointed October 2011). Mr. Poole serves as chairman of this committee. The compensation committee met seven times during 2011.

The Compensation Committee has the authority to directly engage, at our expense, any compensation consultants or other advisers as it deems necessary to carry out its responsibilities in determining the amount and form of employee, executive and director compensation. In 2011, the Compensation Committee engaged Radford, an AON Consulting Company, to obtain market data against which it has measured the competitiveness of our compensation programs. In determining the amount and form of employee, executive and director compensation, the Compensation Committee has reviewed and discussed historical salary information as well as salaries for similar positions at comparable companies. We paid consultant fees to Radford of $24,225 in 2011.

Risk Management Committee

Our board of directors also has a Risk Management Committee, which was formed in August 2011. Pursuant to a charter of the Risk Management Committee approved by our board, the purpose and mandate of the Risk Management Committee is to provide assistance to our board of directors and management in fulfilling the board and management's responsibilities to our stockholders, potential stockholders and investment community by: (i) identifying, assessing, monitoring and providing oversight to management relating to the identification and evaluation of major strategic, operational, regulatory and external risks inherent in our business; (ii) overseeing our company's risk management, compliance and control activities; and (iii) overseeing our company's compliance with legal and regulatory requirements, including, without limitation, with respect to the conduct of our business.

Because the Audit Committee of the board is responsible for reviewing and discussing with management and our independent auditors the major financial risk exposures (including those relating to systems of internal control, accounting and financial reporting) and the steps management has taken to monitor and control such exposures, it is the objective of the Risk Management Committee to coordinate with the Audit Committee and to maintain, as is necessary to fulfill the purposes of the Risk Management Committee, free and open means of communications among the board and its committees, the independent auditors, the internal auditors and our senior management. The Committee does not have responsibility for matters subject to the jurisdiction of another committee of the board pursuant to that committee's charter. Moreover, the Risk Management Committee does not have the power to direct our day-to-day management and operations, such power being vested in our executive management, subject to the oversight and approval of the board of directors.

All members of our board of directors are also members of the Risk Management Committee, but to ensure the efficient and optimal operation of the Risk Management Committee, the Risk Management Committee established an Executive Subcommittee thereof composed of William S. Poole (who acts as Chairman of each of the Risk Management Committee and its Executive Subcommittee), Dr. Frank O'Donnell and Dr. Mark A. Sirgo. The Executive Subcommittee formally reports at least quarterly to the full board.

Lead Director

On July 26, 2007, our board of directors created the position of Lead Director. Our board of directors designated William B. Stone, an existing director, as our Lead Director. Pursuant to the charter of the Lead Director, the Lead Director shall be an independent, non-employee director designated by our board of directors who shall serve in a lead capacity to coordinate the activities of the other non-employee directors, interface with and advise management, and perform such other duties as are specified in the charter or as our board of directors may determine.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the "reporting persons") file with the SEC various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2011, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, except that employee options granted to our officers (Mark A. Sirgo, James A. McNulty and Andrew L. Finn) on February 25, 2011 were reported on Form 4s filed on March 17, 2011 and options to our officer Benny Ward on February 25, 2011 was reported on Form 4 filed on March 18, 2011. Options granted to our directors (Francis E. O'Donnell, Jr., M.D., William B. Stone, John J. Shea, William S. Poole and Mark A. Sirgo) on July 20, 2011 were reported on Form 4s filed on July 27, 2011.

Code of Ethics

We have adopted a code of ethics that applies to all employees, as well as each member of our board of directors. Our code of ethics is posted on our website, and we intend to satisfy any disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of ethics by posting such information on our website, www.bdsi.com. A copy of our code of ethics is also available in print, without charge, upon written request to 801 Corporate Center Drive, Suite #210 Raleigh, NC, 27607 Attn: James A. McNulty.

Compensation Committee Report *

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

Submitted by:

The Compensation Committee of the Board of Directors

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

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

Compensation Discussion and Analysis

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

We currently employ four executive officers, each of whom serves as a "Named Executive Officer" (or "NEO") for purposes of Securities and Exchange Commission ("SEC") reporting: (1) Mark A. Sirgo, Pharm.D., our President and Chief Executive Officer (CEO); (2) James A. McNulty, our Secretary, Treasurer and Chief Financial Officer (3) Andrew L. Finn, Pharm.D., our Executive Vice President of Product Development and (4) Benny Ward, our Executive Vice President of Business and Strategic Development.

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

Objectives of Our Compensation Program

The Committee's philosophy seeks to align the interests of stockholders and management and employees by tying compensation to employee and company performance, both directly in the form of salary or annual cash incentive payments, and indirectly in the form of equity awards. The objectives of our compensation program enhance our ability to:

- attract and retain qualified and talented individuals; and
- provide reasonable and appropriate incentives and rewards to our team for building long-term value within our company.

In addition, we strive to be competitive with other similarly situated companies in our industry. The process of developing pharmaceutical products is a long-term proposition and outcomes may not be measurable for several years. Therefore, in order to build long-term value for our company and its stockholders and in order to achieve our business objectives, we believe that we must compensate our officers and employees in a competitive and fair manner that reflects current company activities but also reflects contributions to building long-term value.

We utilize the services of the Radford Group, an AON consulting company ("Radford") to review compensation programs of peer companies in order to assist the Committee in determining the compensation levels for our executives. Radford is a recognized independent consulting company and services clients throughout the USA. Those companies that comprise the peer group will be reviewed biennially as we do not believe that material differences will occur over a shorter period. However, we may review the peer group more often should circumstances warrant such action. The current peer group used to evaluate senior management compensation includes:

Company	Location
Aastrom Biosciences	Ann Arbor, MI
Achillion Pharmaceuticals	New Haven, CT
Anadys Pharmaceuticals	San Diego, CA
Antigenics Inc.	New York, NY
A.P. Pharma, Inc.	Redwood City, CA
AspenBio Pharma	Castle Rock, CO
Celldex Therapeutics	Needham, MA
Columbia Laboratories	Livingston, NJ
Zalicus	Cambridge, MA
DUSA Pharmaceuticals	Wilmington, MA
Epicept Corporation	Tarrytown, NY
Idera Pharmaceuticals	Cambridge, MA
Insmed Incorporated	Richmond, VA
MDRNA Inc.	Bothell, WA
Molecular Insight Pharmaceuticals	Cambridge, MA
Neurogesx, Inc.	San Mateo, CA
NovaBay Pharmaceuticals	Emeryville, CA
Pozen Inc.	Chapel Hill, NC
Sunesis Pharmaceuticals	South San Francisco, CA
Telik, Inc.	Palo Alto, CA
Threshold Pharmaceuticals	Redwood City, CA
Transcept Pharmaceuticals	Pt. Richmond, CA

With respect to our employees and non-senior management, we will also take into consideration local market data in determining appropriate compensation packages.

Elements of Our Compensation Program and Why We Chose Each

Main Compensation Components

Our company-wide compensation program, including for our executive officers, is broken down into three main components: base salary, performance cash bonuses and potential long-term compensation in the form of stock options. We believe these three components constitute the minimum essential elements of a competitive compensation package in our industry.

Salary

Base salary is used to recognize the experience, skills, knowledge and responsibilities required of our executive officers as well as recognizing the competitive nature of the biopharmaceutical industry. This is determined partially by evaluating our peer companies and the degree of responsibility in each of the experience levels.

Performance Bonus Plan

We have a performance bonus plan under which bonuses are paid to our NEOs based on achievement of extraordinary company performance goals and objectives established by the Committee and/or the board of directors as well as on individual performance. The bonus program is discretionary and is intended to: (i) strengthen the connection between individual compensation and company's achievements; (ii) encourage teamwork among all disciplines within the company; (iii) reinforce our pay-for-performance philosophy by awarding higher bonuses to higher performing employees; and (iv) help ensure that our cash compensation is competitive. Depending on the cash position of the company, senior management, the Committee and our board of directors have decided, from time to time, not to pay cash bonuses in order that we may conserve cash and support ongoing development programs. Regardless of our cash position, we consistently grant annual merit-based stock options to continue incentivizing both our senior management and our employees.

Each NEO is assigned a target payout under the performance bonus plan, expressed as a percentage of base salary for the year. Actual payouts under the performance bonus plan are based on the achievement of corporate performance goals and an assessment of individual performance, each of which is separately weighted as a component of such officer's target payout. For the NEOs, the corporate goals receive the highest weighting in order to ensure that the bonus system for our management team is closely tied to our corporate performance. Each employee has specific individual goals and objectives as well that are tied to the overall corporate goals. For employees, mid-year and end of year progress is reviewed with the employees' managers.

Equity Incentive Compensation

We view long-term compensation, currently in the form of stock options, generally vesting in annual increments over three years, as a tool to align the interests of our NEOs and employees generally with the creation of stockholder value, to motivate our employees to achieve and exceed corporate and individual objectives and to encourage them to remain employed by the company. While cash compensation is a significant component of employees overall compensation, our executive management team, the Committee and the board of directors believe that the driving force of any employee working in a small biotechnology company should be strong equity participation. We believe that this not only creates the potential for substantial longer term corporate value but also serves to motivate employees and retain their loyalty and commitment with appropriate personal compensation.

Other Compensation

In addition to the three main components of compensation outlined above, we also provide contractual severance and/or change in control benefits to the NEOs as well as Dr. Niraj Vasisht, our Senior Vice President–Product Development and CTO, to Al Medwar, our Vice President of Marketing and to Steven Dykstra, our Senior Vice President of Manufacturing Operations. We believe these severance or change in control benefits are important elements of our compensation program that assist us in retaining talented individuals at the executive and senior managerial levels and that these arrangements help to promote stability and continuity of our executives and senior management team. Further, we believe that the interests of our stockholders will be best served if the interests of these members of our management are aligned with theirs. We believe that providing change in control benefits lessens or eliminates any potential reluctance of these members of our management to pursue potential change in control transactions that may be in the best interests of the stockholders. We also believe that it is important to provide severance benefits to these members of our management, to promote stability and focus on the job at hand.

We also provide benefits to the executive officers that are generally available to all regular full-time employees of the company, including our medical and dental insurance, life insurance and a 401(k) match for all individuals who participate in the 401(k) plan. At this time, we do not provide any perquisites to any executive officers. Further, we do not have deferred compensation plans, pension arrangements or post-retirement health coverage for our executive officers or employees. All of our employees not specifically under contract are "at-will" employees, which mean that their employment can be terminated at any time for any reason by either us or the employee. Our NEOs (as well as certain of our senior managers) have employment contracts that provide lump sum compensation in the event of their termination without cause or, under certain circumstances, upon a change of control.

Determination of Compensation Amounts

A number of factors impact the determination of compensation amounts for the executive officers, including the individual's role in the company and individual performance, competition for talent, each NEO's total compensation package, assessments of internal pay equity and industry data. Stock price performance has generally not been a factor in determining annual compensation because the price of our common stock is subject to a variety of factors outside of our control.

Industry Survey Data

In collaboration with Radford, we have determined that to best assure ourselves that we are compensating our executives on a fair and reasonable basis that we needed to establish a list of peer companies. We have established two peer group reviews with Radford. The first group is for NEOs, which is based on a national review and was set forth above under the heading "Objectives of our Compensation Program." The second is intended for non-NEOs and focuses on similar sized companies located on the East Coast.

Determination of Base Salaries

As a guideline for NEO base salary, we perform formal benchmarks against respective comparable positions in our established peer group. Our guideline is to set NEO salary ranges between the 25th and 50th percentile for comparable positions. We then adjust salaries based on our assessment of the officers' levels of responsibility, experience, overall compensation structure and individual performance. Merit-based increases to salaries of executive officers are based on our assessment of individual performance and the relationship to applicable salary ranges. Cost of living adjustments may also be a part of that assessment.

Performance Bonus Plan

At, or prior to the beginning of each calendar year, draft corporate goals that reflect our business priorities for the coming year are prepared by the CEO with input from the other executive officers. These goals are weighted by relative importance. The draft goals and proposed weightings are presented to the Committee and the board of directors and discussed, revised as necessary, and then approved by the board of directors. The Committee then reviews the final goals and their weightings to determine and confirm their appropriateness for use as performance measurements for purposes of the bonus program. The goals and/or weightings may be re-visited during the year and potentially restated in the event of significant changes in corporate strategy. Following the agreement with the board of directors on the corporate objectives, the goals are then shared with all employees in a formal meeting(s), and are reviewed periodically throughout the year at monthly staff meetings and quarterly Board of Director meetings.

The performance bonus plan for our executive officers in 2011 was adopted by the board of directors in January 2009. The plan sets forth target bonus opportunities, as a percentage of salary, based on the level of responsibility of the position, ranging up to 50% of salary for our CEO, to 40% of salary for our senior executive officers, to 30% of salary for our other officers. In setting these percentages, the Committee determined that the above percentages were reasonable and in line with other companies at our stage of development. Each employee has the opportunity to achieve up to 100% of his targeted amount, depending on how corporate goals and objectives are achieved.

Determination of Equity Incentive Compensation

To assist us in assessing the reasonableness of our stock option grant amounts, historically we have reviewed Radford supplied information and, prior to Radford, we used information supplied by Equilar. Such information included stock option data from a cross-section of the companies in the above-mentioned surveys. On-hire stock option grant amounts have generally been targeted at the 25th to 50th percentile for that position or similar industry position, adjusted for internal equity, experience level of the individual and the individual's total mix of compensation and benefits provided in his or her offer package. Dr. Sirgo, our CEO and President, has been authorized by our board of directors to offer to new employees stock options valued up to 50% of base salary using Black-Scholes valuation for director-level employees and up to 100% of base salary for Vice Presidents and Executive Vice Presidents. These options are to be granted the first day of employment. On-hire grants typically vest over three years. In 2010, the Committee implemented internal guidelines for annual stock option grants for all employees based on performance factors similar to the executive performance bonus plan. These guidelines provide an internal framework for decision-making by the Committee and are not communicated to the individual as a target grant amount. It is generally expected that the target amount would be granted if 100% performance is achieved. This calculation is similar to the bonus plan calculation. The equity guidelines also provide a framework for granting stock options on average that are valued up to 25% of salary using the Black-Scholes valuation method to compute the number of shares. However, the equity model amounts are only guidelines and may be adjusted upward or downward by the Committee on a discretionary basis.

Option Grant Practices

All stock options granted to the NEOs are approved by the Committee. Exercise prices are set using a 30-day volume weighted average price method which we define as the closing price of our common stock on the Nasdaq Capital Market on the trading day of the date of grant and the 30 trading days preceding that date. Grants are generally made: (i) on the employee's start date and (ii) at board of directors meetings held each January and following annual performance reviews. However, grants have been made at other times during the year. The size of year-end grants for each NEO is assessed against our internal equity guidelines. Current market conditions for grants for comparable positions and internal equity may also be assessed. Also, grants may be made in connection with promotions or job related changes in responsibilities. In addition, on occasion, the Committee may make additional special awards for extraordinary performance.

Compensation Setting Process

Near the end of the year and at an in person meeting held each January, the board of directors and Committee assess our overall corporate performance and discuss the relative achievement of the corporate goals. The relative achievement of each goal is assessed and quantified and the summation of the individual components results in the corporate goal rating. The independent directors of the board (who comprise the Compensation Committee) meet privately to further discuss and approve the final corporate goal rating, expressed as a percentage, from 0 to 100%.

Also near the end of the year, the CEO evaluates the individual performance of each executive officer (other than himself) and provides the Committee with an assessment of the performance of each other NEO. In determining the individual performance ratings of the NEOs, we assess performance against a number of factors, including each NEO's relative contributions to our corporate goals, demonstrated career growth, level of performance in the face of available resources and other challenges, and the respective officer's department's overall performance. This assessment is conducted in a holistic fashion, in contrast to the summation of individual components as is done to arrive at the corporate goal rating.

Following a qualitative assessment of individual NEO's performance, our policies provide guidelines for translating this performance assessment into a numerical rating. Both the initial qualitative assessment and the translation into a numerical rating are made by the Committee on a discretionary basis. We believe that conducting a discretionary assessment for the individual component of the executive officers' performance provides for flexibility in the evaluation of our NEOs and their adaptability to addressing potential changes in company priorities throughout the year.

The Committee looks to the CEO's performance assessments of the other NEOs and his recommendations regarding a performance rating for each, as well as input from the other members of the board of directors. These recommendations may be adjusted by the Committee prior to finalization. For the CEO, the Committee evaluates his performance, taking into consideration input from the other members of the board of directors, and considers the achievement of overall corporate objectives by both the CEO specifically and the company generally.

The CEO also presents any recommended changes to base salary and recommendations for an annual stock option grant amount, referencing the equity guidelines, for each of the executive officers (other than himself).

The Committee has the authority to directly engage, at our company's expense, any compensation consultants or other advisors (such as Radford) that it deems necessary to determine the amount and form of employee, executive and director compensation. In determining the amount and form of employee, executive and director compensation, the Committee has reviewed and discussed historical salary information as well as salaries for similar positions at comparable companies.

Concurrently with the CEO's evaluation of the other executive officers' performance, the Committee reviews the CEO's performance, based on input from the other members of the board of directors, and assigns a rating for the CEO, expressed as a percentage from 0 to 100%. The Committee also sets the CEO's base salary for the upcoming fiscal year, referencing the relevant survey data. The CEO is not present during the Committee's deliberations regarding his compensation.

The corporate goals rating and individual performance ratings are applied to each employee's target bonus opportunity under the bonus plan, in the proportions defined for each position. The sum of those components then determines the actual bonus paid for each individual. Under the equity guidelines, described above, the corporate goals rating and individual performance ratings may also be used to determine the size of the annual stock option grant for each employee.

Compensation and benefit consultants who are independent from the company, may, from time to time, be hired by the Committee to assist in developing and reviewing overall salary policies and structures. Other than Radford, we did not engage any consultant related to executive and/or director compensation matters in 2011. We paid consultant fees to Radford of $24,225 in 2011. NEOs may have indirect input in the compensation results for other executive officers by virtue of their participation in the performance review and feedback process for the other executive officers.

2011 Compensation Decisions

General Assessment of Management Performance in 2011

The Committee and the board of directors conducted the performance and compensation review for 2011 during November and December of 2011 and January of 2012. In assessing our performance for the year, the Committee and the board of directors agreed that there was good progress in a number of areas. Notably, this included achievement of a closing of an equity financing in the first quarter that was accomplished with fundamental health care investors at market terms (which were a 10% discount with no warrants) and the closing of a commercial partnership for BEMA® Buprenorphine for the treatment of chronic pain with Endo. This partnership can potentially bring $180 million of revenue to us of which $30 million was received at the closing of the transaction. Unfortunately, the unforeseen negative results of BEMA® Buprenorphine Phase 3 study was a cause of major concern for the Committee, particularly as it negatively affected our stock price and shareholder value. Despite this outcome, the positive work that had been done with this product led to the closure of the Endo partnership and a significant recovery in shareholder value. In addition, the BEMA® Buprenorphine/Naloxone program progressed to a final formulation that we are now taking to final clinical testing in 2012. We are hopeful this will lead to an NDA submission in the first half of 2013. We also achieved a positive result in a requested USPTO patent reexamination in connection with of our defense of the MonoSol patent litigation.

2011 Performance Assessments and Bonus Calculations

For 2011, our performance bonus plan set the following target payouts, expressed as a percentage of base salary. For our CEO, the target bonus opportunity was 50% of base salary and for our Chief Financial Officer, Executive Vice President, Product Development and Executive Vice President, Business and Strategic Development the target bonus opportunity was 40% of base salary.

The elements that the Committee and the board of directors established as our overall corporate goals for 2011 included a variety of development and operational objectives. The 2011 goals were established in January 2011. The objectives were development/clinical, commercial, financial and operational in nature.

In January 2012, the Committee and the board of directors considered year-end compensation for 2011 performance and 2012 compensation matters. Specifically, the Committee and the board of directors observed and recognized that the following key Corporate Objectives were substantially met:

- secured a commercial partnership for BEMA® Buprenorphine for Chronic Pain with Endo worth a potential of $180 million to be received by us in milestones;
- concluded a successful gross $15 million financing at market terms with fundamental health care investors;
- delivered launch supply of ONSOLIS® for Canada that led to a product launch;
- supported MEDA activities to gain approval of the class-wide REMS for ONSOLIS®; and
- completed and analyzed the pivotal Phase 3 study for BEMA® Buprenorphine.

These accomplishments reflected the efforts of our employees, including the NEOs, and were taken into account by the Committee in providing our NEOs and some employees with salary increases. All employees were provided equity grants and performance cash bonus awards. All employees were granted options based on 17% of their base salary, using Black-Scholes valuation. The total options for this award amounted to 318,351 options, have a value of $493,188 and vest in thirds. The award under our performance cash bonus program approximated 45% of target for the corporate performance portion of the awards. This 45% was divided into 50% cash bonuses and 50% stock options using Black-Scholes valuation. The total cash bonuses amounted to $194,995, which will be paid upon the successful issuance of a certain patent and receipt of an associated milestone payment from Endo in 2012. The total options for this award amounted to 154,007 options, have a value of $194,995 and vest immediately.

As a special recognition award to Dr. O'Donnell for his active participation in the Risk Management Committee of our board of directors and the Executive Risk Management Subcommittee thereof for the latter half of 2011, Dr. O'Donnell was granted 10,000 options in February 2012, which have a value of $14,100 and vest immediately.

Individual Performance and Compensation of the President and CEO

Dr. Sirgo's base salary for 2011 was $413,920 as established in January 2010 in connection with the 2009 year-end performance and compensation review conducted by the Committee.

In evaluating Dr. Sirgo's individual performance for 2011 the Committee, with input from the other board members, concluded that Dr. Sirgo's efforts in securing new financing as well as conducting several multi-level meetings with potential commercial partners were excellent. The Committee believes that he concluded a solid contract with a significant pharmaceutical partner that is dedicated to taking BEMA® Buprenorphine to market. Dr. Sirgo provided the necessary leadership to our employees to ensure that appropriate attention and effort were directed at advancing the commercialization of ONSOLIS® in Canada and Europe. He guided our efforts with the FDA with respect to the retail REMS for Meda and our own additional clinical programs. Dr. Sirgo managed to clarify, and share, with our investors and shareholders, the positive aspects and outcomes of our BEMA® Buprenorphine study that was also instrumental in the closing of the Endo partnership. Accordingly, the Committee provided 33,026 stock options valued at $46,566 (11% of base salary) which will vest 100% at the time the grant is issued. In addition upon the issuance of a certain patent and receipt of an associated milestone payment from Endo in 2012, Dr. Sirgo will be awarded a cash bonus in the amount of $46,566 or 11% of base salary. Dr. Sirgo was also granted 45,421 in employee option awards with a value of $70,366, or 17% of base salary. These options vest over a three year period.

Compensation Highlights for the other Executive Officers

Chief Financial Officer

Mr. McNulty's base salary for 2011 was $300,118 as established in January 2011 in connection with the 2010 year-end performance and compensation review conducted by the Committee.

In evaluating Mr. McNulty's individual performance for 2011, the Committee, with input from the other board members, concluded that Mr. McNulty led the finance team in achieving its objectives and supported the company overall by providing timely information on our financial condition and maintained sound internal and financial reporting controls. Accordingly, the committee provided 19,156 stock options valued at $27,011 or 9% of base salary, which will vest 100% at the time of grant. In addition, upon the successful issuance of certain patents and receipt of milestone payments in 2012 Mr. McNulty will be awarded a cash bonus of $27,011 or 9% of base of base pay. Mr. McNulty was also granted 32,933 in employee option awards with a value of $51,020, or 17% of base salary. These options vest over a three year period.

Executive Vice President—Product Development

Dr. Finn's base salary for 2011 was set at $284,000 in February 2011 in connection with the 2010 year-end performance and compensation review conducted by the Committee. The salary adjustment reflected an increase of $31,856.

In evaluating Dr. Finn's individual performance for 2011, the Committee, with input from the other board members, concluded that Dr. Finn completed the pivotal BEMA® Buprenorphine Phase 3 study on time and despite its negative outcome was able to quickly analyze the data and report in a fashion that highlighted the positive aspects of the study that was instrumental in the closing of the Endo licensing deal. Dr. Finn also was instrumental in overseeing the manufacture of ONSOLIS® in support of the launch of product in Canada. In addition Dr. Finn moved the BEMA® Buprenorphine/Naloxone product to a final formulation stage that will allow for the completion of this important clinical program in 2012. Accordingly, the Committee provided 18,128 stock options valued at $25,560 or 9% of base salary, which will vest 100% at the time of grant. In addition upon the successful issuance of certain patents and receipt of milestone payments in 2012, Dr. Finn will be awarded a cash bonus in the amount of $25,560 or 9% of base salary. Dr. Finn was also granted 31,165 in employee option awards with a value of $48,280, or 17% of base salary. These options vest over a three year period.

Executive Vice President—Business and Strategic Development

Mr. Ward joined our company in September 2010 and his base salary was set at $195,000.

In evaluating Mr. Ward's individual performance for 2011, the Committee, with input from the other Board members, concluded that Mr. Ward provided significant support of the successful equity financing in 2011, as well as the Endo partnership. In addition he oversaw the positive execution of an investor relations program for the company that brought a number of new institutional investors to the company. He also supported the activities involving the MonoSol litigation and the advancement of certain manufacturing agreements. Accordingly, the Committee provided 12,447 stock options valued at $17,550 or 9% of base salary which will vest 100% at the time of grant. In addition, upon the issuance of certain patents and receipt of milestone payments in 2012, Mr. Ward will be awarded a cash bonus in the amount of $17,550 or 9% of base salary. Mr. Ward was also granted 21,398 in employee option awards with a value of $33,150, or 17% of base salary. These options vest over a three year period.

Severance and Change in Control Benefits

The change in control benefits for all applicable persons have a "double trigger." A double-trigger means that the executive officers will receive the change in control benefits described in the agreements only if there is both (1) a Change in Control of the Company (as defined in the agreements) and (2) a termination by us of the applicable person's employment "without cause" or a resignation by the applicable persons for "good reason" (as defined in the agreements) within a specified time period prior to or following the Change in Control. We believe this double trigger requirement creates the potential to maximize stockholder value because it prevents an unintended windfall to management as no benefits are triggered solely in the event of a Change in Control while providing appropriate incentives to act in furtherance of a change in control that may be in the best interests of the stockholders.

Accounting and Tax Considerations

ASC 718. On January 1, 2006, we began accounting for share-based payments in accordance with the requirements of Accounting Standards Codification 718 (ASC 718), Share-Based Payments. To date, the adoption of ASC 718 has not impacted our stock option granting practices.

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

Section 409A. Section 409A generally changes the tax rules that affect most forms of deferred compensation that were not earned and vested prior to 2005. Under Section 409(A), deferred compensation is defined broadly and may potentially cover compensation arrangements such as severance or change in control pay outs and the extension of the post-termination exercise periods of stock options. We take Code Section 409A into account, where applicable, in determining the timing of compensation paid to our executive officers.

Code Sections 280G and 4999. Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended (Code Sections 280G and 4999) limit our ability to take a tax deduction for certain "excess parachute payments" (as defined in Code Sections 280G and 4999) and impose excise taxes on each NEO who receives "excess parachute payments" in connection with his or her severance from our company in connection with a change in control. We consider the adverse tax liabilities imposed by Code Sections 280G and 4999, as well as other competitive factors, when structuring post-termination compensation payable to our executive officers and generally provide a mechanism for a "better after tax" result for the NEO, which we believe is a reasonable balance between our interests, on the one hand, and the executive's compensation on the other.

Compensation Risk Assessment

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

Compensation Committee Independence

All members of the Compensation Committee are Independent Directors and do not have any formal ties or relationship with any members of management or their relatives.

Item 11. Executive Compensation.

The following table sets forth all compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2011, 2010 and 2009. Individuals we refer to as our "named executive officers" include our Chief Executive Officer and our most highly compensated executive officers whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2011.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (20)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mark A. Sirgo, Pharm.D.	2011	$413,920	$124,176(1)	—	$107,382(2)	—	—	$ 22,176(3)	$ 667,654
President, Chief Executive	2010	$413,920	$170,699	—	$186,041(4)	—	—	$ 20,367(5)	$ 791,027
Officer and Director	2009	$470,463	$220,378	—	$410,643(6)	—	—	$ 43,602(7)	$1,145,086
James A. McNulty, CPA Chief	2011	$300,118	$ 73,720(8)	—	$ 36,269	—	—	$ 29,529(9)	$ 439,636
Financial Officer, Secretary	2010	$300,118	$ 87,413	—	$110,300	—	—	$ 24,127(10)	$ 521,958
and Treasurer	2009	$290,377	$120,196	—	$326,860	—	—	$ 32,164(11)	$ 769,597
Andrew L. Finn, Pharm.D.	2011	$283,387	$ 60,515(12)	—	$ 34,321	—	—	$ 18,222(13)	$ 396,445
Executive VP of Product	2010	$252,144	$ 73,440	—	$ 92,668	—	—	$ 17,449(14)	$ 435,701
Development	2009	$244,800	$144,480	—	$ 12,239	—	—	$ 21,945(15)	$ 423,464
Benny Ward, Executive VP of	2011	$195,000	$ 14,745(16)	—	$ 7,424	—	—	$ 19,719(17)	$ 236,888
Business & Strategic	2010	$ 59,250	—	—	$141,721	—	—	$ 2,625(18)	$ 203,596
Development	2009	$ —	—	—	—	—	—	—	$ — (19)

(1) The bonus disclosed in this item of $124,176 is related to 2010, but was contingent upon board approval, which occurred January 2011.
(2) The compensation disclosed in this item is composed of 25,000 stock options granted as compensation for serving as a director.
(3) Includes: $9,926 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2011.
(4) The compensation disclosed in this item is composed of 25,000 stock options granted as compensation for serving as a director.
(5) Includes: $9,281 of health insurance premiums paid and 401(k) matching of $11,086 paid in 2010.
(6) The compensation disclosed in this item is composed of 30,000 stock options granted as compensation for serving as a director.
(7) Includes: Vacation payout of $20,902, $10,450 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2009.

(8) The bonus disclosed in this item of $73,720 is related to 2010, but was contingent upon board approval, which occurred January 2011.
(9) Includes: $17,279 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2011.
(10) Includes: $16,658 of health insurance premiums paid and 401(k) matching of $7,469 paid in 2010.
(11) Includes: $19,914 of health insurance premiums paid and 401(k) matching of $12,250 paid in 2009.
(12) The bonus disclosed in this item of $60,515 is related to 2010, but was contingent upon board approval, which occurred January 2011.
(13) Includes: $10,411 of health insurance premiums paid and 401(k) matching of $7,811 paid in 2011.
(14) Includes: $9,239 of health insurance premiums paid and 401(k) matching of $8,210 paid in 2010.
(15) Includes: $12,318 of health insurance premiums paid and 401(k) matching of $9,627 paid in 2009.
(16) The bonus disclosed in this item of $14,745 is related to 2010, but was contingent upon board approval, which occurred January 2011 .
(17) Includes: $9,878 of health insurance premiums paid and 401(k) matching of $9,841 paid in 2011.
(18) Includes: $1,871 of health insurance premiums paid and 401(k) matching of $754 paid in 2010.
(19) Mr. Ward was hired September 2010.
(20) Aggregate grant date fair value according to ASC 718.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

Except as set forth below, we currently have no written employment agreements with any of our officers, directors, or key employees. All directors and officers have executed confidentiality and non-compete agreements with us.

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

Mark A. Sirgo, Pharm.D., President and Chief Executive Officer — Mr. Sirgo's current employment agreement, dated February 22, 2007, is subject to successive, automatic one-year extensions unless either party gives notice of non-extension to the other party at least 30 days prior to the end of the applicable term. The agreement includes a base salary, target bonus of up to 50% of his base salary, and other employee benefits. Under the terms of his agreement, Mr. Sirgo received base salary in 2011 of $413,920 per year and a bonus of $124,176, or 30% of his 2010 base pay.

We may terminate Dr. Sirgo's employment agreement without cause and Dr. Sirgo may resign upon 30 days advance written notice. We may immediately terminate Dr. Sirgo's employment agreement for Good Cause (as defined in the agreement). Upon the termination of Dr. Sirgo's employment for any reason, Dr. Sirgo will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Dr. Sirgo is terminated during the term of the employment agreement other than for Good Cause (as defined in the employment agreement), or if Dr. Sirgo terminates his employment for Good Reason (as defined in the employment agreement), Dr. Sirgo is entitled to a lump sum severance payment equal to 1 times the sum of his annual base salary plus a pro-rata annual bonus based on his target annual bonus. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Dr. Sirgo will equal the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary, multiplied by 2. In addition, Dr. Sirgo's employment agreement will terminate prior to its scheduled expiration date in the event of Dr. Sirgo's death or disability.

Dr. Sirgo's employment agreement also includes a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

James A. McNulty, CPA, Chief Financial Officer, Secretary and Treasurer — Through December 31, 2007 Mr. McNulty served as part-time CFO, devoting approximately 50% of his time to our company. Beginning January 1, 2008, Mr. McNulty devotes substantially all of his time to our company. Mr. McNulty's current employment agreement, dated February 22, 2007, is subject to successive, automatic one-year extensions unless either party gives notice of non-extension to the other party at least 30 days prior to the end of the applicable term. The agreement includes a base salary, target bonus of up to 50% of his base salary, and other employee benefits. Under the terms of his agreement, Mr. McNulty received base salary in 2011 of $300,118 per year and a bonus of $73,720, or 25% of his 2010 base pay. Mr. McNulty is also employed part-time as Secretary/Treasurer of Accentia.

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

The employment agreement also includes a 2 year non-competition, non-solicitation and confidentiality covenants on terms identical to his former employment agreement with us, except that if Mr. McNulty's employment is terminated upon a Change of Control, the non-competition period will be 18 months. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Andrew L. Finn, Pharm.D., Executive Vice President of Product Development — Mr. Finn's current employment agreement, dated February 22, 2007, is subject to successive, automatic one-year extensions unless either party gives notice of non-extension to the other party at least 30 days prior to the end of the applicable term. The agreement includes a base salary, target bonus of up to 50% of his base salary, and other employee benefits. Under the terms of his agreement, Mr. Finn received base salary in 2011 of $283,387 per year and a bonus of $60,515, or 24% of his 2010 base pay.

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

Dr. Finn's employment agreement also includes a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement, except that if Dr. Finn's employment is terminated upon a Change of Control, the non-competition period will be 18 months. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Benny Ward, Executive Vice President of Business and Strategic Development — On September 7, 2010, Mr. Ward executed a one-year employment agreement to be our Executive Vice President of Business and Strategic Development at an annual salary of $195,000. Mr. Ward is eligible for a discretionary annual bonus of up to 40% of his base salary. Under the terms of his agreement, Mr. Ward received base salary in 2011 of $195,000 per year and a bonus of $14,745, or 25% of his 2010 base pay.

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

Mr. Ward's employment agreement also includes a 2 year non-competition and non-solicitation and confidentiality covenants on terms identical to the existing employment agreement, except that if Mr. Ward's employment is terminated upon a Change of Control, the non-competition period will be 18 months. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Outstanding equity awards

The following table summarizes outstanding unexercised options, unvested stocks and equity incentive plan awards held by each of our name executive officers, as of December 31, 2011.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Prices ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not vested (#)
Mark A. Sirgo, Pharm.D.	—	—	22,369[1]	$ 3.55	2/25/21	—	—	—	—
	25,000	—	—	$ 3.47	7/21/21	—	—	—	—
	25,000	—	—	$ 2.26	7/21/20	—	—	—	—
	11,421	—	22,844[2]	$ 2.43	7/21/20	—	—	—	—
	12,449	—	24,899[3]	$ 3.90	1/21/20	—	—	—	—
	25,000	—	—	$ 5.40	7/22/19	—	—	—	—
	66,667	—	33,333[4]	$ 4.83	4/30/19	—	—	—	—
	6,117	—	3,058[5]	$ 3.05	1/22/19	—	—	—	—
	30,000	—	—	$ 2.01	7/24/18	—	—	—	—
	40,985	—	—	$ 2.01	7/24/18	—	—	—	—
	48,448	—	—	$ 2.85	1/31/18	—	—	—	—
	20,000	—	—	$ 4.13	7/25/17	—	—	—	—
	434,000	—	—	$ 6.63	4/13/17	—	—	—	—
	45,891	—	—	$ 2.42	1/26/17	—	—	—	—
	49,000	—	—	$ 3.03	12/1/15	—	—	—	—
	20,000	—	—	$ 2.94	8/22/15	—	—	—	—
	5,147	—	—	$ 3.40	10/21/14	—	—	—	—
James A. McNulty, CPA	—	—	16,219[1]	$ 3.55	2/25/21	—	—	—	—
	8,281	—	16,563[2]	$ 2.43	7/21/20	—	—	—	—
	9,027	—	18,053[3]	$ 3.90	1/21/20	—	—	—	—
	66,666	—	33,334[4]	$ 4.83	4/30/19	—	—	—	—
	8,184	—	4,091[5]	$ 3.05	1/22/19	—	—	—	—
	18,277	—	—	$ 2.01	7/24/18	—	—	—	—
	32,408	—	—	$ 2.85	1/31/18	—	—	—	—
	100,000	—	—	$ 6.63	4/13/17	—	—	—	—

	34,109	—	—	$2.42	1/26/17	—	—	—	—
	15,603	—	—	$2.05	7/27/16	—	—	—	—
	10,000	—	—	$3.03	12/1/15	—	—	—	—
	26,189	—	—	$2.94	7/28/15	—	—	—	—
	3,235	—	—	$3.40	10/21/14	—	—	—	—
	18,616	—	—	$3.83	8/14/13	—	—	—	—
Andrew L. Finn, Pharm.D.	—	—	15,348(1)	$3.55	2/25/21	—	—	—	—
	6,957	—	13,916(2)	$2.43	7/21/20	—	—	—	—
	7,584	—	15,167(3)	$3.90	1/21/20	—	—	—	—
	2,480	—	4,959(5)	$3.05	1/22/19	—	—	—	—
	33,231	—	—	$2.01	7/24/18	—	—	—	—
	39,282	—	—	$2.85	1/31/18	—	—	—	—
	100,000	—	0	$6.63	4/13/17	—	—	—	—
	37,209	—	0	$2.42	1/26/17	—	—	—	—
	10,603	—	0	$2.05	7/27/16	—	—	—	—
	49,000	—	0	$3.03	12/1/15	—	—	—	—
	8,929	—	0	$2.94	7/28/15	—	—	—	—
	5,147	—	0	$3.40	10/21/14	—	—	—	—
Benny Ward, CPA	—	—	3,320(1)	$3.55	2/25/21	—	—	—	—
	28,000	—	57,000(6)	$2.38	9/7/20	—	—	—	—

(1) Of the unvested stock options, one third of the unvested stock options will vest on February 25, 2012, another third will vest on February 25, 2013 and the remaining third will vest on February 25, 2014.
(2) Of the unvested stock options, half of the unvested stock options will vest on July 21, 2012, and another half will vest on July 21, 2013.
(3) Of the unvested stock options, half of the unvested stock options will vest on January 21, 2012, and another half will vest on January 21, 2013.
(4) These unvested stock options will vest on April 30, 2012.
(5) These unvested stock options will vest on January 22, 2012.
(6) Of the unvested stock options, half of the unvested stock options will vest on September 7, 2012, and another half will vest on September 7, 2013.

Outstanding Equity Awards Narrative Disclosure

Amended and Restated 2001 Incentive Plan

In July 2011, our original Amended and Restated 2001 Incentive Plan expired. Options to purchase 4,400,888 shares of common stock were outstanding as of December 31, 2011 under the Amended and Restated 2001 Incentive Plan. Although the Amended and Restated 2001 Incentive Plan expired, the 4,400,888 options still outstanding under such plan are still exercisable. In April 2011, our board approved, and in July 2011, our stockholders approved a new 2011 Equity Incentive Plan, which is discussed below.

2011 Equity Incentive Plan

Our 2011 Equity Incentive Plan is comprised of 4,200,000 shares of our common stock. The purpose of the 2011 Equity Incentive Plan is: (i) to align our interests and recipients of options under the plan by increasing the proprietary interest of such recipients in our growth and success, and (ii) to advance our interests by providing additional incentives to officers, key employees and well-qualified non-employee directors and consultants who provide services to us, who are responsible for our management and growth, or otherwise contribute to the conduct and direction of its business, operations and affairs. The Compensation Committee of our board of directors administers our incentive plan, selects the persons to whom options are granted and fixes the terms of such options.

Options may be awarded during the ten-year term of the plan to our employees (including employees who are directors), or consultants who are not employees and our other affiliates. Our plan provides for the grant of options that qualify as incentive stock options, or Incentive Stock Options, under Section 422A of the Internal Revenue Code of 1986, as amended, and options which are not Incentive Stock Options, or Non-Statutory Stock Options, as well as restricted stock and other awards. Only our employees or employees of our subsidiaries may be granted Incentive Stock Options. Our affiliates or consultants or others as may be permitted by our board of directors, may be granted Non-Statutory Stock Options.

Directors are eligible to participate in our 2011 Equity Incentive Plan. The plan provides for an initial grant of an option to purchase up to 25,000 shares (prorated based on months to be served in the fiscal year in which they join) of common stock to each director upon first joining our board of directors and subsequent grants of options to purchase 25,000 shares upon each anniversary of such director's appointment and an additional 15,000 option grant for serving as Lead Director. The board chairman is also granted 7,500 additional options. Such options are granted at an exercise price equal to a 30-day volume weighted average of the fair market value of the common stock on the grant date and immediately vest.

Options and warrants to purchase 7,847,052 shares of our common stock at prices ranging from $1.38 to $6.63 are outstanding at December 31, 2011. There were no options granted during 2011 whose exercise price was lower than the estimated market price of the stock at the grant date.

Options issued during 2011 to employees and directors under the 2001 Amended and Restated 2001 Incentive Plan (issued prior to plan expiration) totaled 296,174 shares, at exercise prices ranging from $3.20 and $3.55. Options issued during 2011 to directors under the 2011 Equity Incentive Plan totaled 152,363 shares, at exercise prices ranging from $1.38 and $3.47.

Option Exercises and Stock Vested

The following information sets forth stock options exercised by the executive officers during the year ended December 31, 2011:

	OPTION AWARDS		STOCK AWARDS	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
Mark A. Sirgo, Pharm.D.	26,659	$ 24,577	—	—
James A. McNulty, CPA	—	—	—	—
Andrew L. Finn, Pharm.D.	—	—	—	—
Benny Ward, CPA	—	—	—	—

Pension Benefits

None of our employees participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our Compensation Committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our company's best interests.

Nonqualified Deferred Compensation

None of our employees participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our company's best interests.

Grants of Plan-Based Awards

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stocks or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Closing stock price on Award date ($/Sh)	Grant Date Fair Value of Stock and Option Awards
		Threshold ($)	Target ($)	Maximum ($)	Threshold (#)	Target (#)	Maximum (#)					
Mark A. Sirgo, Pharm.D.	2/25/11					22,369(1)				$ 3.55	$ 3.48	$50,022
	7/20/11					25,000(2)				$ 3.47	$ 3.64	$57,360
James A. McNulty, CPA	2/25/11					16,219(1)				$ 3.55	$ 3.48	$36,269
Andrew L. Finn, Pharm.D.	2/25/11					15,348(1)				$ 3.55	$ 3.48	$34,321
Benny Ward, CPA	2/25/11					3,320(1)				$ 3.55	$ 3.48	$ 7,424

(1) Employee stock options granted as award.
(2) Director stock options granted as compensation as serving as a director.

Narrative to Grants of Plan Based Awards Table

See Compensation Discussion and Analysis above for complete description of the targets for payment of annual incentives, as well as performance criteria on which such payments were based.

Options granted to employees vest over 36 months beginning on the first anniversary of the grant date at which time 33% of such options vest. These options expire in 10 years and are outstanding for as long as the individual is an active employee. Employee options qualify as Incentive Stock Options.

Options granted to directors vest immediately. These options expire in 10 years and are outstanding for the life of the option. Director options qualify as Non-Statutory Stock Options.

Potential Payments Under Severance/Change in Control Arrangements

The table below sets forth potential payments payable to our current executive officers in the event of a termination of employment under various circumstances. For purposes of calculating the potential payments set forth in the table below, we have assumed that (i) the date of termination was December 31, 2011 and (ii) the stock price was $0.81, which was the closing market price of our common stock on December 31, 2011, the last business day of the 2011 fiscal year.

Name	If Company Terminates Executive Without Cause or Executive Resigns with Good Reason($)	Termination Following a Change in Control without Cause or Executive Resigns with Good Reason($)
Mark A. Sirgo, Pharm.D.		
Cash Payment	$ 647,498 (1)	$ 1,268,378 (1)
Acceleration of Options	—	— (2)
Total Cash and Benefits	**$ 647,498**	**$ 1,268,378**

Name	If Company Terminates Executive Without Cause or Executive Resigns with Good Reason($)	Termination Following a Change in Control without Cause or Executive Resigns with Good Reason($)
James A. McNulty, CPA		
Cash Payment	$ 459,954 (1)	$ 685,042 (1)
Acceleration of Options	—	— (2)
Total Cash and Benefits	**$ 459,954**	**$ 685,042**
Andrew L. Finn, Pharm.D.		
Cash Payment	$ 446,448 (1)	$ 659,448 (1)
Acceleration of Options	—	— (2)
Total Cash and Benefits	**$ 446,448**	**$ 659,448**
Benny Ward		
Cash Payment	$ 185,243 (1)	448,493 (1)
Acceleration of Options	—	— (2)
Total Cash and Benefits	**$ 185,243**	**$ 448,493**

(1) Includes severance payment and accrued and unused vacation time as of December 31, 2011.
(2) Determined by taking excess of the fair market value of our common stock on December 31, 2011, less the exercise price of each accelerated option.

For each of our executive officers, in their employment agreements the term “change of control” means the occurrence of any one or more of the following events (it being agreed that, with respect to paragraphs (i) and (iii) of this definition below, a “change of control” shall not be deemed to have occurred if the applicable third party acquiring party is an “affiliate” of our company within the meaning of Rule 405 promulgated under the Securities Act of 1933, as amended):

(i) An acquisition (whether directly from our company or otherwise) of any voting securities of our company by any person or entity, immediately after which such person or entity has beneficial ownership of forty percent (40%) or more of the combined voting power of our then outstanding voting securities.

(ii) The individuals who, as of the date hereof, are members of the our board of directors cease, by reason of a financing, merger, combination, acquisition, takeover or other non-ordinary course transaction affecting our company, to constitute at least fifty-one percent (51%) of the members of our board of directors; or

(iii) Approval by our board of directors and, if required, our stockholders of, or our execution of any definitive agreement with respect to, or the consummation of (it being understood that the mere execution of a term sheet, memorandum of understanding or other non-binding document shall not constitute a change of control):

(A) A merger, consolidation or reorganization involving our company, where either or both of the events described in clauses (i) or (ii) above would be the result;

(B) A liquidation or dissolution of or appointment of a receiver, rehabilitator, conservator or similar person for, or the filing by a third party of an involuntary bankruptcy against, our company; or

(C) An agreement for the sale or other disposition of all or substantially all of the assets of our company to any person or entity (other than a transfer to a subsidiary of our company).

The cash component (as opposed to option accelerations) of any change of control payment would be structured as a one-time cash severance payment.

Compensation of Directors Summary Table

DIRECTOR COMPENSATION

Name (a)	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Francis E. O'Donnell, Jr.	$ 50,000	—	$74,568(1)	—	—	—	$124,568
William B. Stone	$ 64,000	—	$91,776(2)	—	—	—	$155,776
John J. Shea	$ 50,000	—	$57,360(3)	—	—	—	$107,360
William S. Poole	$100,450(4)	—	$57,360(5)	—	—	—	$157,810
Samuel P. Sears, Jr.	$ 9,046	—	$ 2,978(6)	—	—	—	$ 12,024

(1) As of December 31, 2011, the outstanding stock options held by Dr. O'Donnell total 280,000, all of which have vested.
(2) As of December 31, 2011, the outstanding stock options held by Mr. Stone total 400,000, all of which have vested.
(3) As of December 31, 2011, the outstanding stock options held by Mr. Shea total 283,700, all of which have vested.
(4) Includes compensation of $48,950 for serving as Chairman of the board-level Risk Management Committee and associated sub-committee.
(5) As of December 31, 2011, the outstanding stock options held by Mr. Poole total 245,000, all of which have vested.
(6) As of December 31, 2011, the outstanding stock options held by Mr. Sears total 4,863, all of which have vested.

Narrative to Director Compensation

The Compensation Committee of our board of directors reviews the Director Remuneration Policy, which establishes the compensation our directors earn for serving on our board of directors and individual committees. The policy follows (all annual cash retainers are paid quarterly in advance);

- $30,000 annual cash retainer to each board member.
- $20,000 annual cash retainer to the Chairman of the Board.
- $10,000 annual cash retainer to the Lead Director.
- $15,000 annual cash retainer to the Chairman of the Audit Committee.
- $10,000 annual cash retainer to the Chairman of the Compensation Committee.
- $7,500 annual cash retainer to the Chairman of the Nominating & Corporate Governance Committee.
- $7,500 annual cash retainer to each non-Chairman Audit Committee member.
- $5,000 annual cash retainer to each non-Chairman Compensation Committee member.
- $4,000 annual cash retainer to each non-Chairman Nominating & Corporate Governance Committee member.
- 25,000 options to purchase shares of our Common Stock per year, to each director.
- 7,500 additional options to purchase shares of our Common Stock per year to the Chairman of the Board.
- 15,000 additional options to purchase shares of our Common Stock per year to the Lead Director.

- New directors will earn a pro-rated portion (based on months to be served in the fiscal year in which they join) of cash and option awards.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the Compensation Committee of our board of directors, or other committee serving an equivalent function. None of the members of our Compensation Committee has ever been our employee or one of our officers.

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

The following table sets forth, as of March 13, 2012, by: (i) each of our directors, (ii) all persons who, to our knowledge, are the beneficial owners of more than 5% of the outstanding shares of common stock, (iii) each of the executive officers, and (iv) all of our directors and executive officers, as a group. Each person named in this table has sole investment power and sole voting power with respect to the shares of common stock set forth opposite such person's name, except as otherwise indicated. Unless otherwise indicated, the address for each person listed below is in care of BioDelivery Sciences International, Inc., 801 Corporate Center Drive, Suite #210, Raleigh, NC 27607.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class as of March 13, 2012[1]
Hopkins Capital Group II, LLC [2]	3,275,490	11.08%
Francis E. O'Donnell, Jr., M.D. [3]	3,727,756	12.49%
Baker Brothers Life Sciences, L.P. [4]	2,595,044	8.78%
Mark A. Sirgo, Pharm.D. [5]	1,811,169	5.94%
James A. McNulty [6]	467,768	1.55%
Andrew L. Finn, Pharm.D. [7]	1,102,622	3.69%
Benny Ward [8]	41,553	*
William B. Stone [9]	435,000	1.45%
John J. Shea [10]	310,000	1.04%
William S. Poole [11]	253,190	*
Samuel P. Sears, Jr [12]	11,863	*
All Directors and Officers as a group (9 persons)	8,157,921	25.10%

* Less than 1%

(1) Based on 29,561,655 shares of common stock outstanding as of March 13, 2012 and shares beneficially owned by the referenced parties as described below.

(2) Includes 400,402 shares of our common stock which were converted from Series B Convertible Preferred Stock in January 2007. The address for Hopkins Capital Group II, LLC is 324 S Hyde Park, Suite 350, Tampa, FL. 33606.

(3) Dr. O'Donnell is our Chairman of the Board and a Director. Includes the shares owned by Hopkins Capital Group II, LLC, as to which Dr. O'Donnell disclaims beneficial interest (see Note 2). Excludes 167,500 shares owned by The Francis E. O'Donnell, Jr. Irrevocable Trust #1, of which Dr. O'Donnell's sister, Kathleen O'Donnell, is trustee, and as to which Dr. O'Donnell disclaims beneficial interest. The remaining 4,577 shares of common stock are owned by Dr. O'Donnell's sister. In addition, this number includes 157,689 shares owned personally by Dr. O'Donnell and options to purchase 290,000 shares of our common stock, all of which is currently exercisable. Dr. O'Donnell's address is 865 Longboat Club Road, Longboat Key FL. 34228.

(4) Based on a Schedule 13G filed with the SEC on February 14, 2012, Felix J. Baker and Julian C. Baker have voting and investment power over the shares held by Baker Brothers Life Sciences, L.P. Includes 6,217 shares owned by 667, L.P. and 7,229 shares owned by 14159, L.P.

(5) Includes 856,721 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Includes options to purchase 954,448 shares of common stock, all of which are currently exercisable. Excludes options to purchase 95,627 shares of common stock which are not currently exercisable. Dr. Sirgo's address is 606 Wayne Drive, Raleigh, NC. 27609.

(6) Mr. McNulty is our Chief Financial Officer, Secretary and Treasurer. Includes 43,159 shares owned by Mr. McNulty. Includes options to purchase 421,609 shares of our common stock, all of which are currently exercisable. Includes 2,288 shares owned by his wife, as to which he disclaims beneficial interest of. Excludes options to purchase 69,335 shares of common stock which are not currently exercisable. Mr. McNulty's address is 4419 W. Sevilla Street, Tampa, FL. 33629.

(7) Dr. Finn is our Executive Vice President of Clinical Development and Regulatory Affairs. Includes 766,413 shares owned by Dr. Finn. Includes options to purchase 336,209 shares of common stock, all of which are currently exercisable. Excludes options to purchase 62,896 shares of common stock which are not currently exercisable. Dr. Finn's address is 3104 Raymond Street, Raleigh, NC. 27607.

(8) Benny Ward is our Executive Vice President of Business and Strategic Development. Includes options to purchase 41,553 shares of common stock, all of which are currently exercisable. Excludes options to purchase 80,612 shares of common stock which are not currently exercisable. Mr. Ward's address is 1705 Point O'Woods Ct. Raleigh, NC. 27604.

(9) Mr. Stone is a Director. Includes 35,000 shares owned and options to purchase 400,000 shares of our common stock, all of which are currently exercisable. Mr. Stone's address is 11120 Geyer Downs Lane, Frontenac MO. 63131.

(10) Mr. Shea is a Director. Includes 26,300 shares owned and options to purchase 283,700 shares of our common stock, all of which are currently exercisable. Mr. Shea's address is 290 Wax Myrtle Trail, Southern Shores, NC. 27949.

(11) Mr. Poole is a Director. Includes 8,190 shares owned and options to purchase 245,000 shares of our common stock, all of which are currently exercisable. Mr. Poole's address is 7813 Hardwick Drive, Raleigh, NC. 27615.

(12) Mr. Sears is a Director. Includes 7,000 shares owned and options to purchase 4,863 shares of our common stock, all of which are currently exercisable. Mr. Sears' address is 1 Fieldstone Drive, Winchester, MA. 01890.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

As of December 31, 2001, our board of directors appointed an audit committee consisting of independent directors. This committee, among other duties, is charged to review, and if appropriate, ratify all agreements and transactions which had been entered into with related parties, as well as review and ratify all future related party transactions. The audit committee and/or our independent directors independently reviewed, ratified and/or approved, as the case may be, the agreements described below. From time to time, after compliance with our internal policies and procedures, we have entered into related party contracts, some of which were amended subsequently in accordance with the same policies and procedures.

The following is a listing of our related party transactions:

HCG II, Accentia and affiliates

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

On November 10, 2008, Accentia and its subsidiaries, including Biovest filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. On November 17, 2010, both companies emerged from Chapter 11. We do not have any projects with Accentia at this time, nor did we in any part of 2011.

Amphotericin B License. On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Pursuant to the license terms, the lack of commercialization within a five year period, and Accentia's emergence from Chapter 11 proceedings, the license was terminated in 2010.

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

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

The Agreement provides that we and Accentia mutually release all claims that either may have against each other and, in connection therewith, we will (a) pay $2.5 million to Accentia (paid to escrow in February 2010) and (b) grant the following royalty rights (the "Product Rights") to Accentia with respect to our BEMA® Granisetron product candidate ("BEMA® Granisetron") (or in the event it is not BEMA® Granisetron, our third product candidate (excluding BEMA® Buprenorphine) as to which we file an NDA, which, together with BEMA® Granisetron, shall be referred to hereinafter as the "Product"): (i) 70/30 split between our company and Accentia, respectively) of royalty received if a third party sells the Product and 85/15 split on net sales if we sell the Product; and (ii) we will, from the sale of the Product, fully recover amounts equal to (1) all internal and external worldwide development costs of the Product ("Costs") plus interest (measured on weighted average prime interest rate from first dollar spent until Product launch) and (2) the $2.5 Million Payment plus interest (measured on weighted average prime interest rate from the time of payment until Product launch) before Accentia begins to receive its split as described in (b) (i) above. In addition, pursuant to the Agreement, we have received a warrant to purchase 2 million shares of Accentia's majority-owned subsidiary, Biovest, from Accentia, with a strike price equal to 120% of the closing bid price of Biovest's common stock as of the date the Bankruptcy Court enters a final order authorizing Accentia to carry out the Agreement, with the issuance of the Warrant to occur upon the $2.5 Million Payment by us. The Warrant will be exercisable immediately and for a period of seven 7 years from the date of issuance. During the initial two 2 year exercise period, any exercise of the Warrant by us will be subject to approval by Biovest.

Other

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

As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to "promoters" as that term is commonly understood by the SEC and state securities authorities.

We believe that the terms of the above transactions with affiliates were as favorable to us or our affiliates as those generally available from unaffiliated third parties. At the time of certain of the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present board of directors includes four independent directors which constitute a majority as required by NASDAQ Stock Market rules. We believe that William B. Stone, John J. Shea, William S. Poole and Samuel P. Sears, Jr. qualify as independent directors for NASDAQ Stock Market purposes.

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

Item 14. Principal Accountant Fees and Services.

Audit Fees. The aggregate fees billed by Cherry, Bekaert & Holland, L.L.P. for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the year ended December 31, 2011 and 2010 totaled $135,850 and $135,850, respectively. The above amounts include interim procedures and audit fees, as well as attendance at audit committee meetings.

Audit-Related Fees. The aggregate fees billed by Cherry, Bekaert & Holland, L.L.P. for audit-related fees for the years ended December 31, 2011 and 2010 were $14,956 and $19,326, respectively.

Tax Fees. The aggregate fees billed by Cherry, Bekaert & Holland, L.L.P. for professional services rendered for tax compliance, for the years ended December 31, 2011 and 2010 were $18,600 and $27,100, respectively.

All Other Fees. None

The Audit Committee of our board of directors has established its pre-approval policies and procedures, pursuant to which the Audit Committee approved the foregoing audit, tax and non-audit services provided by Cherry, Bekaert & Holland, L.L.P. in 2011. Consistent with the Audit Committee's responsibility for engaging our independent auditors, all audit and permitted non-audit services require pre-approval by the Audit Committee. The full Audit Committee approves proposed services and fee estimates for these services. The Audit Committee chairperson has been designated by the Audit Committee to approve any audit-related services arising during the year that were not pre-approved by the Audit Committee. Any non-audit service must be approved by the full Audit Committee. Services approved by the Audit Committee chairperson are communicated to the full Audit Committee at its next regular meeting and the Audit Committee reviews services and fees for the fiscal year at each such meeting. Pursuant to these procedures, the Audit Committee approved the foregoing audit services provided by Cherry, Bekaert & Holland, L.L.P.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Number	Description
3.1	Articles of Incorporation of the Company (1)
3.2	Amended and Restated Bylaws of the Company (24)
3.3	Certificate of Amendment to the Company's Certificate of Incorporation creating a staggered board of directors, dated July 25, 2008 (16)
3.4	Certificate of Elimination, dated February 12, 2009, for the Company's Series A Non-Voting Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Non-Voting Convertible Preferred Stock (14)
3.5	Certificate of Amendment to the Company's Certificate of Incorporation increasing the number of authorized shares, dated July 22, 2011 (29)
4.1	Form of Common Stock Purchase Warrant, dated April 20, 2010, issued by the Company to certain institutional investors (22)
10.1	Amended and Restated 2001 Incentive Plan (2)
10.2	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (3)
10.3	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (3)
10.4	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (3)
10.5	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (3)
10.6	Clinical Development and License Agreement, dated as of July 14, 2005, among Clinical Development Capital LLC, the Company and Arius Pharmaceuticals, Inc. (4)+
10.7	Supply Agreement, dated October 17, 2005, by and between Aveva Drug Delivery Systems, Inc., Arius Pharmaceuticals, Inc. and the Company (5)
10.8	Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC IV, LLC (6)
10.9	Amendment No. 2, dated as of May 16, 2006, to that certain Clinical Development and License Agreement, dated as of July 14, 2005, between the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC (6)
10.10	Amended and Restated Registration Rights Agreement, dated as of May 16, 2006, by and between the Company and CDC IV, LLC (6)
10.11	Amendment No. 1 to Amended and Restated 2001 Incentive Plan (7)
10.12	Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT USA, Inc. and Arius Two, Inc. (8)+
10.13	License and Development Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (8)+
10.14	BEMA Fentanyl Supply Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (8)+
10.15	Sublicensing Consent, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (8)+
10.16	Sublicensing Consent and Amendment, dated August 2, 2006, by the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC (8)+
10.17	Letter agreement, dated August 2, 2006, between Meda AB, Arius Pharmaceuticals, Inc, Arius Two, Inc. and the Company (8)

10.18	Notice of Breach and Demand for Dispute Resolution, sent August 30, 2006, from the Company to CDC IV, LLC (9)
10.19	Notice of Breach and Termination, received August 30, 2006, from CDC IV, LLC to the Company (10)
10.20	Process Development Agreement, effective December 15, 2006, between LTS Lohmann Therapie-Systeme AG and the Company (11)+
10.21	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Mark A. Sirgo (12)
10.22	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Andrew L. Finn (12)
10.23	Employment Agreement, dated February 22, 2007, between the Company and James A. McNulty (12)
10.24	Dispute Resolution Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (13)
10.25	Amendment to Clinical Development and License Agreement, dated March 9, 2007, between the Company and CDC IV, LLC (13)
10.26	Registration Rights Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (13)
10.27	Subscription Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (14)
10.28	Second Amended and Restated Registration Rights Agreement, dated April 10, 2007, between the Company and Laurus Master Fund, Ltd. (11)
10.29	License and Development Agreement, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc. and Meda AB (15)+
10.30	BEMA Fentanyl Supply Agreement, dated September 5, 2007, between the Company and Meda AB (15)+
10.31	Sublicensing Consent dated September 5, 2007, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (15)+
10.32	License Agreement dated, September 5, 2007, by and between Arius Two, Inc., and Arius Pharmaceuticals, Inc. (15)+
10.33	Intellectual Property Assignment Agreement dated, September 5, 2007 by and between QLT USA, Inc. and Arius Two. (15)+
10.34	Assignment of Patent and Trademarks, dated September 5, 2007. (15)
10.35	BEMA Acquisition Consent, amendment and waiver, dated September 5, 2007, between the Company and CDC IV, LLC (15)
10.36	Sublicensing Consent and Amendment, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc., CDC IV, LLC and Meda AB. (15)+
10.37	Royalty Purchase and Amendment Agreement, dated as of September 5, 2007 between BioDelivery Sciences International, Inc., and CDC IV, LLC (15)+
10.38	Amendment to the Clinical Development and License Agreement, dated as of July 14, 2005, amendment dated as of September 5, 2007, by and among CDC IV, LLC, the Company, Arius Pharmaceuticals, Inc., and Arius Two, Inc. (15)+
10.39	Dispute Resolution Agreement, dated September 5, 2007 by and between the Company and CDC IV, LLC (15)
10.40	Acknowledgement by CDC, dated September 5, 2007, of the License and Development Agreement made as of September 5, 2007 between the Company, Arius Pharmaceutical, Inc. and Meda AB (15)
10.41	Letter Amendment, effective January 2, 2009, between the Company, Arius Pharmaceuticals, Inc. and Meda AB relating to European commercialization rights for ONSOLIS® (17)+
10.42	Amendment to License and Development Agreement, effective January 2, 2009, between the Company, Arius Pharmaceuticals, Inc. and Meda AB relating to the North American commercialization rights for ONSOLIS® (17)+
10.43	Amendment Consent (EU), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (17)
10.44	Amendment Consent (NA), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (17)

10.45	Process Development Agreement, dated February 8, 2008, between the Company and LTS (18)+
10.46	Amendment to Amended and Restated 2001 Incentive Plan of the Company, dated November 19, 2008 (18)
10.47	Master Clinical Development Agreement, dated February 12, 2009, between the Company and Premier Research International LLC (19)+
10.48	Proposal for Clinical Research Services, dated March 13, 2009, between the Company and Premier Research International LLC (19)+
10.49	Separation Agreement and General Claims release, effective September 1, 2009, between the Company and Dr. Raphael J. Mannino (20)
10.50	Emezine™ Settlement Agreement, dated December 30, 2009, between the Company, Accentia, Arius Pharmaceuticals, Inc. and TEAMM (21)
10.51	Form of Warrant for the Company to purchase 2,000,000 shares of Biovest International, Inc. from Accentia (21)
10.52	Securities Purchase Agreement, dated April 20, 2010, between the Company and certain institutional investors. (22)
10.53	License and Supply Agreement, dated May 26, 2010, between the Company, Arius Pharmaceuticals and KunWha Pharmaceutical Co., Ltd (23)+
10.54	Employment Agreement, dated September 7, 2010, between the Company and Benny Ward (25)
10.55	Confidentiality, Intellectual Property and Non-Competition Agreement, dated September 7, 2010, between the Company and Benny Ward (25)
10.56	License and Supply Agreement, dated October 4, 2010, between the Company, Arius Pharmaceuticals and TTY Biopharm Co., Ltd. (26)+
10.57	Securities Purchase Agreement, dated March 11, 2011, between the Company and certain institutional investors. (27)
10.58	Amendment to Clinical Development and License Agreement, effective May 12, 2011, between the Company, Arius, Arius Two, Inc., CDC V, LLC and NB Athyrium. (28)
10.59	License and Development Agreement, dated January 5, 2012, by and among the Company, Arius, Arius Two and Endo (30)+
21.1	Subsidiaries of the Registrant *
23.1	Consent of Cherry, Bekaert & Holland, L.L.P.*
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#
101.ins**	XBRL Instance Document
101.xsd**	XBRL Taxonomy Extension Schema Document
101.cal**	XBRL Taxonomy Calculation Linkbase Document
101.def**	XBRL Taxonomy Definition Linkbase Document
101.lab**	XBRL Taxonomy Label Linkbase Document
101.pre**	XBRL Taxonomy Presentation Linkbase Document

* Filed herewith

+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
# A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
** Furnished. Not filed. Not incorporated by reference. Not subject to liability.
(1) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(2) Previously filed with Form 10-QSB/A, September 2, 2003.
(3) Previously filed with Form 8-K, August 26, 2004.
(4) Previously filed with Form 8-K, July 21, 2005.
(5) Previously filed with Form 10-QSB, November 10, 2005.
(6) Previously filed with Form 8-K, May 22, 2006.
(7) Previously filed as Annex A to Schedule 14A, June 27, 2006.
(8) Previously filed with Form 8-K, August 9, 2006.
(9) Previously filed with Form 8-K, August 31, 2006.
(10) Previously filed with Form 8-K, August 31, 2006.
(11) Previously filed with Form 10-K, April 17, 2007.
(12) Previously filed with Form 8-K, February 22, 2007.
(13) Previously filed with Form 8-K, March 16, 2007.
(14) Previously filed with Form 8-K, February 13, 2009.
(15) Previously filed with Form 8-K, September 10, 2007.
(16) Previously filed with Form 8-K, July 28, 2008.
(17) Previously filed with Form 8-K, January 6, 2009.
(18) Previously filed with Form 10-K, March 20, 2009.
(19) Previously filed with Form 10-Q, May 15, 2009.
(20) Previously filed with Form 10-Q, November 3, 2009.
(21) Previously filed with Form 8-K, December 31, 2009.
(22) Previously filed with Form 8-K, April 20, 2010.
(23) Previously filed with Form 8-K, May 27, 2010.
(24) Previously filed with Form 8-K, July 23, 2010.
(25) Previously filed with Form 8-K, September 7, 2010.
(26) Previously filed with Form 8-K, October 8, 2010.
(27) Previously filed with Form 8-K, dated March 16, 2011.
(28) Previously filed with Form 8-K, dated May 13, 2011.
(29) Previously filed with Form 8-K, dated July 25, 2011.
(30) Previously filed with Form 8-K, dated January 11, 2012.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations and stockholders' (deficit) equity and cash flows for each of the years in the three-year period ended December 31, 2011. We also have audited the Company's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in Management's Report on Internal Control over Financial Reporting included in Item 9A—Controls and Procedures in the Company's 2011 Annual Report on Form 10-K. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioDelivery Sciences International, Inc. and subsidiaries as of December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the years in the three year period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion the Company maintained, in all material respects, effective control over financial reporting as of December 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

As discussed in Note 2 to the consolidated financial statements, during 2011, the Company recognized a net loss of approximately $23.3 million. Further, the Company had a net loss of approximately $13 million in 2010 and net income of approximately $33 million in 2009, principally due to the recognition of approximately $58 million of previously deferred revenue. At December 31, 2011, the Company had incurred cumulative net losses of approximately $95.6 million. Management's plans in regard to this matter are described in Note 2.

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

Tampa, Florida
March 19, 2012

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2011 AND 2010

	2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,750,205	$ 18,208,659
Accounts receivable	101,132	633,216
Prepaid expenses and other current assets	229,886	236,112
Total current assets	11,081,223	19,077,987
Equipment, net	3,288,108	3,424,869
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,900,000	1,900,000
Acquired product rights	8,000,000	8,000,000
Accumulated amortization	(3,749,637)	(2,858,657)
Total other intangible assets	6,150,363	7,041,343
Derivative asset, warrant	388,540	1,299,031
Other assets	21,976	21,976
Total assets	$ 23,645,210	$ 33,580,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 5,090,795	$ 4,656,295
Deferred revenue, current	12,507,471	12,491,907
Derivative liabilities (note 7)	279,302	4,989,993
Total current liabilities	17,877,568	22,138,195
Deferred revenue, long-term	1,647,249	1,655,681
Total liabilities	19,524,817	23,793,876
Commitments and contingencies (Notes 6, 7 and 13)	—	—
Stockholders' equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized in 2011 and 2010; 0 shares outstanding in 2011 and 2010	—	—
Common Stock, $.001 par value; 75,000,000 and 45,000,000 shares authorized, 29,577,146 and 24,038,445 shares issued; 29,561,655 and 24,022,954 shares outstanding in 2011 and 2010, respectively	29,578	24,039
Additional paid-in capital	99,709,574	82,055,934
Treasury stock, at cost, 15,491 shares, 2011 and 2010	(47,183)	(47,183)
Accumulated deficit	(95,571,576)	(72,246,460)
Total stockholders' equity	4,120,393	9,786,330
Total liabilities and stockholders' equity	$ 23,645,210	$ 33,580,206

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

	2011	2010	2009
Revenues:			
Product royalty revenues	$ 2,716,452	$ 1,884,080	$ 2,844,415
Product royalties, related party	—	—	15,411
Research revenue	227,668	726,948	177,373
Sponsored research revenue	—	244,479	—
Contract revenue	318,800	549,390	59,777,633
Total revenues	3,262,920	3,404,897	62,814,832
Cost of product royalties	1,756,629	839,208	2,043,693
Expenses:			
Research and development	20,805,177	10,645,414	10,177,644
Related party research and development	—	—	143,065
General and administrative	7,608,090	7,913,370	8,399,812
Related party general and administrative	81,000	82,529	1,921,400
Impairment of intangible license	—	243,648	—
Total expenses	28,494,267	18,884,961	20,641,921
(Loss) income from operations	(26,987,976)	(16,319,272)	40,129,218
Interest income (expense), net	188,701	133,613	35,596
Derivative gain (loss)	3,463,453	3,126,771	(6,790,827)
Other income (expenses), net	10,706	25,946	(15,110)
	3,662,860	3,286,330	(6,770,341)
(Loss) income before taxes	(23,325,116)	(13,032,942)	33,358,877
Income tax expense	—	—	(312,128)
Net (loss) income	($ 23,325,116)	($ 13,032,942)	$33,046,749
Net (loss) income attributable to common stockholders	($ 23,325,116)	($ 13,032,942)	$33,046,749
Basic:			
Weighted average common stock shares outstanding	28,322,477	23,150,975	20,224,706
Basic earnings per share	($ 0.82)	($ 0.56)	$ 1.63
Diluted:			
Diluted weighted average common stock shares outstanding	28,322,477	23,150,975	21,499,083
Diluted earnings per share	($ 0.82)	($ 0.56)	$ 1.54

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balances, January 1, 2009	**19,179,029**	**$19,179**	**$58,706,499**	**$(47,183)**	**$(92,260,267)**	**$(33,581,772)**
Stock-based compensation	—	—	2,003,031	—	—	2,003,031
Stock option exercise	265,551	266	663,105	—	—	663,371
Warrant issuance	—	—	55,452	—	—	55,452
Warrants exercised for cash	1,737,274	1,737	5,106,332	—	—	5,108,069
Reclassification of derivative liability to equity	—	—	7,163,399	—	—	7,163,399
Net income	—	—	—	—	33,046,749	33,046,749
Balances, December 31, 2009	**21,181,854**	**$21,182**	**$73,697,818**	**$(47,183)**	**$(59,213,518)**	**$ 14,458,299**
Stock-based compensation	—	—	1,376,467	—	—	1,376,467
Stock option exercise	31,733	32	97,850	—	—	97,882
Registered direct stock offering, net	2,824,858	2,825	9,744,675	—	—	9,747,500
Warrants related to equity financing	—	—	(2,860,876)	—	—	(2,860,876)
Net loss	—	—	—	—	(13,032,942)	(13,032,942)
Balances, December 31, 2010	**24,038,445**	**$24,039**	**$82,055,934**	**$(47,183)**	**$(72,246,460)**	**$ 9,786,330**
Stock-based compensation	—	—	1,226,724	—	—	1,226,724
Stock option exercise	129,888	130	349,546	—	—	349,676
CDC warrant derivative reclassified to equity	—	—	336,747	—	—	336,747
Exercise of CDC warrants	601,120	601	1,748,658	—	—	1,749,259
Private placement offering, net	4,807,693	4,808	13,991,965	—	—	13,996,773
Net loss	—	—	—	—	(23,325,116)	(23,325,116)
Balances, December 31, 2011	**29,577,146**	**$29,578**	**$99,709,574**	**$(47,183)**	**$(95,571,576)**	**$ 4,120,393**

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

	2011	2010	2009
Operating activities:			
Net (loss) income	$(23,325,116)	$(13,032,942)	$ 33,046,749
Adjustments to reconcile net (loss) income to net cash flows from operating activities			
Depreciation	444,527	422,127	176,405
Amortization of Intangible Assets	890,980	844,216	697,701
Derivative (gain) loss	(3,463,453)	(3,126,771)	6,790,827
Stock-based compensation expense	1,226,724	1,376,467	2,003,031
Warrant issuance expense	—	—	55,452
Loss on Disposal of Equipment	—	—	2,401
Intangible license impairment	—	243,648	—
Warrants received in settlement	—	(382,800)	—
Changes in assets and liabilities:			
Accounts receivable	530,544	635,526	(809,724)
Prepaid expenses and other assets	6,226	51,866	29,328
Accounts payable and accrued expenses	407,441	809,517	216,162
Income Taxes Payable	—	(312,128)	312,128
Deferred Revenue	7,133	788,977	(24,330,426)
Net cash flows from operating activities	(23,274,994)	(11,682,297)	18,190,034
Investing activities:			
Purchase of equipment	(286,973)	(103,985)	(749,983)
Purchase of intangible assets	—	(1,000,000)	(2,000,000)
Net cash flows from investing activities	(286,973)	(1,103,985)	(2,749,983)
Financing activities:			
Proceeds from sales of securities	13,996,773	9,747,500	—
Proceeds from exercise of stock options	349,676	97,882	663,371
Payment on notes payable	—	—	(76,665)
Proceeds from exercise of common stock warrants	1,749,259	—	5,108,069
Proceeds from (repayment of) related party advances, net	7,805	(2,723,844)	1,832,857
Net cash flows from financing activities	16,103,513	7,121,538	7,527,632
Net change in cash and cash equivalents	(7,458,454)	(5,664,744)	22,967,683
Cash and cash equivalents at beginning of year	18,208,659	23,873,403	905,720
Cash and cash equivalents at end of year	**$ 10,750,205**	**$ 18,208,659**	**$ 23,873,403**

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

SUPPLEMENTAL CASH FLOW INFORMATION

Non-cash Financing and Investing Activities

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

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

The Company reclassified derivative liabilities of $7,163,399 to equity during the twelve months ended December 31, 2009 as a result of the exercise of warrants to which the derivatives related.

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

Organization:

BioDelivery Sciences International, Inc. (the "Company") was incorporated in the State of Indiana on January 6, 1997 and reincorporated as a Delaware corporation in 2002. The Company and its subsidiaries (Arius Pharmaceuticals, Inc., a Delaware corporation ("Arius One") and Arius Two, Inc., a Delaware corporation ("Arius Two"), each of which are wholly-owned, and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC, a Delaware limited liability company ("BND") are collectively referred herein to as the "Company."

The Company is a specialty pharmaceutical company that is leveraging its novel, proprietary and patented BioErodible MucoAdhesive ("BEMA®") drug delivery technology to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics, primarily in the areas of pain management and oncology supportive care. The Company's development strategy focuses on utilization of the U.S. Food and Drug Administration's ("FDA") 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved therapeutics.

As used herein, the Company's common stock, par value $.001 per share, is referred to as the "Common Stock".

Principles of consolidation:

The consolidated financial statements include the accounts of the Company, Arius One, Arius Two and BND. BND is currently and has for several years been an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Significant accounting policies:

Cash and cash equivalents:

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. The Company's cash equivalents include Ultra Short Term Government Funds. Because of the short-term maturities of the Company's cash and cash equivalents, the Company does not believe that an increase in market rates would have a significant impact on the realized value of its investments. The Company places cash and cash equivalents on deposit with financial institutions in the United States. On November 9, 2010, the Federal Deposit Insurance Corporation ("FDIC") issued a Final Rule implementing Section 343 of the Dodd-Frank Wall Street Reform and Consumer Protection Act that provides for unlimited insurance coverage of noninterest-bearing transaction accounts. Beginning December 31, 2010, through December 31, 2012, all non-interest bearing transaction accounts are fully insured, regardless of the balance of the account, at all FDIC-insured institutions. The unlimited insurance coverage is available to all depositors, including consumers, businesses, and government entities. This unlimited coverage is separate from, and in addition to, the $250,000 insurance coverage provided to a depositor's other deposit accounts held at an FDIC-insured institution. As of December 31, 2011, the Company had approximately $8.5 million which exceed these insured limits.

Revenue recognition:

Meda License, Development and Supply Agreement:

General

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

License and product development research and development services revenue

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

Reimbursement of direct out-of-pocket costs (research revenue)

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

Research and Development Expenses

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

Product Royalties

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met.

Cost of Product Royalties

The cost of product royalties includes the direct costs attributable to the production of ONSOLIS®. It includes all costs related to creating the product at Aveva Drug Delivery Systems, Inc. ("Aveva"), the Company's contract manufacturer, which can include stability costs directly related to the product sold. Only costs that are directly attributable to the production of the product are considered cost of royalty revenue. Aveva bills the Company for the material cost used in creating the product along with direct labor costs, and certain overhead costs as outlined in the supply agreement. Cost of product royalties also includes royalty expenses owed to third parties. These royalty expenses are directly related to the product sold during the period.

Contract Revenue

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

The Company also earned contract revenue in 2010 related to two similar license, development and supply agreements covering different territories: (i) Kunwha Pharmaceutical Co., Ltd., a Republic of Korea corporation ("Kunwha"), to develop, manufacture, sell and distribute BEMA® Fentanyl in the Republic of Korea, and (ii) TTY Biopharm Co., Ltd., a Taiwanese company ("TTY"), to develop, manufacture, sell and distribute the Company's BEMA® Fentanyl product in Taiwan. Upfront payments from Kunwha and TTY are recorded as contract revenue upon receipt. The Company earned contract revenue in 2011 related to a milestone from TTY upon government approval.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

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.

Certain Risks, Concentrations and Uncertainties

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

Accounts receivable from Meda accounted for 92% of the Company's accounts receivable at December 31, 2011 and 89% at 2010. Deferred revenue balances relate to the Meda Agreements as of December 31, 2011 and 2010. The Company depends significantly upon the collaboration with Meda, and its activities may be impacted if this relationship is disrupted.

Key components used in the manufacture of ONSOLIS® are currently provided by sole or a limited number of suppliers. This could result in the Company's inability to timely obtain an adequate supply of required components and reduce control over pricing, quality and timely delivery. Also, if the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required time frames, if at all, to meet the Company's obligations under the Meda supply agreements. This could delay timely commercialization efforts by Meda, causing the Company to lose royalty revenue and potentially harming its reputation.

Deferred revenue

Consistent with the Company's revenue recognition policy, deferred revenue represents cash received in advance for licensing fees, consulting, research and development services and related supply agreements. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue is classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date.

Equipment

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

Intangibles and Goodwill

The Company reviews intangible assets with finite lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company uses an estimate of the undiscounted cash flows over the remaining life of its long-lived assets, or related group of assets where applicable, in measuring whether the assets to be held and used will be realizable. In the event of impairment, the Company would discount the future cash flows using its then estimated incremental borrowing rate to estimate the amount of the impairment.

During the twelve months ended December 31, 2010, the Company determined not to pursue Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis (Note 12). As such, the Company recorded a $0.2 million impairment charge, which removed the remaining intangible asset related to the Company's Bioral® cochleate drug delivery technology (a second delivery technology held under license by the Company or its predecessor since 1995) There was no impairment charge recognized on finite lived intangibles in 2009 or 2011.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

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

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

The Company incurred amortization expense on other intangible assets of approximately $0.9 million, $0.8 million and $0.7 million for the years ended December 31, 2011, 2010 and 2009, respectively. Estimated aggregate future amortization expenses for other intangible assets for each of the next five years and thereafter are as follows:

Years ending December 31,	
2012	$ 890,981
2013	890,981
2014	890,981
2015	890,981
2016	890,981
Thereafter	1,695,458
	$6,150,363

Goodwill is evaluated for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment analysis involves a two step process. Step one involves the comparison of the fair value of the reporting unit to which goodwill relates (the Company's enterprise value) to the carrying value of the reporting unit. If the fair value exceeds the carrying value, there is no impairment. If the carrying value exceeds the fair value of the reporting unit, the Company determines the implied fair value of goodwill and records an impairment charge for any excess of the carrying value of goodwill over its implied fair value. There were no goodwill impairment charges in 2011, 2010 or 2009.

Use of estimates in financial statements:

The preparation of the accompanying consolidated financial statements conforms with GAAP and requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

Net Income (loss) per common share:

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per common share computations for the years ended December 31, 2011, 2010 and 2009.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

	December 31,		
	2011	**2010**	**2009**
Basic:			
Net (loss) income attributable to common stockholders	($ 23,325,116)	($ 13,032,942)	$33,046,719
Weighted average common shares outstanding	28,322,477	23,150,975	20,224,706
Basic earnings per common share	($ 0.82)	($ 0.56)	$ 1.63
Diluted:			
Effect of dilutive securities:			
Net (loss) income attributable to common stockholders	(23,325,116)	(13,032,942)	33,046,719
Adjustments to Income for Dilutive options and warrants	—	—	—
	(23,325,116)	(13,032,942)	33,046,719
Weighted average common shares outstanding	28,322,477	23,150,975	20,224,706
Effect of Dilutive options and warrants	—	—	1,274,377
Diluted weighted average common shares outstanding	28,322,477	23,150,975	21,499,083
Diluted earnings per common share	($ 0.82)	($ 0.56)	$ 1.54

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. Common equivalent shares from stock options and warrants using the treasury stock method, are also included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the years ended December 31, 2011, 2010 and 2009, outstanding stock options and warrants of 7,847,052, 9,585,460 and 4,084,789, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods.

The following is the total outstanding options and warrants for the years ended December 31, 2011, 2010 and 2009, respectively.

	2011	**2010**	**2009**
Options and warrants to purchase Common Stock	7,847,052	9,585,460	7,548,624

Stock-based compensation:

The Company uses the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (warrants and options). The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of the Company's Common Stock and other factors estimated over the expected term of the options. The expected term of options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

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

	2011	2010	2009
Expected price volatility	69.05%-77.75%	73.41%-79.02%	57.88%-90.24%
Risk-free interest rate	0.90%-1.99%	1.17%-2.36%	.51%-2.71%
Weighted average expected life in years	5-6 years	5-6 years	5-6 years
Dividend yield	—	—	—

Fair Value of Financial Assets and Liabilities

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

GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. GAAP also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. GAAP describes three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

The following table summarizes assets and liabilities measured at fair value on a recurring basis at December 31, 2011 and December 31, 2010, respectively:

	2011				2010			
Fair Value Measurements Using:	**Level 1**	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets								
Derivative asset (warrant)	$ —	$388,540	$ —	$388,540	$ —	$1,299,031	$ —	$1,299,031
Liabilities								
Derivative liabilities	$ —	$279,302	$ —	$279,302	$ —	$4,989,993	$ —	$4,989,993

The table below provides a reconciliation of the beginning and ending balances for the assets and liabilities measured at fair value using significant observable inputs (Level 2). The table reflects net gains and losses for all financial assets and liabilities categorized as Level 2 as of December 31, 2010 and 2011.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

Fair Value Measurements Using Significant Observable Inputs (Level 2)

	Value of Warrants	Number of Warrants
Assets:		
Warrant asset as of January 1, 2010	$ 638,600	2,000,000
Increase in fair value of warrants at settlement 2/17/10, offset by settlement expense	382,800	—
Increase in fair value of warrant after settlement, derivative gain	277,631	—
Warrant asset as of December 31, 2010	$ 1,299,031	2,000,000
Decrease in fair value of warrants	(910,491)	
Warrant asset as of December 31, 2011	$ 388,540	2,000,000
Liabilities:		
Warrant liability as of January 1, 2010	$ 4,978,257	2,909,991
Issuance of new warrants	2,860,876	1,412,430
Decrease in fair value of warrants	(2,849,140)	—
Warrant liability as of December 31, 2010	$ 4,989,993	4,322,421
Increase of fair value of warrants due to ratcheting strike price down to $3.12 from $4.67 as a result of private placement offering	460,452	—
Decrease due to exercise of CDC warrants	(336,747)	(601,120)
Decrease in fair value of warrants	(4,834,396)	—
Expiration of warrants	—	(475,000)
Warrant liability as of December 31, 2011	$ 279,302	3,246,301

Derivative instruments:

The Company generally does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, the Company has entered into certain other financial instruments and contracts, such as debt financing arrangements and freestanding warrants with features that are either not afforded equity classification, embody risks not clearly and closely related to host contracts, or may be net-cash settled by the counterparty. These instruments are required to be carried as derivative liabilities, at fair value, in the Company's consolidated financial statements.

The Company estimates fair values of derivative financial instruments using the Black-Scholes option valuation technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary to fairly value these instruments. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the Company's trading market price which has high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company's income will reflect the volatility in these estimate and assumption changes.

Recent accounting pronouncements:

In April 2010, the FASB issued Accounting Standards Update 2010-12 ("ASU 2010-12"), Income Taxes (Topic 740): Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts. On March 30, 2010, the President of the United States signed the Health Care and Education Reconciliation Act of 2010, which is a reconciliation bill that amends the Patient Protection and Affordable Care Act that was signed on March 23, 2010 (collectively, the "Acts"). ASU No. 2010-12 allows entities to consider the two Acts together for accounting purposes. Upon adoption, the elimination of the future tax deduction for prescription drug costs associated with the Company's post-retirement medical and dental plans was not material to the Company's financial position, results of operations or cash flows. The Company does not believe this amendment will have a material impact on the Company's financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

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

In December 2010, the FASB released Accounting Standards Update 2010-28 ("ASU 2010-28"), Intangibles-Goodwill and Other (Topic 350): When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts. The update requires a company to perform Step 2 of the goodwill impairment test if the carrying value of the reporting unit is zero or negative and adverse qualitative factors indicate that it is more likely than not that a goodwill impairment exists. The qualitative factors to consider are consistent with the existing guidance and examples in Topic 350, which requires that goodwill of a reporting unit be tested for impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying amount. The requirements in ASU 2010-28 were effective for public companies in the first annual period beginning after December 15, 2010. The adoption of this standard had no material impact on the Company's consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs ("ASU 2011-04"). ASU 2011-04 is intended to result in convergence between U.S. GAAP and International Financial Reporting Standards ("IFRS") requirements for measurement of and disclosures about fair value. The amendments are not expected to have a significant impact on companies applying U.S. GAAP. Key provisions of the amendment include: a prohibition on grouping financial instruments for purposes of determining fair value, except when an entity manages market and credit risks on the basis of the entity's net exposure to the group; an extension of the prohibition against the use of a blockage factor to all fair value measurements (that prohibition currently applies only to financial instruments with quoted prices in active markets); and a requirement that for recurring Level 3 fair value measurements, entities disclose quantitative information about unobservable inputs, a description of the valuation process used and qualitative details about the sensitivity of the measurements. In addition, for items not carried at fair value but for which fair value is disclosed, entities will be required to disclose the level within the fair value hierarchy that applies to the fair value measurement disclosed. ASU 2011-04 is effective for interim and annual periods beginning after December 15, 2011. The Company will adopt these standards on January 1, 2012 and does not expect the adoption to have a material impact on its condensed consolidated financial statements.

In September 2011, the FASB issued ASU 2011-08, Intangibles—Goodwill and Other (Topic 350), Testing Goodwill for Impairment ("ASU 2011-08"), to allow entities to use a qualitative approach to test goodwill for impairment. ASU 2011-08 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform the currently prescribed two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. ASU 2011-08 is effective for the Company in fiscal 2013 and earlier adoption is permitted. The Company early adopted this standard at year ending December 31, 2011. The adoption of this standard had no material impact on the Company's consolidated financial statements.

2. Liquidity and management's plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, funded research arrangements and revenue generated as a result of its agreements with MEDA regarding ONSOLIS®. The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

Significant financing and revenue through December 31, 2011 consisted of:

- approximately $14 million in net proceeds from a private placement offering of Common Stock in March 2011;
- approximately $1 million in net royalties;
- approximately $1.7 million from the exercise of Common Stock warrants;
- approximately $0.3 million in contract revenue from licensing and supply agreement (see note 6);
- approximately $0.2 million in research revenues from various contractor agreements; and
- approximately $0.3 million from the exercise of Common Stock options.

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2. Liquidity and management's plans (continued):

Significant financing and revenue through December 31, 2010 consisted of:

- approximately $9.7 million in net proceeds from registered direct offering of Common Stock and warrants in April 2010;
- approximately $1 million in net royalties;
- approximately $0.7 million in research revenues from various contractor agreements;
- approximately $0.5 million in contract revenue from licensing and supply agreement (see note 6);
- approximately $0.2 million in sponsored research revenue from the U.S. Government's Qualifying Therapeutic Discovery Project (see note 8); and
- approximately $0.1 million from the exercise of Common Stock options.

Significant financing and revenue through December 31, 2009 consisted of:

- $26.8 million payment received in July 2009 for the approval milestone for ONSOLIS® (See Note 5).
- $6.0 million payment received in January 2009 which included a $3.0 million advance against the $15 million approval milestone for ONSOLIS® and $3.0 million related to expansion of the territory covered by the Company's European agreement with Meda.
- approximately $5.1 million from the exercise of warrants and approximately $0.7 million from the exercise of Common Stock options.
- approximately $0.8 million in net royalties related to ONSOLIS® sales in the U.S; and
- completion of universal shelf registration in January 2009 for up to $50 million of the Company's securities which can potentially be drawn over a three year period based on certain terms and conditions. Such shelf registration was utilized in connection with the Company's April 2010 financing.

In addition, on January 5, 2012, the Company entered into a definitive License and Development Agreement with Endo Pharmaceuticals, Inc. ("Endo") to grant to Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company's BEMA® Buprenorphine product and to complete U.S. development of the Product for purposes of seeking FDA approval. Pursuant to its agreement with Endo, the Company has received and will receive certain material payments (some portion(s) of which will be utilized by the Company to support its development obligations under the License Agreement with respect to BEMA® Buprenorphine). See Note 14.

At December 31, 2011, the Company had cash and cash equivalents of approximately $10.8 million. The Company used $23.3 million of cash in operations during the twelve months ended December 31, 2011. As of December 31, 2011, the Company had stockholders' equity of $4.1 million, versus $9.8 million at December 31, 2010. In January 2012, the Company received a $30 million, upfront non-refundable milestone payment related to the Company's definitive license and development agreement with Endo to license, develop, manufacture, market and sell its BEMA® Buprenorphine product. In addition, the Company expects to receive an additional $15 million milestone payment from Endo due its achievement of a certain intellectual property related milestone. However, this $45 million in cash is expected to primarily be used to fund the Company's clinical research obligations under its agreement with Endo. As such, the Company's existing cash, even with the aforementioned $45 million milestone payments, together with other expected cash inflows from other milestones and royalties, are anticipated by management to be sufficient to fully fund the Company's operations through the first quarter of 2013 at the planned level. Included in this estimation are costs of between $0.6 million and $1.2 million that the Company expects will be incurred in connection with the reformulation of ONSOLIS®, but also savings in legal expense that the Company expects due to the March 2012 stay of its litigation with MonoSol. Certain planned expenditures are discretionary and could be deferred if the Company is required to do so to fund critical operations.

Accordingly, additional capital will likely be required to support commercialization efforts for ONSOLIS® (including commercial launch in Europe which is expected in 2012), clinical development programs for BEMA® Buprenorphine (the scale of which is being governed in large part by the requirements of the Company's agreement with Endo), planned development of BEMA® Buprenorphine/Naloxone and general working capital. Based on product development timelines and agreements with the Company's development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

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2. Liquidity and management's plans (continued):

In addition, the worldwide financial and credit crisis that began in 2008 and has fluctuated to the present time has strained investor liquidity and contracted credit markets. During the year ending December 31, 2011, the financial and credit crisis did not directly nor materially impact the Company. However, if this environment continues, fluctuates or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when the Company requires additional financial investment. If the Company is unable to attract additional funds it may adversely affect its ability to achieve development and commercialization goals, which could have a material and adverse effect on the business, results of operations and financial condition.

3. Research and development arrangements and related party transactions:

The Company is a party to a collaborative research agreement with the University of Medicine and Dentistry of New Jersey ("UMDNJ"), an entity that is also a Company stockholder, under which the Company paid salary for a UMDNJ employee, laboratory supplies and employee parking costs. The agreement expired at the end of 2005. The Company also leased its Newark, New Jersey facility from UMDNJ under an operating lease agreement which expired on December 31, 2005 and was converted to a month-to-month lease. In September 2009, the Company shut-down, vacated and eliminated all activities performed at the Newark facility. The Company incurred approximately $0.1 million of research expense in connection with this agreement in the year ended December 31, 2009.

There was $0 due to UMDNJ at December 31, 2011 and 2010 for employee or laboratory expenses. However, in October 2010, the Company made royalty payments to both UMDNJ and Albany Medical College in the amount of $0.06 million each, which were related to a 2004 licensing arrangement. No further royalty payments are owed to either University at this time.

The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia Biopharmaceuticals, Inc., a related party ("Accentia"), and shares two employees, with personnel costs paid based on the approximate time spent on Company activities. Rent payments to Accentia were $0.06 million for years 2011, 2010 and 2009, respectively, and are included in general and administrative costs, related party. There were $0.005 million and $0.0 million in rent amounts due to Accentia at December 31, 2011 or 2010, respectively. This is shown in accounts payable and accrued liabilities in the condensed consolidated balance sheet.

On December 30, 2009, the Company entered into an Emezine™ Settlement Agreement (the "Settlement Agreement") with Accentia, Arius One and Accentia Pharmaceuticals, Inc. f/k/a TEAMM Pharmaceuticals Inc., a subsidiary of Accentia. Pursuant to the Settlement Agreement, the Company has received a warrant to purchase 2 million shares of common stock of Accentia's majority-owned subsidiary, Biovest International, Inc. ("Biovest"), from Accentia. Such warrant has an exercise price equal to 120% of the closing bid price of Biovest's common stock as of the date the bankruptcy court overseeing Accentia's Chapter 11 reorganization entered a final order authorizing Accentia to carry out the Settlement Agreement, which was $0.89 per share. The warrant was recorded at December 31, 2009 with a Black-Scholes value of $0.6 million. However, the warrant was not received by the Company until February 17, 2010 (the "Settlement Date"), the date which the bankruptcy court issued the final order authorizing the Settlement Agreement. At the settlement date, the warrant was valued using the Black-Scholes model, which resulted in a gain on settlement of $0.4 million for the year ended December 31, 2010, and is included in related party general and administrative in the accompanying condensed consolidated statement of operations. Subsequent to the Settlement Date and prior to the end of the year ended December 31, 2010, the stock price of Biovest's common stock increased, resulting in a derivative gain of $0.3 million and is included in derivative (loss) gain in the accompanying condensed consolidated statement of operations. During the year ended December 31, 2011, the stock price of Biovest's common stock declined, resulting in a derivative loss of $0.9 million. This derivative loss partially offsets the overall derivative gain that is in the accompanying condensed consolidated statement of operations.

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4. Equipment:

Equipment consists of the following:

	December 31, 2011	December 31, 2010
Office and laboratory equipment	$ 5,426,183	$ 5,118,417
Less accumulated depreciation	(2,138,075)	(1,693,548)
	$ 3,288,108	$ 3,424,869

Depreciation expense for years ended December 31, 2011, 2010 and 2009 was approximately $445,000, $422,000 and $176,000, respectively.

5. Meda License, Development and Supply Agreements:

In August 2006 and September 2007, the Company entered into the Meda Agreements with Meda to develop and commercialize the ONSOLIS® product, a drug treatment for breakthrough cancer pain delivered through a patented transmucosal drug delivery technology, BEMA® (applied to the inner cheek mucosa). The aforementioned agreements relate to the United States, Mexico and Canada (such agreements, the "Meda U.S. Agreements") and to certain countries in Europe (such agreements, the "Meda EU Agreements"). They carry license terms that commence on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of the patents, which begin to expire in January 2017.

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

Contractual Rights and Obligations	Cash flows received and revenue deferred December 31, 2011	Cash flows received and revenue deferred December 31, 2010
North America		
License rights to ONSOLIS® (BEMA® Fentanyl) and milestone payments	$ 59,800,000	$ 59,800,000
Research and Development Services for:		
• Non-cancer subsequent indication of product and further development of initial product	$ 1,541,570	$ 1,541,570
Total North America Agreement Milestones	$ 61,341,570	$ 61,341,570
Europe and Rest of World		
License rights to BREAKYL™ (BEMA® Fentanyl) and milestone payments	$ 8,000,000	$ 8,000,000
Research and Development Services for:		
• BREAKYL™ product through governmental approval in a E.U. country	$ 4,548,720	$ 4,522,788
Total Europe and Rest of World Milestones	$ 12,548,720	$ 12,522,788
Total All Milestones	**$ 73,890,290**	**$ 73,864,358**
Release of Milestones upon and subsequent to first sale	$ (59,735,570)	$ (59,716,770)
Remaining Deferred Revenue	$ 14,154,720	$ 14,147,588

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

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

The Company determined that upon inception of both the U.S. and EU Meda arrangements all deliverables are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable and the research and development efforts provided do not have standalone value apart from the license. As such, all cash payments from Meda that were related to these deliverables were recorded as deferred revenue. All cash payments from Meda for upfront and milestone payments and research and development services provided are nonrefundable. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain deliverables associated with research and development services were deliverable to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, $59.7 million of the aggregate milestones and services revenue 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 to be received at that date 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. The Company has 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, the Company will continue to estimate the time required for ongoing obligations, and adjust the remaining deferral accordingly on a quarterly basis.

In connection with delivery of the license to Meda, the Company has determined that each of the undelivered obligations have stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. Further, the Company obtained third-party evidence of fair value for the non-cancer and other research and development services and other service obligations, based on hourly rates billed by unrelated third-party providers for similar services contracted by the Company. The Company also obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged the Company from the third-party supplier of the product. The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication of the ONSOLIS® product and (3) the combined requirements related to the remaining other service-related obligations due Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.6 million (under the Meda U.S. Agreements) and $0.1 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.

In accordance with GAAP, the Company has determined that it is acting as a principal under the Meda Agreements and, as such, will record product supply revenue, research and development services revenue and other services revenue amounts on a gross basis in the Company's consolidated financial statements.

The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. The Company has earned product royalty revenues of approximately $2.7, $1.9 and $2.8 million for the years ended December 31, 2011, 2010 and 2009, respectively. The Company has incurred cost of product royalties of approximately $1.8, $0.8 and $2.0 million for the years ended December 31, 2011, 2010 and 2009, respectively, related to this royalty revenue.

6. Other license agreements and acquired product rights:

Kunwha License Agreement

In May 2010, the Company entered into a License and Supply Agreement (the "Kunwha License Agreement") with Kunwha to develop, manufacture, sell and distribute the Company's BEMA® Fentanyl product in the Republic of Korea (the "Kunwha Territory"). BEMA® Fentanyl is marketed as ONSOLIS® in North America. The Kunwha License Agreement is for a term beginning on May 26, 2010 until the date of expiration of the patents, or July 23, 2027, whichever is later.

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

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Kunwha Territory, while the Company will retain all other licensing rights to the Licensed Product not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million (net of taxes approximating $0.25 million) and will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes approximating $1.1 million). In addition, Kunwha will pay royalties to the Company based on Net Sales (as defined in the Kunwha License Agreement) and will purchase all supplies of BEMA® Fentanyl from the Company.

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

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. The Company early adopted the provisions of ASU 2010-17 in analyzing the up-front milestone in the license agreement.

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement with TTY for the exclusive rights to develop and commercialize BEMA® Fentanyl in the Republic of China, Taiwan. The agreement results in potential milestone payments to the Company of up to $1.3 million, which includes an upfront payment of $0.3 million, which is recorded as contract revenue in the accompanying condensed consolidated statements of operations. In addition, the Company will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filing of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The term of the agreement with TTY is for the period from October 4, 2010 until the date fifteen (15) years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

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

Agreement with Tolmar to Purchase BEMA® Rights

In August 2006, the Company purchased from QLT USA, Inc. (renamed TOLMAR Therapeutics, Inc. and referred to herein as “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. This is included in acquired product rights in the accompanying condensed consolidated balance sheet. The Company had previously licensed such rights from Tolmar. 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, the Company paid $0.75 million of the $1 million to Tolmar and the remaining $0.25 million was paid in December 2011. 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 September 2007, the Company 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. This is included in acquired product rights in the accompanying condensed consolidated balance sheet. The Company had previously licensed such rights from Tolmar. As part of the transaction, no further milestone payments or ongoing royalties will be due to Tolmar for the North American territory. To secure the Company’s obligation to pay the remaining $2 million amount when due, Tolmar was granted a security interest in the North American BEMA® assets, subject to a license of those assets from Tolmar to us for North America that would be granted to us on the original license terms upon any exercise of rights under such security interest.

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

In January 2012, the Company completed the acquisition of all U.S. and non-U.S. rights to the BEMA® delivery technology. See Note 14.

7. Derivative Financial Instruments:

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Company's Common Stock, are classified as liabilities when either: (a) the holder possesses rights to net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

The following tabular presentation reflects the components of derivative financial instruments as of December 31, 2011 and 2010.

	2011	2010
Derivative asset at fair value:		
Free standing warrants related party	$ 388,540	$1,299,031

	2011	2010
Shares into which derivative asset can be settled:		
Free standing warrants related party	2,000,000	2,000,000

	2011	2010
Derivative liability at fair value:		
Free standing warrants	$ 279,302	$4,989,994

The following tabular presentation reflects the components of derivative financial instruments as of December 31, 2011, 2010 and 2009.

	2011	2010	2009
Shares into which derivative liability can be settled:			
Free standing warrants	3,246,301	4,322,421	2,909,991

	2011	2010	2009
Derivative (expense) income in the accompanying statement of operations related to the derivatives as follows:			
Free standing derivatives (warrants)	$3,463,453	$3,126,771	($6,790,827)

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8. Sponsored Research:

In November 2010, the Company received notification from the U.S. Internal Revenue Service that it was approved to receive a grant in the amount of $0.245 million for qualified investments under the U.S. Government's Qualifying Therapeutic Discovery Project. The grant is for investments related to therapies utilizing the Company's proprietary BEMA® technology. The Company received such grant funds in the fourth quarter of 2010 and reported the receipt as sponsored research revenue in the accompanying consolidated statement of operations. There was no such grant funds received in 2011.

9. Income taxes:

The Company had income tax expense in 2009 of $0.3 million. The Company did not record income tax expense in 2010 or 2011 as the Company had incurred net operating losses. The Company has recognized valuation allowances for all deferred tax assets for years ending 2011, 2010 and 2009. Reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	Year Ended December 31,		
	2011	2010	2009
Federal statutory income tax rate	34.00%	34.00%	34.00%
State taxes, net of federal benefit	3.45	3.45	3.45
Permanent differences	4.26	(2.36)	7.00
Research and development ("R&D") credit	2.92	5.22	(3.32)
Other	(6.63)	(2.79)	(0.66)
Valuation allowance	(38.00)	(37.51)	(39.53)
	0.00%	0.00%	0.94%

The tax effects of temporary differences and net operating losses that give rise to significant components of deferred tax assets and liabilities consist of the following:

	December 31,		
Deferred tax assets (liabilities)	2011	2010	2009
Deferred revenue	$ 5,291,485	$ 5,007,111	$ 3,061,084
Basis difference in equipment	(1,008,114)	(831,921)	(831,921)
Basis difference in intangibles	(1,090,516)	(1,248,886)	(1,004,670)
Accrued liabilities and other	686,809	1,042,745	80,537
loss on extinguishment	—	3,080,454	3,080,454
R&D Credit	5,591,029	4,569,159	3,876,140
Stock options	1,606,254	1,451,561	1,165,932
Derivative	—	(1,751,245)	(765,928)
AMT credit	—	—	312,128
Net operating loss carry-forward (NOL)	19,055,559	9,951,000	7,406,919
	30,132,506	21,269,978	16,380,675
Less: valuation allowance	(30,132,506)	(21,269,978)	(16,380,675)
	$ —	$ —	$ —

In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, the Company recorded a valuation allowance with respect to all of the Company's deferred tax assets.

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9. Income taxes (continued):

The Company has a federal net operating loss of approximately $51 million as of December 31, 2011. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the Company. Some of these losses may be subject to these limitations. The Company's State NOLS are approximately $45.4 million as of December 31, 2011.

10. Stockholders' equity:

Common Stock:

On July 21, 2011, at the 2011 Annual Meeting of Stockholders of the Company, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of common stock, par value $.001, of the Company's Common Stock from 45,000,000 to 75,000,000 shares. Such amendment to the Company's Certificate of Incorporation had previously been approved by the Company's board of directors.

Stock options:

The Company has a 2011 Equity Incentive Plan, which was approved by stockholders in July 2011 and covers a total of 4,200,000 shares of Common Stock. An additional 4,400,888 shares of Common Stock underlying options previously granted under the Company's Amended and Restated 2001 Incentive Plan remain outstanding and exercisable. The Company's Amended and Restated 2001 Incentive Plan expired in July 2011 and no new securities may be issued thereunder. Options may be awarded during the ten-year term of the 2011 Equity Incentive Plan to Company employees, directors, consultants and other affiliates.

Stock option activity for the years ended December 31, 2011, 2010 and 2009 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2009	3,503,467	$ 3.56	
Granted in 2009:			
Officers and Directors	389,663	$ 4.85	
Others	187,995	3.41	
Exercised	(265,552)	2.50	
Forfeitures	(153,440)	3.20	
Outstanding at December 31, 2009	3,662,133	$ 3.78	$2,982,195
Granted in 2010:			
Officers and Directors	399,661	$ 2.68	
Others	382,476	3.22	
Exercised	(31,733)	3.08	
Forfeitures	(100,998)	3.10	
Outstanding at December 31, 2010	4,311,539	$ 3.65	$2,671,309
Granted in 2011:			
Officers and Directors	209,619	$ 3.44	
Others	238,918	3.41	
Exercised	(129,888)	2.69	
Forfeitures	(76,937)	3.09	
Outstanding at December 31, 2011	4,553,251	$ 3.66	$ —

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10. Stockholders' equity (continued):

Options outstanding at December 31, 2011 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 – 5.00	3,612,006	6.26	$ 2.99	
$ 5.01 – 10.00	941,245	5.72	$ 6.26	
	4,553,251			$ —

Options exercisable at December 31, 2011 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 – 5.00	2,835,818	5.65	$ 2.88	
$ 5.01 – 10.00	931,245	5.70	$ 6.27	
	3,767,063			$ —

The weighted average grant date fair value of options granted during the year ended December 31, 2011 was $3.43. There were no options granted during the years ended December 31, 2011, 2010 or 2009 whose exercise price was lower than the estimated market price of the stock at the grant date.

Nonvested stock options as of December 31, 2011, and changes during the year then ended, are as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Intrinsic Value
Nonvested at January 1, 2011	1,036,960		
Granted	296,174		
Vested	(470,009)		
Forfeited	(76,937)		
Nonvested at December 31, 2011	786,188	$ 3.39	$ —

As of December 31, 2011, there was approximately $1.0 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next three years.

Warrants:

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

Warrants outstanding and exercisable at December 31, 2011 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$0.00 – 5.00	3,293,801	2.11	$ 4.47	$ —

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10. Stockholders' equity (continued):

Reclassification of derivative liability to equity:

During the year ended December 31, 2009, Laurus Master Fund, Ltd. exercised warrants to purchase 1,712,274 shares of Common Stock for $.001 to $3.05 per share. Until the time of exercise the warrants were treated as a derivative liability. Upon exercise of the warrants, these amounts were reclassified to equity based on the fair value on the date of exercise. There was no such reclassification in 2010.

During the year ended December 31, 2011, CDC IV, LLC ("CDC") exercised warrants to purchase 601,120 shares of Common Stock for $2.91 per share. Until the time of exercise the warrants were treated as a derivative liability. Upon exercise of the warrants, these amounts were reclassified to equity based on the fair value on the date of exercise.

11. Retirement plan:

The Company sponsors a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation requirements. Participants may contribute up to 90% of their eligible earnings, as limited by law. The Company makes a matching contribution equal to 100% on the first 5% of participant contributions to the plan. The Company made contributions of approximately $0.1 million in 2011, 2010 and 2009, respectively.

12. Impairment of License:

The Company holds patents and patent applications for the Bioral® (cochleate) drug delivery technology, and is the worldwide, exclusive licensee of the technology pursuant to licensing agreements with UMDNJ and Albany Medical College (the "Bioral® License Agreements"). Since 2004, the Company's development and commercialization activities have focused increasingly (and from 2009 through 2011, almost exclusively) on its BEMA® delivery technology and related products and product candidates. The most advanced development of the Bioral® technology was a Phase 1 study performed with Bioral® Amphotericin B, on which preliminary results were reported in February 2009. Regarding the most recent developments with the Bioral® platform, on January 20, 2009, the Company entered into a Research Collaboration and License Agreement with the Drugs for Neglected Diseases initiative ("DNDi"), a not-for-profit foundation, for the development and distribution of Bioral® Amphotericin B for Visceral Leishmaniasis, and on October 6, 2009, the Company announced it was awarded a $1.3 million grant from the Walter Reed Army Institute of Research ("WRAIR") to support the clinical study of Bioral® Amphotericin B in the treatment of Cutaneous Leishmaniasis. Both infections are typically found in third world countries.

During the period ended June 30, 2010, an animal study undertaken by DNDi was found to be marginally positive, but treatment of the infection did not warrant further consideration with Bioral® Amphotericin B. Also during the period ended June 30, 2010, the Company elected not to pursue the application of Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis, and as such to not continue the WRAIR agreement, which was terminated. Accordingly, the aforementioned initial $50,000 funded by WRAIR was refunded in July 2010 and is included in General and Administrative expenses in the Condensed consolidated statements of income. In addition, as previously reported, in September 2009 the Company vacated its Newark, New Jersey research facility (where research on the Bioral® technology was being undertaken) and terminated its relationship with Dr. Raphael Mannino, the Company's then Chief Scientific Officer and the inventor of many of the patents directed to the cochleate technology. The Company dedicated very limited resources to the Bioral® platform during the first half of 2010. The Bioral® platform and its associated intellectual property are presently being reviewed for potential strategic, commercial, licensing and divestiture opportunities.

As a result of these developments, at June 30, 2010, the Company performed an impairment test on the carrying value of the Bioral® License Agreements and determined an impairment charge for the full unamortized carrying value of approximately $0.2 million was warranted. The amount is shown in the accompanying consolidated statement of operations as impairment of intangible license. There were no impairments during the year ended 2011.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

13. Commitments and contingencies:

Employment agreements:

The Company has employment agreements with certain employees, which extend for 12 months, and are renewable for successive (1) year terms. These agreements provide for base levels of compensation and separation benefits. Future minimum payments under these employment agreements as of December 31, 2011 is $0.8 million for the year ended December 31, 2012.

Operating leases:

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

Since November 2007, the Company also leases space for their corporate offices which expires in January 2013. Lease expense for the corporate office was $0.1 million for years ended December 31, 2011 and 2010, respectively and expense for both locations was approximately $0.2 million for year ended December 31, 2009.

The future minimum commitment on the remaining operating lease at December 31, 2011 is as follows:

Years ending December 31,	
2012	$128,949
2013	11,004
2014	—
	$139,953

Indemnifications:

The Company's directors and officers are indemnified against costs and expenses related to stockholder and other claims (i.e., only actions taken in their capacity as officers and directors) that are not covered by the Company's directors and officers insurance policy. This indemnification is ongoing and does not include a limit on the maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost. No events have occurred as of December 31, 2011 which would trigger any liability under the agreement.

Certain Rights of CDC

The Company and CDC are parties to a Clinical Development and License Agreement, dated July 15, 2005 (as amended, the "CDLA") pursuant to which CDC has previously provided funds to the Company for the development of the Company's ONSOLIS® product. Pursuant to the CDLA, in February 2006 the Company entered into a Security Agreement (the "Security Agreement") under which it granted CDC a security interest in the Company's assets related to ONSOLIS®. The Security Agreement terminated at the time of FDA approval of ONSOLIS®. As such, until the July 2009 approval, CDC retained the right to reclaim the ONSOLIS® related assets in the event of a default by the Company under the CDLA. Under the CDLA, as amended, CDC is entitled to receive a mid-single digit royalty based on net sales of ONSOLIS®, including minimum royalties of $375,000 per quarter beginning in the second full year following commercial launch. The royalty term expires upon the latter of expiration of the patent of generic entry into a particular country.

In September 2007, in connection with CDC's consent to the North American Meda transaction, the Company, among other transactions with CDC, granted CDC a 1% royalty on sales of the next BEMA® product, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval (the "Next BEMA® Product"). In connection with the 1% royalty grant: (i) CDC shall have the option to exchange its royalty rights to the Next BEMA® Product in favor of royalty rights to a substitute BEMA® product, (ii) the Company shall have the right, no earlier than six (6) months prior to the initial commercial launch of the Next BEMA® Product, to propose in writing and negotiate the key terms pursuant to which it would repurchase the royalty from CDC, (iii) CDC's right to the royalty shall immediately terminate at any time if annual net sales of the Next BEMA® Product equal less than $7.5 million in any calendar year following the third anniversary of initial launch of the product and CDC receives $18,750 in three (3) consecutive quarters as payment for CDC's one percent (1%) royalty during such calendar year and (iv) CDC shall have certain information rights with respect to the Next BEMA® Product.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

13. Commitments and contingencies (continued):

Certain Rights of CDC (continued)

The amount of royalties which the Company may be required to pay for the Next BEMA® Product (including estimates of the minimum royalties) is not presently determinable because product sales estimates cannot be reasonably determined and the regulatory approvals of the product for sale is not possible to predict. As such, the Company expects to record such royalties, if any, as cost of sales when and if such sales occur.

On May 12, 2011, the Company entered into an Amendment to Clinical Development and License Agreement (the "CDLA Amendment") by and among CDC V, LLC ("CDC"), NB Athyrium LLC ("Athyrium"). The Company is 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 the Company's 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, the Company has recorded $0.3 million as additional cost of product royalties for year ended December 31, 2011. In addition, certain terms of the CLDA were amended and restated to clarify that royalty payments by the Company under the CDLA will be calculated based on Meda's sales of ONSOLIS®, whereas previous Company royalty payments to CDC were calculated based on Company sales of ONSOLIS® to Meda.

The difference between these two calculations resulted in a $1.1 million overpayment by the Company which was recorded as a prepayment. As a result, the Company did not pay any of the 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.

14. Subsequent events:

Endo License Agreement

On January 5, 2012, the Company, Arius and Arius Two, entered into a definitive License and Development Agreement with Endo (the "Endo Agreement"), pursuant to which the Company, Arius and Arius Two agreed to grant to Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company's BEMA® Buprenorphine product and to complete U.S. development of the Product for purposes of seeking FDA approval.

Pursuant to the License Agreement, the Company is responsible for the completion of all clinical trials regarding BEMA® Buprenorphine necessary to submit an NDA to the FDA in order to obtain approval of BEMA® Buprenorphine in the United States, pursuant to a development plan set forth in the Endo Agreement (as it may be amended pursuant to the Endo Agreement). The Company is responsible for all development activities through the filing of the NDA in the U.S., while Endo is responsible for the development following the NDA submission as well as the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. In addition, Endo is responsible for all filings required to be in order to obtain regulatory approval of BEMA® Buprenorphine.

Pursuant to the Endo Agreement, the Company will receive the following payments (some portion(s) of which will be utilized by the Company to support its development obligations under the License Agreement with respect to the Product):

- $30 million non-refundable payment by January 19, 2012 (received January 17, 2012);
- up to an aggregate of $95 million in potential milestone payments based on pre-defined intellectual property, clinical development and regulatory events, including $15 million upon issuance of a certain patent covering the Product; and
- up to an aggregate of $55 million based on the achievement of certain potential sales milestones.

Such milestone payments are further subject to certain other conditions, adjustments and qualifications set forth in the Endo Agreement.

In addition to the milestone payments set forth above, the Company is also entitled to receive 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, which royalty payments are subject to certain restrictions and adjustment features.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

14. Subsequent events (continued):

Endo License Agreement (continued)

The term of the Endo Agreement shall last, on a country-by-country basis, until the later of: (i) 10 years from the date of the first commercial sale of BEMA® Buprenorphine in a particular country or (ii) the date on which the last valid claim of the Company's patents covering BEMA® Buprenorphine in a particular country has expired or been invalidated. The Endo Agreement shall be subject to termination: (i) by Endo, at any time, upon a specific amount of prior written notice to the Company, (ii) by Endo and the Company upon their mutual written agreement, (iii) by either party upon a material default or breach of the Endo Agreement and such default or breach is not cured within a specified timeframe, (iv) the voluntary or involuntary bankruptcy of either party or (v) by the Company if Endo does not meet certain diligence obligations outside of the United States.

Conclusion of BEMA® Purchase From Tolmar

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

Extension of BEMA®-Related Patent

On February 16, 2012, the Company announced that the U.S. Patent and Trademark Office ("USPTO") issued a Notice of Allowance regarding the Company's patent application (No. 13/184306) and, once the patent is granted, will extend the exclusivity of the BEMA® drug delivery technology for its BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone products from 2020 to 2027. As a result, pursuant to the Endo Agreement, the Company is 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 NDA for BEMA® Buprenorphine for the treatment of chronic pain.

Renewal of Shelf Registration Statement

In February 2012, the Company's universal shelf registration statement pursuant to which it could issue up to $50 million of its securities from time to tiem and subject to certain conditions expired. In January 2012, the Company filed a renewal of its shelf registration statement which registered up to $40 million of the Company's securities for potential future issuance, and such registration statement was declared effective on February 24, 2012.

Stay Granted in MonoSol Litigation

On March 7, 2012, the court in the Company's lawsuit with MonoSol Rx, LLC granted the Company's motion for a stay of further litigation. The court ordered that the case would be stayed pending resolution by the USPTO of reexamination proceedings and follows the prior rejection by the USPTO of all claims in all three patents asserted by MonoSol against the Company and its commercial partners for ONSOLIS®. Management estimates that up to $1.0 million of expense previously budgeted for the defense of the MonoSol litigation could be saved by the stay of the litigation, although such estimate may vary depending on future circumstances.

Reformulation of ONSOLIS®

On March 12, 2012, the Company announced the postponement of the U.S. relaunch of ONSOLIS® until the product formulation can be modified to address two appearance issues raised by the FDA following an inspection of the ONSOLIS® manufacturing facility. 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. Management estimates that the total cost of the ONSOLIS® reformulation project will be between $0.6 million and $1.2 million, although such project in its early stages and such estimate may vary.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011, 2010 AND 2009

SELECTED QUARTERLY RESULTS (UNAUDITED)

The following table sets forth certain quarterly financial data for the periods indicated (in thousands, except per share data):

	Quarter Ended			
	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011
Revenue	$ 229,463	$ 38,406	$ 2,663,728	$ 331,323
Gross profit	(67,956)	464,336	1,156,603	(46,692)
Loss from operations	(8,541,869)	(6,205,497)	(7,672,666)	(4,567,944)
Net (loss) income	(9,019,311)	(5,098,351)	(5,123,551)	(4,083,903)
Basic (loss) income per share	(0.36)	(0.18)	(0.17)	(0.14)
Diluted (loss) income per share	(0.36)	(0.18)	(0.17)	(0.14)

	Quarter Ended			
	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010
Revenue	$ 227,382	$ 2,216,566	$ 217,203	$ 743,746
Gross profit	214,953	1,420,041	197,713	732,982
(Loss) income from operations	(3,078,773)	(2,563,524)	(5,131,803)	(5,545,172)
Net (loss) income	(191,222)	775,861	(6,168,384)	(7,449,197)
Basic (loss) income per share	(0.01)	0.03	(0.26)	(0.32)
Diluted (loss) income per share	(0.01)	0.01	(0.26)	(0.32)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Under date of March 15, 2012, we reported on the consolidated balance sheets of BioDelivery Sciences International Inc., and subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations and stockholders' (deficit) equity and cash flows for each of the years in the three-year period ended December 31, 2011, which are included in BioDelivery Sciences International Inc.'s Annual Report on Form 10-K. In connection with our audits of the aforementioned consolidated financial statements, we also audited the related financial statement schedule in BioDelivery Sciences International Inc.'s Annual Report on Form 10-K. This financial statement schedule is the responsibility of BioDelivery Sciences International Inc.'s management. Our responsibility is to express an opinion on this financial statement schedule based on our audits. In our opinion, the financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

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

Tampa, Florida
March 19, 2012

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Years ended December 31, 2011, 2010 and 2009

Description	Balance at beginning of the period	Charged to income	Charged to other accounts	Balance at the end of the period
		(In millions)		
Valuation allowance for deferred tax assets				
Year ended December 31, 2011:	$ 21.27	$ 8.86	$ —	$ 30.13
Year ended December 31, 2010:	$ 16.40	$ 4.87	$ —	$ 21.27
Year ended December 31, 2009:	$ 29.57	($ 13.17)	$ —	$ 16.40

SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: March 19, 2012

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

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

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

Person	Capacity	Date
/S/ FRANCIS E. O'DONNELL, JR. **Francis E. O'Donnell, Jr.**	Executive Chairman and Director	March 19, 2012
/S/ MARK A. SIRGO **Mark A. Sirgo**	President, Chief Executive Officer and Director	March 19, 2012
/S/ WILLIAM B. STONE **William B. Stone**	Lead Director	March 19, 2012
/S/ JOHN J. SHEA **John J. Shea**	Director	March 19, 2012
/S/ WILLIAM S. POOLE **William S. Poole**	Director	March 19, 2012
/S/ SAMUEL P. SEARS, JR. **Samuel P. Sears, Jr.**	Director	March 19, 2012

Exhibit 21.1

Subsidiaries of the Registrant

The following are the subsidiaries of BioDelivery Sciences International, Inc.:

1. Arius Pharmaceuticals, Inc., a Delaware corporation (wholly-owned subsidiary of the Registrant).
2. Arius Two, Inc., a Delaware corporation (wholly-owned subsidiary of the Registrant).
3. Bioral Nutrient Delivery, LLC, a Delaware limited liability company (94.5% of Class B Shares and 100% of Class A Shares are owned by the Registrant).

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in each of the Registration Statements of BioDelivery Sciences International, Inc. (the "Company") on Form S-3 (No. 333-133629), on Form S-3 (No. 333-133630), on Form S-3 (No. 333-135746), on Form S-3 (No. 333-143247), on Form S-3 (No. 333-149671), on Form S-3 (No. 333-157173), on Form S-3 (No. 333-156839), on Form S-8 (No. 333-143590), on Form S-3 (No. 333-173261), on Form S-3 (No. 333-160121), on Form S-8 (No. 333-176476), and on Form S-3 (No. 333- 179257) of our report, dated March 15, 2012, relating to the consolidated financial statements of the Company which appear in this Form 10-K and the related financial statement schedule and the effectiveness of internal control over financial reporting as of December 31, 2011.

/s/ CHERRY, BEKAERT & HOLLAND, L.L.P.

Tampa, Florida
March 19, 2012

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a)

I, Mark A. Sirgo, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of BioDelivery Sciences International, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 19, 2012

/s/ Mark A. Sirgo
Mark A. Sirgo
President and Chief Executive Officer

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, James A. McNulty, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of BioDelivery Sciences International, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 19, 2012

/s/ James A. McNulty

James A. McNulty, Secretary, Treasurer
and Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of (18 U.S.C. 1350), the undersigned officer of BioDelivery Sciences International, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2010 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 19, 2012

/s/ Mark A. Sirgo
Mark A. Sirgo, President and Chief Executive Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

Exhibit 32.2

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), the undersigned officer of BioDelivery Sciences International, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2010 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 19, 2012

/s/ James A. McNulty

James A. McNulty, Secretary, Treasurer and
Chief Financial Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.