BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-K
March 20, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number 001-31361

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

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

801 Corporate Center Drive, Suite #210

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

Issuer s telephone number: 919-582-9050

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

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

Common Stock, $.001 par value NASDAQ Capital Market

(Title of class)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark 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. ¨

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2008 was approximately $26,782,825 based on the closing sale price of the company s common stock on such date of $2.32 per share, as reported by the NASDAQ Capital Market.

As of March 20, 2009, there were 19,248,302 shares of company common stock issued and 19,233,812 shares of company common stock outstanding.

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Note on Forward-Looking Statements

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NOTE ON FORWARD LOOKING STATEMENTS

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

- our plans regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the BEMA and Bioral technology platforms and any proposed formulations or products relating thereto, including our lead product candidate, ONSOLIS ;
- the domestic and international regulatory process relating to our technologies and proposed products and formulations, including the timing, status and results of our filings with the U.S. Food and Drug Administration and the timing, status and results of pre-clinical work and clinical studies;
- our ability to generate commercial viability and acceptance of our BEMA and Bioral technology platforms and our proposed formulations and products;
- 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 partnerships;
- the protection and control afforded by our patents and any interest in licensed patents, or our ability to enforce our rights under such patents or licenses;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and formulations;
- the ability of our commercial partners to market and sell the products we license to them;
- our ability to retain members of our management team and our employees; and
- competition existing today or that will likely arise in the future.

The foregoing does not represent an exhaustive list of risks. Please see Risk Factors for additional risks which could adversely impact our business and financial performance. Moreover, new risks regularly emerge and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Report are based on information available to us on the date of this Report. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Report.

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PART I

Item 1. Description of Business.

Overview

We are a specialty pharmaceutical company that is utilizing licensed and owned proprietary drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, significant new formulations of proven therapeutics. Utilizing our drug delivery technologies, we are developing formulations of pharmaceuticals aimed principally at acute (i.e., short term) conditions occurring in patients, mostly notably in the areas of pain and fungal infections.

Our patented drug delivery technologies include:

- the BEMA (transmucosal, or applied to the inner cheek mucosa) drug delivery technology; and
- the Bioral cochleate drug delivery technology, designed for a potentially broad base of applications.

Our current development strategy focuses on the utilization of the U.S. Food and Drug Administration s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved 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 less time consuming than other approval methods of the U.S. Food and Drug Administration, which we refer to herein as the FDA.

On August 28, 2008, we announced that we received a Complete Response on our New Drug Application, or NDA, for our lead product candidate, ONSOLIS (formerly known as BEMA Fentanyl), a potential treatment for breakthrough pain (i.e., episodes of severe pain which break through the medication used to control the persistent pain) in opioid tolerant patients with cancer. The Complete Response letter from FDA requested that we submit a proposed Risk Evaluation and Mitigation Strategy (REMS) for ONSOLIS . This was the only deficiency noted in our application. The proposed REMS was submitted to the FDA in December 2008, and we expect a decision from FDA regarding ONSOLIS in the first half of 2009.

We have granted commercialization and distribution rights for ONSOLIS on a worldwide basis (except in South Korea and Taiwan) to Meda AB (which we refer to herein as Meda), a leading international specialty pharmaceutical company based in Sweden. BEMA Fentanyl will be marketed in the United States as ONSOLIS and in Europe as BREAKYL . In this Report, we refer to BEMA Fentanyl, ONSOLIS and BREAKYL collectively as ONSOLIS .

Meda s U.S. division, located in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets, and sells branded prescription therapeutics. Although Meda was founded in 2001, it draws upon a long history, entering the U.S. market in 2007 through the acquisition of Medpointe Pharmaceuticals (previously known as Carter-Wallace, Inc.). Meda has an experienced, well trained and highly regarded sales force of over 400 representatives with a focus in specialty therapeutic areas including pain and central nervous system conditions. Meda has established a track record of commercializing products with their top two products, Astelin® and the more recently launched Soma® 250 mg. They have proven their ability to launch products and sustain growth in highly competitive

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pharmaceutical markets, as demonstrated by Astelin®, which has out-performed competitors in the anti-histamine, nasal steroid and rhinitis markets with regard to total prescription growth. We expect Meda to also effectively compete in the transmucosal opioid market. Meda has secured access to additional markets through acquisition of European businesses from Valeant, and a joint venture with Valeant covering Australia, Mexico and Canada.

Our next planned product utilizing the BEMA technology is BEMA Buprenorphine, a treatment for moderate to severe pain conditions. A new formulation of BEMA Buprenorphine was evaluated in a single dose, Phase 1 study started in late November 2008. In March 2009, we announced favorable preliminary results from this Phase 1 study and our intention to commence a Phase 2 efficacy study in June 2009.

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

Some of our products, such as ONSOLIS and BEMA Buprenorphine, may also have broader indications that would allow for chronic use. When such products present a viable commercial opportunity we will consider developing the product for chronic use.

To date, we have not generated revenue from sales of our products or royalty revenue from such sales. Since inception, we have recorded accumulated losses totaling approximately $92.2 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Ultimately, if we secure approval from the FDA and other regulatory bodies throughout the world for our licensed and/or proprietary products, our goal will be to augment our current sources of revenue and deferred revenue (principally licensing fees) with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

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

- Commercializing our product candidates, with the ultimate goal of generating revenues from sales of such products;
- partnering with other pharmaceutical companies to assist in the distribution of our products for which we will 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 product; and
- proceeds raised from public and private financings and strategic transactions.

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Key Technologies and Product Candidates

BEMA Technology and Products in Development

Our BEMA drug delivery technology consists of a small, erodable 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 like breakthrough cancer pain or trauma cases where intravenous lines or injections are unavailable or not practical. We previously licensed the BEMA drug delivery technology in the United States on an exclusive basis from QLT USA Inc., which we refer to herein as QLT. In August 2006, we entered into an agreement with QLT to purchase the non-U.S. rights to the BEMA technology and in September 2007, we entered into an agreement with QLT to purchase the U.S. rights to the BEMA technology. The final payments to QLT for these rights are due concurrently with FDA approval of a BEMA™ product and then upon achievement of certain net sales targets.

Our lead BEMA product under development is ONSOLIS , a potential treatment for breakthrough pain in opioid tolerant patients with cancer. We have previously received funding for our ONSOLIS program in part from CDC IV, LLC, which we refer to herein as CDC, under a clinical development and licensing agreement (which agreement we refer to herein as the CDLA). As a result, CDC has certain rights to our ONSOLIS assets until such time as ONSOLIS is approved by the FDA.

The following are the clinical development milestones achieved with ONSOLIS :

The product entered into Phase 3 trials for breakthrough cancer pain in the second half 2005.

In February of 2006, enrollment in the Phase 3 clinical program commenced.

In April and May 2006, we announced results from pharmacokinetic studies demonstrating dose proportionality and reproducibility with ONSOLIS .

In September 2006, we conducted a second meeting with the FDA to discuss the status of the ONSOLIS development program.

In April 2007, we announced the preliminary results of our Phase 3 efficacy study for ONSOLIS , which showed that patients treated with ONSOLIS showed a statistically significant improvement on the primary efficacy endpoint at 30 minutes (SPID 30) compared to placebo ($p < 0.004$), meaning a greater reduction in pain. Eighty (80) patients participated in the double-blind, placebo-controlled portion of the study.

In May 2007, we announced certain secondary endpoint results of our Phase 3 clinical trial and results of a bioavailability study for ONSOLIS , which showed that: (i) the absolute bioavailability (i.e. the total amount absorbed from the delivery system) of fentanyl from the ONSOLIS film was more than 70%, with 50% absorbed through the buccal mucosa (the inner lining of the cheek), (ii) equal doses administered as either a single film or multiple films produced identical plasma concentrations (i.e. four-200 mcg film provided the same plasma concentrations as a single-800 mcg film) and (iii) the SPID 15 (Summary of Pain Intensity Difference at 15 minutes) was significantly higher (i.e. improved) for ONSOLIS than placebo.

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In January 2008, we announced the expansion of our clinical development program for ONSOLIS to assess the efficacy and safety of the product for the treatment of breakthrough pain associated with other chronic pain conditions beyond cancer. The initial supporting toxicology studies for the non-cancer breakthrough pain program are underway.

On November 1, 2007, we announced that, given our NDA filing for ONSOLIS and our receipt of a $30 million non-refundable upfront payment from Meda for the U.S. distribution rights to ONSOLIS in the U.S., Mexico and Canada, we would increase our development efforts on BEMA Buprenorphine, our second analgesic product.

A second single dose, Phase 1 study was started in November 2008 with BEMA Buprenorphine. In March 2009, we announced favorable preliminary results from this Phase 1 study and our intention to commence a Phase 2 efficacy study in June 2009.

Bioral Technology and Products in Development

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

Our lead Bioral formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for treating systemic fungal infections. We believe that the Bioral formulation of Amphotericin B (which we refer to as Bioral Amphotericin B) has the potential to allow for oral delivery of an Amphotericin B, which is currently only given by intravenous administration. Following the completion of preclinical testing in 2006, we submitted an Investigational New Drug Application, or IND, to the FDA for Bioral Amphotericin B in December 2006, which IND was accepted by the FDA.

In 2008, we completed the manufacturing of Bioral Amphotericin B clinical supplies and conducted our first Phase 1 trial in normal volunteers to evaluate the safety and pharmacokinetics of the product. Forty-eight healthy volunteers participated in the study, with sixteen recruited for each of three dose groups. In each dose group, twelve volunteers received a single dose of Bioral Amphotericin B and four received a placebo. Amphotericin B plasma concentrations were measured over a period of fourteen days. The study identified doses that were well-tolerated with no meaningful changes in laboratory safety values including those associated with renal function.

The preliminary pharmacokinetic evaluation, available in February 2009, revealed that plasma concentrations were comparable to those seen in prior animal toxicology studies using the same formulation. In previous animal studies that we have conducted, doses used in toxicology studies have been shown to produce measureable tissue concentrations and efficacy against the fungal infections candidiasis and aspergillosis.

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In January 2009, we announced the signing of a research collaboration and licensing agreement with the Drugs for Neglected Diseases initiative, or DND*i*, a not-for-profit foundation focused on the development of new drugs and new formulations of existing drugs for patients suffering from some of the world s most neglected communicable diseases. DND*i* will collaborate with us on a non-exclusive basis in the design and conduct of a research and clinical development program to assess the efficacy and safety of Bioral Amphotericin B for the treatment of neglected diseases like leishmaniasis and Chagas disease. These potentially fatal parasitic diseases afflict millions worldwide and cause significant morbidity and mortality.

Under the terms of the agreement, DND*i* will execute a mutually agreed upon clinical development plan for Bioral Amphotericin B and seek regulatory approvals and distribution outside the U.S. and Europe for the diseases specified. The agreement covers many of the poor and marginalized countries of the world. We will be responsible for manufacturing and providing clinical trial materials. All costs incurred will be the responsibility of DND*i*.

A second Bioral formulation for the intranasal administration of Amphotericin B to treat chronic rhinosinusitis, or CRS, is now in initial in vitro studies. These studies suggest that Bioral Amphotericin B may provide enhanced efficacy and stability. In April 2004, we licensed this second opportunity to Accentia Biopharmaceuticals, Inc. (Pink Sheets:ABPIQ.PK), an affiliate of ours which we refer to herein as Accentia, for use in the treatment of CRS and asthma. Certain of our officers and directors (including Dr. Frank O Donnell, Jr., who is also the managing partner of Hopkins Capital Group II, LLC, a significant stockholder of ours which we refer to herein as HCG II) are officers, directors and/or stockholders of Accentia or its subsidiaries.

We have also explored other potential applications of our Bioral technology, including the creation of cochleate formulations of siRNA therapeutics, other therapeutics, certain vaccines and important nutrients. We have an ongoing evaluation agreement with a major company developing siRNA therapeutics and we are seeking additional collaborations and strategic partners in this area. Additionally, we have ongoing evaluation agreements in place with other companies to evaluate their proprietary molecules in the Bioral delivery system. In 2006, we signed a master research agreement with a major pharmaceutical company where we can evaluate a series of compounds from the sponsor company with predefined terms. If any of the evaluations from this agreement are positive, we will have an option to license the Bioral technology for use with the specified compound. To date, no opportunity for such an option has arisen.

On January 20, 2005, we signed a definitive licensing agreement with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., or Sigma-Tau, for the application of our Bioral cochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau. Sigma-Tau is an affiliate of The Sigma-Tau Group, one of Italy s leading pharmaceutical companies. As a result of our collaboration with Sigma Tau, using an encochleated formulation of ST1959, a proprietary Sigma Tau drug, in 2008 we reported the results of a published study designed to determine whether nanocochleate technology could be successfully utilized to deliver ST1959 and protect mice undergoing lethal acute graft-versus-host disease (GVHD). Orally-administered encochleated ST1959 significantly protected animals from lethality, whereas oral administration of ST1959, mixed with empty nanocochleates, was inactive. Increased survival was associated with diminished serum chemokine levels and donor CD8 T-cells in the spleen of ST1959-treated mice. Moreover, ST1959 treatment significantly counteracted GVHD-induced normocitic anemia by increasing hemoglobin, hematocrit, platelet, and red and white blood cell counts. Overall, these data showed that orally-administered encochleated ST1959 protected mice from GVHD. We are currently not working on any other products in this capacity under this agreement with Sigma-Tau.

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We also have a collaboration for the development of Bioral Amphotericin B with the National Institutes of Health, or NIH, which has supported in part the preclinical program, and for clinical development in Cutaneous Leishmaniasis with Walter Reed Army Institute for Research. Data generated through these collaborations is expected to assist us in the ongoing development of Bioral Amphotericin B for broader use in treating a variety of common systemic fungal infections.

Emezine®

In 2004 and 2005, we were developing Emezine® , a formulation of prochlorperazine, which we believe would be one of the first drugs to be delivered transmucousally for treatment of nausea and vomiting. Emezine® does not utilize the BEMA or Bioral delivery technologies. On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. After a thorough re-evaluation of the program that would be required to gain approval of Emezine®, we decided to return the product license, IND and all data associated with the program, to Reckitt Benckiser Healthcare (UK) Limited, or Reckitt. On December 17 2008, in conjunction with Reckitt s termination of the Emezine® agreement, and our returning to Reckitt the product license, IND and other information associated with the Emezine®, the agreement between us (through our subsidiary Arius Pharmaceuticals, Inc., which we refer to herein as Arius) and TEAMM Pharmaceuticals, Inc., an affiliate of Accentia, for the distribution of Emezine® was terminated according to the terms of agreement between Arius and TEAMM.

Recent and Key Historical Events

Meda Licensing Agreements

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

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

- $30.0 million milestone payment upon closing (which was received on September 14, 2007). We have recorded the $30.0 million payment received as deferred revenue.

- An additional aggregate $30.0 million milestone payment (of which $3.0 million was advanced to us by Meda) in January 2009) concurrently with receipt of approval of ONSOLIS by the FDA, unless we have not, at such time, manufactured stocks of ONSOLIS , in bulk or finished form, sufficient for commercial launch of ONSOLIS in the U.S., in which case $11.9 million will be paid upon FDA approval and $15.0 million will be paid upon the earlier of: (A) the date that such sufficient launch stocks are manufactured or (B) the first commercial sale of ONSOLIS . We anticipate that we will have sufficient launch stocks of ONSOLIS product concurrently with FDA approval of ONSOLIS , which is anticipated in the first half of 2009.

- A significant double digit royalty on net sales of ONSOLIS in the covered territories, subject to certain third party royalty payment costs and adjustments, as well as other adjustments in the event of certain specific supply disruptions. The license agreement provides for certain guaranteed minimum annual royalties to us during the second through seventh years following the product s first commercial sale.

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Sales milestones equaling an aggregate of $30 million payable at:

$10.0 million when and if annual sales exceed $75.0 million;

$10.0 million when and if annual sales exceed $125.0 million; and

$10.0 million when and if annual sales exceed $175.0 million.

Also, pursuant to the U.S. license agreement with Meda, we have been granted certain rights to co-promote ONSOLIS using our own sales force (which we currently do not have), with financial support by Meda for such efforts. Per our agreement with Meda, this financial support, if we elect to co-promote, will not begin for a period of time following FDA approval of ONSOLIS . In addition, Meda is subject to certain minimum sales representative calls and advertising and promotional expenditure requirements under the U.S. license agreement and has agreed to support all future costs of clinical development that do not involve studies in support of the NDA such as additional indications for ONSOLIS . We announced the expansion of our clinical development program for ONSOLIS in January 2008 to include a potential indication for breakthrough pain in non-cancer patients.

On January 2, 2009, we entered into an amendment to our U.S. agreements with Meda pursuant to which we received $3.0 million in January 2009 as an advance against the anticipated aggregate $30.0 million U.S. ONSOLIS approval milestone payment amount.

European Agreement. In August 2006, we announced collaboration with Meda to develop and commercialize ONSOLIS in Europe. Under terms of the agreement, we granted Meda rights to the European development and commercialization of ONSOLIS , in exchange for an upfront fee paid to us, certain milestone payments and double digit royalties to be received by us on product sales. Payments include a $2.5 million payment upon execution of the agreement and additional milestones that would, if achieved, provide us with up to an additional aggregate of $7.5 million in revenue. Meda will manage the clinical development and regulatory submissions in Europe. Upon regulatory approval, Meda will exclusively commercialize ONSOLIS in Europe.

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

Relationship with CDC IV, LLC

On July 14, 2005, we entered into the CDLA with CDC. On February 16, 2006, we announced that, as a result of our achievement of certain milestones called for under our CDC agreement, CDC made its initial $2 million payment to us. On May 16, 2006, we issued CDC 2 million shares of our common stock in return for accelerating the funding of the $4.2 million balance of $7 million of aggregate commitment under the CDLA and for eliminating the then required $7 million milestone repayment to CDC upon the approval by the FDA of ONSOLIS .

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Under the CDLA, CDC is entitled to receive a royalty based on net sales of ONSOLIS (including minimum royalties). In addition, we granted CDC a warrant exercisable for up to 500,000 shares of our common stock at an exercise price of $3.50 per share. As a result of the anti-dilution provisions of the CDC warrant and the pricing of our October 2005 public offering, the conversion price of the CDC warrant is now $2.91. We also issued to CDC a warrant to purchase 904,000 shares of our common stock in connection with the May 2006 amendment to the CDLA. Such warrant is exercisable at $3.00 per share. All of the shares of common stock issued to CDC (as well as the shares underlying CDC s warrants) as described above have been registered with the SEC.

Upon execution of the CDLA, all information and intellectual property rights concerning ONSOLIS were exclusively licensed to CDC for a limited purpose and limited duration. The license terminates on FDA approval of ONSOLIS . CDC granted us in return an exclusive license to utilize all such information and rights prior to FDA approval of ONSOLIS . Under the CDLA, CDC owns all data generated in the course of the product development supported by its funds, provided that we shall have an exclusive license to use such data for purposes of our development and commercialization of ONSOLIS .

Royalties under the CDLA are subject to upward adjustments: (i) for delays in obtaining regulatory approval for ONSOLIS , (ii) for the market entry of certain defined competing products in the United States prior to the first commercial sale of ONSOLIS , or (iii) if the average selling price of ONSOLIS is less than that of certain defined competing products. In the event we do not diligently pursue the development and regulatory approval of ONSOLIS or if we encounter certain specified negative circumstances regarding the development of ONSOLIS , CDC has the right to pursue development and commercialization of ONSOLIS pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of our ONSOLIS assets to CDC, provided that, under certain conditions, we may, despite such negative circumstances, retain our rights to ONSOLIS and continue pursuing its development and/or commercialization itself subject to the reimbursement of all funding provided by CDC and payment of all royalties due, pro rated based on the amount of funding provided by CDC, under the development agreement.

The warrant issued to CDC in July 2005 is currently exercisable at $2.91. The warrant expires after the earlier of: (i) 5:00 p.m. Eastern Time on the second anniversary of the approval by the FDA of the first NDA relating to ONSOLIS , (ii) the closing of a sale of all or substantially all of our assets or the acquisition of our company by another entity by means of merger or other transaction as a result of which our stockholders immediately prior to such acquisition possess a minority of the voting power of the acquiring entity immediately following such acquisition, or (iii) any liquidation or winding up of our company.

Pursuant to the CDLA, and concurrently with the timing of CDC s initial $2.0 million payment to us in February 2006, we entered into a security agreement granting CDC a security interest in assets related to ONSOLIS . The formal security interest terminates at the time of FDA approval of ONSOLIS . Until such NDA approval, CDC retains the right to reclaim our ONSOLIS -related assets in the event of a default under the CDLA. Events of default include: (i) failure to pay royalties, (ii) acceleration of a debt in excess of $1.0 million and our failure to pay such debt, (iii) judgment of $500,000 and our failure to satisfy such judgments, or (iv) our insolvency, among other things.

On August 30, 2006, we delivered to CDC a notice in which we claimed that CDC breached the CDLA and damaged us when it acted or failed to act in accordance with or in contravention of the terms of the CDLA. In our notice, we reserved the right to make additional claims against CDC. Also on August 30, 2006, we received written notice from CDC of CDC s claim of termination of the CDLA. In its notice, CDC alleged that we undertook certain actions which materially breached the CDLA, which

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breaches, CDC alleged, required us to transfer certain specified rights and assets relating to ONSOLIS to CDC. Pursuant to the CDLA, any claim of breach of material terms is subject to the dispute resolutions procedures, including arbitration, contained within the CDLA.

On October 17, 2006, CDC filed an action in New York State Supreme Court against us seeking to enjoin us from entering into a financing transaction with a third party pursuant to a purported right of first negotiation provision (the ROFN) granted to CDC under a Securities Purchase Agreement, dated May 16, 2006, between us and CDC (the SPA). On October 26, 2006, we entered into a Stipulation, Index no. 06/603626 (the Stipulation), with CDC to settle this case without prejudice pursuant to which we and CDC agreed to follow a procedure regarding the ROFN as modified by the Stipulation.

On March 12, 2007, we entered into a Dispute Resolution Agreement, which we refer to herein as the DRA, with CDC, pursuant to which we and CDC have terminated the previously instituted dispute resolution procedures between the parties relating to the allegations and demands made by the parties against each other in August 2006. The effect of the DRA was that CDC withdrew its claims to ownership of the ONSOLIS asset, which had been asserted by CDC as part of the disputed matters, and we have withdrawn our claims against CDC. We had previously rejected CDC s August 2006 allegations and demands. The resolution of the disputes under the DRA was without prejudice to the disputed matters of both us and CDC. Simultaneously with our entry into the DRA, we entered into an amendment to the CDLA. The purpose of the amendment to the CDLA is to clarify certain reporting and other obligations between the parties regarding the development and commercialization of ONSOLIS .

Concurrently with the parties negotiation of the DRA, CDC alleged that we had violated CDC s ROFN provided for in the May 2006 Securities Purchase Agreement between the parties. Specifically, in January 2007, CDC alleged by written notice that our December 2006 note deferral agreements with Laurus Master Fund Ltd., which we refer to as Laurus, triggered the ROFN provisions. Under such transaction, we deferred all principal and interest under then existing convertible notes with Laurus in exchange for a warrant to purchase shares of our common stock. In order for us to avoid CDC s continued assertion of its alleged ROFN with respect to the Laurus deferral transaction, and in order to enter into the DRA with the resulting resolution of the August 2006 disputes, CDC required that, simultaneously with the entry into the DRA, we enter into a $1.9 million financing with CDC. This new financing was intended to resolve CDC s January 2007 ROFN claims, notwithstanding our rejection of CDC s assertion that the ROFN was triggered by the Laurus deferral transaction. The $1.9 million CDC financing involved a one-year, 10.25% loan from CDC and a warrant to purchase 1 million shares of our common stock with an exercise price of $3.80. Such loan was repaid in January 2008 and during 2008, the shares underlying such warrant were registered with the SEC for resale.

On September 5, 2007, in connection with CDC s consent to the Meda U.S. licensing transaction, we and CDC entered into a second Dispute Resolution Agreement (DRA II) pursuant to which we and CDC agreed to waive and dismiss with prejudice all current disputes between us and CDC concerning each of the CDLA and the SPA. As a condition to CDC s entrance into DRA II and its consent to the Meda U.S. licensing transaction, we and CDC entered into a Royalty Purchase and Amendment Agreement, dated September 5, 2007 (the RPAA) pursuant to which: (i) ROFN as set forth in the Stipulation was amended to covert such right into a right of first refusal on our financings (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

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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.

Laurus Financings

In February and May 2005, we entered into two separate $2.5 million convertible note and warrant financings with Laurus. The notes were extended and amended five times through 2007. All principal and interest under the Laurus convertible notes with Laurus has been either paid or fully converted into shares of our common stock. Laurus continues to hold warrants to purchase an aggregate of 2,476,871 shares of our common stock with a weighted average exercise price of $3.71.

Acquisition of Arius Pharmaceuticals, Inc.

On August 24, 2004, we consummated the acquisition of Arius Pharmaceuticals, Inc., a privately held company founded by Dr. Mark A. Sirgo and Dr. Andrew L. Finn. In 2004, Arius acquired an exclusive worldwide license to the BEMA delivery technology developed by QLT and also acquired the U.S. license rights to a transmucousally delivered tablet formulation of Emezine®. Simultaneously with the closing of the Arius acquisition, Drs. Sirgo and Finn joined our company as, respectively, Senior Vice President of Commercialization and Corporate Development and Senior Vice President of Product Development. Subsequently, each of Drs. Sirgo and Finn have been promoted, and they now serve,

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respectively, as our President and Chief Executive Officer and Executive Vice President of Product Development. As consideration for our acquisition of Arius, we issued the former Arius stockholders an aggregate of 1,647,059 shares of our Series A Non-Voting Convertible Preferred Stock, which have all subsequently been converted into shares of our common stock on a one-for-one basis. Drs. Sirgo and Finn were the principal stockholders of Arius and collectively received approximately 97% of the consideration paid for Arius. Arius remains a subsidiary of our company.

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

The drug delivery industry develops technologies for the improved administration of certain drugs. These technologies, including our own, have focused primarily on safety, efficacy, ease of patient use and patient compliance.

Since our inception, we have focused primarily on research and development of our licensed Bioral encochleation technology and the application of such technology to specific drugs. In 2004, however, as a result of our acquisition of Arius, we began (and continue) to shift our corporate focus to what we call the area of specialty pharmaceuticals : applying our licensed technologies to existing therapeutics to create our own proprietary formulations, for which we then seek proprietary protection, to obtain FDA approval and subsequently commercialize. We believe that focusing our drug delivery technologies for use with existing FDA approved drugs to be less risky than attempting to discover new drugs, sometimes called new chemical entities, or NCEs. This transition in corporate focus continued in 2007 as we continued development of our principal products and formulations, received positive Phase 3 data on ONSOLIS and submitted our first BEMA related NDA (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 findings of third parties which the FDA has published on approved pharmaceuticals, including clinical and non-clinical testing, thereby reducing, though not eliminating, the need to engage in these costly and time consuming activities. A typical development program for a 505(b)(2) submission will include:

a single genotoxicity study with the drug substance,

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

thorough pharmacokinetic evaluation of the new dosage form in humans,

at least one placebo controlled clinical study in humans,

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

stability of drug substance,

full description of drug product manufacturing process,

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

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special studies specific to the formulation.

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

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

We have and intend to continue to target drugs that have established markets and an opportunity to introduce a new form of delivery of that product in order to meet an unmet market need. As a result of employing well known drugs in our technologies, we believe health care providers will be familiar with the drug and accustomed to prescribing them. As with ONSOLIS and Bioral Amphotericin B, most of the drug candidates we target will have been through the regulatory process and therefore the safety and efficacy of the drug has been established. Consequently, we believe that our clinical trials would primarily need to show that our Bioral or BEMA based products will deliver the drug without causing unintended safety or tolerability concerns for the patient or changing the clinical attributes of the drug. Focusing on drug delivery as compared to drug discovery should allow us to also potentially form a number of collaborations to deliver a wide variety of medicines without limiting rights to utilize our proprietary technology with additional drug opportunities.

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Pipeline of Proposed Formulations and Products

The following table summarizes the status of our currently proposed formulations and products:

Product/Formulation	Indication	Development Status	Commercial Status
ONSOLIS /BREAKYL	Breakthrough cancer pain	NDA Filed October 2007; Complete Response: August 2008; NDA resubmission December 2008; Expect FDA decision 1H 2009; EU regulatory submission April 1, 2008	Partnered worldwide with Meda except in Taiwan and South Korea
BEMA Buprenorphine	Moderate to severe acute and chronic pain	Preparing Phase 2 for Preliminary Phase 1; results announced 2Q09	In-house commercialization for specialty indications possible; primary care rights to be partnered
Bioral Amphotercin B	Fungal infections	Phase 1	Partner will be sought in U.S. with co promote option for specialty indication

Although we have investigated other projects in the past, we are presently dedicating our corporate resources toward the development and commercialization of ONSOLIS , BEMA Buprenorphine and Bioral Amphotericin B. As each of these programs completes, and depending on the availability of corporate resources, we will begin funding the development of other programs.

Description of Our Drug Delivery Technologies and Proposed Formulations and Products

We have based our estimates of development costs and related matters described below 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 INDs or NDAs, our estimates of development costs and our projected sales associated with each of our formulations discussed below and elsewhere in this Report are merely estimates and subject to many factors, many of which may be beyond our control, which could cause delays and or cost overruns or otherwise cause us to revise such estimates. Readers are also advised that our projected sales figures do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our management s reasonable judgments given the information available and their previous experiences, although such estimates may not prove to be accurate.

BEMA Technology Overview

BEMA stands for BioErodible MucoAdhesive. BEMA films are approximately the size of a coin, but vary in size dependant on the drug and desired dose of active to be delivered, and are composed of an adhesive layer and a non-adhesive backing layer made of polymers, with both layers capable of holding the desired drug. Upon application, the film adheres to the buccal mucosal surface (inner lining of the cheek) and delivers the dose of medication rapidly and efficiently, making it a potentially excellent delivery system for time-critical conditions where rapid onset is important such as pain and nausea and vomiting, and in those situations where oral formulations are not desirable or inefficient. The BEMA system permits control of two critical factors allowing for better dose to dose reproducibility: (i) the contact area for mucosal drug delivery, and (ii) the time the drug is in contact with that area, known as residence time.

In contrast to competing transmucosal delivery systems like lozenges, buccal tablets and matrix-based delivery systems placed under the tongue or sprayed in the oral cavity, BEMA products:

- Adhere to mucosa in seconds and dissolve in minutes;

Permit absorption to be determined by the product, with patients not being required to swish or move the product around in the mouth for absorption, thus avoiding patient intervariability;

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Have a reproducible delivery rate, not susceptible to varying or intermittent contact with oral membranes; and

Dissolve completely, leaving no residual product or waste and avoiding patient removal.

In 2006 and 2007, we acquired from QLT (subject to scheduled payments upon the occurrence of certain events), respectively, the non-U.S. and U.S. rights to the BEMA technology. After purchasing the intellectual property rights from QLT, we will not owe any future milestone payments or royalties.

Current BEMA Formulations in Development

ONSOLIS

Datamonitor estimates the global market for branded medications to treat breakthrough pain will reach $1.3 billion by 2017, with the U.S. being the single largest market and likely to account for well over half of global sales. In 2008, the leading fentanyl product for the treatment of breakthrough cancer pain in the U.S. market was Actiq® which is marketed by Cephalon, Inc. (NASDAQ:CEPH) and available as a generic from Barr Laboratories and Watson Pharmaceuticals. Cephalon introduced a second fast dissolving fentanyl product, Fentora® in late 2006. The reported combined sales of these products in 2008 was $744 million. We believe that ONSOLIS potentially has significant advantages over the marketed and pipeline Fentanyl products:

Attribute	Actiq® buccal lozenge (Cephalon)	Fentora® buccal tablet (Cephalon)	Rapinyl® sublingual tablet* (Prostrakan)	ONSOLIS buccal film* (BDSI)
Dose Range	200 1600 µg	100 800 µg	100 1200 µg	200 1200 µg
Dose Linearity	Yes	Up to 800 µg	TBD	Yes
Patients Unable to Reach an Effective Dose	3%	16%	TBD	3%
Application Site Reactions	Occurred in >1% of patients in long term study	10% of all patients 3% of all patients with ulcerations	TBD	2.0%
Convenience	Low Requires active manipulation of dose form until dissolved	Moderate May require maintaining dose form in place, requires adequate amount of saliva to dissolve	TBD	High Simple placement, no need for manipulation, dissolves in 15-30 minutes

* Projected as product is not presently being marketed.

We believe there is a clear need and growing market for additional narcotic agents in alternative dosage forms to provide rapid and convenient pain relief. Fentanyl belongs to the group of medicines called narcotic analgesics. Narcotic analgesics are used to relieve pain. The transmucosal form of fentanyl is a powerful narcotic used to treat breakthrough cancer pain. Fentanyl using our licensed BEMA technology has the potential to meet the need for new narcotics and, we believe, will be ideal for breakthrough pain in opioid-tolerant patients.

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

BEMA Buprenorphine

In addition to ONSOLIS , we are also developing a BEMA Buprenorphine second analgesic product with a longer duration of action suited for a broad range of pain conditions. In November 2005, we announced our intention to enter clinical development with BEMA Buprenorphine in the first quarter of 2006 and our expectation of commencing Phase 3 trials in the second half of 2006. Also, in early January 2006, we announced that we submitted an IND with the FDA for BEMA Buprenorphine. In August 2006, we announced the completion of the initial Phase 1 study for BEMA Buprenorphine. The results of this study demonstrated achievement of plasma concentrations that are associated with analgesia.

We intended to progress the development of BEMA Buprenorphine through scale up of manufacturing and pursuit of further clinical studies; however, due to financial constraints in 2007 and our focus on the ONSOLIS NDA submission, along with preparations for a potential commercial launch, we did not progress BEMA Buprenorphine into Phase 2 in 2008. We did however initiate a second Phase 1 study that involved two different formulations of buprenorphine in our BEMA technology. The preliminary results of this study, announced in March 2009, were favorable. Fourteen healthy volunteers participated in this randomized, blinded, cross-over study which compared two formulations of BEMA Buprenorphine with intravenous buprenorphine and placebo. Following administration of both formulations, buprenorphine plasma concentrations were measureable within 15 minutes and accompanied by changes in pupillometry, a standard measure of opioid pharmacodynamic effect. Notably, this effect was maintained over the 8-hour duration of the study without evidence of significant decline. Local application of the BEMA films in the mouth were well tolerated. Due to these favorable results, we plan to progress BEMA Buprenorphine into Phase 2 clinical development in June 2009 and, assuming positive results, this will be followed by the initiation of Phase 3 in the first half of 2010.

Buprenorphine is a marketed opioid analgesic which has equal potency to morphine but with a lower propensity for adverse reactions, abuse and addiction. The lower potential for abuse and addiction places BEMA Buprenorphine as a Schedule III controlled substance versus the majority of the other potent opioids, such as morphine and oxycodone, which are Schedule II. We believe that this attribute will help create a broader market opportunity for BEMA Buprenorphine as many doctors are reluctant to prescribe narcotics particularly on a chronic basis for the fear of addiction. Also, since buprenorphine is a Schedule III controlled substance, physicians will be able to phone, fax or otherwise electronically deliver the prescription to the pharmacy with refills permitted for up to 6 months, thus making chronic therapy easier for both the patient and the physician. A prescription for a Schedule II controlled substance must be obtained by the patient from the doctor s office which the patient must then take to the pharmacy. Refills are not permitted for Schedule II controlled substances, requiring the patient to obtain a new prescription each time the medication is required.

Buprenorphine has been shown to produce comparable pain relief to morphine, with an improved safety profile and extended duration of action, but poor oral bioavailability. The BEMA delivery system may enable us to provide this opioid in a form suitable for ambulatory care and, because of the safety advantage associated with this opioid, we believe that BEMA Buprenorphine will be an ideal next step product for patients with incomplete pain relief on non-narcotic analgesics.

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BEMA Buprenorphine is intended to meet the need for a new narcotic and could be used for:

- post-operative pain; and
- chronic pain, including lower back, osteoarthritis and rheumatoid arthritis.

Compared to currently marketed products and products under development, we believe that BEMA Buprenorphine will be differentiated based on the following features:

- efficacy equivalent to morphine, but unlike morphine, is a Schedule III narcotic making it less prone to abuse and addiction and more convenient for physicians to prescribe (with prescription refills possible), pharmacists to dispense, and patients to obtain;
- broad applicability across a wide spectrum of patients with varying types of moderate to severe pain, and can be used in combination with less potent analgesics such as nonsteroidal anti-inflammatory drugs, or NSAIDS, or as sole therapy;
- a longer half life which allows for less frequent dosing, thus potentially increasing patient compliance;
- an established safety profile compared to agents in development; and
- potential for improved tolerability, including a lower incidence of constipation and, based on its Schedule III designation, a lower propensity for addiction and abuse versus other opioid analgesics.

The pain market is well established, with many pharmaceutical companies marketing innovative products as well as generic versions of older, non-patent protected products. The overall global pain market is estimated to total approximately $30 billion in sales. Of this, approximately $10 billion is for narcotic analgesics.

Due to the ability of BEMA Buprenorphine to potentially participate in the principal key pain markets (chronic pain as well as acute and post-operative pain), we believe that BEMA Buprenorphine has the potential to achieve up to a 2% share of the total worldwide pain market. Based on the estimated market size, this would translate into over $500 million in peak annual sales.

We believe that other pharmaceuticals have the potential to be formulated for delivery using our BEMA technology, and we have explored, and will continue to explore, such potential applications.

Encochleation Technology Overview

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

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Our licensed Bioral cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our Bioral cochleate technology are phosphatidylserine, or PS , and calcium. PS is a natural component of essentially all biological membranes, and is most concentrated in the brain. Clinical studies by other investigators (more than 30 have been published of which we are aware) to evaluate the potential of phosphatidylserine as a nutrient supplement indicate that PS is safe and may play a role in the support of mental functions in the aging brain.

Research and development of cochleates has been conducted at the Universities for a number of years. Our scientists, some of whom were former researchers and others who still hold teaching positions with these Universities, supervised their cochleate research programs. As a result of the relationship between our scientists and the Universities, we became the exclusive worldwide licensee to develop this cochleate technology and in some cases co-own the patents with them.

Potential Advantages

We believe that our licensed Bioral drug delivery technology represents a potentially important new delivery mechanism. While the characteristics and benefits of this technology will ultimately be established through FDA clinical trials, our research, based upon pre-clinical studies indicates that our Bioral technology may have the following characteristics:

All-natural ingredients. Our Bioral drug delivery technology uses phosphatidylserine, which can be sourced from soy beans and calcium.

Encapsulation. Our Bioral drug delivery encapsulates, or entraps within a crystal matrix, the subject drug, rather than chemically bonding with the drug.

Enhanced Availability. Our Bioral drug delivery technology is being developed to enable oral availability of a broad spectrum of compounds, such as those with poor water solubility, and protein and peptide biopharmaceuticals, which have been difficult to administer. Our Bioral drug delivery technology also has the potential to be applied to substances which are not currently deliverable by traditional means so that they may be delivered orally.

Minimizing Side Effects. Our Bioral drug delivery technology may reduce toxicity, stomach irritation and other side effects of the encapsulated drug.

Cellular Delivery. Our Bioral drug delivery technology is being developed as membrane fusion intermediates. We believe that, when drugs encapsulated in our Bioral drug delivery technology come into close approximation to a target membrane, a fusion event between the outer layer of the cochleate cylinder and the cell membrane may occur. This fusion may result in the delivery of a small amount of the encochleated material into the cytoplasm of the target cell. Further, we believe that drugs encapsulated in our Bioral drug delivery technology may slowly fuse or break free of the cell and be available for another fusion event, either with this or another cell.

Stability. Our Bioral drug delivery technology employs cochleates which consist of multi-layered structures of large, continuous, solid, lipid bilayer sheets, either stacked or

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rolled up in a spiral, with little or no internal aqueous space. We believe that our cochleate preparations can be stored in cation-containing buffer, or dried to a powder, which is then stored at room temperature and reconstituted with liquid prior to administration. Our cochleate preparations have been shown to be stable for more than two years in cation-containing buffer, and at least one year as a powder at room temperature.

Resistance to Environmental Attack. Our Bioral drug delivery technology is being developed to provide protection from degradation of the encochleated drug. Traditionally, many drugs can be damaged from exposure to adverse environmental conditions such as sunlight, air, water and temperature. Since the multilayered structure consists of a series of solid layers, we believe that components within the interior of the cochleate structure remain intact, even though the outer layers of the cochleate may be exposed to these conditions.

Patient Compliance. We believe that a potential benefit of our cochleate technology may include reducing unpleasant taste, intestinal irritation, and in some cases providing oral availability.

Release Characteristics. Our cochleate technology may offer the potential to be tailored to control the release of the drug depending on desired application.

Initial Bioral Products in Development

We believe a diverse pipeline of products can be developed by applying our Bioral drug delivery technology to a potentially broad array of established and promising pharmaceuticals. Each intended Bioral product (i.e., drug encapsulated with our drug delivery technology) will, upon completion of development, require separate FDA regulatory approval, and accordingly, will be subject to the uncertainty, time and expense generally associated with the FDA regulatory process. Even though we are targeting FDA approved, market-accepted drugs for use in our Bioral technology, each of the products currently in development face development hurdles, regulatory requirements and uncertainty before market introduction. Due to our limited corporate resources, we are focusing primarily on our Bioral Amphotericin B formulation, as described below.

Bioral Amphotericin B

Fungal infections continue to be a major domestic and international health care problem. Amphotericin B, which is delivered intravenously, is an established, commonly used drug to treat these infections. We are currently developing a Bioral formulation of Amphotericin B for treatment of fungal infections which we expect will be for the treatment of esophageal candidiasis.

In February 2007, we announced the acceptance by the FDA of our Bioral Amphotericin B IND application we made at the end of 2006. This represents the first IND that involves the Bioral technology. In 2008, we completed the scale up manufacturing of Bioral Amphotericin B and conducted our initial Phase 1 single escalating dose human clinical trial. Forty-eight healthy volunteers participated in the study, with sixteen recruited for each of three dose groups. In each dose group, twelve volunteers received a single dose of Bioral Amphotericin B and four received a placebo. Amphotericin B plasma concentrations were measured over a period of fourteen days. The study identified doses that were well-tolerated with no meaningful changes in laboratory safety values including those associated with renal function.

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The preliminary pharmacokinetic evaluation, available in February 2009, revealed that plasma concentrations were comparable to those seen in prior animal toxicology studies using the same formulation. In previous animal studies we have conducted, doses used in toxicology studies have been shown to produce measureable tissue concentrations and efficacy against the fungal infections candidiasis and aspergillosis.

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

In late July 2005, we received an indication from National Institute of Allergy and Infectious Diseases, or NIAID, which is affiliated with the National Institutes of Health, or NIH, that the NIAID would, at its expense and following our achievement of certain milestones, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. We believe these studies, if they occur, represent an important third-party validation of our encochleation technology. We also believe these studies will result in cost savings for us as they are being funded by NIAID. In 2008, 28 day rat and dog toxicity studies were conducted which were funded in part through a contract from The National Institutes of Health, Divison of AIDS (DAIDS). We expect that the results of those studies will be available in the first quarter of 2009.

In 2005, we were able to source PS from lecithin derived from soybeans rather than synthetic PS, thereby reducing the costs of goods for our delivery system. In addition, we have simplified our manufacturing approach to Bioral Amphotericin B, thereby facilitating commercial scale-up. Also, we have changed the ratio of PS to active molecules, thus improving the efficacy while moderating costs. We continue investigating the pharmacology and toxicology.

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

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

The global antifungal market was approximately $3.1 billion in 2006 and is projected to grow to over $4 billion by 2016. According to our market research, annually, there are an estimated 500,000 severe fungal infections globally for which we believe Bioral Amphotericin B may be an appropriate treatment. Our market research indicates that Bioral Amphotericin B may be able to achieve projected peak sales of approximately $400 million annually for the treatment of esophageal candidiasis.

In the development of this drug, we have collaborated with the NIH, the Public Health Research Institute of New York, the Drugs for Neglected Diseases initiative, and the University of Kentucky. We have been awarded and received all funds under a grant totaling approximately $2.7 million from the NIH to support the further development of this drug formulation.

Separately, on April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from Mayo Foundation for Medical Education and Research, or the Mayo Foundation, for the treatment of CRS and asthma on a worldwide basis. The technology consists of using low-dose topical antifungal to control the debilitating symptoms of CRS and asthma. Presently, Accentia is developing the encochleated Amphotericin B

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formulation (which is called BioNasal®) for potential use in a pump spray for the treatment of CRS. Accentia has not yet determined if the application of Amphotericin B to the asthma field is feasible. Accentia will not submit an IND regarding the asthma application of intrapulmonary Amphotericin B, either encochleated or unencochleated, until and if the proof of principle is completed by the Mayo Foundation pursuant to the terms of the Accentia license with the Mayo Foundation. Formulation efforts for the CRS product are underway. Initial in vitro studies suggest that Bioral Amphotericin B may provide enhanced efficacy and stability in this context.

Our license agreement with Accentia was amended effective June 1, 2004, then modified in September 2004 by the asset purchase agreement with Accentia described below, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. According to the terms of the license as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales of covered products in the designated field. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

On September 8, 2004, we entered into a definitive Asset Purchase Agreement with Accentia pursuant to which we sold to Accentia an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of $2.5 million. The royalty revenue stream sold was a fifty percent (50%) interest in the future royalties earnable by us on sales by Accentia for products utilizing our topical formulation of our encochleated Amphotericin B for the treatment of CRS, thus effectively reducing our royalty on the sales of such CRS products by 50%. We agreed with Accentia, however, that the future royalty stream sold shall not include royalty payments that are payable by Accentia based on the sale of encochleated products exclusively intended to treat asthma, and the rights to such royalty payments, as originally set forth in the license agreement, shall remain with us.

Bioral siRNA

Small interfering RNA, or siRNA, is a class of oligonucleotides that may offer the ability to identify therapeutics directly based on genomic information of the host or pathogens. Like other oligonucleotide candidates such as antisense, siRNA is very susceptible to degradation by plasma enzymes. In 2006, we continued our collaboration and research efforts in this area. In August 2006, we announced the successful in vivo delivery of a Bioral siRNA therapeutic in a mouse model of influenza. The results of the study demonstrated a decrease of viral titers by 200 fold when administered by inhalation and a reduction of viral titers by almost 20 fold when administered intravenously. During 2008, we continued our ongoing evaluation agreement with one of the major companies developing siRNA therapeutics and we sought additional collaborations and strategic partners. If the results of the collaborations are positive, we intend to pursue the licensing of certain rights associated with the delivery of nucleic acids to these partners.

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Other Bioral Products. Other potential products in the Bioral system include Bioral Paclitaxel, Bioral NSAIDS, the Subunit HIV Vaccine and Autologous HIV therapy. In 2006, we decided that we would not at this time apply any internal resources to these programs and, hence, no further progress has been made. We may decide to pursue them at some future date, and they remain available for licensing.

Bioral Nutrient Delivery, LLC. In January 2003, we formed Bioral Nutrient Delivery, LLC, or BND, to investigate the potential application of our proprietary encochleation technology for use in processed food and beverages and personal care products. While our preliminary findings suggested that, by using our encochleation technology, a variety of nutrients, which are substances with potentially beneficial properties, might be protected from degradation during the manufacturing process and delivered with substantially all of the characteristics of the nutrient intact, the BND opportunity is not presently a high priority for us and we do not plan to utilize any corporate resources toward this application of the Bioral technology. BND is inactive at December 31, 2008.

Relationship with UMDNJ and Historical Relationship with Albany Medical College

We have had and continue to have critical relationships with UMDNJ and Albany Medical College. Some of our scientists were former researchers and educators at these Universities researching cochleate technology. All of our current research and development is done using facilities on the campus of UMDNJ, pursuant to a lease, or at the facilities of our contractors or collaborators. Both of these Universities are stockholders in our company and have a substantial financial interest in our business.

In September 1995, our predecessor company entered into a license agreement with the Universities to be the exclusive worldwide developer and co-licensor of the cochleate technology, in conjunction with the Universities right to permit the use of the technology by non-profit organizations for research purposes on a non-commercial basis. Under the license agreement, we and the Universities have also jointly patented certain aspects of the cochleate technology. Pursuant to the license agreement, we agreed that each University would be issued an equity interest in our capital stock, originally equal to 2% of our outstanding capital stock. These arrangements were subsequently revised in December 2002. On December 16, 2002, we amended our license agreement with the Universities to provide for a decrease in the royalty payments to be paid to the Universities on sublicenses in consideration of an increase in the royalty on product sales and the issuance to the Universities of options to purchase shares of our common stock. As of December 31, 2008, UMDNJ owned 139,522 shares (which include shares issued under a research agreement) and Albany Medical College owned 2,222 shares of our common stock. There are no further requirements to provide either University any additional equity interests in our company.

The license agreement, grants us an exclusive license to the cochleate technology owned by these Universities and obligates us to pay a royalty fee structure as follows:

(a) For commercial sales made by us or our affiliates, we shall pay to the Universities a royalty equal to 5% of net sales of cochleate products; and

(b) For commercial sales of cochleate products made by any of our sublicensees, we shall pay to the Universities royalties up to 5% of our revenues received from the sublicensee from the sale of such products.

Our royalty payments to the Universities will be divided equally among them pursuant to the license. In 2004, we accrued a $125,000 royalty payment to the Universities in connection with our $2.5 million asset sale to Accentia.

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We lease our research facilities totaling approximately 8,000 square feet at a cost of $5,340 per month located on the UMDNJ campus. We have been leasing space under a monthly contract since December 31, 2005 and we have engaged in discussions with UMDNJ regarding this space but anticipate that the monthly rent will not change. However, we may be unable to continue, extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations.

In addition to our rent payments, we have also agreed to pay for certain other services provided by UMDNJ. This includes one employee from UMDNJ of approximately $125,000 and a budget to purchase supplies and chemicals (adjusted to exact cost).

Research and Development

The significant majority of our research and development relating to our BEMA™ technology is conducted through third parties in collaboration with us. With respect to our Bioral™ technology, we perform most of our research and development in our Newark, New Jersey laboratory.

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 preclinical 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, 2008 and 2007, we spent approximately $10.9 million and $14.3 million, respectively, on research and development expenses, and such expenses represented approximately 60% and 66%, respectively, of our total operating expenses for such fiscal years. For the year ended December 31, 2008, Meda has reimbursed approximately $2.7 million of our research and development expenses, which represents approximately 25% of our total research and development costs.

Collaborative and Supply Relationships

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

Meda. On September 5, 2007, we entered into a definitive License and Development Agreement with Meda and our Arius subsidiary pursuant to which we and Arius agreed to grant to Meda an exclusive commercial license to market, sell, and, following regulatory approval, continue to commercial development of ONSOLIS in the United States, Mexico and Canada. We received a $30 million initial license fee payment in September 2007 and expect to receive additional milestone payments. Also, pursuant to the U.S. 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 from Meda, if we elect to co-promote, for a period of 3 years beginning 2 years after FDA approval of ONSOLIS . In addition, Meda is subject to certain minimum sales call and advertising and promotional expenditure requirements under the U.S. license agreement, and has agreed to support costs of clinical development undertaken following FDA approval to pursue approval of additional indications for ONSOLIS .

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We announced the expansion of our clinical development program for ONSOLIS in January 2008.

In August 2006, we announced a collaboration with Meda to develop and commercialize ONSOLIS in Europe. Under terms of the agreement, we granted Meda rights to the European development and commercialization of ONSOLIS , in exchange for an upfront fee, certain milestone payments, and double digit royalties to be received by us on product sales. Payments include a $2.5 million payment upon execution of the agreement. We received an additional $2.5 million payment March 2008 on completion of the clinical requirements for a European marketing application. We are entitled to additional milestone payments that would, if achieved, provide up to an additional aggregate of $5 million in revenue. Meda will manage the clinical development and regulatory submissions in all of Europe. Upon regulatory approval, Meda will exclusively commercialize ONSOLIS in Europe.

On January 2, 2009, we entered into amendments to both our U.S. and European agreements with Meda pursuant to which, respectively: (i) we received a $3.0 advance against our anticipated aggregate $30.0 million milestone payment from Meda upon FDA approval and commercial launch of ONSOLIS and (ii) in consideration of an additional $3.0 million, we granted to Meda the worldwide commercialization right to ONSOLIS , but excluding Taiwan and South Korea.

Aveva Drug Delivery Systems. Effective October 17, 2005, we entered into an agreement with Aveva Drug Delivery Systems, Inc. (which we refer to herein as Aveva) pursuant to which Aveva will supply ONSOLIS product to us for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of ONSOLIS for the United States, Mexico and Canada. We will pay for formulation development, commercial quantity scale-up work and the manufacture of clinical supplies, as well as for the cost of commercial supplies of ONSOLIS based on Aveva s fully-burdened cost of manufacturing such supplies plus an established profit margin. The agreement has an initial term which is subject to automatic renewal for additional terms unless either party provides notice of termination in advance of such renewal. In connection with this agreement, we issued Aveva a warrant to purchase up to 75,000 shares of our common stock (which shares vest based on the occurrence of specified milestones) at a price equal to $3.50 per share.

LTS Lohmann Therapie-Systeme AG. Effective December 15, 2006, we entered into a Process Development Agreement with LTS Lohmann Therapie-Systeme AG, or LTS, pursuant to which LTS will undertake process development and scale up activities and supply ONSOLIS product to us for European clinical trials. Under the terms of this agreement, LTS is anticipated to be the sole supplier of ONSOLIS for clinical trials and commercial distribution within the European Union. Further, under the agreement LTS has granted a license to European Patent No. 0 949 925, in regard to our ONSOLIS product in the European Union.
Effective February 2008, we entered into a Process Development Agreement with LTS pursuant to which LTS will undertake process development and scale up activities and supply BEMA Buprenorphine product to us for clinical trials. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BEMA Buprenorphine for clinical trials and commercial distribution throughout the world.

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Doyen Medipharm. On August 28, 2007, we agreed with Doyen Medipharm Inc. to purchase a BEMA related pharmaceutical device production machine. We have made payments or have accrued approximately $2.9 million (included in deposits on equipment in the accompanying condensed consolidated balance sheet) toward the total cost, which is approximately $3.3 million. Payments are being made in separate increments during the production of the equipment. As of December 2008, the equipment was in final testing at the Doyen Medipharm facility.

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

QLT. On May 27, 2004, prior to our acquisition of it, Arius entered into a worldwide, exclusive royalty-bearing license agreement with Atrix Laboratories (now a subsidiary of QLT) to develop, market, and sell products incorporating QLT s BEMA technology, including its ONSOLIS product, and to use the BEMA trademark in conjunction therewith. All research and development related to the BEMA technology, including three existing INDs, were transferred to Arius in accordance with the QLT license agreement. However, in August 2006, we purchased from QLT all of the non-U.S. rights to the BEMA drug delivery technology, including all patent rights and related intellectual property. The aggregate purchase price for the non-U.S. portion of the BEMA technology is $3 million, to be paid over time as follows: (i) $1 million was paid at closing, (ii) $1 million by the end of first quarter 2007 (which was paid March 30, 2007) and, (iii) $1 million to be paid within 30 days of regulatory approval of the first non-U.S. BEMA product. As part of the transaction as it relates to the non-U.S. portion of the former license with QLT, no further milestone payments or ongoing royalties will be due to QLT. In addition, we were granted the option to purchase the remaining U.S. asset for $7 million dollars.

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

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

Sigma-Tau. In January 2005, we signed a definitive licensing agreement with Sigma-Tau Pharma for the application of our Bioral cochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of U.S. $250,000 from Sigma-Tau. This upfront payment was made in consideration of unregistered shares of our common stock priced at $4.25 a share. The stock purchase agreement with Sigma-Tau provides for the acquisition by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of our common stock, up to an aggregate potential of $1.5 million worth of such shares. These milestones lead up to and include the submission of product INDs by Sigma-Tau Pharma for one or more of the four subject encochleated compounds

Working with Sigma-Tau s immunosuppressant compound, we were able during 2006 to undertake additional in vivo efficacy studies versus a subcutaneous formulation of the compound and a 28 day toxicology test. With the completion of this test, we have demonstrated of proof of principal. This was formally recognized by Sigma Tau in February 2007. We received a $250,000 payment which took the form of a purchase of our common stock by Sigma-Tau at a price of $3.38 per share. The results of these studies were published in 2008. Sigma Tau has not yet informed us of their decision concerning the further development of this product. We are currently not working on any other products in this capacity under this agreement with Sigma-Tau.

Walter Reed Army Institute for Research. In 2006, we entered into a Cooperative Research and Development Agreement (CRADA) with the Walter Reed Army Institute for Research (WRAIR) to investigate the use of Bioral Amphotericin B for the treatment of leishmaniasis. Leishmaniasis is a disease that can cause skin and other organ problems in personnel deployed to countries where it is common, such as Iraq and Afghanistan. Amphotericin B is highly effective in the treatment of leishmaniasis, but the practicality of utilizing currently available formulations of Amphotericin B is significantly limited by the requirement for intravenous administration. We continued to work with WRAIR on animal models in connection with this program during 2008.

Pharmaceutical Product Development, Inc. On December 31, 2002, we entered into an agreement with Pharmaceutical Product Development, Inc. (NASDAQ:PPDI), which we refer to herein as PPDI, pursuant to which PPDI was granted a license to apply our Bioral delivery technology to two therapeutic products. In connection therewith, we received a $2 million up-front royalty payment. In addition, the terms of the license require additional royalty payments based on regulatory milestones and a running royalty rate based on worldwide sales.

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Reckitt Benckiser Healthcare (UK) Limited. Effective January 6, 2004, Arius entered into an exclusive royalty-bearing license with Reckitt Benckiser Healthcare (UK) Limited to develop, market, and sell Reckitt s Emezine® (buccal prochlorperazine maleate) product for the treatment of nausea and vomiting in the United States, and to use the Emezine® trademark in conjunction therewith. Given the FDA non-approvable decision on this product in 2006, Reckitt terminated our agreement on December 17, 2008. All assets regarding the Emezine® agreement will be returned to Reckitt.

National Institutes of Health. To investigate the properties of new antifungal cochleate formulations, SBIR grants totaling approximately $2.7 million have been awarded to us by NIH for the development of our proposed Bioral Amphotericin B product. Additionally, we are conducting anti-fungal studies using our Bioral drug delivery technology through NIH selected and paid contractors. The NIH has reserved broad and subjective authority over future disbursements under the grant. While no objective or specific milestones for future disbursements have been established by the NIH, we must generally demonstrate to the satisfaction of the NIH that our research and use of proceeds are consistent with the goal of developing a formulation for the oral delivery of Amphotericin B. Furthermore, we are required to submit to the NIH an annual report of activities under the grant.

Additionally, in late July 2005, we received an indication from the NIAID, which is affiliated with the NIH, that the NIAID would, at its expense and following our achievement of certain milestones, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of Bioral Amphotericin B. We have continued our dialog with the NIAID concerning the performance of these studies during 2007. During 2008, two 28 day toxicology studies, one with rats and one with dogs, were funded in part from a contract through the National Institutes of Health, Divison of AIDS.

Other Bioral Collaborations. In 2006 and 2007, we entered into collaborations to combine the Bioral technology with other companies intellectual property in the form of Evaluation and Material Transfer Agreements. Some of these collaborations did not eventuate in license or other material agreements, and others were still ongoing in 2008. If promising, these may turn into licenses with significant financial terms, although we presently have no indications that any such licenses will be entered into.

We also have collaboration agreements with entities (including Accentia) that are affiliated with and partially-owned by key 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 PPDI, Accentia, Sigma-Tau and Meda are examples of these types of relationships, and we will continue to seek other similar arrangements.

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Competition

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

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

BEMA

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

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

For ONSOLIS , in the breakthrough cancer pain area, the principal competitor in the short-term remains Cephalon, Inc. (NASDAQ:CEPH). In 2008, the overall market for transmucosal fentanyl products for breakthrough pain totaled $744 million. The transmucosal fentanyl class has faced a challenging year following safety issues stemming from inappropriate use of Cephalon s Fentora® product 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®.

Cephalon s first product for the breakthrough cancer pain indication was Actiq® (oral transmucosal fentanyl citrate) which generated $130 million in sales in 2008. Cephalon licensed a generic of this product to Barr Laboratories upon approval of Fentora®. Total sales for generic versions of Actiq, available from Barr Laboratories and Watson Pharmaceuticals, totaled $432 million over the same period. Fentora® utilizes an effervescent tablet which is administered buccally. Fentora® was approved and launched in late 2006 and generated $182 million in sales in 2008.

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Endo Pharmaceuticals, who originally licensed Rapinyl , a polymer formulated sublingual fentanyl tablet in clinical development for breakthrough cancer pain, from Orexo AB, returned all rights to Orexo in 2008 following its own internal strategy changes. Prostrakan Group plc (LSE: PSK) announced in July 2008, that its licensing agreement with Orexo would be extended to include North America. Prostrakan is a specialty pharmaceutical company headquartered in Scotland and employees approximately 200 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 new 67-person U.S. sales force established in collaboration with NovaQuest (partnering group of Quintiles). In December 2008, Prostrakan announced receipt of marketing authorization from the German regulatory authorities for their fentanyl sublingual tablet (under the brand name Abstral) and launch is anticipated in Germany and the U.K. in early 2009, with further launches expected through the year. In the U.S., fentanyl sublingual tablet is in Phase 3 clinical development with regulatory submission expected in 2009.

Additional products are under development utilizing intranasal delivery of fentanyl include Nasalfent (Archimedes) and an intranasal fentanyl spray from Nycomed, while other companies are focusing on delivery using sublingual spray formulations. YM Biosciences, Akela Pharma/Janssen and Alexza are developing inhaled formulations of fentanyl for administration across the alveoli in the lungs. Recently, Alexza/Endo reported termination of their agreement to develop Staccato Fentanyl, and following downsizing and reorganization, Alexa plans no investment in its inhaled fentanyl product through 2009. Other potent pain products are also in development, including Javelin Pharmaceuticals, Inc. (AMEX:JAV) who is developing an intranasal morphine and AcelRx Pharmaceuticals with a sublingual tablet combining sufentanil and a benzodiazepine. 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 products may potentially have a higher level of abuse based on how they are delivered. Early trials of at least one of these products have demonstrated safety concerns by FDA, at least one product has been put on clinical hold and development suspended on another.

The chart below lists products in development that we believe may compete directly with ONSOLIS .

Product	Company	Description	Status
Actiq® (oral transmucosal fentanyl citrate)	Cephalon/Generics	Fentanyl lollipop, 2 generics	Marketed (2 generics)
Fentora (fentanyl buccal tablet)	Cephalon	Effervescent buccal tablet, irritation reported, dose capped at 800mcg	Marketed
ONSOLIS (BEMA Fentanyl)	BDSI	Buccal soluble film	Under FDA review

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Product	Company	Description	Status
Rapinyl /Abstral (fentanyl sublingual tablet)	Orexo/Prostrakan	Sublingual tablet	Phase 3 in U.S. Initiated Fall 2005 NDA submission expected in 1H09approved in Europe
Fentanyl nasal spray	Nycomed	Nasal spray	Phase 3 U.S.A., Marketing application filed in EU
Nasalfent®	Archimedes	Fentanyl nasal spray	Phase 3 Initiated January 2007
AD923	Sosei	Sublingual Sprayspray	Phase 1 U.S.A., Phase 3 rest of world
Fentanyl TAIFUN®	Akela/ Janssen (EU)	Dry Powder powder Inhaler	Phase 3
AeroLEF	YM Biosciences	Liposomal fentanyl delivered via nebulizer	Phase 2 FDA Placed on Clinical Hold (1/17/08)
AZ003-Stacatto Fentanyl	Alexza	Aerosolized fentanyl for inhalation	Phase 1 (Endo discontinued partnership; Clinical program on hold)

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 increasing prospect of healthcare reform in the U.S. are likely to have increasing influence on the pharmaceutical market, including pain products, since the cost of such products heavily rely on reimbursement and third party payers. Additionally, the increasing number of FDA imposed Risk Evaluation and Mitigation Strategy (REMS) programs result 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 a sales force and/or medical affairs infrastructure to implement effectively. At this time, it is unknown how receptive healthcare providers will be to components of a REMS program.

A number of products may be competitors to BEMA Buprenorphine. A potential focus will be to position BEMA Buprenorphine as a step up from NSAIDs and instead of or prior to Schedule II narcotics. Indications for such use include pain associated with severe arthritis and lower back conditions. Marketed competitors for these indications include Tramadol (Ultram® ER from PriCara) and the potent opioids such as Opana from Endo, OxyContin® from Purdue, Avinza® and Kadian® from King Pharmaceuticals and Duragesic® from Johnson & Johnson. Other competition includes multiple new chemical entities in clinical development with different mechanisms of action as well as various combination formulations. Additionally, a number of abuse deterrent formulations of pain products are currently under FDA review and clinical development using a variety of technologies, including Remoxy and Embeda (King Pharmaceuticals).

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BEMA Buprenorphine is also planned to have indications for the treatment of acute and chronic pain. Market competitors for these indications include but are not limited to: non-steroidal anti-inflammatory (NSAIDs, e.g. ibuprofen), COX-2 inhibitors (Celebrex® from Pfizer), Tramadol (Ultram ER® from PriCara, a division of Ortho-McNeil-Janssen Pharmaceuticals) and potent opioids (hydrocodone and oxycodone combination products from various companies).

Bioral Technology

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

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

Specific to Bioral Amphotericin B, competitors may include currently marketed liposomal amphotericin B products, such as AmBisome from Gilead Sciences, Inc. (NASDAQ:GILD) and Abelcet from Enzon Pharmaceuticals Inc. (NASDAQ:ENZN). Sales of liposomal Amphotericin B products were approximately $200 million in 2008. However, neither formulation is available in a dosing form that allows for oral administration. iCo Therapeutics Inc. is evaluating an oral formulation of amphotericin B under an exclusive option from the University of British Columbia. This product is a lipid-based reformulation of amphotericin B for oral administration. In 2008, iCo Therapeutics announced results of an animal study showing plasma levels of amphotericin B following oral administration of their product, iCo-009.

A potential differentiating factor is that we believe that our technology may have cell-targeted delivery attributes as well. Additional companies which are developing potentially competitive technologies in this area may include Enzon, Flamel Technologies S.A. (NASDAQ:FLML), and mdRNA (formerly Nastech Pharmaceutical Company Inc. (NASDAQ: MRNA) which we believe may be seeking to develop technologies for cell-targeted delivery of drugs. While we have limited information regarding these potential competitors and their development status and strategy, we believe that our technology may be differentiated because unlike these potential competitors, we seek to use our cochleate to encapsulate the therapeutic to achieve drug delivery into the interior of the cells such as inflammatory cells.

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

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Licenses, Intellectual Property and Proprietary Information

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

In general, the patent position of biotechnology and pharmaceutical organizations is considered to be uncertain and involves complex legal and technical issues. There is considerable uncertainty regarding the breadth of claims in patent cases and the degree of protection thus afforded. While we believe that our intellectual property position is sound and that we can develop our drug delivery technologies, it may be that our pending patent applications will not be granted or that our current or future intellectual property will not afford us protection against competitors. It is possible that our intellectual property will be successfully challenged or that patents issued to others may preclude us from commercializing our products. It is also possible that other parties could have or obtain patent rights which may cover or block our products or dominate our patent position.

BEMA Technology

The mucoadhesive erodible drug delivery device technology space is congested, although we do not believe that our BEMA products are in conflict with or dominated by or infringing any external patents and do not believe that we require licenses under these 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 ONSOLIS . We may be unable to obtain such licenses from the patent holders. If we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

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

Through Arius, and subject to our agreements with QLT, we own various patents and patent applications relating to the BEMA™ technology. Below is a table summarizing patents and patent applications we believe are of value to our business and technology platform relating to the BEMA delivery technology.

Patent Number	Country	Application Number	Application Date	Grant Date	Expiration Date	Title
5,800,832	U.S.	08/734,519	10/18/1996	9/1/1998	10/18/2016	Bioerodable Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces

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Patent Number	Country	Application Number	Application Date	Grant Date	Expiration Date	Title
6,159,498	U.S.	09/144,827	9/1/1998	12/12/2000	10/18/2016	(same as above)
Pending	U.S.	09/069,703	4/29/1998			Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
Pending	U.S.	11/069,089	3/1/2005			(same as above)
Pending	U.S.	12/141,858	6/18/2008			(same as above)
729 516	Australia	9 747 574	10/16/1997	5/17/2001	10/16/2017	(same as above)
769 500	Australia	2001/38924	10/16/1997	5/13/2004	10/16/2017	(same as above)
2,268,187	Canada	2,268,187	10/16/1997	6/5/2007	10/16/2017	(same as above)
3,964,465	Japan	10 519 467	10/16/1997	6/1/2007	10/16/2017	(same as above)
Pending	Japan	2005/182 632	10/16/1997			(same as above)
0 973 497	EP*	97910117.7	10/16/1997	12/11/2002	10/16/2017	(same as above)
Pending	Japan	2000/545 511	4/29/1999			(same as above)
Pending	Japan	2005/233 505	4/29/1999			(same as above)
746 339	Australia	9939678	4/29/1999	11/16/1999	4/29/2019	(same as above)
Granted	Canada	2,329,128	4/29/1999	3/18/2008	4/29/2019	(same as above)
1 079 813.1	EP**	99922753.1	4/29/1999	2/9/2005	4/29/2019	(same as above)
Pending	U.S.	11/639,408	12/13/2006			Abuse Resistance Transmucosal Drug Delivery Device
Pending	Austraila	2006/326377	12/13/2006			(same as above)
Pending	Canada	2,629,046	12/13/2006			(same as above)
Pending	Brazil	P10619806-6	12/13/2006			(same as above)
Pending	India	Pending	Pending			(same as above)
Pending	China	200680046781.1	6/12/2008			(same as above)
Pending	Japan	100102978	6/12/2008			(same as above)
Pending	Algeria	Pending	Pending			(same as above)
Pending	Europe	06,845,401.6	7/10/2008			(same as above)
Pending	U.S.	11/817,915	9/6/2007			Transmucosal Delivery Devices With Enhanced Uptake
Pending	Europe	Pending	Pending			(same as above)
Pending	Austraila	Pending	Pending			(same as above)
Pending	Belarus	Pending	Pending			(same as above)
Pending	Brazil	Pending	Pending			(same as above)
Pending	Canada	Pending	Pending			(same as above)
Pending	China	Pending	Pending			(same as above)
Pending	South Korea	Pending	Pending			(same as above)
Pending	India	Pending	Pending			(same as above)
Pending	Isreal	Pending	Pending			(same as above)
Pending	Japan	Pending	Pending			(same as above)
Pending	Mexico	Pending	Pending			(same as above)
Pending	New Zealand	Pending	Pending			(same as above)

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Patent Number	Country	Application Number	Application Date	Grant Date	Expiration Date	Title
Pending	Russian Federation	Pending	Pending			(same as above)
Pending	Singapore	Pending	Pending			(same as above)
Pending	South Africa	Pending	Pending			(same as above)
Pending	Ukraine	Pending	Pending			(same as above)
Pending	United Arab Emirates	Pending	Pending			(same as above)
Pending	U.S.	61/074,918	6/23/2009			Multidirectional Mucosal Delivery Devices and Methods of Use

* Validated in Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Greece, Ireland, Italy, Netherlands and Sweden.

** Validated in Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

Cochleate Technology and Products

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

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

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

Below is a table summarizing patents we believe are currently of value to our business and technology position relating to the Bioral delivery technology.

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Patent Number	Country	Application Number	Application Date	Grant Date	Expiration Date	Title
Pending	U.S.	11/578,187	1/24/2008			Nucleotide-Cochleate Compositions and Methods of Use
Pending	Australia	2005/244,262	11/3/2006			(same as above)
Pending	Canada	2,562,499	4/11/2005			(same as above)
Pending	Europe	05 776 976.2	11/6/2006			(same as above)
Pending	Hong Kong	07 107 141.6	7/3/2007			(same as above)
Pending	Japan	2007/507,542	4/11/2005			(same as above)
Pending	U.S.	11/653,093	1/11/2007			Cochleate Compositions Directed Against Expression of Proteins
Pending	Europe	04 759 369.4	4/9/2004			(same as above)
Pending	Japan	2006/509875	10/11/2005			(same as above)
Pending	PCT	PCT/U.S.2007/018553	8/22/2007			Amphiphilic Nucleotide Cochleate Compositions and Methods of Using the Same
5,643,574	U.S.	08/130,986	10/4/1993	7/1/1997	7/1/2014	Protein- or Peptide-Cochleate Vaccines and Methods of Immunizing Using the Same
689,505	Australia	1994000079590	9/30/1994	4/2/1998	9/30/2014	(same as above)
00 722 338	Europe***	949 304 84.4	9/30/1994	7/25/2001	9/30/2014	(same as above)
5,840,707	U.S.	08/394,170	2/22/1995	11/24/1998	11/24/2015	Stabilizing and Delivery means of Biological Molecules
5,994,318	U.S.	08/803,662	2/21/1997	11/30/1999	11/24/2015	Cochleate Delivery Vehicles
Pending	Australia	2006/236 007	11/14/2006			(same as above)
753,008	Australia	32599/00	8/15/2002	1/23/2003	2/22/2016	(same as above)
Pending	Australia	2002/300 615	2/22/1996			(same as above)
Pending	Australia	2006/236 007	11/14/2006			(same as above)
2,212,382	Canada	2,212,382	2/22/1996		2/22/2016	(same as above)
2,169,297	Canada	2,169,297	9/30/1994	10/22/2002	2/21/2014	(same as above)
2,246,754	Canada	2,246,754	2/21/1997	10/22/2002	2/21/2017	(same as above)
0 812 209	Europe*	969 063 34.6	2/22/1996	5/6/2004	2/22/2016	(same as above)
Pending	Japan	8-525713	2/22/1996			(same as above)
Pending	Japan	2007/122 913	5/7/2007			(same as above)
6,592,894	U.S.	09/613,840	7/11/2000	7/15/2003	1/22/2019	Hydrogel-Isolated Cochleate Formulations, Process of Preparation and Their Use for the Delivery of Biologically Relevant Molecules

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Patent Number	Country	Application Number	Application Date	Grant Date	Expiration Date	Title
6,153,217	U.S.	09/235,400	1/22/1999	11/28/2000	1/22/2019	Nanocochleate Formulations, Process of Preparation And Method of Delivery of Pharmaceutical Agents
Pending	U.S.	12/148,942	4/23/2008			(same as above)
Pending	Australia	2007/200 813	2/23/2007			(same as above)
Pending	Canada	2,358,505	1/24/2000			(same as above)
1 143 933	Europe**	0 0909 961.5	1/24/2000	7/25/2007	1/24/2020	(same as above)
Pending	Japan	2000/594 446	1/24/2000			(same as above)
Pending	U.S.	10/701,364	11/3/2003			Geodate Delivery Vehicles
Pending	Australia	2003/296,923	11/3/2003			(same as above)
Pending	Canada	2,504,329	11/3/2003			(same as above)
Pending	Europe	03 810 828.8	11/3/2003			(same as above)
Pending	Japan	2005/502 267	11/3/2003			(same as above)
Pending	U.S.	11/653,434	1/11/2007			Novel Encochleation Methods, Cochleates and Methods of Use
Pending	Europe	04 759 375.1	11/9/2005			(same as above)
Pending	U.S.	61/109,450	10/29/2008			Encochleation of siRNAs with Covalently attached Lipid Tails
6,165,502	U.S.	09/188,120	11/9/1998	12/26/2000	9/11/2016	Protein-Lipid Vesicles and Autogenous Vaccine Comprising the Same
5,834,015	U.S.	08/712,020	9/11/1996	11/10/1998	9/11/2016	(same as above)
6,340,591	U.S.	09/210,578	12/14/1998	1/22/2002	12/14/2018	Integrative Protein-DNA Cochleate Formulations and Methods for Transforming Cells

* Validated in Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

** Validated in Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

*** Validated in United Kingdom, Ireland, Italy, Germany, France, Sweden, Austria and Switzerland.

Manufacturing

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

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ONSOLIS

Effective October 17, 2005, we entered into an agreement with Aveva pursuant to which Aveva will supply ONSOLIS to us for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of ONSOLIS for the United States and Canada.

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

BEMA Buprenorphine

Effective February 8, 2008, we entered into a Process Development Agreement with LTS pursuant to which LTS will undertake process development and scale up activities and supply BEMA Buprenorphine product to us for clinical trials and commercial distribution throughout the world. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BEMA Buprenorphine commercial product throughout the world. Further, under the agreement LTS has granted a license to European Patent No. 0 949 925 in regard to ONSOLIS in the European Union.

As our other intended products near market introduction, we intend to outsource manufacturing to third party manufacturers, which comply with the FDA s applicable Good Manufacturing Practices. We are currently seeking manufacturing partners for certain of our products and formulations and believe that such commercial manufacturing arrangements are likely to be available to us.

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

Sales and Marketing

Following (and assuming) completion of our clinical development and regulatory approval for each proposed product, we will pursue one of several approaches (or a combination thereof) for marketing our products. These include licensing the products to appropriate partners so that they can market and distribute the products for us. We have already implemented this strategy with regard to our lead product, ONSOLIS , with our U.S. and European partnership with Meda, which was expanded to include rest of world (with the exception of Taiwan and South Korea.)

In September 2006, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for ONSOLIS in the European Union. Under terms of the agreement, we granted Meda rights to the European development and commercialization of ONSOLIS (which will be marketed in Europe under the trade name BREAKYL), in exchange for an upfront fee to be paid to us, certain milestone payments and double digit royalties to be received by us on product sales. Payments include a $2.5 million payment upon execution of the agreement and additional milestones that would, if achieved, provide us with up to an additional aggregate of $7.5 million in revenue. Meda will manage the clinical development and regulatory submissions in Europe. Upon regulatory approval, Meda will exclusively commercialize ONSOLIS in Europe.

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We made progress in 2008 toward preparations for the approval and launch of ONSOLIS in Europe. We have focused our activities in Europe on gaining thought leader input and building support through the use of advisory boards and other meetings. Data has also been presented at some of the important European medical conferences including the 11th Congress of the European Association for Palliative Care, and numerous publications are under development.

In September 2007, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for ONSOLIS covering the United States, Canada and Mexico. Under the terms of the September 2007 agreement, Meda is responsible for the sales, marketing and distribution of ONSOLIS in the U.S., Canada and Mexico. The agreement between us and Meda outlines specific marketing minimum expenditures and sales call volumes in addition to minimum royalty payments beginning in the second full year of sales. The agreement specifies that ONSOLIS will be detailed in the primary position for a specified duration among target prescribers, and that we will have the option for a future co-promotion of ONSOLIS to be subsidized by Meda. Additionally, Meda is responsible for all post-approval clinical studies and label expansion trials, including the clinical development activity for ONSOLIS in patients with breakthrough pain associated with other non-cancer related conditions such as back pain and osteoarthritis.

We made significant progress in 2008 toward preparations for a commercial launch of ONSOLIS™, particularly in the United States. Meda has invested in efforts to prepare the market for the introduction of ONSOLIS . Pre-launch activities have included exhibits and sponsorships at major scientific and medical conferences, where efforts were focused on the benefits of the BEMA drug delivery technology. A comprehensive publication plan was executed to build awareness of data from the clinical development program. In 2008, a total of 14 abstracts were accepted to major U.S. medical meetings and conferences, including the American Pain Society (APS) and the American Society of Clinical Oncology (ASCO). Data was presented with 11 scientific posters, and numerous full publications were in process or submitted to medical journals. A substantial amount of marketing research has also been undertaken to solidify key aspects of the future promotion and promotional materials for ONSOLIS . An advertising agency and medical education companies were contracted to develop promotional materials and educational programs. Advertising and medical education providers have been selected to implement the pre-launch and launch product strategy, and to support educational activities that are part of the comprehensive REMS program.

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

We believe that securing a commercial partner for two major global pharmaceutical markets will allow us to competitively launch ONSOLIS without the burden associated with a significant increase in expenditures or headcount otherwise associated with a commercial launch. Additionally, we believe our commercial partnership with Meda will allow internal efforts to be focused on the development of additional product opportunities. Partner efforts will focus on pain specialists, oncologists and other relevant healthcare professionals specifically providing care for patients with breakthrough cancer pain. Our agreements with Meda provide additional benefit by leveraging a single commercial partner for a global launch of ONSOLIS .

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Government Regulation

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

In the United States, drugs are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our drugs. Drug development and approval within this regulatory framework is difficult to predict, requires a number of years and involves the expenditure of substantial resources. Moreover, ongoing legislation by Congress and rule making by the FDA presents an ever moving landscape where we could be required to undertake additional activities before any governmental approval is granted allowing us to market our products.

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

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

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

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

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

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

In addition to obtaining FDA approval for each product, each product-manufacturing establishment must be registered with, and approved by, the FDA. Manufacturing establishments are subject to biennial inspections by the FDA and must comply with the FDA s Good Manufacturing Practices for products, drugs and devices.

Pre-clinical Trials

Pre-clinical testing includes laboratory evaluation of chemistry and formulation, as well as tissue culture and animal studies to assess the safety and potential efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices. Pre-clinical testing is inherently risky and the results can be unpredictable or difficult to interpret. The results of pre-clinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of clinical trials. Unless the FDA objects to an IND, clinical studies may begin thirty (30) days after the IND is submitted.

We have relied and intend to continue to rely on third party contractors to perform pre-clinical trials.

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Clinical Trials

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA prior to its conduct. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution where the study will be conducted. The institutional review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The drug product used in clinical trials must be manufactured according to Good Manufacturing Practices.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the product into healthy human subjects, the drug is tested for safety (adverse side effects), absorption, metabolism, bio-distribution, excretion, food and drug interactions, abuse potential as well as limited measures of pharmacologic effect. Phase 2 is the proof of principle stage and involves studies in a limited patient population in order to:

- assess the potential efficacy of the product for specific, targeted indications;
- identify the range of doses likely to be effective for the indication; and
- identify possible adverse events and safety risks.

When there is evidence that the product may be effective and has an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to establish and confirm the clinical efficacy and establish the safety profile of the product within a larger population at geographically dispersed clinical study sites. Phase 3 frequently involves randomized controlled trials and, whenever possible, studies are conducted in a manner so that neither the patient nor the investigator knows what treatment is being administered. We, or the FDA, may suspend clinical trials at any time if it is believed that the individuals participating in such trials are being exposed to unacceptable health risks.

We intend to rely upon third party contractors to advise and assist us in the preparation of our INDs and the conduct of clinical trials that will be conducted under the INDs. Seven studies have been performed since 2005 under the IND for ONSOLIS . Multiple preclinical studies were conducted with Bioral Amphotericin B and one clinical study was done in 2008. One human pharmacokinetic study was conducted with BEMA Buprenorphine in 2006 and a second initiated in 2008. We expect that additional studies in normal volunteers and potentially patients will be performed with ONSOLIS , BEMA Buprenorphine and Bioral Amphotericin B in 2009.

New Drug Application and FDA Approval Process

The results of the manufacturing process development work, pre-clinical studies and clinical studies are submitted to the FDA in the form of a New Drug Application (NDA) for approval to market and sell the product. The testing and approval process is likely to require substantial time and effort. In addition to the results of pre-clinical and clinical testing, the NDA applicant must submit detailed information about chemistry, manufacturing and controls that will describe how the product is made and tested through the manufacturing process. The manufacturing process continues to develop throughout the period of clinical trials such that at the time of the NDA, it has been demonstrated that there is control of the process and the product can be made consistently at commercial scale.

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

The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Consequently, there is a risk that approval may not be granted on a timely basis, if at all. The FDA may deny an NDA if applicable regulatory criteria are not satisfied, require additional testing or information or require post-marketing testing (Phase 4) and surveillance to monitor the safety of a company s product if it does not believe the NDA contains adequate evidence of the safety and efficacy of the drug. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or health problems are identified that would alter the risk-benefit analysis for the product. Post-approval studies may be conducted to explore the use of the product for new indications or populations such as pediatrics.

Among the conditions for NDA approval is the requirement that any prospective manufacturer s quality control and manufacturing procedures conform to Good Manufacturing Practices and the specifications approved in the NDA. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of drug and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by other federal, state or local agencies. Additionally, in the event of non-compliance, FDA may issue warning letters and seek criminal and civil penalties, enjoin manufacture, seize product or revoke approval.

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 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 or local 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.

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Employees

As of March X, 2009, we have 20 full-time employees and 2 part-time employees. Four are laboratory scientists and 11 are involved in our clinical and program development and operations and eight handle our administration, accounting and information technology. Advanced degrees and certifications of our staff include five Ph.D s, two Pharm.D s, one M.D., one J.D., one LL.M., one M.B.A. and two CPA s. 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.

Risk Factors

An investment in our company is extremely risky. You should carefully consider the following risks, in addition to the other information presented in this Report before deciding to buy or exercise our securities. If any of the following risks actually materialize, our business and prospects could be seriously harmed, the price and value of our securities could decline and you could lose all or part of your investment.

Risks Relating to Our Business

Since we have not generated any revenues from the sale of products to date and have incurred significant losses since inception, you cannot rely upon our historical operating performance to make an investment decision.

Since our inception in January 1997 and through December 31, 2008, we have recorded accumulated losses totaling approximately $92.2 million. As of December 31, 2008, we had a working capital deficit of approximately $43.7 million. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed formulations and products, obtain the required regulatory approvals and manufacture, market and sell our proposed formulations and products. We may be unable to achieve these goals.

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

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

As a result of our current lack of financial liquidity, continued losses and a negative stockholders deficit, our auditors report for our 2008 financial statements, which are included in this Report, contains a statement concerning our ability to continue as a going concern. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

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

We may need to raise additional capital to continue our operations, and our failure to do so would significantly impair our ability to fund our operations, develop our technologies, attract commercial partners or promote our formulations or products.

Our operations have relied almost entirely on external financing to fund our operations. 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 loans. At December 31, 2008, we had cash of approximately $1.0 million. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) and financings we have undertaken prior to the date of this Report, that our current working capital and committed financing will be sufficient to satisfy our contemplated cash requirements through approximately the second quarter of 2009, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could effect our cash requirements.

We expect to receive an additional aggregate $31.9 million from Meda representing milestone payments in connection with FDA approval and commercial launch of ONSOLIS in both the U.S. ($26.9 million) and Europe ($5 million). However, if ONSOLIS is not approved in either or both of the U.S. and Europe and we do not receive such payments, and given that our current cash on hand will not fully fund all development costs of our leading product formulations, we may need to raise additional capital to fund our anticipated operating expenses and progress our business plans. If ONSOLIS is not approved, we may be unable to find the needed capital, whether from external sources or related parties, to progress our business plan. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make the raising of capital more difficult and may also result in a lower price for our securities.

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 an approved product and revenues from sales, as well as the inherent business risks associated with our company and present and future market conditions. Our business currently does not generate any sales, and current sources of revenue are limited and may not be sufficient to meet our present and

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future capital requirements. We have expended and plan to continue to expend substantial funds in the research, development and pre-clinical and clinical testing of our drug delivery technologies and product candidates. We will require additional funds to conduct research and development, establish and conduct pre-clinical and clinical trials, secure clinical and commercial-scale manufacturing arrangements and provide for the marketing and distribution, especially if ONSOLIS is not approved by the FDA and we therefore do not receive expected additional milestone payments from Meda. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs, product launches or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are subject to numerous risks.

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

- the number of potential formulations, products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drug formulations or products;
- costs involved in establishing manufacturing capabilities for commercial quantities of our drug formulations or products;
- competing technological and market developments;
- market acceptance of our drug formulations or products;
- costs for recruiting and retaining employees and consultants;
- costs for training physicians; and
- legal, accounting, insurance and other professional and business related costs.

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

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

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

If we breach our agreements with CDC, CDC has rights to gain control of our ONSOLIS asset.

Under our agreements with CDC, if we do not meet certain conditions, CDC can assume control of the ONSOLIS product and related intellectual property assets. For example, in the event that we do not diligently pursue the development and regulatory approval of ONSOLIS or encounter certain specified negative circumstances regarding the development of ONSOLIS , CDC has the right to require the assignment of our ONSOLIS assets to CDC and to pursue development and commercialization of ONSOLIS pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense. CDC has made claims against us in the past under our agreements with them. Our loss of ONSOLIS to CDC would have a material adverse effect on our business.

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.

Acceptance of our formulations or products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Our future financial performance will depend, at least in part, upon the introduction and physician and patient acceptance of our proposed formulations or products. Even if approved for marketing by the necessary regulatory authorities, our formulations or products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- receipt of regulatory clearance of marketing claims for the uses that we are developing;
- establishment and demonstration of the advantages, safety and efficacy of our formulations, products and technologies;

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pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;

our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our proposed formulations or products; and

our ability to market our formulations or 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 proposed formulations or products. If we are unable to obtain regulatory approval, or are unable to manufacture, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

We are dependent on our collaborative agreements for the development of our drug delivery technologies and business development which exposes us to the risk of reliance on the viability of third parties.

In conducting our research and development activities, we currently rely, and will continue to rely, on numerous collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements is our U.S. and European commercialization agreements with Meda and our manufacturing development and supply agreement with Aveva and LTS relating to ONSOLIS and with LTS relating to BEMA Buprenorphine. The loss of, or failure to perform by us or our partners under, any applicable agreements or arrangements, or our failure to secure additional agreements for other products in development, would substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials. 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 commercialization partner for our lead product ONSOLIS .

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

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

Our business exposes us to likely product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims will 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.

Since we do not currently have any FDA-approved products or formulations, we do not currently have any product liability insurance covering commercialized products, and we maintain liability insurance relating only to clinical trials on our products in development. We may be unable to obtain or

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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 could have a material adverse effect on our business, financial condition and results of operations.

We may be sued by third parties who claim that our products, and formulations, methods of manufacture or methods of use infringe on their intellectual property rights.

We may be exposed to future litigation by third parties based on claims that our technologies, 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 are complex. Any litigation or claims against us, whether or not valid, could result in substantial costs, could place a significant strain on our financial and human resources and could harm our reputation. Most of our license agreements require that we pay the costs associated with defending this type of litigation. Such a situation may force us to do one or more of the following:

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

With respect to our BEMA™ delivery technology, the mucoadhesive erodible drug delivery device technology space is congested. There is a risk that a court of law in the United States or elsewhere could determine that ONSOLIS or another of our BEMA™ based products is in conflict with or covered by external patents. We have a been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market ONSOLIS within the countries of the European Union. Freedom to operate searches and analyses is currently ongoing, but has not been completed for other proposed BEMA™ based products.

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

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If a lawsuit were to be filed against us for patent infringement, we would incur significant attorney costs to defend ourselves. Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our Bioral and/or BEMA™ products (including, without limitation, ONSOLIS). We may be unable to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, we might be precluded from developing or commercializing these products, which would likely have a material adverse effect on our results of operations and business plans.

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

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

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

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

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements provide that materials and confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. 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.

Although our trade secrets and technical know-how are important, our continued access to

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patented technology is a significant factor in the development and commercialization of our drug delivery products. Aside from the general body of scientific knowledge from other drug delivery processes and lipid technology, access to patented technologies, to the best of our knowledge and based upon our current scientific data, is the only intellectual property necessary to develop and apply our Bioral ™ and BEMA™ drug delivery systems to the drugs to which we are attempting to apply them.

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 is 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 and products.

Key components of our drug delivery technologies 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, and lipids, are currently purchased from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

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

Except for our agreements with Aveva and LTS, we do not have long-term agreements with any of our suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. Any interruption in the supply of components from Aveva or other third party suppliers could cause us to seek alternative sources of supply or manufacture these components internally. If the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient purity or in volumes within required time frames, if at all, to meet our 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, components from a new supplier may not be identical to those provided by the original supplier. Such differences, if they exist 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 our products.

Our expertise is primarily in the research and development and pre-clinical and clinical trial phases of product development. We have more limited experience or expertise in the formulation and manufacturing of our products and 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 may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample

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commercial supplies to successfully launch and maintain the marketing of our products. Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to commercialize our products.

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

We expect that we will be required to enter into agreements with commercial partners (such as our agreements with Meda) to engage in sales, marketing and distribution efforts around our products in development. 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, 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.

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

Use of our proposed formulations and products may require physicians to be informed regarding our proposed pharmaceutical formulations or products and the intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully 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

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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 formulations or products is created, if at all.

We currently rely on the facilities of the University of Medicine and Dentistry of New Jersey (UMDNJ) for a significant portion of our research activities relating to our Bioral technology, which activities could be materially delayed should we lose access to those facilities.

We have no research and development facilities of our own. As of the date of this Report, we are entirely dependent on third parties to use their facilities to conduct research and development. To date, we have relied on UMDNJ for this purpose in relation to our Bioral technology, as well as third party providers of testing and trial services. Additionally, the Universities own certain of the patents to our encochleation drug delivery technology. Our inability to conduct research and development, or our inability to find suitable third party providers of research and development services on an outsourcing basis, may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technologies, formulations and products.

We leased our research facility from UMDNJ, which expired December 31, 2005. We are currently leasing the space on a month to month basis. No assurances can be given that we will be able to continue, extend or renew this arrangement, and we may decide to relocate, scale back and/or outsource such operations. Should the lease expire or if we are otherwise are required to relocate on short notice, we do not currently have an alternate facility where we could relocate. The cost and time to establish or locate an alternative research and development facility to develop our technologies, or to find suitable third party providers of research and development services on an outsourcing basis, could be substantial and might delay gaining FDA approval and commercializing our formulations and products, assuming that we have not defaulted on the terms of our intellectual property licenses and can continue with our approval process.

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

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Risks Related to Our Products in Development and Regulation

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

Our research and development activities and the manufacture and marketing of our proposed formulations and products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA or foreign regulatory clearance to market our proposed formulations and products, we will have to demonstrate that our formulations and products are safe and effective on 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, we may never receive regulatory approval of our proposed products and formulations, and we have received one non-approvable letter from the FDA in the past regarding our Emezine® NDA. 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. This is especially true with respect to our lead product, ONSOLIS , on which we submitted an NDA in October 2007. We expect a decision by FDA on our ONSOLIS NDA during the second quarter of 2009. However, it is possible that a decision by FDA could come after such date.

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

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

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

The required capital and time-frame necessary to achieve these developmental milestones is uncertain, and we may not be able to achieve these milestones for any of our proposed formulations or products in development. Our failure to meet these or other critical milestones would adversely affect the viability of our company.

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

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do 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 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 without FDA approval.

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

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

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

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

We rely, in large part, on drug delivery technologies that we license from third parties such as the Universities and QLT. Although we have purchased the BEMA™ technology from QLT, we may be unable to fulfill our obligations under such agreement. The loss of our key technologies would seriously impair our business and future viability. After the expiration of these licenses, this technology may not continue to be available on commercially reasonable terms, if at all, and may be difficult to replace. The loss of any of these technologies 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 may license in the future could prevent the implementation or impair the functionality of our products or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

Competitors in the drug development or specialty pharmaceutical industries may develop competing technologies or products which outperform or supplant our technologies or products.

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

Should competing or dominating technologies could come into existence and the owners of such technology patent these 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 inability to manufacture, market and sell the impacted products would have a material adverse effect on us.

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Our lead product candidates contain tightly controlled narcotic ingredients. 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 lead product candidates, most notably ONSOLIS and BEMA™ Buprenorphine, contain tightly controlled and highly regulated narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. The FDA or the U.S. Drug Enforcement Administration, or DEA, currently impose and may impose additional regulations concerning the development, manufacture, transportation and sale of prescription narcotics. Such regulations include labeling requirements, the development and implementation of risk management programs, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. This is particularly true with respect to the Risk Evaluation and Mitigation Strategy (REMS) that FDA has 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. In either case, 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 our products in development 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 lead products in development, including fentanyl and buprenorphine, 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.

Furthermore, the DEA limits the availability of the active ingredients used in our products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to complete clinical trials or meet commercial demand. We must annually apply to the DEA for procurement quota in order to obtain these substances. The DEA may not establish procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides 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 or product launches which could have a material adverse effect on our business and results of operations.

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Risks Related to Our Industry

The market for our proposed formulations and products 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 and proposed formulations or products 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 diversifying into the field is intense and is expected to increase. Many of these entities 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.

We are engaged in the development of drug delivery technologies. As a result, our resources are limited and we may experience technical 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 technology. 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 proposed formulations or products 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 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 could materially harm our business, financial condition and results of operations.

Our ability to commercialize our proposed formulations or products 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. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

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

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. We currently have a general liability policy with an annual aggregate limit of $2 million with a $2 million limit per occurrence which does not exclude coverage for product liability for commercial products, but only would cover up to the foregoing amounts. All of our pre-clinical trials have been and all of our proposed pre-clinical and clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have insurance relating to product liability or insurance related to pre-clinical or clinical trials only with respect to our developmental product portfolio, for which we have a clinical trial liability policy providing for a $2 million aggregate limit. 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 affordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs. Product liability claims or other claims related to our proposed formulations and 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 drug delivery technology. 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 programs like ONSOLIS , such partners may face similar insurance related risks.

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

In connection with our research and development activities and our manufacture of materials and drugs, we 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. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development may in the future involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. The hazardous chemicals that we currently use, which may change as our research progresses, are chloroform and methanol. We are authorized to use these and other hazardous chemicals in our facilities through our affiliation with the UMDNJ. UMDNJ also disposes these chemicals from our premises as part of our agreement to use the facilities and carries general liability insurance in this regard. Although we believe that our safety procedures for storing, handling and disposing of such materials will comply with the standards prescribed by state and federal regulations, 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.

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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 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 36.21% of our outstanding common stock. These figures do not reflect any future potential exercise of common stock purchase warrants (including those issued to Laurus, CDC and others) into shares of common stock.

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

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

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

Dr. O Donnell, who is the Chairman of our board of directors and also is a substantial beneficial owner of our securities through HCG II, 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.

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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, Dr. Mannino is a member of the board of directors of Biovest International, Inc. (Pink Sheets:BVTI.PK), a subsidiary of Accentia, and Mr. McNulty is employed 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.

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

We have commercial ties to Accentia, a related party, through our license agreement with them and the sharing of certain corporate resources. On November 10, 2008, Accentia and its subsidiaries, including Biovest International, Inc. filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. As such, there is a risk that projects which we are working on with Accentia may not progress in the future and that we may not receive royalty payments which we are due from Accentia.

Risks Related to Our Common Stock

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

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

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

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

We are authorized to issue 45 million shares of our common stock. As of March 20, 2009, there were 19,248,302 shares of common stock issued and 19,232,812 shares of common stock outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. We will likely, subject to the approval of our stockholders, increase the size of our option plan at our next annual meeting of stockholders. To the extent such options (including options under our larger, amended option plan) or warrants are exercised, the holders of our common stock may experience further dilution.

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

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

We have a material number of shares of common stock underlying securities of our company, the future sale of which could depress the price of our publicly-traded stock. As of the date of this Report, (i) 3,503,467 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.56 per share, and (ii) 5,848,765 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.69 per share. If and when these securities are exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

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

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

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

authorizing the issuance of blank check preferred stock without any need for action by stockholders;

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

permitting stockholder action by written consent; and

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

These provisions could allow our board of directors to affect your rights as a stockholder since our board of directors can make it more difficult for common stockholders to replace members of the board. 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.

Item 2. Description of Property.

In November 2007, we relocated our principal executive offices to Raleigh, North Carolina. The lease for this approximately 5,500 square foot space has a term of approximately 63 months and base rent for this term is $589,454, payable in monthly installments, and subject to yearly price increases and increases for our share of common area maintenance costs. The landlord for this space is Highwoods Realty Limited Partnership. We believe this space is adequate as our principal executive office location.

We conduct our research operations at a single site located on the campus of UMDNJ. We are currently leasing this space month to month at a cost of $5,340 per month. We also make payments to UMDNJ for certain executive salaries and facility expenses which totaled $120,000 and approximately $6,000, respectively for 2008. We may be unable to enter into a long term lease for this laboratory space, and we may decide to relocate, scale back or outsource some or all of such operations.

Item 3. Legal Proceedings.

Not applicable.

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

None.

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PART II

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

Our common stock is listed for quotation on the NASDAQ Capital Market under the symbol BDSI . The range of reported high and reported low sales prices per share for our common stock for each fiscal quarter during 2008 and 2007, as reported by the NASDAQ Capital Market, is set forth below.

Quarterly Common Stock Price Ranges

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

Fiscal Year 2007, Quarter Ended:	High	Low
March 31, 2007	$ 5.96	$ 2.25
June 30, 2007	$ 8.26	$ 3.92
September 30, 2007	$ 5.11	$ 3.55
December 31, 2007	$ 3.95	$ 2.45

As of March X, 2009, we had approximately 166 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain any earnings for further business development.

We have never declared or paid any cash dividend on our common stock. We currently intend to retain any potential future earnings and do not expect to pay any dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (c)
Equity compensation plans approved by security holders	3,500,000	$ 3.56	
Equity compensation plans not approved by security holders	3,467(*)	$ 2.54	
Total	3,503,467	$ 3.56	

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(*) As of the date of this Report, we have issued stock options under our Amended and Restated 2001 Incentive Plan in excess of the 3,500,000 shares of common stock currently authorized under such plan. Any such excess issuances are subject to approval by our stockholders. Readers are advised that we plan on proposing an increase in the number of shares available for issuance under our Amended and Restated 2001 Incentive Plan to be voted upon at our upcoming 2009 Annual Meeting of Stockholders.

Item 6. Selected Financial Data.

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

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those which are not within our control.

Background of Our Company

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

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. Our NDA for ONSOLIS was submitted and accepted for filing by the FDA in the fourth quarter of 2007. Upon signing our U.S. commercialization agreement with Meda, we received an up-front, non-refundable payment of $30.0 million. Additional payments aggregating $30.0 million (of which $3.0 million was advanced to us by Meda in January 2009) are due when the FDA approves ONSOLIS and the product is launched. The target date for FDA approval of ONSOLIS was August 31, 2008, with Meda s expected launch in the fourth quarter of 2008, or within 90 days of expected approval. However, on August 28, 2008 we announced receipt of a Complete Response letter from the FDA regarding our NDA for ONSOLIS . The FDA has requested we make modifications to the submitted risk management program. All aspects of the review were complete and no deficiencies were noted in chemistry, manufacturing and controls, nonclinical, or clinical efficacy/safety. We submitted the requested information in the fourth quarter of 2008 and anticipate a first half of 2009 FDA approval. Assuming Meda s commercial launch of ONSOLIS occurs as expected, we will begin receiving royalties from Meda from sales of ONSOLIS in the third quarter 2009.

We expect to continue research and development of our drug delivery technologies, some of which will be funded by Meda under specific programs as described below. We will continue to seek

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additional license agreements, which may include up-front payments. For all other programs and products under development, revenues and payments (other than milestone payments under our Meda agreements) in 2009 are expected to be nominal. We anticipate that funding for the next several years will come primarily from milestone payments and royalties from Meda, potential sale of securities, collaborative research agreements, including those with pharmaceutical companies and potential exercises of our warrants.

We have a relatively limited history of operations, and while we have received: (i) up-front non-refundable license payments in 2007 and 2008 (which are classified as deferred revenue), (ii) revenue from the sale of a royalty stream in 2004, (iii) research and collaboration revenues and (iv) minimal royalty revenue from a license with Accentia, 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 evolving 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, seek regulatory approval for and commercialize our proposed products, which may not occur. We may not be able to appropriately address these risks and difficulties.

Moreover, as a result of our lack of financial liquidity and negative stockholders equity, there is substantial doubt about our ability to continue as a going concern. Our auditors report for our 2008 financial statements, which are included as part of this Report, contains a statement concerning this matter.

Critical Accounting Policies and Estimates

Valuation of Goodwill and Intangible Assets

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for based on Financial Accounting Standard Statement No. 142 *Goodwill and Other Intangible Assets* (FAS 142). As described below, goodwill is not amortized but is tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Our carrying value of goodwill at December 31, 2008 was $2.72 million.

We amortize intangible assets with limited useful lives using the straight-line method over their estimated period of benefit. Such period ranges from ten to twelve years. A number of factors are considered for these estimations, including the longevity of our license agreements. Our carrying value of other, amortizing intangible assets at December 31, 2008 was $5.83 million, net of accumulated amortization of $1.6 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test has two steps. The first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired and the second step is not necessary. If the carrying value exceeds the fair value, the second step calculates the possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded. The determination of goodwill impairment is highly subjective. It considers many factors both internal and external and subject to significant changes from period to period. No goodwill impairment charges have resulted from this analysis for 2008 or 2007.

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In accordance with SFAS 144, which relates to impairment of long-lived assets other than goodwill (our other amortizing intangibles), impairment exists if the sum of the future estimated undiscounted cash flows related to the asset is less than the carrying amount of the intangible asset or to its related group of assets. In that circumstance, then an impairment charge is recorded for the excess of the carrying amount of the intangible over the estimated discounted future cash flows related to the asset.

In making this assessment, we predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our impairment testing. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In addition, selection of a risk-adjusted discount rate on the estimated undiscounted cash flows is susceptible to future changes in market conditions, and when unfavorable, can adversely affect our original estimates of fair values. In the event that our management determines that the value of intangible assets have become impaired using this approach, we will record an accounting charge for the amount of the impairment. No impairment charges have been recorded to other amortizing intangible in either 2008 or 2007.

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

We account for stock-based awards to employees and non-employees using the accounting provisions of SFAS 123R *Accounting for Share-Based Payments,* which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our common stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

We use the Black-Scholes options-pricing model to determine the fair value of stock option and warrant grants. In applying the Black-Scholes options-pricing model during 2008, we assumed no dividend yield, risk-free interest rates ranging from 2.67% to 3.88%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor range between 54.41% to 87.13% and option exercise prices ranging from $2.01 to $2.93.

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

Revenue Recognition

Meda License, Development and Supply Agreements:

We recognize revenue associated with the Meda Agreements in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104), Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), and EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Our deliverables under the Meda Agreements, including our related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 7 to the accompanying financial statements.

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Based on our assessment upon inception of each arrangement, all deliverables of the Meda Agreements have been accounted for as one combined unit of accounting and as such, all cash payments from Meda (upfront payments and product development research and development services revenue) related to these deliverables have been recorded as deferred revenue.

Upon delivery of the license rights to Meda (date of first commercial sale in each territory), we will recognize revenue associated with the license and the research and development services rendered related to development of the ONSOLIS product through the date of FDA and other governmental approval delivered to Meda. A portion of the upfront payments will be attributed to our continuing obligation to participate in joint committees with Meda and to provide certain other specified services and this revenue will be recognized as services are provided through expiration of the license agreements.

Research and development services revenue associated with the non-cancer indication and further development of the first indication for treatment of breakthrough cancer pain of the ONSOLIS product which have been performed prior to the commencement of the license term has been deferred and will be recognized upon delivery of the license rights to Meda. Services provided subsequent to commencement of the license term will be recognized when the services are performed, if all other revenue recognition criteria are met. Based on the guidance of EITF 99-19, we have determined that it is acting as a principal under the Meda Agreements and, as such, will record these amounts on a gross basis as research and development services revenue.

Revenue associated with product sold to Meda prior to the commencement of the license term has been deferred and will be recognized upon delivery of the license rights to Meda. Subsequent to the commencement of the license term, we will recognize revenue for product supplied to Meda when title and risk of loss have passed to Meda and the remaining criteria in SAB 104 have been met. Based on the guidance of EITF 99-19, we have determined that we are acting as a principal as it relates to these activities under the product supply agreements and, as such, will record the amounts on a gross basis as product supply revenue.

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

Accounting for Meda License, Development and Supply Agreements:

In August 2006 and September 2007, we entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda to develop and commercialize ONSOLIS , a drug treatment for breakthrough cancer pain delivered through our patented BEMA technology (applied to the inner cheek mucosa) in the United States, Mexico and Canada and in certain countries in Europe. 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 refer to the agreements entered into with Meda covering the European Union (subsequently amended in January 2009 to cover worldwide rights, excluding Taiwan, South Korea and North America) as the Meda EU Agreements and the agreements enter into with Meda covering North American as the Meda U.S. Agreements.

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

	Contractual Cash Flow Upfront and Milestone Payments			Cash Flows Received and Revenue Deferred	
Contractual Rights and Obligations	**U.S. Arrangement**	**EU Arrangement**	**As Delivered**	**December 31, 2008**	**December 31, 2007**
License rights to ONSOLIS (BEMA Fentanyl) patents and trademarks	$ 30,000,000	$ 5,500,000**		$ 32,500,000	$ 32,500,000
Milestones:					
FDA approval	$ 15,000,000*	n/a			
Completion of Phase 3 clinical trials	n/a	$ 2,500,000		$ 2,500,000	
Governmental Approval in an EU country	n/a	$ 2,500,000			
Earlier of date of first commercial sale or availability of launch supply product inventory	$ 15,000,000	n/a			
Date of first commercial sale in an EU country	n/a	$ 2,500,000			
Research and Development Services for:					
ONSOLIS product through FDA approval			None		
ONSOLIS product through governmental approval in a EU country			Contract Hourly Rates	$ 1,553,624	
Non-cancer subsequent indication of product and further development of initial product			Contract Hourly Rates	$ 1,135,412	
Other services:					
Participation on Steering, Development, and Commercialization Committees			None		
Other contractual services			None		
Product supply			Company s Fully-burdened Cost		
Royalties			Contract percentage of product net sales revenue		
Commercialization bonuses			Up to $30,000,000		
Total				$ 37,689,036	$ 32,500,000

* We received a $3.0 million advance in January 2009 against the $15.0 million approval milestone.

** Includes $3.0 million received January 2009 for expansion of EU license.

We have assessed the arrangement deliverables under the guidance of Emerging Issues Task Force Issue No. 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) to determine which deliverables to these arrangements are considered separate units of accounting at the inception of the arrangement and upon delivery of the items required in the arrangements. The application of EITF 00-21 requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

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We have determined that upon inception of both the Meda U.S. Agreements and Meda EU Agreements, 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. As such, all cash payments from Meda related to these deliverables have been recorded as deferred revenue. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain research and development services deliverables will have been delivered to Meda and an estimated $59.5 million (under Meda U.S. Agreements) and $14.4 million (under the Meda EU Agreements) of the aggregate upfront and product development milestones payments will be recognized as revenue using the residual method. In the twelve months ended of 2008, we reclassified approximately $36.1 million of deferred revenue from non-current to current based on management s estimate that this deferred amount will be recognized within the twelve months ended December 31, 2009.

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 and 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 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 for by us. We 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 for treatment of breakthrough cancer pain of the ONSOLIS product and (3) the combined requirements related to the remaining other service-related obligations due Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.6 million (under the Meda U.S. Agreements) and $0.2 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided over the performance period through expiration of the license terms, as defined above.

Based on Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), we have 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 consolidated financial statements.

We will earn royalties based on a percentage of net sales revenue of the ONSOLIS product. Product royalty revenues are computed on a quarterly basis when Meda s third-party sales revenues are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met. Commercialization bonuses represent additional nonrefundable royalties due if commercial sales exceed certain predefined thresholds. They will be recognized as revenue if and when they are earned.

License Arrangements

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

Non-refundable, upfront fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue over the established or

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estimated term of the license when the license arrangement commences and the licensed data, technology and/or product or supplies to manufacture the product is delivered. Such deliverables may include physical quantities of products, supplies, or design of the products, the conceptual framework and mechanism of actions taken by a third party, and rights to the patents or patents pending for such products.

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

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

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

Royalty and Contract Revenues

Royalty revenue amounts are recognized as revenue on a monthly basis based on net sales under our license agreement with Accentia relating to CRS. This is shown as royalty revenue, related party on the accompanying consolidated statements of operations. In accordance with generally accepted accounting principles in the United States, or GAAP, and our revenue recognition policy, the Meda up-front and milestone payments of $2.5 million in 2006, $30.0 million in 2007, $2.5 million in 2008 and the $6.0 million received in January 2009 (as discussed in subsequent events) have been recorded as deferred revenue, and will be recognized in accordance with our revenue recognition policy once commercialization revenues begin.

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.

For the Year Ended December 31, 2008 Compared to the Year Ended December 31, 2007

Royalty and Contract Revenues. We recognized $0.05 million and $0.07 million in royalty revenue during the years ended 2008 and 2007, respectively, under our license agreement with Accentia relating to CRS. In addition, we also recognized $0.2 million and $0.1 million of revenue related to various contractor agreements during the years ended 2008 and 2007, respectively.

License revenues. In accordance with GAAP and our revenue recognition policy, the Meda up-front payments of $2.5 million in 2006, $30.0 million in 2007, $2.5 million in 2008, and the $6.0 million received on January 2,

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2009 (as discussed in subsequent events) from Meda have been recorded as deferred revenue, and will be recognized in accordance with our revenue recognition policy over the license term once commercialization revenues begin.

Research and Development Expenses. During the years ended December 31, 2008 and 2007, research and development expenses totaled $10.9 million and $14.3 million, respectively. Our scientific staff continued to work toward increased development and application of our BEMA and Bioral cochleate technologies, but particularly with respect to ONSOLIS . Funding of this research in 2007 and 2008 was obtained through deferred license revenue, sponsored research revenue, exercise of options by employees and directors and sales of securities. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA and Bioral drug delivery technologies.

General and Administrative Expenses. During the years ended December 31, 2008, and 2007, general and administrative expenses totaled $7.3 million and $7.5 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, executive personnel costs, consulting fees and business development costs. General and administrative expenses in 2008 are primarily related to salary expense, professional and legal fees incurred in connection with our licensing transactions, patent costs, stock-based compensation and investor relations.

Product Development Expense. Product development cost in 2007 was related to warrant expense. In 2007, we issued 25,000 warrants valued at $0.03 million in connection with milestones achieved with our third-party manufacturer of ONSOLIS . There were no such product development costs in 2008.

Interest Income (Expense), Net. During the year ended December 31, 2008, we had net interest expense of $0.46 million, compared to $2.24 million in 2007. The decrease in net interest expense is primarily due to amortization of debt discount and interest converted by Laurus for the two convertible notes fully converted to common stock by April 2007. Interest income was $0.17 million and $0.28 million in 2008 and 2007 respectively.

Derivative Gain (loss). Derivative gain in 2008 and 2007 is related to the adjustment of derivative liabilities to fair value as of December 31, 2008 and December 31, 2007. These derivatives relate to the Laurus financing (see Notes 1 and 9 to financial statements) and warrants issued to CDC and HCG II.

Debt extinguishment (loss). During the year ended December 31, 2007, we had a debt extinguishment loss related to the debt modification that arose from the amendments to the Laurus convertible term notes and related deferral warrants.

Income Tax Benefit and tax net operating loss carryforwards. While we had positive cash flow from operations in 2007 as a result of the Meda non-refundable up-front payment of $30.0 million in the third quarter of 2007, which is treated for GAAP purposes as deferred revenue, we incurred net operating losses during both years presented. We did not recognize any benefit associated with the 2008 or 2007 loss. We had federal and state net operating loss carryforwards (NOL) of approximately $35.1 million and $28 million at December 31, 2008, respectively. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 for state purposes. Financial Accounting Standards Board Statement No.109 provides for the recognition of deferred tax assets if realization is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured. Under Section 382 and

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383 of the Internal Revenue Code of 1986, as amended, 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. We have determined that such an ownership change occurred on May 16, 2006. Approximately $23.1 million of the NOL was generated before the ownership change, and is subject to limitation on an annual basis. Our annual limitation for utilizing this portion of the NOL is approximately $1.5 million.

Major Research and Development Projects

In 2008, we continued to dedicate the vast majority of our corporate resources to the development of ONSOLIS and, to a lesser extent, BEMA Buprenorphine and Bioral Amphotericin B. Substantial amounts of money were devoted to the manufacturing efforts required to support the commercial launch of ONSOLIS and the preclinical and clinical development of Bioral Amphotericin B and BEMA Buprenorphine. Clinical research expenses in 2008 were dedicated to initial studies with Bioral Amphotericin and BEMA Buprenorphine. Further clinical development of ONSOLIS is the responsibility of Meda both in the U.S. and Europe.

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

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

ONSOLIS . We licensed the U.S. rights to the BEMA drug delivery technology from QLT. We acquired this license when we acquired Arius in August 2004. In August 2006, we purchased the non-U.S. rights to the technology from QLT for a total of $3.0 million; $1.0 million was paid in August 2006, and a note for $1.0 million due in March 2007 was paid. The final $1.0 million is due upon European approval of a BEMA product. The agreement included an option to buy the U.S. rights within 12 months of the non-U.S. purchase. We exercised our option in September 2007 with a payment to QLT of $3.0 million, a note for $2.0 million which is due upon FDA approval of ONSOLIS , and a final $2.0 million due when net sales reach $30.0 million. As a result of these transactions, and subject to making final payments to QLT, we now own the BEMA technology and will have no royalty obligations to QLT.

Our lead BEMA product ONSOLIS is a formulation of the narcotic analgesic medication fentanyl. In 2005, we announced that we received confirmation from the FDA that we could utilize the FDA s 505(b)(2) process for submission of the NDA for ONSOLIS . As a result of this guidance, we began our preparations for Phase 3 clinical studies in the fourth quarter of 2005. In early 2006, we began enrollment on the Phase 3 clinical studies. We projected that due to the nature of treating patients with breakthrough cancer pain, our patient recruitment process for the ONSOLIS clinical program

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would take anywhere from 6 to 18 months. Subsequently, we completed enrollment in our efficacy study (FEN 201) and reported our findings in April 2007. The data demonstrated that our primary efficacy endpoint of the Summary of the Pain Intensity Difference at 30 minutes (SPID 30) was statistically significantly different from placebo (p value less than 0.0004). We completed the analysis and documentation of the results from our FEN 201 study as well as our FEN 202 safety study and submitted them as part of our NDA for ONSOLIS on October 31, 2007. The FDA subsequently accepted our NDA for filing on December 31, 2007, and provided us with a PDUFA date (i.e., the date by which FDA expects to provide a decision on the approvability of an NDA) of August 31, 2008. In August 2008, we received a Complete Response Letter from FDA citing a new requirement for approval, the preparation and submission of an acceptable Risk Evaluation and Mitigation Strategy (REMS). Submission of this document was made in December of 2008 and FDA has a 6 month period prior to the action date. It is possible, however, that FDA could take longer to review the resubmission.

We believe that ONSOLIS may have the potential to capture a significant share of the breakthrough cancer pain market in the U.S., which we estimate could result in annual projected peak sales of over $200 million, on which we will pay a royalty to CDC. We do not expect to generate any royalty revenue from ONSOLIS until into the third quarter of 2009.

In addition, our U.S commercialization agreement with Meda includes a provision under which Meda will fund all of our non-cancer breakthrough pain program costs. In January 2008, we announced the expansion of our clinical development program for ONSOLIS to assess the efficacy and safety of the product for the treatment of breakthrough pain associated with other chronic pain conditions beyond cancer. Initial preclinical studies to support long term toxicology testing were performed in 2008 with the full toxicology program scheduled to start, following FDA agreement, in 2009. Clinical studies are also anticipated to start in 2009. Meda will be fully responsible for funding the expanded development program in non-cancer breakthrough pain.

The risks to our company associated with the ONSOLIS project include: (i) delays in reaching agreement with FDA on an acceptable REMS and on otherwise obtaining FDA approval of ONSOLIS ; (ii) claims of CDC against the ONSOLIS intellectual property or otherwise; (iii) inability of our contract manufacturer to make commercial supplies or meet our commercial supply requirements; (iv) the development of unexpected safety issues with the product; and (v) failure of our commercial partner Meda to launch and sell the product. The failure of the ONSOLIS project for these or any other reason, or a failure of the product to meet commercial forecasts, would seriously impair our viability, including revenues, investor confidence and potentially our public stock price, as we believe ONSOLIS is the first of our products with a significant market opportunity.

BEMA Buprenorphine. BEMA Buprenorphine will be our second BEMA analgesic product. This product is not covered under any commercial marketing agreements. We submitted an IND for BEMA Buprenorphine to the FDA in December 2005 which was accepted by the FDA. We conducted an initial Phase 1 single dose pharmacokinetic trial in normal volunteers during 2006 which demonstrated that therapeutic blood concentrations of the active ingredient could be achieved in these healthy volunteers. In 2008, additional clinical trial supplies were manufactured at LTS in Germany and a second single dose study in normal healthy volunteers was started in November 2008. The preliminary results of this study, announced in March 2009, were favorable, and as a result, we plan to begin our Phase 2 program to evaluate its effectiveness in a dental pain model in June 2009. The Phase 2 program will likely require 6 months to complete, including data analysis. If we meet our Phase 2 objectives, we would then move into our Phase 3 program during the first half of 2010, under which we would be treating patients who have acute moderate to severe postoperative pain with the doses identified from our Phase 2 program. The BEMA Buprenorphine Phase 3 program for an acute pain indication may take up to 24 months to complete from the time Phase 2 is started. After completing the Phase 3 program, it would

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likely take approximately 3 to 6 months to compile and submit our NDA to the FDA. After submission, the FDA will then have up to 10 months from the date of the submission to render a decision on the approvability of our application. If the FDA approves the application, we would anticipate launching the product within 3 months of that approval.

Due to the ability of BEMA Buprenorphine to participate in the key pain markets (chronic pain, acute pain, post-operative pain), we believe that BEMA Buprenorphine has the potential to achieve up to a 5% share of the $10 billion dollar U.S. market for the opioid narcotics. This would translate into over $500 million in peak annual sales. We do not expect to generate any royalty revenue from sales of BEMA Buprenorphine, if ever, until at least 2011. We may begin partnering discussions for BEMA Buprenorphine in 2009, depending on our progress in our Phase 1 and Phase 2 programs, as described above.

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) lack of corporate funding to progress the program; (iv) failure of clinical trials; (v) product safety issues; (vi) clinical trial data that does not support an NDA submission; (vii) failure of or delay by the FDA to approve an NDA; (viii) failure to secure a commercial partner for the product or to develop our own internal commercial capability; and (ix) failure of a commercial partner or us to effectively launch and sell the product. A technical or commercial failure of BEMA Buprenorphine would have a material adverse effect on our future revenue stream, and could negatively affect investor confidence in our company and potentially our public stock price.

Bioral Amphotericin B. We license the encochleation drug delivery technology which we use in our Amphotericin B formulation from the Universities. We filed the IND on this oral formulation of Amphotericin B, for the treatment of fungal infections including esophageal candidiasis in the fourth quarter 2006. The IND was accepted by the FDA. We began Phase 1 studies in normal volunteers in the second half of 2008. These studies assessed the oral absorption and safety of Amphotericin from our cochleate formulation in normal volunteers. Preliminary results were announced in December 2008. Following completion of Phase 1 trials, we will move into a Phase 2 study in patients in late 2009. Based on the outcome of our Phase 2 program our Phase 3 program could start sometime in 2010. A Phase 3 program would run approximately 18-24 months after which we would spend approximately 3-6 months compiling and submitting the NDA. If the FDA accepts the NDA for filing, they will then have up to 10 months from the date the submission is accepted to decide whether the application is approvable. If we receive approval within this timeframe we would be prepared for a product launch within 3 months from this time. We may be unable to complete any clinical phase of clinical trials.

Our market research indicates that as a treatment for esophageal candidiasis, Bioral Amphotericin B formulation may be able to achieve projected peak sales of approximately $400 million annually, on which we will pay a royalty to UMDNJ. We do not anticipate generating any revenue for Bioral Amphotericin B, if ever, until at least late 2012.

The risks to our company associated with the Bioral Amphotericin B project include: (i) inability of a contract manufacturer to produce clinical supplies; (ii) Phase 1 not showing significant oral absorption of product; (iii) failure of subsequent clinical trials, including if the Phase 2 study shows drug is ineffective in treating the fungal infection in question; (iv) product safety issues; (v) lack of corporate funding to progress the program; and (vi) failure to effectively commercialize the product.

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

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily from the private sales of our convertible preferred stock, convertible debt and common stock, our public offering in 2002 and follow-on public offering in 2005, exercise of options, various strategic and licensing agreements (including the CDLA and our Meda Agreements), NIH grants, bank financing, and through the sale of a royalty stream asset.

In September 2004, we entered into an Equity Line of Credit Agreement with HCG II, an affiliated entity which is controlled and partially-owned by our Chairman. Pursuant to the Equity Line Agreement, as amended March 30, 2006, HCG II was obligated, as requested by us, to invest up to $4.0 million in our company through December 31, 2006, in consideration of shares of our Series B Convertible Preferred Stock. As of December 31, 2006, $1.45 million was drawn under the Equity Line Agreement. The holders of the Series B Preferred were entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred were convertible into shares of our common stock at a price equal to $4.25 per share, at any time as of or after April 1, 2006, or earlier upon a change of control of our company. On January 10, 2007, HCG II converted all 341,176 shares of Series B Convertible Preferred Stock of our company into 341,176 shares of common stock. No other consideration was paid. HCG II also acquired 59,226 shares of common stock pursuant to the conversion of accrued and unpaid dividends on the Series B Preferred Stock.

In January 2005, we signed a definitive licensing agreement with Sigma-Tau Pharma for the application of our Bioral nanocochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of U.S.$250,000 from another Sigma Tau-related entity. This upfront payment was made in consideration of unregistered shares of our common stock priced at $4.25 a share. The stock purchase agreement with Sigma-Tau provides for the acquisition by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of our common stock, up to an aggregate potential of $1.5 million worth of such shares. Such additional unregistered shares will be issued at the lesser of: (i) $4.25 and (ii) the average of the closing trade price of our common stock for the ten (10) trading days through and including the applicable payment date, with an absolute floor $3.38 per share. In January 2007, under our development agreement with Sigma Tau, we were paid a milestone payment of $250,000 for which we issued 73,964 shares of common stock at $3.38. Sigma-Tau, through other holding entities, is currently a stockholder of our company. In addition to the milestone payments, we will receive a royalty on future sales of each of the four products which may arise from the encochleated compounds.

In February and May 2005, we closed two separate $2.5 million secured convertible debt financings from Laurus. Net proceeds from the financing have been used primarily to support our research, development and commercialization opportunities and for general working capital purposes. The February 2005 Laurus note and May 2005 note were both fully converted into shares of our common stock as of April 2007. As of December 31, 2007, the balances owed were zero.

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On May 16, 2006, we consummated a transaction with CDC pursuant to which $7 million in funds previously committed by CDC under the CDLA to fund our clinical development of ONSOLIS was converted into shares of our common stock at a value of $3.50 per share. As a result of this transaction, CDC was issued 2 million shares of our common stock and 904,000 warrants at $3.50 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 $7 million milestone repayment to CDC which had been required under the same agreement upon the approval by the FDA of ONSOLIS .

In August 2006 and September 2007, we received up-front non-refundable payments in connection with our license, development and supply agreements with Meda of $2.5 million and $30.0 million, respectively. In March 2008 we received a milestone payment of $2.5 million in connection with our Meda EU Agreements.

In March 2007, we entered into a $1.9 million loan financing with CDC. This financing involved a one-year, 10.25% loan from CDC and a warrant to purchase 1 million shares of our common stock with an exercise price of $3.80. This loan was repaid in March 2008.

At December 31, 2008, we had cash and cash equivalents of approximately $1.0 million. The adequacy of cash for our operations and continued research is dependent on, among other things, licensing and milestone payments, and additional equity or debt financing opportunities that we are able to negotiate in the coming year. We used $9.8 million of cash from operations in the year ended December 31, 2008. This resulted from a net loss of $17.2 million, which included net non-cash charges of $2.5 million. We received a milestone payment from Meda of $2.5 million, and were reimbursed and additional $2.5 million of costs incurred on the non-cancer breakthrough pain program, which increased our deferred revenue accordingly. Finally, our accounts payable and accrued liabilities were reduced by $0.2 million.

We invested an additional $2.0 million in 2008 in special equipment we will require for packaging ONSOLIS , which together with $0.7 million expended in 2007 and final payments of $0.6 million in 2009 will result in total cost of the equipment of $3.3 million, which we intend to finance upon acceptance and validation of the equipment.

We have incurred significant net losses and negative cash flows from operations since our inception. As of December 31, 2008, we had stockholders deficit of $33.6 million, versus $18.8 million at December 31, 2007.

We anticipate that cash used in operations and our investment in facilities will continue beyond our ONSOLIS agreements with Meda, as we research, develop, and, potentially, manufacture and commercialize additional drug formulations with our BEMA and Bioral technologies. While we believe further application of our BEMA and Bioral technologies to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, our plan of operations for the foreseeable future will be focused on our further development of the BEMA and Bioral technologies and their use in a limited number of applications. Such focus will not be on the marketing, production or sale of FDA approved products.

Until FDA approval, we are required under our Meda agreement to pay certain chemistry, manufacturing and control, as well as clinical and regulatory costs associated with the NDA, as well as

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manufacturing and packaging equipment costs for ONSOLIS . Our agreement with Meda requires all pre-launch marketing and commercialization costs for ONSOLIS to be paid by Meda, as well as all required amendments or change to risk assessment and mitigation programs, clinical costs associated with ONSOLIS after FDA approval. Meda will pay for costs of Phase 3-b and Phase 4 studies which, although not required as part of our NDA, may be done to support the program with additional market data.

Under our existing Meda Agreements, we expect to receive additional payments aggregating $31.9 million upon approval and commercial launch of ONSOLIS in the U.S. ($26.9 million) and Europe ($5 million). We expect a decision from FDA regarding ONSOLIS in the first half of 2009. We received an advance of our approval milestone of $3.0 million and $3.0 million for expansion of the Meda EU license on January 2, 2009. Additional capital may be required in order to proceed with our support of the launch of ONSOLIS , clinical development programs for BEMA Buprenorphine and Bioral Amphotericin B (the scale of which is dependent in part on the success of ONSOLIS and on the results from our Phase I studies for each of these products), and for general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

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

Until FDA approval, we are required under our Meda Agreements to pay certain chemistry, manufacturing and control and clinical and regulatory costs associated with the ONSOLIS NDA, as well as manufacturing and packaging equipment costs for ONSOLIS . The Meda Agreements require all pre-launch marketing and commercialization costs for ONSOLIS to be paid by Meda, as well as all required clinical costs associated with ONSOLIS after FDA approval. Meda will pay for costs of Phase 3-b and Phase 4 studies which, although not required as part of our ONSOLIS NDA, may be done to support the program with additional market data. In addition, Meda is paying for the development costs for ONSOLIS in non-cancer breakthrough pain.

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

Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned basic operations (minimal research and development activities beyond those covered under our Meda and other related agreements), debt repayment obligations and capital expenditures through the second quarter of 2009.

However, we may never receive FDA approval or the timing of such approval, if received, may

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take substantially longer than anticipated. Additional capital will be required in order to proceed with our support of the commercial launch of ONSOLIS , clinical development programs for other products in our pipeline, such as BEMA Buprenorphine and Bioral Amphotericin B (the scale of which is dependent in part on the success of ONSOLIS and on the results from our clinical studies for each of these products), and for general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

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

Readers are cautioned that additional capital may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations in 2009 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2008 are as follows:

	Payments Due by Period				
	Total	**2009**	**2010**	**2011**	**thereafter**
Long-term and short-term debt	$ 76,666	$ 76,666	$	$	$
Leases	505,436	118,371	121,794	125,318,	139,953
Employment agreements	870,413	822,089	48,324		
Total contractual cash obligations	$ 1,452,515	$ 1,017,126	$ 170,118	$ 125,318	$ 139,953

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Off Balance Sheet Arrangements

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

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

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

Item 8. Financial Statements.

Our Consolidated Financial Statements and Notes thereto and the report of Cherry, Bekaert & Holland, LLP, our independent registered public accounting firm, are set forth on pages F-1 through F-27 of this Report.

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

On June 5, 2008, Aidman, Piser & Company, P.A. (Aidman Piser) resigned as our independent registered public accounting firm. Effective May 1, 2008 Aidman Piser s practice was acquired by Cherry, Bekaert & Holland, L.L.P. (Cherry Bekaert) in a transaction pursuant to which Aidman Piser merged its operations into Cherry Bekaert and certain of the professional staff and partners of Aidman Piser joined Cherry Bekaert either as employees or partners of Cherry Bekaert and will continue to practice as members of Cherry Bekaert. On June 5, 2008, and concurrently with the resignation of Aidman Piser, we, through and with the approval of the Audit Committee of our board of directors, engaged Cherry Bekaert as its independent registered public accounting firm.

Prior to engaging Cherry Bekaert, we did not consult with Cherry Bekaert regarding the application of accounting principles to a specific completed or contemplated transaction or regarding the type of audit opinions that might be rendered by Cherry Bekaert on our financial statements, and Cherry Bekaert did not provide any written or oral advice that was an important factor considered by us in reaching a decision as to any such accounting, auditing or financial reporting issue.

The report of Aidman Piser regarding our financial statements for the fiscal year ended December 31, 2007 did not contain any adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles, except that substantial doubt was raised as to our ability to continue as a going concern. During the year ended December 31, 2007 and during the period from the end of the most recently completed fiscal year through June 5, 2008, the date of resignation, there were no disagreements with Aidman Piser on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Aidman Piser, would have caused it to make reference to such disagreement in its reports.

Item 9A(T). Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, at December 31, 2008, such disclosure controls and procedures were effective.

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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 fourth fiscal quarter ended December 31, 2008 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 accounting principles generally accepted in the United States of America. 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.

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Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2008. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2008.

This Report does not include an attestation report of our registered public accounting firm regarding our internal controls over financial reporting. The disclosure contained under this Item 9A was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only the disclosure under this Item 9A(T) in this Report.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of March 20, 2009 are as follows:

Name	Age	Position(s) Held
Francis E. O Donnell, Jr., M.D.	59	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	55	President, Chief Executive Officer and Director
Raphael J. Mannino, Ph.D.	62	Executive Vice President, Chief Scientific Officer
Andrew L. Finn, Pharm.D.	59	Executive Vice President of Product Development
James A. McNulty	58	Chief Financial Officer, Secretary and Treasurer
William B. Stone	65	Lead Director
John J. Shea	82	Director
William S. Poole	61	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 59, has been of our Chairman of the Board and a Director since March 29, 2002. Dr. O Donnell has previously served as our President and Chief Executive Officer. In January 2005, he relinquished the title of President and in August 2005 he relinquished the title of Chief Executive Officer. For more than the last six years, Dr. O Donnell has served as managing director of The Hopkins Capital Group, an affiliation of limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare. He is a co-founder and chairman of RetinaPharma Technologies, Inc. He serves as Chairman and CEO of Accentia Biopharmaceuticals, Inc., a holding company with commercialization assets representing a vertically-integrated platform for specialty pharmaceuticals and biologics. Dr. O Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. Dr. O Donnell holds 34 U.S. Patents. Dr. O Donnell is the 2000 Recipient of the Jules Stein Vision Award sponsored by Retinitis Pigmentosa International. He is a trustee of the Health Careers Foundation and of St. Louis University.

Mark A. Sirgo, Pharm.D., age 55, has been our President and Chief Executive Officer since July 2005. He joined our company in August 2004 as Senior Vice President of Commercialization and Corporate Development upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder and Chief Executive Officer. He has also served as our Executive Vice President, Corporate and Commercial Development and our Chief Operating Officer. Dr. Sirgo has more than 25 years of experience in the pharmaceutical industry, including 16 years in clinical drug development, 7 years in marketing, sales, and business development and 5 years in executive management. Prior to his involvement with Arius Pharmaceuticals from 2003 to 2004, he spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 while at Glaxo Wellcome, among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc. (NASDAQ:PPDI), a leading contract service provider to the pharmaceutical industry. Dr. Sirgo serves on the Board of Salix

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Pharmaceuticals (NASDAQ:SLXP), a specialty pharmaceutical company specializing in gastrointestinal products. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

Raphael J. Mannino, Ph.D., age 62, has been our Executive Vice President and Chief Scientific Officer since October 2000, and a Director from October 2001 through June 2008. Dr. Mannino has served as President, CEO, Chief Scientific Officer, and a member of the Board of Directors of BioDelivery Sciences, Inc., our predecessor, since its incorporation in 1995. Dr. Mannino s previous experience includes positions as Associate Professor, at the University of Medicine and Dentistry of New Jersey (1990 to present), Assistant, then Associate Professor, Albany Medical College (1980 to 1990), and Instructor then Assistant Professor, Rutgers Medical School (1977 to 1980). His postdoctoral training was from 1973 to 1976 at the Biocenter in Basel, Switzerland. Dr. Mannino received his Ph.D. in Biological Chemistry in 1973 from the Johns Hopkins University, School of Medicine.

Andrew L. Finn, Pharm.D., age 59, has been our Executive Vice President of Product Development since January 2007. He joined the company in August 2004 upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder. Dr. Finn has previously served as our Senior Vice President of Product Development and Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn has more than 25 years experience in pharmaceutical product development. Prior to his involvement with Arius, he was, from 2000 to 2003, Executive Vice President of Product Development at POZEN Inc. with responsibilities for formulation development, non-clinical development, clinical research and regulatory affairs. He participated in the activities leading up to the initial public offering and submitted marketing applications in Europe and the U.S. for two migraine products. From 1996 to 1999, Dr. Finn was Co-Founder and Chief Executive Officer of enVision Sciences, a regulatory and clinical service company. From 1991 to 1996, he was Vice President of U.S. Clinical Research for Solvay Pharmaceuticals, where he oversaw NDA submissions in the areas of inflammatory bowel disease, osteoporosis prevention and treatment of obsessive-compulsive disorder. Prior to this he spent 10 years in positions of increasing responsibility at Glaxo Inc., where he oversaw a number of NDA submissions, including Zofran for chemotherapy induced nausea and vomiting. Dr. Finn received his BS in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

James A. McNulty, age 58, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis since October 2000 until January 1, 2008 when his position became full-time. Mr. McNulty has, since May 2000, also served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture activities. Hopkins Capital Group is owned and controlled by Dr. Francis E. O Donnell, Jr. Mr. McNulty also serves as the Treasurer and Corporate Secretary of Accentia Biopharmaceuticals, Inc., a holding company with commercialization assets in specialty pharmaceuticals and biologics, and through December 31, 2007 as Chief Financial Officer for Biovest International, a majority-owned subsidiary of Accentia. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, which became one of Florida s largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He served as CFO of Star Scientific, Inc. from October 1998 to May 2000. From June 2000 through January 2002 he served as CFO/COO of American Prescription Providers, Inc. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, and is a member of the American and Florida Institutes of CPA s.

William B. Stone, age 65, is a member of our board of directors and is our Lead Director and Chairman of the Audit Committee of our board of directors. For thirty years, until his retirement in

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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. 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 82, is a member of our board of directors and Chairman of the Nominating and Corporate Governance Committee of our board of directors. He is currently the head of his own firm of J. Shea Inc. and has also been a Quality Systems Adviser with Quintiles, a private consulting firm. Mr. Shea has also served in the capacity of Director of Quality Assurance and was responsible for the implementation of quality assurance procedures in a number of public companies. From 1987-1989, he served as Director of Quality Assurance at NeoRx Corporation. Mr. Shea was also the Director of Corporate Quality Assurance at Hexcel Corporation from 1980-1987. Mr. Shea has also served as the quality assurance person for other companies including, Teledyne Relays, Ortho Diagnostics, Inc. and Bio Reagents & Diagnostics, Inc. Mr. Shea earned a B.S. in Chemistry at Bethany College.

William S. Poole, age 61, is a member of our board of directors and Chairman of the Compensation Committee of our board of directors. He has extensive experience in the biopharmaceutical and medical device industries for over thirty years. From 1972 to early 1996, Mr. Poole worked for Lederle Laboratories, a Division of American Cyanamid Company. During his 24-year career at Cyanamid, Mr. Poole held positions of increasing responsibility and held the position of World-Wide Division President of the Medical Device Division when Wyeth acquired Cyanamid in 1995. He later served as President, North American Pharmaceuticals, of Novo Nordisk Pharmaceuticals, and also as President of Biovail Pharmaceuticals. In both of these companies, Mr. Poole was instrumental in aggressively growing revenue, building solid management teams and dramatically improving profitability. As President of these firms, Mr. Poole had total P&L responsibility and directly managed vice presidents in charge of each business department within the organizations. In recent years, Mr. Poole has acted as a private consultant and, until his appointment to the board, Mr. Poole served as a member of the Commercial Advisory Board of our subsidiary, Arius Pharmaceuticals. Mr. Poole was Acting President/CEO of Spherics, Inc., a biotechnology company focusing on unique delivery mechanisms of certain drugs for the treatment of CNS diseases during 2007-08. In addition, Mr. Poole is a member of the board of directors of Accentia BioPharmaceuticals Inc.

Key Employees

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

Niraj Vasisht, Ph.D. has been our Vice President of Product Development since joining the company in February 2005 with over 14 years of experience in pharmaceutical development. In his position, Dr. Vasisht is responsible for the pharmaceutical development, manufacturing and supply chain management for our drug portfolio. He directs and oversees the product design, formulation development, quality control, process engineering, and stability testing of the drug product, and is responsible for the chemistry, manufacturing and controls (CMC) section in IND and NDA filings. Prior to joining our company, Dr. Vasisht held positions of increasing responsibility at Southwest Research Institute and was most recently the Director of Microencapsulation, Pharmaceutical Development and Nanomaterials, where he was responsible for leading the group that provides R&D and product development services to pharmaceutical, consumer health, and nutraceutical companies. Dr. Vasisht is the inventor/co-inventor on multiple patents in drug delivery. Dr. Vasisht received a BTech degree in Chemical Engineering from the Indian Institute of Technology at Kanpur, a Masters of Science from the University of New Hampshire and a Doctorate in Chemical Engineering from Rensselaer Polytechnic Institute.

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

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

Director Independence

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

Board Committees

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

Audit Committee

Our board of directors has an Audit Committee, composed of William B. Stone, John J. Shea and William S. Poole, all of whom are independent directors as defined in accordance with section 3(a)(58)(A) of the Exchange Act and the rules of NASDAQ. Mr. Stone serves as chairman of the committee. The board of directors has determined that Mr. Stone is an audit committee financial expert as defined in Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee met six times during 2008. Each member of the Audit Committee was present at all of the Audit Committee meetings held during such director s tenure as a member of the Audit Committee. The Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee has a charter and performs several functions. The Audit Committee evaluates the independence and performance of, and assesses the qualifications of, our independent auditors, and engages such independent auditors. The Audit Committee approves the plan and fees for the annual audit, performs a review of quarterly reports, tax and other audit-related services, and approves in advance any non-audit service to be provided by the independent auditors. The Audit Committee monitors the independence of the independent auditors and the rotation of partners of the independent auditors on our engagement team as required by law. The Audit Committee reviews the financial

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statements to be included in our Annual Report on Form 10-K and reviews with management and the independent auditors the results of the annual audit and our quarterly financial statements. In addition, the Audit Committee oversees all aspects our systems of internal accounting control and corporate governance functions on behalf of the board. The Audit Committee provides oversight assistance in connection with legal and ethical compliance programs established by management and the board, including Sarbanes-Oxley implementation, and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our board of directors has a Nominating and Corporate Governance Committee composed of William S. Poole, John J. Shea and William B. Stone. Mr. Shea serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The Nominating and Corporate Governance Committee was formed in May of 2004 and met one time in 2008. The Nominating and Corporate Governance Committee has a charter. 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 the Company, Attn: James A McNulty. There are no minimum qualifications for consideration for nomination to be a director of the Company. The nominating committee will assess all director nominees using the same criteria. All of the current nominees to serve as directors on our board of directors have previously served in such capacity. During 2008, we did not pay any fees to any third parties to assist in the identification of nominees. During 2008, we did not receive any director nominee suggestions from stockholders.

Compensation and Investment Committees

Our board of directors also has a Compensation Committee, which, either alone or in conjunction with the full board, as the case may be, reviews or recommends the compensation arrangements for our management and employees. The Compensation Committee has a charter and is comprised of three members: John J. Shea, William B. Stone and William S. Poole, who acts as chairman of this committee. The compensation committee met four times during 2008.

Our board of directors also has an investment committee, which either alone or in conjunction with the full board, as the case may be, reviews and recommends the investment arrangements for our company. The members of the investment committee are Dr. Francis E. O Donnell and William B. Stone. The investment committee as such did not meet during 2008.

Lead Director

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

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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 2008, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

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.bdsinternational.com.

Item 11. Executive Compensation.

The following table sets forth all annualized compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2008 and 2007. 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, 2008.

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SUMMARY COMPENSATION TABLE

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(12)	Option Awards ($)(12)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mark A. Sirgo, Pharm.D. President, Chief Executive Officer and Director	2008	$ 301,920	$ 150,000	0	$ 119,288	$ 30,516(1)	0	$ 22,871(3)	$ 624,595
	2007	$ 286,169	0	0	$ 1,522,035	$ 44,770(2)	0	$ 32,404(4)	$ 1,885,378
Andrew L. Finn, Pharm.D. Executive Vice President of Product Development	2008	$ 244,800	$ 120,000	0	$ 96,720	0	0	$ 18,259(5)	$ 479,779
	2007	$ 236,941	0	0	$ 383,897	0	0	$ 9,838(6)	$ 630,677
James A. McNulty Chief Financial Officer, Secretary and Treasurer	2008	$ 202,252	$ 100,000	0	$ 69,696	0	0	$ 26,475(7)	$ 398,423
	2007	$ 114,400	0	0	$ 380,033	0	0	$ 17,714(8)	$ 512,147
Raphael J. Mannino, Ph.D Executive Vice President and Chief Scientific Officer	2008	$ 222,768(11)	0	0	$ 43,681	0	0	$ 20,532(9)	$ 286,981
	2007	$ 218,026(11)	0	0	$ 40,580	$ 44,770(2)	0	$ 11,726(10)	$ 315,102

(1) The compensation disclosed in this item is comprised of 30,000 stock options granted as compensation for serving as a director.
(2) The compensation disclosed in this item is comprised of 20,000 stock options granted as compensation for serving as a director.
(3) Includes: Vacation payout of $4,554, $6,817 of health insurance premiums paid and 401(k) matching of $11,500 paid in 2008.
(4) Includes: Vacation payout of $21,154 and 401(k) matching of $11,250 paid in 2007.
(5) Includes: $6,759 of health insurance premiums paid and 401(k) matching of $11,500 paid in 2008.
(6) Includes: 401(k) matching of $9,838 paid in 2007.
(7) Includes: Vacation payout of $2,640, $12,335 of health insurance premiums paid and 401(k) matching of $11,500 paid in 2008.
(8) Includes: Vacation payout of $11,243 and 401(k) matching of $6,291 paid in 2007.
(9) Includes: Car allowance of $6,500, $8,569 of health insurance premiums paid and 401(k) matching of $5,463 paid in 2008.
(10) Includes: Car allowance of $6,500 and 401(k) matching of $5,226 paid in 2007.
(11) Includes $120,000, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2007 and 2008 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.
(12) The amounts included in these columns are the aggregate dollar amounts of compensation expense recognized by us for financial statement reporting purposes in accordance with FAS 123R for the fiscal years ended December 31, 2008 and December 31, 2007, and thus include amounts from option awards granted in and prior to the indicated year. Pursuant to SEC rules, the amounts in this column exclude the impact of estimated forfeitures related to service-based vesting conditions. For information on the valuation assumptions used in calculating these dollar amounts, see Note 1 to our audited financial statements included in this Report for the fiscal years ended December 31, 2008 and December 31, 2007, each as filed with the SEC. These amounts reflect our accounting expense for these awards and do not correspond to the actual value that may be recognized by the individuals upon option exercise. During the fiscal year ended December 31, 2008, there were no option award forfeitures related to service-based vesting conditions.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

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

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

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

holds the position of President and Chief Executive Officer of our company.

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

We may terminate Dr. Sirgo s employment agreement without cause and Dr. Sirgo may resign upon 30 days advance written notice. We may immediately terminate Dr. Sirgo s employment agreement for Good Cause (as defined in the agreement). Upon the termination of Dr. Sirgo s employment for any reason, Dr. Sirgo will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any 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).

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

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

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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).

James A. McNulty, CPA, Chief Financial Officer, Secretary and Treasurer Through December 31, 2007 he served as part-time CFO , devoting approximately 50% of his time to our company. Beginning January 1, 2008, Mr. McNulty devotes substantially all of his time to our company. He has an employment agreement with us (which was amended on August 31, 2002, and subsequently amended again in June 2003) for a base salary of $185,000, reduced to $110,000 in June 2003 and then increased to $114,400 in February 2007 concurrently with Mr. McNulty s entry into his new employment agreement described below. Mr. McNulty s employment agreement, dated February 22, 2007, is for a term of ending on February 22, 2008 and is subject at the end of that term to successive, automatic one-year extensions unless either party gives notice of non-extension to the other party at least 30 days prior to the end of the applicable term. Mr. McNulty is also employed part-time as Secretary/Treasurer of Accentia Biopharmaceuticals, Inc. Under the terms of the his agreement, Mr. McNulty received base salary in 2008 of $198,000 per year and a target bonus of up to 50% of his base salary.

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

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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).

Dr. Raphael Mannino, Ph.D., Executive Vice President and Chief Scientific Officer On September 1, 2002, Dr. Mannino executed an employment agreement with us at an annual salary of $210,000. In 2006, this agreement expired. On February 22, 2007, we entered into a new employment agreement with Dr. Mannino calling for a base salary of $218,400.

Dr. Mannino s employment agreement, dated February 22, 2007, is for a term of ending on February 22, 2008 and is subject at the end of that term to successive, automatic one-year extensions unless either party gives notice of non-extension to the other party at least 30 days prior to the end of the applicable term. Under the terms the agreement, Dr. Mannino will receive base salary of $218,400 per year and a target bonus of up to 50% of his base salary.

We may terminate Dr. Mannino s employment agreement without cause and Dr. Mannino may resign upon 30 days advance written notice to the other party. We may immediately terminate Dr. Mannino s employment agreement for Good Cause (as defined in the employment agreement). Upon the termination of Dr. Mannino s employment for any reason, Dr. Mannino 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. Mannino is terminated during the term of the his employment agreement other than for Good Cause (as defined in the employment agreement), or if Dr. Mannino terminates his employment for Good Reason (as defined in the employment agreement), Dr. Mannino 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. Mannino 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 Dr. Mannino 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 Dr. Mannino 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, 2008.

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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 (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	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.	30,000			$ 2.01	7/24/2018				
			40,985 (1)	$ 2.01	7/24/2018				
			48,448 (2)	$ 2.85	1/31/2018				
	20,000			$ 4.13	7/25/2017				
	144,667		289,333 (3)	$ 6.63	4/13/2017				
	30,594		15,297 (4)	$ 2.42	1/26/2017				
	11,820		5,910 (5)	$ 2.05	7/27/2016				
	49,000			$ 3.03	12/1/2015				
	20,000			$ 2.94	8/22/2015				
	8,929			$ 2.94	7/28/2015				
	5,147			$ 3.40	10/21/2014				
Andrew L. Finn, Pharm.D.			33,231 (1)	$ 2.01	7/24/2018				
			39,282 (2)	$ 2.85	1/31/2018				
	33,334		66,666 (3)	$ 6.63	4/13/2017				
	24,804		12,405 (4)	$ 2.42	1/26/2017				
	5,402		5,201 (5)	$ 2.05	7/27/2016				
	49,000			$ 3.03	12/1/2015				
	8,929			$ 2.94	7/28/2015				
	5,147			$ 3.40	10/21/2014				
James A. McNulty			18,277 (1)	$ 2.01	7/24/2018				
			32,408 (2)	$ 2.85	1/31/2018				
	33,334		66,666 (3)	$ 6.63	4/13/2017				
	22,738		11,371 (4)	$ 2.42	1/26/2017				
	10,402		5,201 (5)	$ 2.05	7/27/2016				

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	10,000		$ 3.03	12/1/2015
	26,189		$ 2.94	7/28/2015
	3,235		$ 3.40	10/21/2014
	18,616		$ 3.83	8/14/2013
Raphael J Mannino, Ph.D.		19,765 (1)	$ 2.01	7/24/2018
		14,299 (2)	$ 2.85	1/31/2018
	20,000		$ 4.13	7/25/2017
	21,704	10,854 (4)	$ 2.42	1/26/2017
	9,929	4,965 (5)	$ 2.05	7/27/2016
	20,000		$ 2.05	7/27/2016
	20,000		$ 2.94	8/22/2015
	10,714		$ 2.94	7/28/2015
	6,176		$ 3.40	10/21/2014
	20,000		$ 2.29	7/29/2014
	31,449		$ 3.83	8/14/2013
	20,000		$ 3.83	8/14/2013

(1) Of the unvested stock options, one third of the unvested stock options will vest on July 24, 2009, another third will vest on July 24, 2010 and the remaining third will vest on July 24, 2011.
(2) Of the unvested stock options, one third of the unvested stock options will vest on January 31, 2009, another third will vest on January 31, 2010 and the remaining third will vest on January 31, 2011.
(3) Of the unvested stock options, half of the unvested stock options will vest on April 13, 2009 and another half will vest on April 13, 2010.
(4) These unvested stock options will vest on January 26, 2009.
(5) These unvested stock options will vest on July 27, 2009.

Outstanding Equity Awards Narrative Disclosure

Amended and Restated 2001 Incentive Plan

The purpose of the Amended and Restated 2001 Incentive Plan is: (i) to align our interests and recipients of options under the plan by increasing the proprietary interest of such recipients in our growth and success, and (ii) to advance our interests by providing additional incentives to officers, key employees and well-qualified non-employee directors and consultants who provide services to us, who are responsible for our management and growth, or otherwise contribute to the conduct and direction of its business, operations and affairs. The Compensation Committee of our board of directors administers our incentive plan, selects the persons to whom options are granted and fixes the terms of such options.

Under our original 2001 Incentive Plan, we reserved 572,082 shares. The plan was approved by our stockholders at our 2001 annual meeting. Our board of directors subsequently voted to amend the plan to increase it to 1,100,000 shares, and later, through an amendment and restatement of the 2001 Incentive Plan, to 2,100,000 shares, which amendment and restatement was approved by our stockholders at the 2003 Annual Meeting in August 2003 in July 2006 to increase it to 3,500,000 shares. Options to purchase 3,503,467 shares of common stock are outstanding as of December 31, 2008 under the Amended and Restated 2001 Incentive Plan. Readers are advised that we plan on proposing an increase in the number of shares available for issuance under our Amended and Restated 2001 Incentive Plan to be voted upon at our upcoming 2009 Annual Meeting of Stockholders.

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All options were issued under our Amended and Restated 2001 Incentive Plan. Options may be awarded during the ten-year term of the plan to our employees (including employees who are directors), consultants who are not employees and our other affiliates. Our plan provides for the grant of options that qualify as incentive stock options, or Incentive Stock Options, under Section 422A of the Internal Revenue Code of 1986, as amended, and options which are not Incentive Stock Options, or Non-Statutory Stock Options, as well as restricted stock and other awards. Only our employees or employees of our subsidiaries may be granted Incentive Stock Options. Our affiliates or consultants or others as may be permitted by our board of directors, may be granted Non-Statutory Stock Options.

Directors are eligible to participate in our Amended and Restated 2001 Incentive Plan. The plan provides for an initial grant of an option to purchase up to 30,000 shares of common stock to each director upon first joining our board of directors and subsequent grants of options to purchase 30,000 shares upon each anniversary of such director s appointment and an additional 15,000 option grant for serving as Lead Director. Additionally, directors will be granted 15,000 options for each committee chairmanship and 7,500 options for each committee membership. Such options are granted at an exercise price equal to the fair market value of the common stock on the grant date and immediately vest.

Options and warrants to purchase 9,352,232 shares of our common stock at prices ranging from $0.001 to $6.63 are outstanding at December 31, 2008. None of our options have been granted at less than the fair market value at the time of grant. Options issued during 2008 to employees and directors totaled 982,561 shares, at exercise prices ranging from $2.01 and $2.93. In addition, during 2007, we issued warrants to purchase 833,871 shares of common stock at an exercise price of $5.00 to Laurus related to the principal note payment deferral. We issued warrants to purchase 1,000,000 shares of common stock at an exercise price of $3.80 to CDC in conjunction with a license agreement with them. And finally we issued warrants to purchase 475,000 shares of common stock at an exercise price of $5.55 to HCG II in conjunction with the termination of a royalty option agreement.

On November 19, 2008, under delegated authority from the Compensation Committee of our board of directors, the Chairman of the Compensation Committee approved an amendment to our Amended and Restated 2001 Incentive Plan to provide that all options outstanding immediately prior to a Change in Control of our company (as defined in the plan amendment) shall immediately become fully vested and exercisable.

Compensation of Directors Summary Table

DIRECTOR COMPENSATION

Name (a)	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Francis E. O Donnell, Jr.[1]	0	0	0	$ 38,145	0	0	$ 38,145
William B. Stone [2]	$ 7,000	0	0	$ 76,290	0	0	$ 83,290
John J. Shea [3]	$ 8,000	0	0	$ 61,032	0	0	$ 69,032
William S. Poole [4]	$ 7,000	0	0	$ 61,032	0	0	$ 68,032

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(1) As of December 31, 2008, the outstanding stock options held by Dr. O Donnell total 182,500, all of which have vested.
(2) As of December 31, 2008, the outstanding stock options held by Mr. Stone total 280,000, all of which have vested.
(3) As of December 31, 2008, the outstanding stock options held by Mr. Shea total 208,700, all of which have vested.
(4) As of December 31, 2008, the outstanding stock options held by Mr. Poole total 170,000, all of which have vested.

Narrative to Director Compensation

As compensation for their duties, directors receive $1,000 for appearing in person at a board of directors meeting. Compensation also includes 30,000 options to purchase common stock for each year served as a director and an additional 15,000 options to purchase common stock per year for serving as Lead Director. Additionally, each director is granted 7,500 options to purchase common stock per year for serving on a committee of the board of directors and an additional 7,500 options to purchase common stock per year for serving as chairman of a committee of the board of directors. Dr. O Donnell declined cash compensation due to him for serving of Chairman of the Board of Directors.

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

The following table sets forth, as of March 20, 2009, 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 of Beneficial Owner	Number of Shares of Common Stock Owned[1]	Percentage of Class as of March 20, 2009
Hopkins Capital Group II, LLC [2]	3,835,802	19.57%
Francis E. O Donnell, Jr., M.D.[3]	4,180,567	21.13%
The Francis E. O Donnell, Jr. Irrevocable Trust #1[4]	4,003,302	20.42%
CDC IV, LLC [5]	4,505,120	20.72%
Laurus Master Fund. Ltd. [6]	959,871	4.99%
Mark A. Sirgo, Pharm.D. [7]	1,209,779	6.18%
Andrew L. Finn, Pharm.D. [8]	954,528	4.92%
Raphael J. Mannino, Ph.D. [9]	408,201	2.10%
James A. McNulty [10]	228,347	1.18%
William B. Stone [11]	315,000	1.61%
John J. Shea [12]	235,000	1.21%
William S. Poole [13]	178,190	*
All Directors and Officers as a group (8 persons)	7,814,300	36.21%

* Less than 1%
(1) Based on 19,233,812 shares of common stock outstanding as of March 20, 2009.

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(2) Includes 400,402 shares of our common stock which were converted from Series B Convertible Preferred Stock in January 2007. Includes a warrant held in the name of Hopkins Capital Group II, LLC to purchase 400,000 shares of our common stock with an exercise price of $5.55, which warrant was acquired September 2007.

(3) Dr. O Donnell is our Chairman of the Board and a Director. Includes the shares and warrant owned by Hopkins Capital Group II, LLC (see Note 2). Excludes 167,000 shares owned by The Francis E. O Donnell, Jr. Irrevocable Trust #1, of which Dr. O Donnell s sister, Kathleen O Donnell, is trustee, and as to which Dr. O Donnell disclaims beneficial interest (see Note 4). The remaining 4,576 shares of common stock are owned by Dr. O Donnell s sister. In addition, this number includes 157,689 shares owned personally by Dr. O Donnell and options to purchase 182,500 shares of our common stock, all of which is currently exercisable. Dr. O Donnell s address is 865 Longboat Club Road, Longboat Key FL 34228.

(4) Includes the shares and warrant owned by Hopkins Capital Group II, LLC (see Note 3). The remaining 167,500 shares of common stock are held directly by this trust. Includes a warrant beneficially owned to purchase 400,000 shares of our common stock with an exercise price of $5.55, which warrant was acquired September 2007.

(5) Includes 2,000,000 shares of common stock owned by CDC, IV, LLC and includes 2,505,120 warrants to purchase shares of our common stock. The address for CDC IV, LLC is 47 Hullfish Street, Suite 310, Princeton, NJ. 08542.

(6) Up to a maximum potential of 2,476,871 shares of common stock are issuable upon exercise, as the case may be, of warrants with Laurus. However, the terms of the warrants issued by us to Laurus provide that Laurus is not entitled to receive shares upon exercise of the warrants, if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% or 9.99% (depending on the warrant) of the outstanding shares of our common stock on the date of issuance of such shares (such provision may be waived by Laurus upon 75 days prior written notice to us or without notice upon an event of default). Laurus address is 335 Madison Avenue, 10th Floor, New York, NY 10017.

(7) Includes 858,175 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Includes options to purchase 351,604 shares of common stock, all of which are currently exercisable. Excludes options to purchase 399,973 shares of common stock which are not currently exercisable. Dr. Sirgo s address is 1203 Clematis Street, Knightdale, North Carolina 27545.

(8) Dr. Finn is our Executive Vice President of Clinical Development and Regulatory Affairs. Includes 802,413 shares owned by Dr. Finn. Includes options to purchase 152,115 shares of common stock, all of which are currently exercisable. Excludes options to purchase 133,923 shares of common stock which are not currently exercisable. Dr. Finn s address is 3104 Raymond Street, Raleigh, NC 27607.

(9) Dr. Mannino is our Executive Vice President, Chief Scientific Officer and was a Director from October 2001 to June 2008. Includes 212,609 shares owned by Dr. Mannino. Includes options to purchase 195,592 shares of our common stock, all of which are currently exercisable. Excludes options to purchase 49,883 shares of common stock which are not currently exercisable. Mr. Mannino s address is 518 Lannon Lane Glen Gardner, NJ 08826.

(10) Mr. McNulty is our Chief Financial Officer, Secretary and Treasurer. Includes 81,659 shares owned by Mr. McNulty. Includes options to purchase 146,688 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 133,923 shares of common stock which are not currently exercisable. Mr. McNulty s address is 4419 W. Sevilla Street, Tampa, FL 33629.

(11) Mr. Stone is a Director. Includes 35,000 shares owned and options to purchase 280,000 shares of our common stock, all of which are currently exercisable. Mr. Stone s address is 11120 Geyer Downs Lane, Frontenac MO 63131.

(12) Mr. Shea is a Director. Includes 26,300 shares owned and options to purchase 208,700 shares of our common stock, all of which are currently exercisable. Mr. Shea s address is 290 Wax Myrtle Trail, Southern Shores, NC 27949.

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(13) Mr. Poole is a Director. Includes 8,190 shares owned and options to purchase 170,000 shares of our common stock, all of which are currently exercisable. Mr. Poole s address is 7813 Hardwick Drive, Raleigh, NC 27615.

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

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

The following is a listing of our related party transactions:

CDC

Since 2005, we have entered into several financing and related agreements with CDC, which is a significant stockholder of ours. For further detail please see Item 1. Description of Business Recent and Key Historical Events Relationship with CDC.

HCG II, Accentia and affiliates

We also have several business relationships with Accentia and its affiliates. HCG II, which is controlled by Dr. Frank O Donnell Jr., our Chairman of the Board and a director 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. In addition, William S. Poole, a director of our company, is also a director of Accentia and Dr. Raphael Mannino, our Chief Scientific Officer, is a member of the board of directors of Biovest International, Inc. (Pink Sheets:BVTI.PK), a subsidiary 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 International, Inc. filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. As such, readers are advised that projects which we are working on with Accentia may not progress in the future and that we may not receive royalty payments which we are due from Accentia.

Amphotericin B License. On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from the Mayo Foundation for Medical Education and Research for the treatment of CRS and asthma on a worldwide basis. Under our license agreement with Accentia as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales in the U.S. of its CRS products and other products in the designated field. On September 8, 2004, we entered into a definitive Asset Purchase Agreement with Accentia pursuant to which we sold to Accentia an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of $2.5 million. The royalty revenue stream sold was a fifty percent (50%) interest in the future royalties earnable by us on sales by Accentia for products utilizing our topical formulation of our encochleated Amphotericin B for the treatment of CRS, thus effectively reducing our royalty on the sales of such CRS products by 50%. We agreed with Accentia,

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however, that the future royalty stream sold shall not include royalty payments that are payable by Accentia based on the sale of encochleated products exclusively intended to treat asthma, and the rights to such royalty payments, as originally set forth in the license agreement, shall remain with us. The license agreement was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

Arius/TEAMM Distribution Agreement. On March 17, 2004, Arius granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc. with respect to our 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 has 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 Reckitt s termination of the Emezine®, the Arius TEAMM Distribution Agreement was terminated.

HCG II Loan. On April 2, 2007, we obtained a $1.0 million financing from HCG II in the form of an unsecured, non-interest bearing note, due June 30, 2007. The proceeds from this loan were used by us to make a required installment payment to QLT in connection with our August 2006 purchase of the non-U.S. rights to the BEMA™ drug delivery technology from QLT. In connection with the loan made by HCG II, we granted HCG II the right, for a period of six months, to enter into a royalty purchase agreement with us. The consideration to be paid by HCG II upon exercise of the right, which can be demanded by us or HCG II in our respective discretion at any time before September 30, 2007, is $5.0 million in cash. On September 5, 2007, we entered into an agreement to terminate HCG II s royalty purchase rights and, as consideration, we issued a warrant to HCG II to purchase 475,000 shares of our Common Stock at $5.55 per share (the closing price on April 2, 2007). On September 14, 2007, we paid the note in full to HCG II.

During 2001, we entered into agreements with RetinaPharma, Inc. (now called RetinaPharma Technologies, Inc.) and Tatton Technologies, LLC (now a part of RetinaPharma). Both are biotechnology companies which are developing nutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson s disease. We are entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into the proposed products with potential application to various neuro-degenerative diseases. The planned RetinaPharma products are in early stage development and no sales of such products or royalty revenue therefrom is anticipated in the foreseeable future. We are also entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into RetinaPharma s proposed product with potential application to various neuro-degenerative diseases. This latter product (which was transferred to RetinaPharma in its merger with Tatton Technologies, LLC) is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future. HCG II, one of our significant stockholders, and Dr. Francis E. O Donnell, Jr., our Chairman of the Board and a director, are affiliated as stockholders and a director of RetinaPharma Technologies, Inc. Dr. O Donnell is the managing director of HCG II.

We have also entered into an agreement with Biotech Specialty Partners, LLC, or BSP, an emerging alliance of early stage biotechnology and specialty pharmaceutical companies. BSP to date has not distributed any pharmaceutical products. Under this agreement, BSP will serve as a nonexclusive distributor of our Bioral drugs in consideration of a ten (10%) percent discount to the wholesale price, which our

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board of directors has determined to be commercially reasonable. BSP has waived its rights under this agreement with respect to Arius products. Hopkins Capital Group, which is affiliated with Dr. Francis E. O Donnell, Jr., our Chairman of the Board and a director, are affiliated as stockholders, and a member of the management, of BSP.

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 parities. At the time of certain of the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present board of directors includes three independent directors which constitute a majority as required by NASDAQ Stock Market rules. We believe that William B. Stone, John J. Shea and William S. Poole qualify as independent directors for NASDAQ Stock Market purposes.

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

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

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, 2008 and Aidman Piser whose practice was merged into Cherry, Bekaert & Holland, L.L.P. in 2008 for 2007 totaled $155,745 and $179,172, respectively. The above amounts include interim procedures as audit fees as well as attendance at audit committee meetings.

Audit-Related Fees. The aggregate fees billed by Cherry, Bekaert & Holland, L.L.P. for audit-related fees for the years ended December 31, 2008 and Aidman Piser whose practice was merged into Cherry, Bekaert & Holland, L.L.P. in 2008 for 2007 were $11,539 and $18,725, respectively.

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Tax Fees. The aggregate fees billed by Cherry, Bekaert & Holland, LLP. for professional services rendered for tax compliance, for the years ended December 31, 2008 and Aidman Piser whose practice was merged into Cherry, Bekaert & Holland, L.L.P. in 2008 for 2007 were $58,501 and $18,725, 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 2008. 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.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated August 10, 2004, by and among the Company, Arius Acquisition Corp., Arius, Dr. Mark Sirgo and Dr. Andrew Finn (12)
2.2	Asset Purchase Agreement, dated September 8, 2004, by and between the Company and Accentia, Inc. (14)
3.1	Articles of Incorporation of the Company (3)
3.2	Bylaws of the Company (3)
3.3	Secretary s Certificate regarding amendments to Company s Bylaws, dated August 23, 2005 (22)
3.4	Certificate of Amendment to the Company s Certificate of Incorporation creating a staggered board of directors, dated July 25, 2008 (37)
3.5	Certificate of Elimination, dated February 12, 2009, for the Company s Series A Non-Voting Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Non-Voting Convertible Preferred Stock (40)
4.1	Common Stock Purchase Warrant, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (16)
4.2	Common Stock Purchase Warrant, dated May 31, 2005, by the Company in favor of Laurus Master Fund, Ltd. (18)
4.3	Common Stock Purchase Warrant (22,500 shares), dated June 29, 2005, by the Company in favor of Laurus Master Fund, Ltd. (20)
4.4	Common Stock Purchase Warrant (7,500 shares), dated June 29, 2005, by the Company in favor of Laurus Master Fund, Ltd. (20)
4.5	Common Stock Purchase Warrant, dated July 15, 2005, by the Company in favor of Clinical Care Development, LLC (21)
4.6	Common Stock Purchase Warrant, dated July 15, 2005, by the Company in favor of Aveva Drug Delivery Systems, Inc. (23)
4.7	Common Stock Purchase Warrant (39,574 shares), dated December 28, 2005, by the Company in favor of Laurus Master Fund, Ltd. (24)
4.8	Common Stock Purchase Warrant (29,700 shares), dated December 28, 2005, by the Company in favor of Laurus Master Fund, Ltd. (24)
4.9	Warrant, dated May 16, 2006, made by the Company in favor of CDC IV, LLC (25)
4.10	Common Stock Purchase Warrant (62,887 shares), dated July 31, 2006, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.11	Common Stock Purchase Warrant (47,113 shares), dated July 31, 2006, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.12	Common Stock Purchase Warrant (943,305 shares), dated December 28, 2006, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.13	Common Stock Purchase Warrant (556,695 shares), dated December 28, 2006, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.14	Common Stock Purchase Warrant, dated March 12, 2007, by the Company in favor of CDC IV, LLC (33)
4.15	Common Stock Purchase Warrant, dated April 10, 2007, issued by the Company in favor of Laurus Master Fund, Ltd. (34)

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4.16	Common Stock Purchase warrant (475,000 shares), dated September 5, 2007, by the Company in favor of HCG II (35)
10.1	Research Agreement with the University of Medicine and Dentistry of New Jersey (1)
10.2	Licensing Agreement with the University of Medicine and Dentistry of New Jersey (2)
10.3	Licensing Agreement with Albany Medical College (2)
10.4	License Agreement with Tatton Technologies, LLC (3)
10.5	Addendum to License Agreement with Tatton Technologies, LLC (5)
10.6	License Agreement with RetinaPharma, Inc. (17)
10.7	Addendum to License Agreement with RetinaPharma, Inc. (4)
10.8	License Agreement with Biotech Specialty Partners, LLC (3)
10.9	Sub-License Agreement, effective as of December 31, 2002, by and between the Company and Pharmaceutical Product Development, Inc. (6)+
10.10	Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated January 8, 2003, by the Company, as Managing Member and the other members signatory thereto, as Class B Members (7)
10.11	Promissory Note, dated February 13, 2003, by Bioral Nutrient Delivery, LLC in favor of the Company (7)
10.12	First Amendment to Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, dated March 31, 2003 (9)
10.13	Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (9)
10.14	Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (9)
10.15	Amended and Restated 2001 Incentive Plan (9)
10.16	Amended and Restated Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated October 1, 2003, by the Company, as Managing Member (10)
10.17	First Amendment to Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (10)
10.18	License Agreement, dated effective April 12, 2004, between the Company and Accentia, Inc. (11)
10.19	Amendment to License Agreement, dated effective June 1, 2004, between the Company and Accentia, Inc. (11)
10.20	Registration Rights Agreement, dated August 24, 2004, by and among the Company and the former stockholders of Arius Pharmaceuticals, Inc. (13)
10.21	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (13)
10.22	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (13)
10.23	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (13)
10.24	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (13)
10.25	Common Stock Purchase Agreement, dated January 20, 2005, between the Company and Sigma Tau Finanziaria S.p.A. (15)+
10.26	Licensing Agreement, dated January 20, 2005, between the Company and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (15)+
10.27	Letter Amendment to License Agreement, dated March 28, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (17)

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10.28	Letter Amendment to License Agreement, dated April 25, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (17)
10.29	Registration Rights Agreement, dated May 31, 2005, by and between the Company and Laurus Master Fund, Ltd. (18)
10.30	Letter Amendment to License Agreement, dated June 6, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (19)
10.31	Clinical Development and License Agreement, dated as of July 14, 2005, among Clinical Development Capital LLC, the Company and Arius Pharmaceuticals, Inc. (21)+
10.32	Form of Security Agreement to be entered into by and among the Company, Arius Pharmaceuticals, Inc and Clinical Development Capital LLC (21)
10.33	Registration Rights Agreement, dated as of July 14, 2005, by and between the Company and Clinical Development Capital LLC (21)
10.34	Supply Agreement, dated October 17, 2005, by and between Aveva Drug Delivery Systems, Inc., Arius Pharmaceuticals, Inc. and the Company (23)
10.35	Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC IV, LLC (25)
10.36	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 (25)
10.37	Amendment No. 1, dated as of May 16, 2006, to that certain Security Agreement, dated as of February 15, 2006, between the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC. (25)
10.38	Amended and Restated Registration Rights Agreement, dated as of May 16, 2006, by and between the Company and CDC IV, LLC (25)
10.39	Amendment No. 1 to Amended and Restated 2001 Incentive Plan (26)
10.40	Registration Rights Agreement, dated July 31, 2006, between the Company and Laurus Master Fund, Ltd. (27)
10.41	Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT USA, Inc. and Arius Two, Inc. (28)+
10.42	Secured Promissory Note dated August 2, 2006, by Arius Two, Inc. in favor of QLT USA, Inc. (28)+
10.43	Security Agreement, dated August 2, 2006, between Arius Two, Inc. and QLT USA, Inc. (28)
10.44	Patent and Trademark Security Agreement, dated August 2, 2006, between Arius Two, Inc. and QLT USA, Inc. (28)
10.45	Guaranty, dated August 2, 2006, by the Company in favor of QLT USA, Inc. (28)
10.46	Assignment of Patents and Trademarks, dated August 2, 2006, by QLT USA, Inc. in favor of Arius Two, Inc. (28)
10.47	BEMA Acquisition Consent, Amendment, and Waiver, dated August 2, 2006, by and between Arius Pharmaceuticals, Inc., Arius Two, Inc. and CDC IV, LLC. (28)
10.48	Letter agreement, dated August 2, 2006 between the Company, Arius Pharmaceuticals, Inc. and Arius Two, Inc. (28)
10.49	Consent and Waiver Agreement, dated August 2, 2006, by and among Laurus Master Fund, the Company, Arius Pharmaceuticals, Inc. and Arius Two, Inc. (28)
10.50	Second Amendment Agreement, dated August 2, 2006, between QLT USA, Inc. and Arius Pharmaceuticals, Inc. (28)+
10.51	BEMA License Agreement, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (28)+
10.52	First Amendment Agreement, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (28)+

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10.53	License and Development Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (28)+
10.54	BEMA Fentanyl Supply Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (28)+
10.55	Sublicensing Consent, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (28)+
10.56	Sublicensing Consent and Amendment, dated August 2, 2006, by the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC (28)+
10.57	Letter agreement, dated August 2, 2006, between Meda AB, Arius Pharmaceuticals, Inc, Arius Two, Inc. and the Company (28)
10.58	Notice of Breach and Demand for Dispute Resolution, sent August 30, 2006, from the Company to CDC IV, LLC (29)
10.59	Notice of Breach and Termination, received August 30, 2006, from CDC IV, LLC to the Company (30)
10.60	Amended and Restated Registration Rights Agreement, dated December 28, 2006, between the Company and Laurus Master Fund, Ltd. (31)
10.61	Process Development Agreement, effective December 15, 2006, between LTS Lohmann Therapie-Systeme AG and the Company (34)+
10.62	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Mark A. Sirgo (32)
10.63	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Andrew L. Finn (32)
10.64	Employment Agreement, dated February 22, 2007, between the Company and Raphael J. Mannino (32)
10.65	Employment Agreement, dated February 22, 2007, between the Company and James A. McNulty (32)
10.66	Dispute Resolution Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (33)
10.67	Amendment to Clinical Development and License Agreement, dated March 9, 2007, between the Company and CDC IV, LLC (33)
10.68	Promissory Note, dated March 12, 2007, by the Company in favor of CDC IV, LLC (33)
10.69	Registration Rights Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (33)
10.70	Subscription Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (33)
10.71	Cooperative Research and Development Agreement, dated June 7, 2006 between the Company and Walter Reed Army Institute of Research (34)
10.72	Second Amended and Restated Registration Rights Agreement, dated April 10, 2007, between the Company and Laurus Master Fund, Ltd. (34)
10.73	Registration Rights Agreement, dated September 5, 2007, by and among the Company and HCG II (35)
10.74	License and Development Agreement, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc. and Meda AB (35)+
10.75	Bema Fentanyl Supply Agreement, dated September 5, 2007, between the Company and Meda AB (35)+
10.76	Sublicensing Consent dated September 5, 2007, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (35)+
10.77	License Agreement dated, September 5, 2007, by and between Arius Two, Inc., and Arius Pharmaceuticals, Inc. (35)+

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10.78	Intellectual Property Assignment Agreement dated, September 5, 2007 by and between QLT USA, Inc. and Arius Two. (35)+
10.79	Amended and Restated Patent and Trademark Agreement, dated as of September 5, 2007, by and between Arius Two, Inc., and QLT USA, Inc. (35)
10.80	Amended and Restated Patent and Trademark Security Agreement, dated as of September 5, 2007, made between Arius Two, Inc., and QLT USA, Inc. (35)
10.81	Assignment of Patent and Trademarks, dated September 5, 2007. (35)
10.82	Patent and Trademark Security Agreement, dated as of September 5, 2007, between Arius Two, Inc., and QLT USA, Inc. (35)
10.83	Security Agreement, dated as of September 5, 2007, between Arius Two, Inc., and QLT USA, Inc. (35)
10.84	Second Amendment Agreement dated September 5, 2007, by Arius Two, Inc. and Arius Pharmaceuticals, Inc. (35)
10.85	Secured Promissory Note, dated September 5, 2007, between Arius Two, Inc. and QLT USA, Inc. (35)+
10.86	Guaranty, dated as of September 5, 2007, made between BioDelivery Sciences International, Inc. and in favor of QLT USA, Inc. (35)
10.87	Bema Acquisition Consent, amendment and waiver, dated September 5, 2007, between the Company and CDC IV, LLC (35)
10.88	Sublicensing Consent and Amendment, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc., CDC IV, LLC and Meda AB. (35)+
10.89	Royalty Purchase and Amendment Agreement, dated as of September 5, 2007 between BioDelivery Sciences International, Inc., and CDC IV, LLC (35)+
10.90	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. (35)+
10.91	Dispute Resolution Agreement, dated September 5, 2007 by and between the Company and CDC IV, LLC (35)
10.92	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 (35)
10.93	Side Letter Agreement, dated September 5, 2007, between CDC IV, LLC and QLT USA, Inc. (35)
10.94	Side Letter Agreement, dated September 5, 2007, between CDC IV, LLC, the Company, Arius Pharmaceuticals, Inc., and Arius Two, Inc. (35)
10.95	Side Letter Agreement, dated September 5, 2007, between MEDA AB and QLT USA, Inc. (35)
10.96	Allonge, effective date, September 5, 2007, between the Company and CDC IV, LLC (35)
10.97	Promissory Note, dated September 11, 2007, by the Company in favor of Meda AB (36)
10.98	Letter Amendment, effective January 2, 2009, between the Company, Arius Pharmaceuticals, Inc. and Meda AB relating to European commercialization rights for ONSOLIS (38)+
10.99	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 (38)+
10.100	Amendment Consent (EU), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (38)
10.101	Amendment Consent (NA), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (38)

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10.102	Research Collaboration and License Agreement, dated January 20, 2009, between the Company and The Drugs for Neglected Diseases Initiative (39)+
10.103	Process Development Agreement, dated February 8, 2008, between the Company and LTS *^
10.104	Amendment to Amended and Restated 2001 Incentive Plan of the Company, dated November 19, 2008 *
10.105	Termination Letter Agreement, dated December 17, 2008, between Arius Pharmaceuticals, Inc. and Reckitt Benckiser Healthcare (UK) Limited *
21.1	Subsidiaries of the Registrant *
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#

* Filed herewith
\+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
^ Confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
\# A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
(1) Previously filed with Form 10QSB, for the quarter ended March 31, 2001.
(2) Previously filed with Form 10KSB, for the fiscal year ended December 31, 2000 filed on August 15, 2001.
(3) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(4) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.
(5) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.
(6) Previously filed with Form 8-K, January 7, 2003.
(7) Previously filed with Form 8-K, February 26, 2003.
(8) Previously filed as Annex A to Schedule 14A, July 8, 2003
(9) Previously filed with Form 10-QSB/A, September 2, 2003.
(10) Previously filed with Form 8-K, November 19, 2003.
(11) Previously filed with Form 8-K, June 4, 2004.
(12) Previously filed with Form 8-K, August 12, 2004.
(13) Previously filed with Form 8-K, August 26, 2004.
(14) Previously filed with Form 8-K, September 8, 2004.
(15) Previously filed with Form 8-K, January 24, 2005.
(16) Previously filed with Form 8-K, February 25, 2005.
(17) Previously filed with Form 10-KSB/A, April 29, 2005.
(18) Previously filed with Form 8-K, June 3, 2005.
(19) Previously filed with Form 10-KSB/A, June 10, 2005.
(20) Previously filed with Form 8-K, June 30, 2005.
(21) Previously filed with Form 8-K, July 21, 2005.

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(22) Previously filed with Form 8-K, August 24, 2005.
(23) Previously filed with Form 10-QSB, November 10, 2005.
(24) Previously filed with Form 8-K, January 1, 2006.
(25) Previously filed with Form 8-K, May 22, 2006.
(26) Previously filed as Annex A to Schedule 14A, June 27, 2006.
(27) Previously filed with Form 8-K, August 4, 2006.
(28) Previously filed with Form 8-K, August 9, 2006.
(29) Previously filed with Form 8-K, August 31, 2006.
(30) Previously filed with Form 8-K, August 31, 2006.
(31) Previously filed with Form 8-K, December 28, 2006.
(32) Previously filed with Form 8-K, February 22, 2007.
(33) Previously filed with Form 8-K, March 16, 2007.
(34) Previously filed with Form 10-K, March 7, 2008.
(35) Previously filed with Form 8-K, September 10, 2007.
(36) Previously filed with Form 8-K, September 12, 2007.
(37) Previously filed with Form 8-K, July 28, 2008.
(38) Previously filed with Form 8-K, January 6, 2009.
(39) Previously filed with Form 8-K, January 23, 2009.
(40) Previously filed with Form 8-K, February 13, 2009.

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

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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, 2008 and 2007, and the related consolidated statements of operations and stockholders deficit and cash flows for each of the years in the two-year period ended December 31, 2008. The Company s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements 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 audit to obtain reasonable assurance whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but nor for the purpose of expressing an opinion on the effectiveness of the company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates used by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material aspects, the financial position of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2008 and 2007, and the consolidated results of their operations and cash flows for each of the years in the two-year period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company incurred cumulative net losses of approximately $42.4 million during the two years ended December 31, 2008 and has a stockholders deficit of approximately $33.6 million as of December 31, 2008. These conditions raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are described in Note 2. The consolidated financial statements do not include any adjustments with respect to the possibly future effects of recoverability and classification of assets nor the amounts and classification of liabilities that might arise from the outcome of this uncertainty.

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

Tampa, Florida
March 20, 2009

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2008 AND 2007

	2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 905,720	$ 13,797,093
Certificate of deposit		2,800,000
Accounts receivable	468,987	305,497
Due from related party		14,414
Prepaid expenses and other current assets	184,007	160,704
Total current assets	1,558,714	17,077,708
Equipment, net	126,734	222,806
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	542,171	542,171
Acquired product rights	6,900,000	6,900,000
Accumulated amortization	(1,615,263)	(974,208)
Total other intangible assets	5,826,908	6,467,963
Deposits on equipment	2,954,460	1,344,311
Other assets	11,571	15,937
Restricted cash	144,000	144,000
Total assets	$ 13,337,387	$ 27,987,725
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Notes payable, related party	$	$ 1,296,164
Notes payable	76,666	90,834
Accounts payable and accrued liabilities, other	2,684,015	1,535,077
Accounts payable and accrued liabilities, related party	260,614	166,219
Clinical trial payables and accrued liabilities, other	857,996	2,568,564
Clinical trial payables and accrued liabilities, related party		1,922,708
Deferred revenue, current	36,060,500	120,121
Derivative liabilities (Note 10)	5,350,829	6,543,571
Total current liabilities	45,290,620	14,243,258
Deferred revenue, long-term	1,628,539	32,532,252
Total liabilities	46,919,159	46,775,510
Commitments and contingencies (Notes 3, 7, 8 14 and 15)		
Stockholders deficit:		
Common Stock, $.001 par value; 45,000,000 shares authorized, 19,179,029 and 19,101,037 shares issued; 19,163,538 and 19,085,546 shares outstanding in 2008 and 2007, respectively	19,179	19,101
Additional paid-in capital	58,706,499	56,267,563
Treasury stock, at cost, 15,491 shares, 2008 and 2007	(47,183)	(47,183)

Accumulated deficit	(92,260,267)	(75,027,266)
Total stockholders deficit	(33,581,772)	(18,787,785)
Total liabilities and stockholders deficit	$ 13,337,387	$ 27,987,725

See notes to consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2008 AND 2007

	2008	2007
Revenues:		
Royalty revenue, related party	$ 50,821	$ 74,988
Research fees	212,359	127,000
Total revenues	263,180	201,988
Expenses:		
Research and development	10,282,244	8,468,983
Related party research and development	641,511	5,832,154
Product development costs		25,603
General and administrative	7,242,191	7,497,319
Related party general and administrative	61,400	37,802
Total expenses	18,227,346	21,861,861
Loss from operations	(17,964,166)	(21,659,873)
Interest expense, net	(461,577)	(2,239,360)
Derivative gain	1,192,742	2,307,433
Loss on extinguishment of debt		(3,595,169)
	731,165	(3,527,096)
Loss before income taxes	(17,233,001)	(25,186,969)
Income tax (expense) benefit		
Net loss	$ (17,233,001)	$ (25,186,969)
Constructive dividends		(3,870,587)
Loss attributable to common stockholders	$ (17,233,001)	$ (29,057,556)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (0.90)	$ (1.64)
Weighted average common stock shares outstanding basic and diluted	19,164,982	17,771,055

See notes to consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT

YEARS ENDED DECEMBER 31, 2008 AND 2007

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred stock		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Deficit
Balances, January 1, 2007	1,647,059	$ 3,705,883	341,176	$ 1,450,000		$	14,048,637	$ 14,049	$ 32,132,609	$ (47,183)	$ (45,969,710)	$ (8,714,352)
Stock-based compensation									1,066,532			1,066,532
Stock option exercise for cash							268,117	268	692,279			692,547
Shares issued for cash							73,964	74	249,926			250,000
Expenses paid with common stock							54,524	55	209,100			209,155
Warrant exercises for cash							850,879	851	3,234,586			3,235,437
Issuance of warrants for product development									25,603			25,603
Conversion of notes payable to common stock							1,757,454	1,757	4,304,002			4,305,759
Reclassification of derivative liability to equity									5,175,700			5,175,700
Conversion of Series A to Series C Preferred stock	(1,647,059)	(3,705,883)			1,647,059	7,576,471						3,870,588
Conversion of Series B Preferred stock to common stock			(341,176)	(1,450,000)			341,176	341	1,449,659			
Conversion of Series C Preferred stock to common stock					(1,647,059)	(7,576,471)	1,647,059	1,647	7,574,824			
Payment of accrued dividends with common stock							59,227	59	152,743			152,802
Constructive dividends											(3,870,587)	(3,870,587)
Net loss											(25,186,969)	(25,186,969)

Balances, December 31, 2007	0	0	0	0	0	0	19,101,037	19,101	56,267,563	(47,183)	(75,027,266)	(18,787,785)
Stock-based compensation									2,330,951			2,330,951
Stock option exercise for cash							65,000	65	107,985			108,050
Warrants exercised for cash							12,992	13				13
Net loss											(17,233,001)	(17,233,001)
Balances, December 31, 2008	$		$		$		19,179,029	$ 19,179	$ 58,706,499	$ (47,183)	$ (92,260,267)	$ (33,581,772)

See notes to consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2008 AND 2007

	2008	2007
Operating activities:		
Net loss	$ (17,233,001)	$ (25,186,969)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of common stock		209,155
Expenses paid through the issuance of warrants		609,711
Depreciation	124,727	262,482
Amortization of intangible assets	641,055	412,440
Derivative gain	(1,192,742)	(2,307,433)
Loss on extinguishment of debt		3,595,169
Accretion of debt discount	603,836	1,971,531
Stock-based compensation expense	2,330,952	1,066,532
Changes in assets and liabilities:		
Accounts receivable	(163,490)	(263,379)
Prepaid expenses and other assets	172,446	309,823
Accounts payable and accrued liabilities	(136,185)	1,455,682
Deferred revenue	5,036,463	30,082,013
Net cash flows from operating activities	(9,815,939)	12,216,757
Investing activities:		
Purchase of equipment	(28,364)	(74,438)
Purchase of investments	(375,044)	
Sale of investments	375,044	
Proceeds from (purchase of) certificate of deposit	2,800,000	(2,800,000)
Deposits on equipment	(2,041,162)	(736,545)
Purchase of intangible assets		(3,000,000)
Net cash flows from investing activities	730,474	(6,610,983)
Financing activities:		
Proceeds from issuance of common stock		250,000
Proceeds from exercise of stock options	108,050	692,547
Payment on notes payable, related parties	(1,900,000)	(3,756,435)
Payment on notes payable, other	(205,831)	(251,119)
Proceeds from exercise of common stock warrants	13	3,235,437
Proceeds from notes payable		4,000,000
(Repayment of) proceeds from related party advances, net	(1,808,140)	1,848,785
Net cash flows from financing activities	(3,805,908)	6,019,215
Net change in cash and cash equivalents	(12,891,373)	11,624,989
Cash and cash equivalents at beginning of year	13,797,093	2,172,104
Cash and cash equivalents at end of year	$ 905,720	$ 13,797,093

See notes to consolidated financial statements

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SUPPLEMENTAL CASH FLOW INFORMATION

Non-cash Financing and Investing activities

The Company financed an insurance policy with proceeds from notes payable in the amount of $191,664 and $254,300 during the twelve months ended December 31, 2008 and 2007, respectively.

The Company converted $4,305,759 of convertible notes payable through the issuance of 1,757,454 shares of common stock to Laurus Master Fund Ltd. during the twelve months ended December 31, 2007.

The Company reclassified derivative liabilities of $5,175,700 from debt to equity during the twelve months ended December 31, 2007 as a result of the conversions of notes payable and interest to which the derivative related.

The Company paid $152,802 of accrued dividends payable through the issuance of 59,227 shares of common stock with a fair value of $152,802 during the twelve months ended December 31, 2007.

The Company recorded a constructive dividend of $3,870,587 related to the redemption of Series A Non-Voting Convertible Preferred Stock during the twelve months ended December 31, 2007.

See notes to consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

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 later reincorporated as a Delaware corporation in 2002. The Company and its subsidiaries are collectively referred herein to as the Company. The Company is a specialty pharmaceutical company that is leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. The development strategy focuses on utilization of the FDA s 505(b)(2) approval process to potentially obtain timely and efficient approval of new formulations of previously approved therapeutics which incorporate the company s licensed drug delivery technologies. The Company s drug delivery technologies include: (i) the patented BEMA (transmucosal or mouth) drug delivery technology and (ii) the patented Bioral cochleate technology, designed for a potentially broad base of applications. As used herein, the Company s common stock, par value $.001 per share, is referred to as the Common Stock .

Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. (Arius One) and Arius Two, Inc. (Arius Two) and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND). BND is currently an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Significant accounting policies:

Cash and cash equivalents:

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. The Company places its cash and cash equivalents with financial institutions in the United States. In October and November 2008 the Federal Deposit Insurance Corporation (FDIC) temporarily increased coverage to $250,000 for substantially all depository accounts and temporarily provides unlimited coverage for certain qualifying and participating non-interest bearing transaction accounts. The increased coverage is scheduled to expire on December 31, 2009, at which time it is anticipated that amounts insured by the FDIC will return to $100,000. As of year end the Company had approximately $280,000 which exceeds these amounts.

Revenue recognition:

Meda License, Development and Supply Agreement:

General

The Company entered into license, development and supply agreements (collectively, the Meda Agreements) with Meda AB, a Swedish company (Meda), in September 2007 (covering the United States, Canada and Mexico) and August 2006 (covering certain countries in Europe) to develop and commercialize the Company s lead product, ONSOLIS (formerly known as BEMA Fentanyl), a treatment with an initial indication for breakthrough cancer pain. ONSOLIS is a product consisting of the narcotic fentanyl formulated with the Company s patented BEMA drug delivery technology (BEMA). The Company recognizes revenue associated with the Meda Agreements in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104), *Emerging Issues Task Force* (EITF) Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Significant accounting policies (continued):

Revenue recognition (continued):

Meda License, Development and Supply Agreement (continued):

(EITF 99-19), and EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). The Company s deliverables under the Meda Agreements, including the Company s related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 7.

License and product development research and development services revenue

Based on the Company s assessment upon inception 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 have been recorded as deferred revenue. Upon delivery of the license rights to Meda (date of first commercial sale in each territory), the Company will recognize revenue associated with the license and the research and development services rendered related to development of the ONSOLIS product through the date of U.S. FDA and other governmental approval. A portion of the upfront payments will be attributed to the Company s continuing obligation to participate in joint committees with Meda and to provide certain other specified services and this revenue will be recognized as services are provided through expiration of the license agreements.

Non-Cancer Indication and other research and development services revenue

Research and development services revenue associated with the non-cancer indication of the ONSOLIS product and further development of the first indication of the ONSOLIS product which have been performed prior to the commencement of the license term, has been deferred and will be recognized upon delivery of the license rights to Meda. Services provided subsequent to commencement of the license term will be recognized when the services are performed, if all other revenue recognition criteria are met. Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal under the Meda Agreements and, as such, will record these amounts on a gross basis as research and development services revenue.

ONSOLIS product supply

Revenue associated with product sold to Meda prior to the commencement of the license term is recorded as deferred revenue and will be recognized upon delivery of the license rights to Meda. Subsequent to the commencement of the license term, the Company will recognize revenue for product supplied to Meda when title and risk of loss have passed to Meda and the remaining criteria in SAB 104 have been met. Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal as it relates to these activities under the product supply agreements and, as such, records this revenue on a gross basis as product supply revenue.

Royalties

Product royalty revenue is based on third-party sales of the ONSOLIS product. The Company will recognize product royalty revenues from Meda on the accrual basis in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably

assured and all other revenue recognition criteria are met.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Significant accounting policies (continued):

Revenue recognition (continued):

Royalty revenue, related party:

Royalty revenue, related party consists of royalties from Accentia in connection with our agreement for encochleated Amphotericin B. The Company recognizes royalty revenue on an accrual basis when all revenue recognition criteria have been met.

Research fee revenue:

The Company provides other research and development services based on various fixed-price and time and materials contracts. Revenues earned from fixed-price contracts are recognized based on the percentage of completion of the contract terms. Revenues from time and materials contracts are generally recognized as revenue when the services are performed, if all other revenue recognition criteria are met.

Reimbursement of direct out-of-pocket costs:

The Company pays fees to regulatory agencies and other out-of-pocket costs for which they are reimbursed at cost, without mark-up or profit. Revenues derived from reimbursement of these direct out-of-pocket costs associated with research and development services are presented in the accompanying consolidated financial statements based on guidance under EITF Issue No. 01-14, *Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses Incurred* (EITF 01-14). According to the criteria established by EITF 01-14, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and may perform part of the services required in the transactions, revenue is presented at the gross amount of the reimbursement. The Company recognizes the revenue associated with these reimbursed costs as research and development services revenue in the consolidated statements of operations. The expense associated with these reimbursements is reflected as a component of 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.

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 approved by the FDA, or international regulatory agencies, there is a risk that the products will not receive the necessary approval. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company.

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 in its industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services could have a material

adverse effect on the Company s business, operating results and future cash flows.

Accounts receivable from Meda accounted for 100% and 50% of the Company s accounts receivable at December 31, 2008 and 2007, respectively. Substantially all of the deferred revenue balances relate to the Meda Agreements as of December 31, 2008 and 2007, respectively. The Company depends significantly upon the collaboration with Media, and its activities may be impacted if this relationship is disrupted.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Significant Accounting Policies (continued):

Certain Risks, Concentrations and Uncertainties (continued):

Key components used in the manufacture of ONSOLIS are currently 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. The reliance on a sole or limited number of suppliers could potentially result in the Company s inability to timely obtain an adequate supply of required components and could result in reduced control over pricing, quality and timely delivery. Except for the Company s agreements with Aveva Drug Delivery Systems, Inc. (Aveva) and with LTS Lohmann Therapie-Systeme AG (LTS), the manufacturers of the ONSOLIS product, for distribution in the United States, Mexico and Canada and in certain countries in Europe, respectively, under the Meda Agreements, the Company does not have long-term agreements with any other suppliers. Therefore, the supply of a particular component could be terminated without penalty to the supplier. Any interruption in the supply of components from Aveva, LTS, or other third party suppliers could cause the Company to seek alternative sources of supply. 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 Aveva s or LTS s ability to timely produce supplies for commercial sale, which could delay commercialization or decrease sales by Meda and therefore could cause the Company to lose royalty revenues or incur additional costs, affect the royalty rates payable by Meda, or potentially harm the Company s 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 revenue can be 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 12 months of the balance sheet date.

Equipment and deposits on equipment:

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

Deposits on equipment consists of payments made to Doyen Medipharm Inc. for the purchase of manufacturer equipment to be used in the production of ONSOLIS (Note 14)

Goodwill and other intangible assets:

The Company periodically reviews intangible assets with finite lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company uses an estimate of the undiscounted cash flows over the remaining life of its long-lived

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Goodwill and other intangible assets (continued):

assets, or related group of assets where applicable, in measuring whether the assets to be held and used will be realizable. In the event of impairment, the Company would discount the future cash flows using its then estimated incremental borrowing rate to estimate the amount of the impairment. There were no impairment charges recognized on finite lived intangibles in 2008 or 2007.

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

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

The Company incurred amortization expense on other intangible assets of approximately $.6 million and $.4 million for the years ended December 31, 2008 and 2007, 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,	
2009	$ 641,056
2010	641,056
2011	641,056
2012	641,056
2013	641,056
Thereafter	2,621,628
	$ 5,826,908

Goodwill is evaluated for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment analysis involves a two step process. Step one involves the comparison of the fair value of the reporting unit to which goodwill relates (the Company s enterprise values) to the carrying value of the reporting unit. If the fair value exceeds the carrying value, there is no impairment. If the carrying value exceeds the fair value of the reporting unit, the Company determines the implied fair value of goodwill and records an impairment charge for any excess of the carrying value of goodwill over its implied fair value. There were no goodwill impairment charges in 2008 or 2007.

Restricted cash:

Restricted cash consists of amounts held by a bank as a security deposit by the Company s corporate office lease (Note 14). The Company is also required to keep a letter of credit in the amount of $144,000 under this lease agreement.

Use of estimates in financial statements:

The preparation of the accompanying consolidated financial statements conforms with accounting

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Use of estimates in financial statements (continued):

principles generally accepted in the United States of America 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 loss per common share:

The following table sets forth the calculations of basic and diluted net loss per share:

	2008	2007
Numerator:		
Net loss attributable to Common Stockholders	$ (17,233,001)	$ (29,057,556)
Denominator:		
For basic loss per share weighted average shares	19,164,982	17,771,055
Effect of dilutive securities		
Weighted average shares for dilutive loss per share	19,164,982	17,771,055
Net loss per share attributable to Common Stockholders, basic and dilutive	$ (0.90)	$ (1.64)

The Company had net losses for all periods presented in which potential common shares were in existence. Diluted loss per share assumes conversion of all potentially dilutive outstanding Common Stock equivalents. Potential common shares outstanding are excluded from the calculation of diluted loss per share if their effect is anti-dilutive. As such, dilutive loss per share is the same as basic loss per share for all periods presented as the effect of all the following Common Stock equivalents outstanding is anti-dilutive:

	2008	2007
Options and warrants to purchase Common Stock	9,352,232	8,582,661

Stock-based compensation:

Effective January 1, 2006, the Company adopted the accounting provisions of Statement of Financial Accounting Standards No. 123R *Accounting for Stock-Based Compensation* (FAS 123(R)), which requires the use of the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (warrants and options). The fair value of each

option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on historical volatility of the Company s stock and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Stock-based compensation(continued):

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

	2008	2007
Expected price volatility	54.41%-87.13%	50.43-65.78%
Risk-free interest rate	2.67%-3.88%	3.71%-5.07%
Weighted average expected life in years	5-6 years	5-6 years
Dividend yield	0	0

Fair Value of Financial Assets and Liabilities

The Company measures the fair value of financial assets and liabilities based on the guidance of Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (Statement No. 157) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

Effective January 1, 2008, the Company adopted the provisions of Statement No. 157 for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis. The adoption of the provisions of Statement No. 157 did not materially impact the Company s consolidated financial position and results of operations.

Statement No. 157 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. Statement No. 157 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. Statement No. 157 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 liabilities measured at fair value on a recurring basis at December 31, 2008, as required by Statement No. 157:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Liabilities				
Derivative liabilities	$	$ 5,350,829	$	$ 5,350,829

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Derivative instruments:

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

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

Reclassification:

The Company reclassified the December 31, 2007 balances of clinical trial payables, other and clinical trial payables, related party of $2.57 million and $1.9 million, respectively, from accrued liabilities to conform to the December 31, 2008 presentation.

The reclassification had no impact on results of operations for the years ended December 31, 2008 or 2007.

Recent accounting pronouncements:

In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position 157-2, which provides for a one-year deferral of the provisions of Statement No. 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a non-recurring basis. The Company has evaluated the impact of adopting the provisions of Statement No. 157 for non-financial assets and liabilities that are recognized or disclosed on a non-recurring basis and deems there to be no material impact on the financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* (Statement No. 161), an amendment of SFAS No. 133 *Accounting for Derivative Instruments and Hedging* (Statement No. 133). Statement No. 161 requires companies with derivative instruments to disclose information about how and why a company uses derivative instruments, how derivative instruments and related hedged items are accounted for under Statement No. 133, and how derivative instruments and related hedged items affect a company s financial position, financial performance, and cash flows. The required disclosures include the fair value of derivative instruments and their gains or losses in tabular format, information about credit-risk-related contingent features in derivative agreements, counterparty credit risk, and the company s strategies and objectives for using derivative instruments. Statement No. 161 expands the current disclosure framework in Statement No. 133. Statement 161 is effective prospectively for periods beginning on or after November 15, 2008. The Company plans to provide these additional disclosures in the first quarter of 2009.

In April 2008, FASB Staff Position No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP 142-3) was issued. This standard amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. Basis of presentation (continued):

Recent accounting pronouncements (continued):

FASB Statement No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company does not believe the adoption will have a material impact on its financial statements.

In May 2008, the FASB issued Financial Accounting Standard (FAS) No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. The statement is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are prepared in conformance with GAAP. Unlike Statement on Auditing Standards (SAS) No. 69, *The Meaning of Present in Conformity With GAAP*, FAS No. 162 is directed to the entity rather than the auditor. The statement is effective 60 days following the approval by the U.S. Securities and Exchange Commission (SEC) of the Public Company Accounting Oversight Board (PCAOB) amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with GAAP*, and is not expected to have any impact on the Company s results of operations, financial condition or liquidity.

In June 2008, the Emerging Issues Task Force issued EITF Consensus No. 07-05 *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* for periods beginning after December 15, 2008. The objective of this Consensus is to provide guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity s own stock and it applies to any freestanding financial instrument of embedded feature that has all the characteristics of a derivative in a Statements of Accounting Standards No. 133 *Accounting for Derivative Financial Instruments and Hedging Activities*, for purposes of determining whether the financial instrument or embedded feature qualifies for the first part of the scope exception in paragraph 11(a) of Statement 133 (the Paragraph 11(a) Exemption). This Issue also applies to any freestanding financial instrument that is potentially settled in an entity s own stock, regardless of whether the instrument has all the characteristics of a derivative in Statement 133, for purposes of determining whether the instrument is within the scope of Issue 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock*. The Consensus requires the application of a two-step approach that required us (1) evaluate the instrument s contingent exercise provisions and (2) evaluate the instrument s settlement provisions. Based upon applying this approach to instruments within the scope of the consensus, we have determined that adoption will have no impact on our January 1, 2009 financial position.

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, and from funded research arrangements. The Company has not generated revenue from the sale of any product, but has generated deferred revenues from licensing arrangements and research fees in 2008 and 2007. The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, 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 in 2007 consisted of:

$1.9 million loan from CDC IV, LLC, a material stockholder of the Company (CDC) (which was repaid in March 2008, see Note 5);

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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YEARS ENDED DECEMBER 31, 2008 AND 2007

2. Liquidity and management s plans (continued):

$1.0 million loan from Hopkins Capital Group II, LLC, a material stockholder of the Company controlled by the Company s Chairman of the Board (HCG II) (which was repaid in September 2007);

$0.250 million received from the sale of Common Stock to Sigma Tau Industrie Farmaceutiche Riunite S.p.A in January 2007 pursuant to a previously executed Stock Purchase Agreement;

Approximately $0.693 million from the exercise of Common Stock options;

Approximately $3.2 million from the exercise of Common Stock warrants held by Laurus Master Fund, Ltd. (Laurus);

$3.0 million loan from Southwest Bank of St. Louis (which was repaid in September 2007); and

$30.0 million up-front, non-refundable payment received in September 2007 under the U.S. Agreements with Meda relating to the licensing rights for ONSOLIS in the U.S., Mexico and Canada (see Note 7).

Significant financing in 2008 consisted of:

Approximately $0.11 million from the exercise of Common Stock options; and

$2.5 million non-refundable milestone payment received in March 2008, under the EU agreements with Meda relating to the licensing rights for the ONSOLIS product in Europe (see Note 7).

Significant financing and commitments to date in 2009 have consisted of:

$6.0 million payment received in January 2009 which included a $3.0 million advance against the $15 million approval milestone for ONSOLIS and $3.0 million related to amendments to the material agreements between the Company, Arius and Meda for the expansion of the territory covered by the EU agreement.

Company management believes that the Company s existing cash and cash equivalents are sufficient to finance planned basic operations (minimal research and development activities beyond those covered under the Company s Meda and related agreements) through the second quarter of 2009.

While the Company expects that significant additional payments (aggregating an additional $35.0 million) will be received in 2009 under the Meda U.S. and EU License agreements, the receipt of such payments is conditional upon, among other things, FDA approval of the Company s FDA new drug application (NDA) for ONSOLIS and the subsequent 2009 approval in Europe. As such, payments may not be received in 2009

or at all. Accordingly, and especially if such payments are not received, additional outside capital will be required in order to support the Company s 2009 operations, as well as future development activities around the Company s current pipeline of products in development or other initiatives that the Company may elect to pursue.

Also, the Company is currently negotiating an equipment loan financing, which the Company expects will be finalized in the second quarter of 2009 for specialized equipment manufactured for the Company by Doyen Medipharm Inc. and which will be used by our third-party manufacturer of the ONSOLIS product.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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YEARS ENDED DECEMBER 31, 2008 AND 2007

2. Liquidity and management s plans (continued):

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

The Company believes that it will be able to secure outside funding or loans at levels sufficient to support planned operations. However, there can be no assurance that additional capital or loans will be available on favorable terms, if at all. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company s financial condition and viability.

The recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues 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 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.

3. Research and development arrangements and related party transactions:

The Company had a collaborative research agreement with the University of Medicine and Dentistry of New Jersey (UMDNJ), an entity that is also a Company stockholder, under which the Company pays salary for a UMDNJ employee, laboratory supplies and employee parking costs. The agreement expired at the end of 2005. As further discussed in Note 14, the Company also leases its Newark, New Jersey facility from UMDNJ in an operating lease agreement which expired on December 31, 2005 and is now month to month. The Company incurred approximately $0.1 million of research expense in connection with this agreement in each of the years ended December 31, 2008 and 2007. Amounts due to UMDNJ at December 31, 2008 and 2007 are approximately $.1 million and $0.4 million, respectively.

The Company has an agreement with Pharmaceutical Product Development, Inc., a former Company stockholder as of 2008, for research work in connection with a product under development. The Company incurred research expense of $5.6 million under this agreement in 2007. Amounts due to PPD at December 31, 2007 were approximately $1.9 million. There were no amounts due to PPD at December 31, 2008.

The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia Biopharmaceuticals, Inc., a related party, 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 and $0.01 million in 2008 and 2007, respectively, and are included in general and administrative costs, related party. There were no amounts due to Accentia at December 31, 2008 and 2007.

See Note 5 regarding related party notes payable.

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4. Equipment:

Equipment consists of the following:

	December 31, 2008	December 31, 2007
Office and laboratory equipment	$ 2,039,838	$ 2,011,934
Less accumulated depreciation	(1,913,104)	(1,789,128)
	$ 126,734	$ 222,806

Depreciation expense for years ended December 31, 2008 and 2007 was approximately $125,000 and $262,000, respectively.

5. Note payable, related party:

Note payable, related party consists of the following:

	December 31, 2008	December 31, 2007
Note payable, CDC (stockholder)(1)	$	$ 1,900,000
Less unamortized discount		(603,836)
Total	$	$ 1,296,164

(1) On March 12, 2007, the Company closed a one-year, unsecured loan from CDC for $1.9 million, at 10.25% per annum due March 12, 2008 and a warrant (the New CDC Warrant) to purchase 1 million shares of Common Stock with an exercise price of $3.80 per share. The Company filed a registration statement with the SEC to register the shares of Common Stock underlying the New CDC Warrant on March 12, 2008. CDC was also granted piggyback registration rights with respect to such shares of Common Stock. The New CDC Warrant contains weighted average anti-dilution protection. The Company repaid this loan plus accrued interest in March 2008 and the warrant remains outstanding.

On March 30, 2007, HCG II funded a $1.0 million unsecured, non-interest bearing note, due September 30, 2007. As consideration for the loan made by HCG, the Company granted HCG II the right, for a period of six months, to participate in and enter into a royalty purchase agreement. The consideration to be paid upon exercise of the right, which could have been demanded by either the Company or HCG II at any time before September 30, 2007, was $5.0 million. On September 5, 2007, the Company and HCG II entered into an agreement to terminate HCG II s royalty purchase rights and, as consideration; the Company issued a warrant to HCG II to purchase 475,000 shares of Common Stock at $5.55 per share (the closing price on April 2, 2007). On September 14, 2007, the Company repaid the note in full.

6. Notes payable:

Notes payable at December 31, 2008, consist of insurance premium financing. The short-term financing from First Insurance Funding Corp., at 5.95% per annum is payable monthly through April, 2009.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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7. Meda License, Development and Supply Agreements:

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

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

	Contractual Cash Flow				
Contractual Rights and Obligations	**Nonrefundable Upfront and Milestone Payments**			**Cash Flows Received and Revenue Deferred**	
	U.S. Arrangement	**EU Arrangement**	**As Delivered**	**December 31, 2008**	**December 31, 2007**
License rights to ONSOLIS (BEMA Fentanyl) patents and trademarks	$ 30,000,000	$ 5,500,000**		$ 32,500,000	$ 32,500,000
Milestones:					
FDA approval	$ 15,000,000*	n/a			
Completion of Phase 3 clinical trials	n/a	$ 2,500,000		$ 2,500,000	
Governmental Approval in an EU country	n/a	$ 2,500,000			
Earlier of date of first commercial sale or availability of launch supply product inventory	$ 15,000,000	n/a			
Date of first commercial sale in an EU country	n/a	$ 2,500,000			
Research and Development Services for:					
ONSOLIS product through FDA approval			None		
ONSOLIS product through governmental approval in a EU country			Contract Hourly Rates	$ 1,553,624	
Non-Cancer subsequent indication of product and further development of initial product			Contract Hourly Rates	$ 1,135,412	
Other services:					
Participation on Steering, Development, and Commercialization Committees			None		
Other contractual services			None		
Product supply			Company s Fully-burdened Cost		
Royalties			Contract percentage of product net sales revenue		
Commercialization bonuses			Up to $30,000,000		
Total				$ 37,689,036	$ 32,500,000

* The Company received a $3.0 million advance in January 2009 against the $15.0 million approval milestone.

** Includes $3.0 million received January 2009 for expansion of Meda EU license.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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

The Company has assessed the arrangement deliverables under the guidance of EITF Issue No. 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) to determine which deliverables within these arrangements are considered separate units of accounting at the inception of the arrangement and upon delivery of the items required in the arrangements. The application of EITF 00-21 requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

The Company 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 have been 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 will have been delivered to Meda and based on the residual method an estimated $59.5 million (U.S. arrangement) and $14.4 million (EU arrangement), inclusive of the 2009 amendments, and of the aggregate upfront, product development milestone, and research and development services revenue earned will be recognized. In the year ending 2008, the Company reclassified approximately $36.1 million of deferred revenue from non-current to current based on management s estimate that this deferred amount will be recognized within the twelve months ended December 31, 2009.

Upon 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 and but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. The Company 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 the Company. The Company 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 $0.2 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided over the performance period through expiration of the license terms, as defined above.

Based on EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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YEARS ENDED DECEMBER 31, 2008 AND 2007

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

The Company will earn royalties based on a percentage of net sales revenue of the ONSOLIS product. Product royalty revenues are computed on a quarterly basis when Meda s third-party sales revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. Commercialization bonuses represent additional nonrefundable royalties due if commercial sales exceed certain predefined thresholds. They will be recognized as revenue if and when they are earned.

8. Acquired product rights and license agreements:

On August 2, 2006, Arius Two, a newly formed, wholly-owned subsidiary of the Company, entered into an Intellectual Property Assignment Agreement and related agreements with QLT U.S.A, Inc. (QLT) pursuant to which Arius Two purchased intellectual property rights owned by QLT related to its BEMA technology for territories located outside of the United States. The Company, through its Arius One subsidiary, previously licensed exclusive rights to the BEMA technology for such territories. Arius Two paid $3.0 million for the acquired intellectual property rights, consisting of $1.0 million in cash and a promissory note, secured by the purchased assets, for $2.0 million. Payments under such note are due as follows: (i) $1.0 million on March 31, 2007, (payment made on March 30, 2007) and (ii) $1.0 million within 10 business days of initial non-U.S. approval of any BEMA product.

Management deems the last $1.0 million payment a contingent liability and therefore will not record the $1.0 million as a liability or intangible asset until the conditions occur which would trigger the requirement to make this payment. On September 5, 2007, the Company purchased from QLT the BEMA drug delivery technology and intellectual property assets specifically related to the development and commercialization of the BEMA technology in the United States (the BEMA U.S. Rights) for a purchase price of $7.0 million, which would be paid over time. The Company had previously licensed the BEMA U.S. Rights from QLT. In consideration for the BEMA U.S. Rights, the Company agreed to pay QLT $7.0 million, consisting of $3.0 million in cash and a $4.0 million promissory note, secured by the purchased assets. Payments under such note are due as follows: (i) $2.0 million within ten (10) business days of FDA approval of a product based on the BEMA technology and (ii) $2.0 million within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA -based products reach $30.0 million.

The Company has recorded the $3 million payment as additional acquired product rights in the accompanying December 31, 2008 consolidated balance sheet. Management deems the $4 million balance a contingent liability and, therefore, will not record the $4 million (or parts thereof) as a liability or intangible asset until such time as the conditions which trigger the payment obligation have been satisfied. On the date of this transaction, the Company will allocate the remaining license amounts to BEMA to acquired product rights.

9. Convertible notes payable:

During February and May, 2005, the Company consummated an aggregate $5.0 million secured convertible debt financing from Laurus. The Laurus investments took the form of convertible notes secured by certain of the Company s assets. The notes had a 3-year term and were payable in monthly installments plus interest at prime plus 2%, with a floor ranging from 7.5% to 8%. The notes were convertible, under certain conditions, into shares of the Company s Common Stock. As a result of the anti-dilution provisions of the notes and the pricing of the Company s October 2005 public offering, the conversion price of the Laurus notes were reduced. In connection with these financings, the Company also issued Laurus Common Stock purchase warrants to purchase up to 833,871 shares of Common Stock.

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9. Convertible notes payable (continued):

From June 2005 through December 2006, the Company entered into amendments to the financing agreements with Laurus under which Laurus agreed to defer certain principal payments otherwise required under the agreements. In consideration for these amendments, the Company issued Laurus warrants to purchase shares of the Company s Common Stock as follows:

Amendment Date	Number of Warrants	Exercise Price	Warrant Expiration Date
June 29, 2005	30,000	$ .001	June 29, 2012
December 29, 2005	69,274	$ .001	December 29, 2012
July 25, 2006	110,000	$ 3.00	July 25, 2013
September 20, 2006	33,000	$ 3.00	September 20, 2011
December 28, 2006	1,500,000	$ 3.05	December 28, 2013

Except for the exercise price of these warrants, these warrants were substantially similar to the warrants issued in February and May, 2005, and none of the loan modifications associated with the issuance of these warrants resulted in a debt extinguishment for financial reporting purposes.

During the first quarter of 2007, Laurus exercised its right to convert $2.4 million of principal and $0.1 million of interest (which fully extinguished the February 2005 note).

On April 10, 2007, the Company entered into a fifth amendment to the May 2005 convertible note with Laurus. Pursuant to the Fifth Amendment, Laurus agreed: (i) to exercise an aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of Common Stock, resulting in cash proceeds of approximately $3.2 million to the Company and (ii) to defer all principal payments under the Company s May 2005 note with Laurus to July 1, 2008. In consideration of these agreements, the Company issued to Laurus a new warrant to purchase 833,871 shares of Common Stock at $5.00 per share. The Company applied the provisions of EITF 06-06 *Debtor s Accounting for Modification (or exchange) of Convertible Debt Instruments* to the above amendment dated April 10, 2007. Since the post-modification present value of the cash flows to the lender, including the $3,746,666 fair value of the new warrants, exceeded the fair value of such cash flows before the modification by more than 10%, the debt modification was accounted for as a debt extinguishment. As such, the debt was adjusted to its fair value; the $151,497 excess of the carrying value of the debt over its fair value (gain), net of the $3,746,666 fair value of the warrants was recorded as a loss on extinguishment of debt.

Subsequently, Laurus converted all remaining outstanding principal and interest into shares of Common Stock. As a result, all principal and interest under the Company s February and May 2005 convertible notes with Laurus has been either paid or fully converted into shares of Common Stock.

The Laurus financings included registration rights related to share settlement of the embedded conversion features and the warrants (both initially and subsequently issued) which the company determined not to be within its control. In addition, certain features associated with the financings, such as anti-dilution protection afforded to Laurus, rendered the number of shares issuable under the financings to be variable. In these instances, EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock*, required allocation of the proceeds between the various instruments and the derivative elements carried at fair value.

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9. Convertible notes payable (continued):

The following tabular presentation reflects the allocation of the proceeds of the financing as well as activity during the reporting periods:

Principal balance of note	$ 5,000,000
Less reduction for:	
Fair value of beneficial conversion option	(1,450,404)
Fair value of warrants	(993,501)
Recorded at inception	2,556,095
Accretion of discount (interest expense) through December 31, 2006	1,891,896
Conversion of debt to equity through December 31, 2006	(694,237)
Adjustment of carrying value to fair value resulting from debt extinguishment	249,496
Carrying value at December 31, 2006	4,003,250
Accretion of discount during 2007	454,007
Extinguishment of debt during 2007	(151,497)
Conversion of debt to equity during 2007	(4,305,760)
Carrying value at December 31, 2007	$

10. Derivative Financial Instruments:

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

	2008	2007
Free standing warrants	$ 5,350,829	$ 6,543,571

Shares into which derivative liabilities can be settled:	**2008**	**2007**
Free standing warrants	4,622,265	4,622,265

Derivative income (expense) in the accompanying statements of operations is related to the individual derivatives as follows:	**2008**	**2007**
Embedded derivative instruments		$ (3,430,698)
Free standing derivatives (principally warrants)	1,192,742	5,738,131

Total	$ 1,192,742	$ 2,307,433

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11. Income taxes:

The Company has no income tax expense or benefit for 2008 or 2007 as the Company has incurred net operating losses and has recognized valuation allowances for all deferred tax assets. The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	Year Ended December 31,	
	2008	2007
Federal statutory income tax rate	34.00%	34.00%
State taxes, net of federal benefit	3.45	3.45
Permanent difference compensation expense	(2.52)	(4.59)
Research and development (R&D) credit	7.42	0.79
Other	(0.41)	(0.01)
Valuation allowance	(41.94)	(33.64)
	%	%

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,	
	2008	2007
Deferred tax assets (liabilities)		
Deferred revenue	$ 12,228,901	$ 993,361
Basis difference in equipment	(26,423)	(30,357)
Basis difference in debt		(87,557)
Basis difference in intangibles	(1,073,793)	(1,244,232)
Accrued liabilities and other	444,786	442,867
Loss on extinguishment	3,080,454	
R&D credit	2,767,494	1,489,421
Stock options	653,633	159,945
Derivative liabilities	(1,390,767)	1,853,035
Net operating loss carry-forward (NOL)	12,884,154	18,765,169
	29,568,439	22,341,652
Less: valuation allowance	(29,568,439)	(22,341,652)

FAS 109 requires 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 that is more likely than not to be realized.

As a result the Company recorded a valuation allowance with respect to the all the Company s deferred tax assets.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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11. Income taxes (continued):

The Company has a Federal net operating loss carryforward of approximately $35.1 million and a State net operating loss of approximately $28.0 million as of December 31, 2008. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 for state purposes. Under Section 382 and 383 of the U.S. 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. The Company has determined that such an ownership change occurred on May 16, 2006. Approximately $23.1 million of the NOL was generated before the ownership change, and is subject to limitation. The Company s annual limitation for utilizing this portion of the NOL is approximately $1.5 million.

12. Stockholders equity:

Preferred stock:

The Company has authorized five million shares of $.001 par value preferred stock. At January 1, 2007, 2,588,236 shares were designated as follows: Series A Preferred Stock of 1,647,059 shares and Series B preferred Stock of 341,176 shares.

On February 22, 2007, all 1,647,059 shares of the Company s Series A Preferred (which were issued to the former stockholders of Arius One upon the Company s acquisition of Arius One in August 2004) were exchanged with the holders thereof via a redemption for an identical number of shares of newly designated Series C Non-Voting Convertible Preferred Stock (Series C Preferred). The rights associated with the Series C Preferred Stock were identical to those associated with the Series A Preferred in all material respects except that the Series C Preferred had different terms of conversion into shares of Common Stock.

The Company recorded the $3,870,587 excess of the fair value of the Series C Preferred (based upon the fair value of the underlying Common shares into which the Series C Preferred was deemed likely to be convertible in the near term) over the carrying value of the Series A Preferred Stock redeemed as a preferred Stock constructive dividend. As of December 31, 2007, all 1,647,059 shares of Series C Preferred had been converted into a like number of shares of Common Stock.

On January 10, 2007, HCG II converted 341,176 shares of the Company s Series B Convertible Preferred Stock (consisting of all said Series B Preferred Shares outstanding) into 341,176 shares of Common Stock. No other consideration was paid. HCG II also acquired 59,226 shares of Common Stock pursuant to the conversion of accrued and unpaid dividends on the Series B Convertible Preferred Stock.

Stock options:

The Company has an Amended and Restated 2001 Incentive Plan, which covers a total of 3,500,000 shares of Common Stock (as amended). Options may be awarded during the ten-year term of the 2001 stock incentive plan to Company employees, directors, consultants and other affiliates. 3,467 options were granted to employees outside of the stock incentive plan during 2008.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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12. Stockholders equity (continued):

Stock option activity for the years ended December 31, 2008 and 2007 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2007	2,023,704	$ 3.04	
Granted in 2007:			
Officers and Directors	1,023,767	5.43	
Others	379,150	3.90	
Exercised	(268,118)	2.58	
Forfeitures	(462,599)	3.99	
Outstanding at December 31, 2007	2,695,904	$ 3.95	$ 606,414
Granted in 2008:			
Officers and Directors	509,195	2.23	
Others	473,366	2.40	
Exercised	(65,000)	1.66	
Forfeitures	(109,998)	3.34	
Outstanding at December 31, 2008	3,503,467	$ 3.56	$ 1,044,112

Options outstanding at December 31, 2008 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	2,739,722	7.86	$ 2.75	
$5.01 10.00	763,745	8.29	$ 6.48	
	3,503,467			$ 1,044,112

Options exercisable at December 31, 2008 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining	Weighted Average Exercise	Aggregate Intrinsic Value

			Contractual Life (Years)	Price	
$1.00	5.00	1,855,339	7.27	$ 2.87	
$5.01	10.00	287,916	8.31	$ 6.33	
		2,143,255			$ 629,686

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12. Stockholders equity (continued):

The weighted average grant date fair value of options granted during 2008 and 2007 whose exercise price is equal to the market price of the stock at the grant date was $2.31 and $3.68, respectively. The weighted average grant date fair value of options granted during 2007 whose exercise price is greater than the estimated market price of the stock at the grant date is $6.63. There were no options granted during 2008 whose exercise price is greater than the estimated market price of the stock at the grant date.

A summary of the status of the Company s nonvested stock options as of December 31, 2008, and changes during the year then ended, is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Intrinsic Value
Nonvested at January 1, 2008	1,178,696		
Granted	982,561		
Vested	(722,444)		
Forfeited	(78,601)		
Nonvested at December 31, 2008	1,360,212	$ 3.91	$ 414,427

As of December 31, 2008, there was approximately $1.9 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next three years.

On November 19, 2008, under delegated authority from the Compensation Committee of the Company s board of directors, the Chairman of the Compensation Committee approved an amendment to the Amended and Restated 2001 Incentive Plan to provide that all options outstanding immediately prior to a Change in Control of the Company (as defined in the plan amendment) shall immediately become fully vested and exercisable.

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, 2008 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	5,148,765	4.58	$ 3.42	
$5.01 10.00	700,000	2.79	$ 5.45	

	5,848,765	$ 200,895

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13. 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 and $0.08 million in 2008 and 2007, respectively.

14. Commitments and contingencies:

Employment agreements:

The Company has employment agreements with certain employees, which extend for 36 months. These agreements provide for base levels of compensation and separation benefits. Future minimum payments under these employment agreements as of December 31, 2008 are $0.8 million and $0.05 million for the years ended December 31, 2009 and 2010, respectively.

Operating leases:

Since April 2001, the Company leased a facility from UMDNJ (a stockholder), under an operating lease which expired on December 31, 2005. The Company is currently leasing the space under a month to month contract. Since November 2007, the Company also leases space for their corporate offices which expires January 2013. Lease expense for both locations was approximately $0.2 and $0.1 million for years ended December 31, 2008 and 2007, respectively.

The future minimum commitments on all operating leases at December 31, 2008 are as follows:

Years ending December 31,	
2009	$ 118,371
2010	121,794
2011	125,318
2012	128,949
2013	11,004
	$ 505,436

Royalty commitment:

Upon its formation, the Company originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, the Company issued shares of Common Stock and agreed to make future royalty payments to the universities upon (a) the licensing of rights to sub-licensees (up to 5% of fees as amended on December 16, 2002); (b) sales by sub-licensees (25% of Company proceeds); or (c) Company sales (3% of revenue). Amounts due to these universities at December 31, 2008 and 2007 for royalties are both approximately $.06 million. Royalty expense was $0.0 million for each of the years ended December 31, 2008 and 2007.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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14. Commitments and contingencies (continued):

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, 2008 which would trigger any liability under the agreement.

Equipment purchase commitment:

On August 28, 2007, the Company agreed with Doyen Medipharm Inc. to purchase a BEMA related pharmaceutical device production machine. The Company has made payments or has accrued approximately $2.9 million (included in deposits on equipment in the accompanying consolidated balance sheet) toward the total cost, which is approximately $3.3 million. Payments are being made in separate increments during the production of the equipment. Equipment financing negotiations are pending and the Company anticipates closing a transaction in the second quarter in 2009.

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 terminates at the time of FDA approval of ONSOLIS . As such, until such approval, CDC retains the right to reclaim the ONSOLIS -related assets in the event of a default by the Company under the CDLA. Events of default include: (i) failure to pay royalties, (ii) acceleration of a debt in excess of $1.0 million and the Company s failure to pay such debt, (iii) judgment of $500,000 and the Company s failure to satisfy such judgments, or (iv) the Company s insolvency, among other things.

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

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14. 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.

15. Subsequent events:

On January 2, 2009, the Company entered into amendments to the material agreements between the Company, Arius and Meda which relate to the commercialization of the Company s lead product candidate, ONSOLIS (see Note 7).

Pursuant to the amendment made to the Meda EU Agreements (the EU Amendment), the Company received $3 million in consideration of the grant to Meda of the worldwide commercialization rights to ONSOLIS , with the exception of Taiwan and South Korea (the rights to which shall be retained by the Company). The sales royalties to be received by the Company will be the same for all territories as that agreed to for Europe. As such, the definition of Territory in the Meda EU Agreements has been amended to mean all countries of the world other than the United States, Canada, Mexico, Taiwan and the Republic of Korea and the definition of Licensed Patent Rights has been amended to include patents owned by the Company and that have been issued in Australia and that are pending in Japan. In addition, various terms of the Meda EU Agreements have been modified to reflect the rights and obligations of both the Company and Meda in recognition of the expansion of the scope of the Meda EU Agreements. The Company and Meda also modified several terms of the related ONSOLIS Supply Agreement between the parties, dated September 5, 2007, to reflect the changes in the territorial scope of the expanded territory definition of the Meda EU Agreements.

Pursuant to the amendment made to the Meda U.S. Agreements (the U.S. Amendment), the Company received $3 million as an advance against the anticipated aggregate $30 million ONSOLIS approval milestone provided for in the Meda U.S. Agreements. Under the original Meda U.S. Agreements, the Company was to receive an aggregate milestone payment of $30 million associated with the approval and commercial launch of ONSOLIS , as follows: $15 million upon approval by the U.S. FDA, and an additional $15 million upon the completion of quantities of ONSOLIS sufficient for launch stocks. As a result of the U.S. Amendment, the definition of the U.S. Approval Milestone in the Meda U.S. Agreements has been amended and replaced with the following definition: U.S. Approval Milestone means (i) $11,900,000 if FDA approval of an NDA filed with respect to the Fentanyl Product occurs on or before June 30, 2009, (ii) $11,800,000 if FDA approval of an NDA filed with respect to the Fentanyl Product occurs after June 30, 2009 and on or before December 1, 2009, or (iii) $15,000,000 if FDA Approval of an NDA filed with respect to the Fentanyl Product occurs after December 1, 2009. Both milestones are anticipated to be paid to the Company upon FDA approval which is anticipated in the second quarter of 2009.

On January 20, 2009 the Company entered into a Research Collaboration and License Agreement (the Agreement) with The Drugs for Neglected Diseases initiative, a not-for-profit foundation organized under the laws of Geneva, Switzerland (DND*i*) for the development and distribution of the Company s Bioral Amphotericin B product for certain targeted applications, specifically African Human Trypanosomiasis (HAT), Chagas disease and both visceral and cutaneous Leishmaniasis (the Target Applications).

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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15. Subsequent events (continued):

Under the Agreement, the Company and DND*i* will, on a non-exclusive basis, collaborate in assessing the efficacy of Bioral Amphotericin B in the Target Applications (the period of efficacy assessment collaboration being referred to herein as the Assessment Period). Following the Assessment Period, should efficacy be established, DND*i* will be responsible for obtaining (including providing required funding to secure) regulatory approvals for the Target Applications in all countries of the world, but excluding Japan, Australia, New Zealand, Russia, CIS countries, China, and all countries in North America and any country in, or that joins, the European Union (the Territory), with the rights to non-Territory countries to remain with the Company. DND*i* will also be responsible for conducting and funding the distribution of Bioral Amphotericin B through public sector non-profit or public benefit agencies for use in the Target Applications in the Territory (but excluding any military organization, branch, department or agency, the rights to which shall remain with the Company).

On February 11, 2009, the Board of Directors of the Company approved, by unanimous written consent to action, an amendment to the Company s Certificate of Incorporation (the Certificate of Incorporation) by way of a Certificate of Elimination for the Company s Series A Non-Voting Convertible Preferred Stock, Series B Convertible Preferred Stock, and Series C Non-Voting Convertible Preferred Stock (the Certificate of Elimination). On February 12, 2009, the Company filed the Certificate of Elimination with the Secretary of State of the State of Delaware, which is the effective date of the amendment. The Company may reissue up to 5 million shares of Preferred Stock.

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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 20, 2009

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer

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

Person	Capacity	Date
/s/ Francis E. O Donnell, Jr. Francis E. O Donnell, Jr.	Chairman of the Board and Director	March 20, 2009
/s/ Mark A. Sirgo Mark A. Sirgo	President and Chief Executive Officer (Principal Executive Officer)	March 20, 2009
/s/ James A. McNulty James A. McNulty	Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)	March 20, 2009
/s/ William B. Stone William B. Stone	Director	March 20, 2009
/s/ John J. Shea John J. Shea	Director	March 20, 2009
/s/ William S. Poole William S. Poole	Director	March 20, 2009