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

Form 10-K

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

For the fiscal year ended December 31, 2007

☐ **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 ☒ 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. Yes ☐ No ☒

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 6, 2008 was approximately $29,681,244 based on the closing sale price of the company's common stock on such date of U.S. $2.54 per share, as reported by the Nasdaq Capital Market.

As of March 6, 2008, there were 19,160,637 shares of company common stock issued and 19,145,546 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc.

Form 10-K

For the fiscal year ended December 31, 2007

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NOTE ON FORWARD LOOKING STATEMENTS

This Report, including the documents 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 expectations or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements included in this Report or our other filings with the 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, BEMA™ Fentanyl;
- 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 interest in licensed patents, or our ability to enforce our rights under such 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 may 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 emerge from time to time 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.

PART I

Item 1. Description of Business.

Overview

We are a specialty pharmaceutical company that is utilizing its licensed, owned and proprietary drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, clinically significant new formulations of proven therapeutics.

Our 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 which incorporate our licensed 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.

Our drug delivery technologies include:

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

Utilizing our licensed delivery technologies, we are currently developing formulations of pharmaceuticals aimed principally at acute (i.e., short term) conditions occurring in cancer and surgical patients, mostly notably in the areas of pain and fungal infections. We have completed the principal Phase III studies and submitted a New Drug Application, or NDA, to the FDA for our lead product, BEMA™ Fentanyl, a treatment for "breakthrough" cancer pain (i.e., episodes of severe pain which "break through" the medication used to control the persistent pain). Our next product utilizing the BEMA™ technology is BEMA™ Buprenorphine, a treatment for moderate to severe pain conditions, which is currently in Phase I.

Our lead Bioral® formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for systemic fungal infections. We also believe our Bioral® technology has the potential to be applied to other types of pharmaceuticals and also to other therapeutics such as small interfering RNA, or siRNA.

Some of our products, such as BEMA™ Fentanyl and BEMA™ Buprenorphine, may also have broader indications that would allow for chronic use. When such products present a viable commercial opportunity we will also 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. In 2006 and 2007, we received initial up-front non-refundable licensing payments of $2.5 million and $30.0 million for, respectively, the rights to commercialize BEMA™ Fentanyl in Europe and the U.S., Canada and Mexico. We generated $2.5 million from the sale of a royalty stream asset in 2004 and have also historically generated nominal revenue from research collaborations and grants. 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 sources of revenue 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 where they exist.

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

- applying our drug delivery technologies to existing therapeutics to create our own proprietary products, which we will then seek to obtain approval from the FDA and other worldwide regulatory approval for and, subsequently, commercialize;
- partnering with pharmaceutical companies to assist in the distribution of our products for which we will receive milestone and royalty payments,
- licensing and joint venture arrangements with third parties, including pharmaceutical companies whose own proprietary pharmaceutical products may benefit from our drug delivery technologies; and
- proceeds raised from public and private financings and strategic transactions.

BEMA™ Technology and Products in Development

Our BEMA™ drug delivery technology consists of a small, erodable polymer disc for application to the buccal mucosa (the lining inside the cheek). BEMA™ discs 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. After purchasing these intellectual property rights from QLT, we will not owe any future milestone payments or royalties to QLT.

Our lead BEMA™ product under development is BEMA™ Fentanyl, a treatment for breakthrough cancer pain. The following are the clinical development milestones achieved with BEMA™ Fentanyl:

- The product entered into Phase III trials for breakthrough cancer pain in the second half 2005.
- In February of 2006, enrollment in the Phase III clinical program commenced.
- In April and May 2006, we announced results from pharmacokinetic studies demonstrating dose proportionality and reproducibility with BEMA™ Fentanyl.
- In September 2006, we conducted a second meeting with the FDA to discuss the status of the BEMA™ Fentanyl development program.
- In April 2007, we announced the preliminary results of our Phase III efficacy study for BEMA™ Fentanyl, which showed that patients treated with BEMA™ Fentanyl 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 III clinical trial and results of a bioavailability study for BEMA™ Fentanyl, which showed that: (i) the absolute bioavailability (i.e. the total amount absorbed from the delivery system) of fentanyl from the BEMA™ Fentanyl disc 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 disc or multiple discs produced identical plasma concentrations (i.e. four-200 mcg discs provided the same plasma concentrations as a single-800 mcg disc) and (iii) the SPID 15 (Summary of Pain Intensity Difference at 15 minutes) was significantly higher (i.e. improved) for BEMA™ Fentanyl than placebo.

In September 2007, we entered into a U.S. commercial partnership for the distribution of BEMA™ Fentanyl with Meda AB, a Swedish company which we refer to herein as Meda, which is also our commercialization partner in Europe for this product. In late October 2007, we submitted our BEMA™ Fentanyl NDA to the FDA, and in January 2008 we announced that the NDA had been accepted for review by the FDA. The PDUFA date for this NDA (the date we expect a decision by the FDA on the approvability of BEMA™ Fentanyl) is August 31, 2008, although the FDA may take longer to complete its review.

We have previously received funding for our BEMA™ Fentanyl 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 BEMA™ Fentanyl assets.

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

In January 2008, we announced the expansion of our clinical development program for BEMA™ Fentanyl to assess the efficacy and safety of the product for the treatment of breakthrough pain associated with other chronic pain conditions beyond cancer. This expanded clinical program will be undertaken with our partner Meda. Meda will be fully responsible for funding the expanded clinical development program in non-cancer breakthrough pain.

Bioral® Technology and Products in Development

Our Bioral® (cochleate) drug delivery technology encapsulates (encochleates) the 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 provides an effective delivery mechanism without forming a chemical bond, or otherwise chemically altering, the selected drug. We believe this technology will allow us to take certain drugs that were 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. A Bioral® formulation of Amphotericin B (which we refer to as CAMB) would have the potential for oral delivery of a drug that is currently only given by intravenous injection. Following the completion of preclinical testing in 2006, we submitted an IND to

the FDA for CAMB in December 2006 which was accepted by the FDA. We believe that the opportunity to move forward with testing a Bioral® formulation in humans represents a major milestone for us. The next step for CAMB will be to manufacture clinical supplies and proceed with our first Phase I trial in normal volunteers to evaluate the safety of the product and its pharmacokinetics. We expect to conduct our first Phase I trial for CAMB in normal volunteers in the first half of 2008.

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 CAMB may provide enhanced efficacy and stability. In April 2004, we licensed this second opportunity to Accentia Biopharmaceuticals, Inc., 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, 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® encochleation 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.

Emezine®

In 2004 and 2005, we were developing Emezine,® a formulation of prochlorperazine, which we believe would be one of the first drug to be delivered transmucously 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. We have had interactions with the FDA regarding Emezine® and are currently determining whether we will proceed with the continued development of Emezine®. We plan to meet and discuss with our partners in 2008 to make a final determination regarding the future of the Emezine® project. We do not expect to spend material resources on the Emezine® project for the foreseeable future. We licensed Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

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 Pharmaceuticals, Inc. (which we refer to herein as 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 BEMA™ Fentanyl in the United States, Mexico and Canada.

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

- $30 million milestone payment upon closing (which was received on September 14, 2007). We have recorded the $30 million payment received as deferred revenue.

- An additional $30 million milestone payment concurrently with receipt of approval of BEMA™ Fentanyl by the FDA, unless we have not, at such time, manufactured stocks of BEMA™ Fentanyl, in bulk or finished form, sufficient for commercial launch of BEMA™ Fentanyl in the U.S., in which case $15 million will be paid upon FDA approval and $15 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 BEMA™ Fentanyl. We anticipate that we will have sufficient launch stocks of BEMA™ Fentanyl product concurrently with FDA approval of BEMA™ Fentanyl.
- A significant double digit royalty on net sales of BEMA™ Fentanyl 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.
- Sales milestones equaling an aggregate of $30 million payable at:
    - $10 million when and if annual sales exceed $75 million;
    - $10 million when and if annual sales exceed $125 million; and
    - $10 million when and if annual sales exceed $175 million

Also, pursuant to the U.S. license agreement with Meda, we have been granted certain rights to co-promote BEMA™ Fentanyl 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 will not begin for a period of time following FDA approval of BEMA™ Fentanyl. 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 all future costs of clinical development that do not involve studies in support of the NDA such as additional indications for BEMA™ Fentanyl. We announced the expansion of our clinical development program for BEMA™ Fentanyl in January 2008 to include a clinical development program to support a potential indication for breakthrough pain in non-cancer patients.

European Agreement. In August 2006, we announced collaboration with Meda to develop and commercialize BEMA™ Fentanyl in Europe. Under terms of the agreement, we granted Meda rights to the European development and commercialization of BEMA™ Fentanyl, in exchange for an upfront fee to BDSI, certain milestone payments and double digit royalties to be received by BDSI on product sales. Payments include a $2.5 million payment upon execution of the agreement and additional milestones that would, if achieved, provide BDSI 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 BEMA™ Fentanyl in Europe. We retain all development and commercial rights in Japan, Australia and other territories outside of Europe (other than the U.S., Mexico and Canada).

Relationship with CDC

On July 15, 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 BEMA™ Fentanyl.

Under the CDLA, CDC is entitled to receive a single digit royalty based on net sales of BEMA™ Fentanyl (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 BEMA™ Fentanyl were exclusively licensed to CDC for a limited purpose and limited duration. The license terminates on FDA approval of BEMA™ Fentanyl. CDC granted us in return an exclusive license to utilize all such information and rights prior to FDA approval of BEMA™ Fentanyl. 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 BEMA™ Fentanyl.

Royalties under the CDLA are subject to upward adjustments: (i) for delays in obtaining regulatory approval for BEMA™ Fentanyl, (ii) for the market entry of certain defined competing products in the United States prior to the first commercial sale of BEMA™ Fentanyl, or (iii) if the average selling price of BEMA™ Fentanyl is less than that of certain defined competing products. In the event we do not diligently pursue the development and regulatory approval of BEMA™ Fentanyl or if we encounter certain specified negative circumstances regarding the development of BEMA™ Fentanyl, CDC has the right to pursue development and commercialization of BEMA™ Fentanyl pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of our BEMA™ Fentanyl assets to CDC, provided that, under certain conditions, we may, despite such negative circumstances, retain our rights to BEMA™ Fentanyl 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 per share (originally $3.50, which exercise price was adjusted as a result of our October 2005 public financing) and contains certain anti-dilution provisions with respect to certain issuances of stock (or issuance of securities convertible into stock) at a price per share less than the exercise price stated in the warrant during the six months following its issuance Also, the number of shares for which the warrant may be exercised are subject to adjustment based on the amount of funding provided by CDC, provided the warrant shall not, in any event, be exercisable for less than 100,000 shares of our common stock. Finally, such 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 BEMA™ Fentanyl, (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 BEMA™ Fentanyl. The formal security interest terminates at the time of FDA approval of BEMA™ Fentanyl. Until such NDA approval, CDC retains the right to reclaim our BEMA™ Fentanyl-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 breaches, CDC alleged, require the Company to transfer certain specified rights and assets relating to BEMA™ Fentanyl 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 the Company 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 BEMA™ Fentanyl 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 BEMA™ Fentanyl.

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 triggered the ROFN provisions. Under such transaction, we deferred all principal and interest under Laurus' existing convertible notes 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 is 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 new CDC financing involves 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. We are not required to file a registration statement to register the shares of common stock underlying such warrant for a period of one year (i.e., a registration statement must be filed by March 12, 2008). CDC was also granted "piggyback" registration rights with respect to such shares of common stock which come into effect only after March 12, 2008. This warrant contains "weighted average" anti-dilution protection. The proceeds from this financing are being used for general corporate purposes and for the continued development of BEMA™ Fentanyl.

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 Company 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 BEMA™ Fentanyl product or (ii) any debt financing from a federal or state accredited bank, provided the annualized interest rate thereunder will not exceed 18% (a "Financing Transaction"), we shall first provide CDC a written notice containing all of the terms and conditions pursuant to which we would enter the Financing Transaction (the "Definitive Terms"). For a period of ten (10) days following CDC's receipt of the Definitive Terms (the "Acceptance Period"), CDC shall have the right, but not the obligation (the "Acceptance Right"), to elect in writing to engage in the Financing Transaction on the Definitive Terms. If, during the Acceptance Period, CDC elects to exercise its Acceptance Right, we and CDC agree to then exclusively negotiate definitive documentation relating to the Financing Transaction for a period not to exceed thirty (30) days from the date of CDC's exercise of its Acceptance Right. The definitive documentation shall be based upon, and shall be consistent in all material respects with, the Definitive Terms, without modification. If, during the Acceptance Period, CDC does not elect to exercise its Acceptance Right, or, in the event the Acceptance Right is exercised but a closing of the Financing Transaction does not occur within the thirty (30) day period referred to above, then we shall have sixty (60) days in which to consummate a Financing Transaction with any third party with no further action or approval required by the CDC; provided, however, that the terms and conditions of such transaction shall be not less favorable to us than the terms and conditions set forth in the Definitive Terms.

The ROFR will cease at any time the Company maintains 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. In connection with the RPAA, we and CDC amended the promissory note dated March 12, 2007 in the amount of $1,900,000 so that any breach or default under the RPAA shall also be considered an event of default under such note.

Laurus Financings

In February and May 2005, we entered into two convertible note and warrant financings with Laurus Master Fund, Ltd., which we refer to herein as Laurus. These notes were secured. The notes were extended and amended five times through 2007. On April 10, 2007, we entered into a fifth amendment to the May 2005 convertible note with Laurus. Pursuant to such amendment, Laurus agreed: (i) to exercise an aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of our common stock, resulting in cash proceeds of approximately $3.2 million to us and (ii) to defer all principal payments under the May 2005 note with Laurus to July 1, 2008. In consideration of these agreements, we issued to Laurus a new warrant to purchase 833,871 shares of our common stock at $5.00 per share. We agreed to file by May 25, 2007 a registration statement registering the shares underlying such warrant, together with certain other shares of common stock beneficially held by Laurus (such statement was filed on May 24, 2007 and declared effective by the SEC on June 29, 2007). Subsequently, Laurus converted all outstanding principal and interest under its May 2005 note into shares of Common Stock. As a result, all principal and interest under the February and May 2005 convertible notes with Laurus has been either paid or fully converted into shares of common stock.

2005 Public Offering

In early October 2005, we announced the consummation of a “follow on” public offering of 4,400,000 shares of our common stock, resulting in gross proceeds of $8.8 million to us. The public price per share for the offering was $2.00. The offering was underwritten by Ferris, Baker Watts Incorporated, Maxim Group LLC and GunnAllen Financial, Inc. The underwriters were granted an option to purchase up to an additional 660,000 shares of our common stock to cover over-allotments, which option was partially exercised in late October 2005, generating additional gross proceeds of $107,900.

Acquisition of Arius Pharmaceuticals, Inc.

On August 24, 2004, we consummated the acquisition of Arius Pharmaceuticals, Inc. Arius was a specialty drug delivery company developing products for the “acute” treatment opportunities such as pain, anxiety, nausea and vomiting, targeted primarily to surgical and oncology patients. 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, Mark A. Sirgo, Pharm.D., a founder and the President and CEO of Arius, entered into an employment agreement with us and was named Senior Vice President of Commercialization and Corporate Development. Andrew L. Finn, Pharm.D., also a founder and the Chief Operating Officer of Arius, also entered into an employment agreement with us and was named our Senior Vice President of Product Development. Subsequent to the Arius closing, Dr. Sirgo was promoted through several positions and currently serves as the President and Chief Executive Officer of our company. Dr. Finn was, subsequent to the Arius closing, promoted to the position of Executive Vice President of Clinical Development and Regulatory Affairs of our company and now serves as 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 we refer to herein as the Series A Preferred. Drs. Sirgo and Finn, as the principal stockholders of Arius, were each issued 797,413 shares of Series A Stock, representing an aggregate of approximately 97% of the outstanding shares of Series A Stock. The Series A Stock were convertible into shares of our common stock under certain conditions on a one-for-one basis at a value of $4.25 per share. All shares of Series A Stock have subsequently been exchanged by the holders thereof for shares of newly-designated Series C Non-Voting Convertible Preferred Stock, which we refer to herein as the Series C Stock. Following such exchange, all shares of Series A Stock were cancelled. The rights associated with the Series C Stock were identical to those associated with the Series A Stock in all material respects except that the Series C Stock had different terms of conversion into shares of our common stock. Shares of Series C Stock were convertible into shares of our common stock upon the earliest to occur of: (i) our public announcement of positive outcome of our Phase III efficacy trials (FEN-201) for BEMA™ Fentanyl, with the term "positive outcome" meaning a statistically significant difference (p less than or equal to 0.05) in the primary efficacy endpoint comparing active to placebo; or (ii) August 24, 2009. A positive outcome of our Phase III efficacy trial was announced in April 2007 and all shares of Series C Stock were converted into shares of our common stock by September 30, 2007.

Sigma-Tau License and Stock Purchase Transaction

On January 20, 2005, we signed a definitive licensing agreement with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., or 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. Sigma-Tau Pharma is an affiliate of The Sigma-Tau Group, one of Italy's leading pharmaceutical companies. Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of US$250,000 from, Sigma-Tau, a holding company of The Sigma-Tau Group. This upfront payment was applied toward the purchase by Sigma Tau of unregistered shares of our common stock priced at $4.25 a share. The stock purchase agreement with Sigma-Tau provides for the purchase 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. 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.

We continued to work with Sigma-Tau on this project during 2007. 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 principle. 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 as described above. 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.

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, and in particular 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 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 III data on BEMA™ Fentanyl and submitted our first BEMA™-related NDA (for BEMA™ Fentanyl).

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,
- limited pharmacokinetic evaluation of the new dosage form in humans,
- two placebo controlled clinical studies in humans,
- stability of drug substance,
- full description of drug product manufacturing process,
- 1 year stability data on 3 batches at commercial scale, and
- special studies specific to the formulation.

This approval program is designed to be significantly 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 new formulations of established pharmaceuticals that could potentially benefit from association with our delivery technologies, we believe that we will more quickly and efficiently navigate the FDA approval process, and, if such approval is obtained, of which no assurances can be given, move our formulations to market.

As part of our strategy, however, we will also continue on a more limited basis to seek partners, such as Sigma Tau and Accentia, 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. Drug delivery companies 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 desire in the pharmaceutical industry for improved delivery systems.

We have and intend to continue to primarily target drugs that have large 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 doctors will be familiar with the drug compounds and accustomed to prescribing them. As with BEMA™ Fentanyl and CAMB, we anticipate that many 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™ technologies 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 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.

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
BEMA™ Fentanyl	Breakthrough cancer pain	NDA Filed October 2007; PDUFA Date: August 31, 2008	Partnered in U.S., Canada, Mexico and EU with Meda AB
BEMA™ Buprenorphine	Moderate and severe Pain	Phase I	In-house commercialization for specialty indications possible; primary care rights to be partnered
Bioral® Amphotercin B	Fungal infections	IND Filed/Phase I	Partner will be sought in US with co promote option for specialty indication
BEMA™ Zolpidem	Insomnia	Pre-clinical	In-house commercialization for specialty indications possible, primary care rights to be partnered
Emezine®	Nausea/Vomiting	FDA non-approvable received*	Partnered

* Discussions with FDA complete; corporate decision forthcoming on next steps.

Although we have investigated other projects in the past, we are presently dedicating most of our corporate resources toward the development and commercialization of BEMA™ Fentanyl, BEMA™ Buprenorphine and CAMB. After these programs, and depending on the availability of corporate resources, we will consider funding the development of BEMA™ Zolpidem, Bioral® siRNA and potentially 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, but no assurances can be given that such estimates will prove to be accurate.

BEMA™ Technology Overview

BEMA™ stands for bioerodible mucoadhesive. BEMA™ discs are approximately the size of a coin 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 disc 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 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;
- Have a narrow, reproducible delivery rate, not susceptible to varying or intermittent contact with mucus membranes; and
- Dissolve completely, leaving no residual product or waste.

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

BEMA™ Fentanyl

Datamonitor estimates the global market for medications to treat breakthrough pain will reach $2.5 billion by 2016, with the U.S. being the single largest market and likely to account for well over half of global sales. The leading fentanyl product for the treatment of breakthrough cancer pain in the U.S. market was Actiq® which is marketed by Cephalon 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 2007 was $915 million, an increase of 16% over the prior year.

We believe that BEMA™ Fentanyl potentially has significant advantages over the marketed and pipeline Fentanyl products:

Attribute	Actiq® buccal lozenge (Cephalon)	Fentora® buccal tablet (Cephalon)	Rapinyl® sublingual tablet* (Endo)	BEMA™ Fentanyl buccal disc* (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	1.3%
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 15-20 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.

After receiving approval for the initial indication of break-through cancer pain, we may pursue additional indications for BEMA™ Fentanyl in:

- Breakthrough pain in non-cancer patients (we expect to move forward with the clinical development work on this indication in 2008 in partnership with Meda);

- Post-operative patients following step-down from intravenous narcotics;
- Hospitalized patients or outpatients without intravenous access; and
- Emergency room patients where available intravenous lines are limited or impractical.

We believe that BEMA™ Fentanyl 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 peak sales of approximately $250 million, although no assurances can be given of this estimation. Additionally, we expect to pursue secondary indications as part of a lifecycle management plan, including non-cancer breakthrough pain that could potentially double the peak sales estimates for BEMA™ Fentanyl if obtained.

BEMA™ Buprenorphine

In addition to our lead BEMA™ Fentanyl product, we are also developing a 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 III 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 I study for BEMA™ Buprenorphine. The results of this study demonstrated achievement of plasma concentrations that are associated with analgesia. This data potentially indicates that BEMA™ Buprenorphine has the potential to be the first long acting opioid analgesic that can be delivered buccally in the U.S. We intend to progress the development of BEMA™ Buprenorphine through scale up of manufacturing and pursuit of further clinical studies working toward an NDA. However, due to financial constraints in 2007 and our focus on the BEMA™ Fentanyl NDA submission, we did not progress BEMA™ Buprenorphine into Phase II. We do plan to finalize the Phase I studies in 2008 and take the final formulation and dosage strengths into a Phase II proof of concept study e.g. dental pain model, before the end of the year. Based on the results of the data this would put us in position to initiate a Phase III post operative pain program in the first half of 2009.

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 and also allow for refills to be included on the prescription, 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. Consequently, we believe that BEMA™ Buprenorphine will have the potency of a product such as morphine but with the attributes afforded a Schedule III narcotic.

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 product in a form suitable for ambulatory care and, because of the safety advantage associated with this product, we believe that BEMA™ Buprenorphine will be an ideal next step product for patients with incomplete pain relief on non-narcotic analgesics.

BEMA™ Buprenorphine is intended to meet the need for a new narcotic and will be ideally 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, 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 safety, 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. Datamonitor estimates that the global pain market is projected to generate $30 billion in 2008. 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. This would translate into an estimated $500 million in peak annual sales, although no assurances can be given of this estimation.

BEMA™ Zolpidem

In addition to our two BEMA™ analgesic products, we may potentially develop a BEMA™ formulation of Zolpidem, an FDA-approved compound that has been shown to effectively treat transient and chronic insomnia with few next day residual effects. The standard form of Zolpidem, a swallowed pill, has a typical onset of action 30-45 minutes after taking an oral dose, although this could vary depending on, among other things, the content of the stomach at the time of ingestion. The BEMA™

delivery system may enable us to provide an onset of action which is in the 10-15 minute range and, since the digestive tract is avoided, potentially provide drug absorption on a more consistent basis. Our proposed BEMA™ formulation of Zolpidem is intended to meet the need for a product to treat insomnia that has a rapid onset and will be ideally used as a short term treatment for patients with insomnia.

The global insomnia market is well established with many pharmaceutical companies marketing new products as well as generic versions of older, non-patent protected products. The U.S. market for insomnia treatments (non-barbituate) has grown to over $5.5 billion in 2007. BEMA™ Zolpidem will compete in this market with an indication for the short term treatment of insomnia. Zolpidem is the active ingredient in Ambien®. Ambien®/Ambien® CR is the best selling product for insomnia in the U.S. with 2007 sales of $2.3 billion, with additional sales of approximately $1.9 billion for generic equivalents. Lunesta®, which contains a different active ingredient and was launched in 2005, achieved sales of $887 million in 2007.

Compared to currently marketed products and potential products in development, we believe that BEMA™ Zolpidem is differentiated based on the following features:

- onset of effect in 10-15 minutes versus 30-45 minutes with orally dosed products, no water necessary for administration, reducing the need for elderly patients to urinate during the night, and
- absorption not effected by delayed stomach emptying or first pass metabolism therefore provides for a predictable response.

Due to these advantages, we believe that BEMA™ Zolpidem will effectively compete against current and future insomnia products.

Based primarily on conserving and targeting our financial and human resources to more near term products, in 2007 we strategically decided to focus primarily on completing all work in support of the submission of the of BEMA™ Fentanyl NDA. As such, we did not initiate the development of the BEMA™ Zolpidem program in 2007. In 2008, we plan to assess the continued commercial viability of a formulation for BEMA™ Zolpidem. However, it is unlikely that formulation development work will be started in 2008 as our focus will be on supporting activities around the BEMA™ Fentanyl NDA and continuing the clinical development of BEMA™ Buprenorphine and Bioral® Amphotericin B.

Due to the rapid onset characteristics of BEMA™ Zolpidem, our preliminary market research indicates that BEMA™ Zolpidem has the potential to achieve a 5% share of the total worldwide insomnia market. This would translate into an estimated $250 million in peak annual sales, although no assurances can be given of this estimation.

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 nanocrystalline structures, termed “cochleates,” after the Greek name for a snail with a spiral shell.

Our licensed Bioral® cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our Bioral® cochleate technology are phosphatidylserine, or PS, and calcium. PS is a natural component of essentially all biological membranes, and is most concentrated in the brain. 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. As an indication of its non-toxic nature, today phosphatidylserine isolated from soybeans is sold in health food stores as a nutritional supplement.

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. Phosphatidylserine from soybeans is available commercially as a nutritional supplement with FDA-allowed health promotion claims.
- *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 via injection or 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 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, by freezing in a high vacuum environment, 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, oxygen, 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 cylinders may include reducing unpleasant taste, unpleasant 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 encapsulation, each of the products currently in development face development hurdles, regulatory requirements and uncertainty before market introduction. Due to our current availability of corporate resources, in connection with our Bioral® portfolio, we are currently focusing primarily on our Bioral® Amphotericin B (CAMB) formulation, as described below.

Bioral® Amphotericin B (CAMB)

Systemic 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 CAMB IND application we made at the end of 2006. This represents the first IND that involves the Bioral® technology. We plan to scale up manufacturing and conduct our initial Phase I study in the first half of 2008.

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 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 CAMB, 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. CAMB may have uses in other diseases such as Leishmaniasis and Chagas disease.

The primary advantage which we are seeking for our proposed CAMB 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 CAMB and that we obtain FDA approval, we believe that CAMB 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 CAMB may be an appropriate treatment. Our market research indicates that CAMB may be able to achieve peak sales of approximately $400 million annually for the treatment of esophageal candidiasis, although no assurances can be given of this estimation.

In the development of this drug, we have collaborated with the NIH, the Public Health Research Institute of New York 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 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 CAMB 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 new 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 2007, 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.

Other Bioral® Products. Other products in the Bioral® system include Bioral® Paclitaxel, Bioral® NSAIDS the Subunit HIV Vaccine and the 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 therefore inactive at December 31, 2007.

Emezine®

We have licensed the U.S. rights to, and in 2004 and 2005 we were developing, a

transmucously delivered formulation of prochlorperazine called Emezine®, an anti-nausea and vomiting medication used for treating nausea and vomiting which occurs after surgeries, chemotherapy and for nausea and vomiting associated with flu and migraines. This is not a BEMA™ formulation, but rather a formulation administered by placing a tablet between the bridge of the upper front teeth and gum where it dissolves, enabling the active ingredient to be absorbed through the lining of the cheek. We license Emezine® from Reckitt.

On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. The non-approvable letter stated that additional information would be required to address remaining questions. Our receipt of this non-approvable notification regarding Emezine® was unexpected because:

- We believe we strictly adhered to the FDA sanctioned plan from March 2004 and generated data that, we believe, supported Emezine®'s approvability;
- On June 30, 2005, the FDA accepted the Emezine® NDA for filing, meaning that such NDA contained all necessary elements for review by the FDA;
- The review appeared to be normal and customary based on prior experiences of our management and no obvious red flags were presented; and
- Emezine® contains prochlorperazine, which has been on the market in the U.S. for over 40 years in other dosage forms.

We have had interactions with the FDA regarding Emezine® and are currently determining whether we will proceed with the continued development of Emezine®. We plan to meet with our partners in 2008 to make a final determination regarding the future of the Emezine® project. We do not expect to spend material resources on the Emezine® project for the foreseeable future. Importantly, given the relatively small outlays we are actually making on this project, and given that our size of market projections regarding Emezine® are relatively small compared to other formulations in our pipeline such as BEMA™ Fentanyl, we do not presently believe that our abandonment of this project, though potentially continuing to negatively impact our market reputation and our stock price, among other matters, would seriously impair our overall potential future revenue growth.

Relationship with The University of Medicine and Dentistry of New Jersey 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 provided to us 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 entered into a license agreement with the Universities to be the exclusive worldwide developer and sub-licensor of the cochleate technology. Under the license agreement, we and the Universities have also jointly patented certain aspects of the cochleate technology and co-own such patents with them. 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, 2007, 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, as amended, 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.

In April 2001, we entered into a research agreement with UMDNJ whereby we agreed with UMDNJ to share the rights to new research and development that jointly takes place at UMDNJ's facilities until December 31, 2005. We also agreed to provide UMDNJ with progress and data updates and allow its researchers to publish certain projects. We lease our research facilities totaling approximately 8,000 square feet at a cost of $5,340 per month located on their campus pursuant to a lease agreement which ended December 31, 2005. We have been leasing space under a monthly contract and are currently negotiating a lease with UMDNJ but anticipate that the monthly rent will not change. No assurances can be given that we will be able to 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).

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. 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 a few of the key component producers of our delivery technology. In addition to our relationship with CDC, our collaborative and supply relationships include:

- *QLT.* On May 27, 2004, prior to its acquisition by us, 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 BEMA™ Fentanyl 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: (1) $1 million was paid at closing, (2) $1 million by the end of first quarter 2007 (which was paid March 30, 2007) and, (3) $1 million to be paid within 30 days of FDA approval of the first non-U.S. BEMA™-related product. As part of the transaction as it relates to the non-U.S. portion of the former QLT/BDSI license, no further milestone payments or ongoing royalties will be due to QLT. In addition, we were granted the option to purchase the remaining U.S. asset for $7 million dollars.

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

- *Meda AB.* 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 manufacture, market, sell, and, following regulatory approval, continue development of BEMA™ Fentanyl in the United States, Mexico and Canada. We received a $30 million upfront payment in September 2007 and are expected to receive additional milestone payments. Also, pursuant to the U.S. license agreement with Meda, we have been granted certain rights to co-promote BEMA™ Fentanyl using our own sales force (which we currently do not have), with financial support by Meda of such efforts for a period of 3 years. 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 BEMA™ Fentanyl. We announced the expansion of our clinical development program for BEMA™ Fentanyl in January 2008.

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

- *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 BEMA™ Fentanyl product to us for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of BEMA™ Fentanyl for the United States and Canada. We will pay for formulation, commercial quantity scale-up and product development work and the manufacture of clinical supplies, as well as for the cost of commercial supplies of BEMA™ Fentanyl based on Aveva's fully-burdened cost of manufacturing such supplies. 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, pursuant to which LTS will undertake process development and scale up activities and supply BEMA™ Fentanyl product to us for European clinical trials. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BEMA™ Fentanyl 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 BDSI's Fentanyl product in the European Union.
- *Doyen Medipharm*. On August 28, 2007, we agreed with Doyen Medipharm Inc. to purchase a BEMA™-related pharmaceutical device production machine. We made an initial payment in September 2007 of $0.7 million and $0.6 million in January 2008 pursuant to a purchase order (included in other assets in the accompanying financial statements) toward the total cost, which is $2.7 million. Payments will be made in increments as equipment production objectives are achieved.
- *Sigma-Tau* 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 US$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. BDSI 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. 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® CAMB for the treatment of Leishmaniasis. Leishmaniasis is a disease that can cause skin and other organ problems in soldiers 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 2007.
- *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® nano-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.
- *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. Under the terms of the license agreement, we are required to pay Reckitt: (i) an upfront licensing fee, which has been previously paid in accordance with the Reckitt agreement, (ii) an additional cash payment upon achievement of a certain developmental and regulatory milestone, and (iii) royalties on commercial sales of the licensed product. We are responsible for the development of the product, including costs and expenses, and for its sale, marketing, and distribution in the United States. In addition, we would be required to obtain from Reckitt, and Reckitt shall be required to supply to us, at our expense, all product to be sold under the license. Our agreement with Reckitt can be terminated by either Reckitt or us at any time 30 months after the effective date if regulatory approval has not been obtained. Given the FDA non-approvable decision on this product in 2006 and our focus on other products in our pipeline, we plan to meet with our partners, including Reckitt, in 2008 to make a final determination regarding the future of the Emezine® project. We do not expect to spend material resources on the Emezine® project for the foreseeable future.
- *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 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. No assurances can be given that NIAID will proceed with or actually pay for this testing.

- *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 are still ongoing. If positive, these may turn into licenses with significant financial terms, though no assurances can be made that this will occur.

We also have agreements with entities 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 affiliations with our management.

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 independently ratified the agreements described below. At a subsequent meeting of independent board members, with Dr. O'Donnell abstaining, and after seeking and reviewing advice from the audit committee and an independent valuation firm and inquiring about the details of the various transactions, the independent board members ratified the below-described related party transactions. During 2004, after compliance with our internal policies and procedures, we also entered into several new related party contracts, some of which were amended in 2005 in accordance with the same policies and procedures. The following are the related-party agreements entered into prior to our initial public offering and subsequently:

- *Accentia Biopharmaceuticals, Inc.* We have several business relationships with Accentia Biopharmaceuticals, Inc. and its affiliates. HCG II, which is controlled by Dr. Francis E. O'Donnell, Jr., our Chairman of the Board, owns a significant percentage of our common stock as of the date of this Report, and is a significant stockholder of Accentia. In addition, Dr. O'Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, spends substantially all of his time with BDSI, and limited time as Secretary and Treasurer of Accentia, and Chief Financial Officer of HCG II. Dr. Raphael Mannino, our Chief Scientific Officer and a director, is a member of the board of directors of Biovest International, Inc. (OTC BB: BVTI), a subsidiary of Accentia.
  - *BioNasal Amphotericin B- Accentia 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. The technology consists of using low-dose topical antifungals to control the debilitating symptoms of CRS and asthma. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin

B for the indications 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. The license agreement was amended effective June 1, 2004, then modified in September 2004 by our asset purchase agreement with Accentia, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications.

- *Emezine®—Arius/Accentia Distribution Agreement.* On March 17, 2004, Arius granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc., or TEAMM, with respect to Arius' licensed 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, Accentia Pharmaceuticals has agreed to pay for the development costs of Emezine®. We received development cost reimbursements of $1.0 million in 2004 from Accentia Pharmaceuticals in connection with this agreement. In 2005, we received $300,000 from Accentia Pharmaceuticals upon the acceptance by the FDA of the Emezine® NDA for filing. Given the FDA non-approvable decision on this product in 2006 and our focus on other products in our pipeline, we plan to meet with our partners, including Accentia, in 2008 to make a final determination regarding the future of the Emezine® project.
- *Cochleate technology for nutraceutical and neurodegenerative disease products—RetinaPharma Technologies, Inc.* We previously entered into a license agreement with this development-stage biotechnology company to use our cochleate delivery technology in connection with their proposed nutraceutical product with potential application for macular degeneration and retinitis pigmentosa, a disease affecting the retina, and through an agreement with Tatton Technologies, LLC (which subsequently merged into RetinaPharma), certain apoptotic drugs and apoptotic naturally occurring substances to treat certain neuro-degenerative diseases. This exclusive worldwide right to use our Bioral® drug delivery technology in conjunction with their effort to develop, commercialize and manufacture their proposed products, or to sublicense to a third party, is only for the purpose of treating antiapoptotic pharmaceutical and nutraceutical treatment of retinal disease and glaucoma. These licenses shall remain in effect as long as RetinaPharma remains in compliance with the terms of the agreements. HCG II, one of our significant stockholders, and Dr. Francis E. O'Donnell, Jr., our Chairman of the Board, are affiliated as stockholders and Dr. O'Donnell is Chairman of RetinaPharma. Mr. McNulty serves as Chief Financial Officer of RetinaPharma.
- *Cochleate technology—Biotech Specialty Partners, LLC*. We have entered into a non- exclusive distribution agreement with Biotech Specialty Partners, LLC, or BSP, a development-stage distribution company, to market and distribute our proposed products once we have completed the commercialization of our products. Our financial arrangement with BSP requires us to sell to BSP all of our proposed products, as and when purchased by BSP at a cost which is the lesser of: (i) ten percent (10%) below the lowest wholesale acquisition cost, inclusive of rebates, quantity discounts, etc.; and (ii) the lowest cost at which we

are then selling the product(s) to any other purchaser. The term of the agreement shall be for a term of five years once a product becomes available for distribution. BSP is a start-up enterprise, which to date has not distributed any pharmaceutical products.

These agreements generally provide that, except for on-going development costs related to our cochleate drug delivery technology, we are not required to share in the costs of the development of the pharmaceutical product or technologies of these companies. In connection with our acquisition of Arius, BSP waived its rights under its distribution agreement with us with respect to all of Arius' products.

Under these affiliate agreements, we are entitled to receive the following royalty and other payments:

- *BioNasal Amphotericin B—Accentia Biopharmaceuticals, Inc.* 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, 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.
- *Emezine®—Accentia Pharmaceuticals (formerly TEAMM Pharmaceuticals, Inc).* Under the Emezine® distribution agreement with Accentia, Accentia: (i) has previously paid to Arius an upfront fee, (ii) has previously paid to Arius milestone payments upon achievement of certain developmental and regulatory milestones, and (iii) shall pay royalties to us based on the sales of such product. In addition, we shall be obligated to supply Accentia, at Accentia's expense, with such products for sale and promotional use. We received development cost reimbursements of $1.0 million in 2004 from Accentia in connection with this agreement. We also received a $0.3 million milestone payment with the acceptance of the NDA filing for Emezine® by FDA in 2005.
- *Cochleate technology for neurodegenerative diseases—RetinaPharma Technologies, Inc.* 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.

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.

Licenses, Patents and Proprietary Information

Our intellectual property strategy is intended to maximize our potential 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 firms 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, we cannot provide any assurances that our pending patent applications will be granted or that our current or future intellectual property will 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.

We rely on trade secrets and confidentiality agreements with collaborators, advisors, employees, consultants, vendors and other service providers. No assurances can be given that these agreements will not be breached or that our trade secrets will not otherwise become known or be independently discovered by competitors. Our business would be adversely affected if our competitors were able to learn our secrets or if we were unable to maintain our intellectual property.

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 intend to 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 the combination of our delivery technology with various drugs no longer under patent protection.

We are currently aware 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 can be no assurance 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, there can be no assurance that we would be able 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.

With respect to our cochleate technology and liposome technology related to our autologous HIV therapy, we are the owner and/or the exclusive licensee of seven issued United States patents and seven

foreign issued patents. We believe that our licenses to this intellectual property will enable us to develop this new drug delivery technology based upon cochleate and cochleate related technology. Although, if a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our autologous HIV therapy. However, there can be no assurance that we would be able 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. Moreover, we are not presently dedicating corporate resources to our autologous HIV therapy and focusing principally on Bioral® Amphotericin B and cochleate formulations of siRNA.

Most of the inventions claimed in our cochleate patents were made with United States government support. Therefore, the United States government has certain rights in the technology, and we have certain obligations to the United States government, which could be inconsistent with our plans for commercial development of products and/or processes. We believe to the extent the United States government would have rights in our licensed Bioral® technology due to their funding, we have to either obtain a waiver from the United States government relating to the United States government's rights in the technology, or have agreements with the United States government which would grant us exclusive rights.

Below is a table summarizing patents we believe are currently of value to our business and technology position relating to the Bioral® Amphotericin B products and cochleate formulations of siRNA.

Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
11/578187	US	10-Oct-2006	Pending			Nucleotide-Cochleate Compositions and Methods of Use
2005244262	Australia	03-Nov-2006	Pending			(same as above)
2562499	Canada	11-Apr-2005	Pending			(same as above)
05 776 976.2	Europe	06-Nov-2006	Pending			(same as above)
07 107 141.6	Hong Kong	03-Jul-2007	Pending			(same as above)
2007-507542	Japan	11-Apr-2005	Pending			(same as above)
11/653093	US	11-Jan-2007	Pending			Cochleate Compositions Directed Against Expression of Proteins
04 75 9369.4	Europe	09-Apr-2004	Pending			(same as above)
2006-509875	Japan	11-Oct-2005	Pending			(same as above)
PCT/US2007/018553	PCT	22-Aug-2007	Pending			Amphiphilic Nucleotide Cochleate Compositions and Methods of Using the Same

Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
08/803662	US	21-Feb-1997	5994318	30-Nov-1999	24-Nov-2015	Cochleate Delivery Vehicles
2006236007	Australia	14-Nov-2006	Pending			(same as above)
32599/00	Australia	15-Aug-2002	753008	23-Jan-2003	22-Feb-2016	(same as above)
2212382	Canada	22-Feb-1996	Pending			(same as above)
2246754	Canada	21-Feb-1997	2246754	22-Oct-2002	21-Feb-2017	(same as above)
96 90 6334.6	Europe*	22-Feb-1996	812209	06-May-2004	22-Feb-2016	(same as above)
8-525713	Japan	22-Feb-1996	Pending			(same as above)
2007-122913	Japan	22-Feb-1996	Pending			(same as above)
09/235400	US	22-Jan-1999	6153217	28-Nov-2000	22-Jan-2019	Nanocochleate Formulations, Process of Preparation And Method of Delivery of Pharmaceutical Agents
09/613840	US	11-Jul-2000	6592894	15-Jul-2003	22-Jan-2019	(same as above)
11/040615	US	18-Jan-2005	Pending			(same as above)
2007200813	Australia	24-Jan-2000	Pending			(same as above)
2358505	Canada	24-Jan-2000	Pending			(same as above)
00 90 9961.5	Europe**	24-Jan-2000	1143933	25-Jul-2007	24-Jan-2020	(same as above)
2000-594446	Japan	24-Jan-2000	Pending			(same as above)

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

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

BEMA™ Technology

The mucoadhesive erodible drug delivery device technology space is congested, although we do not believe that our BEMA™ Fentanyl product is in conflict with or covered by external patents and do not believe that we require licenses under these patents for BEMA™ Fentanyl in the United States. No assurance can be given, however, that a court of law in the United States or elsewhere might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our BEMA™ Fentanyl product. There can be no assurance that we would be able 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.

We have a been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by Lohmann Therapie Systeme to market the BEMA™ Fentanyl product 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.

Through Arius, and subject to our agreements with QLT, we own the following patents and patent applications relating to the BEMA™ technology:

Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
08/734,519	US	10/18/1996	5,800,832	09/01/1998	10/18/2016	Bioerodable Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
09/144,827	US	09/01/1998	6,159,498	12/12/2000	10/18/2016	(same as above)
09/069,703	US	04/29/1998	Pending			Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
10/962,833	US	10/12/2004	Pending			(same as above)
11/069,089	US	03/01/2005	Pending			(same as above)
10/763,063	US	01/22/2004	Pending			Bioerodible Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
11/639,408	US	12/13/2006	Pending			Abuse Resistance Transmucosal Drug Delivery Device

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Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
11/817,915	US	09/06/2007	Pending			Transmucosal Delivery Devices With Enhanced Uptake
US06/47686	PCT	12/13/2006	Pending			Abuse Resistance Transmucosal Drug Delivery Device
US07/16634	PCT	07/23/2007	Pending			Transmucosal Delivery Devices With Enhanced Uptake
9747574	Australia	10/16/1997	729516	05/17/2001	10/16/2017	Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces)
200138924	Australia	10/16/1997	769500	05/13/2004	10/16/2017	(same as above)
2,268,187	Canada	10/16/1997	Allowed		10/16/2017	(same as above)
98519467	Japan	10/16/1997	Pending		10/16/2017	(same as above)
2005182632	Japan	10/16/1997	Pending		10/16/2017	(same as above)
9791047	EP*	10/16/1997	0973497	12/11/02	10/16/2017	(same as above)
9939678	Australia	04/29/1999	746339	11/16/99	04/29/2019	(same as above)
2,329,128	Canada	04/29/1999	Pending		04/29/2019	(same as above)
2000545511	Japan	04/29/1999	Pending		04/29/2019	(same as above)
2005233505	Japan	04/29/1999	Pending		4/29/2019	(same as above)
99922753	EP**	04/29/1999	1079813	02/09/05	04/29/2019	(same as above)
US03/11313	PCT	04/11/2003	N/A	N/A	N/A	(same as above)

* 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.

Competition

The pharmaceutical industry in general is highly competitive and subject to rapid and substantial 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 necessarily 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.

BEMA™

Included among the companies which we believe are developing potentially competitive technologies to BEMA™ are Orexo AB, Inc. (SX:ORX), a publicly-traded company, and Transcept Pharmaceuticals, Inc. (formerly TransOral Pharmaceuticals), a privately-held company. We believe that these potential competitors are seeking to develop and commercialize technologies for the buccal or sublingual 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. We are aware that ULURU Inc. purchased a technology from Access Pharmaceuticals which is similar to BEMA™. Based on public disclosures, we are not aware of ULURU developing a competitive pain product as of the time of this writing.

For BEMA™ Fentanyl, in the breakthrough cancer pain area, we believe the most advanced competitors are Cephalon, Inc. (NASDAQ:CEPH) and Endo Pharmaceutical Holdings (NASDAQ:ENDP) both publicly-traded companies. In 2007, the overall market for transmucosal fentanyl products for breakthrough pain totaled $915 million, an increase of 16% over the prior year. Cephalon's first product for this indication was Actiq®, which generated $260 million in sales in 2007. 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 $478 million over the same period. Fentora®, formerly known as OraVescent® Fentanyl, utilizes an effervescent tablet which is administered buccally. Fentora® was approved and launched in late 2006 and generated $177 million in sales in 2007. Endo has licensed Rapinyl™ from Orexo AB, which is a polymer formulated sublingual fentanyl tablet in clinical development for breakthrough cancer pain. This product is administered sublingually. Additional products are under development utilizing intranasal delivery of fentanyl (Nasalfent and Instanyl), while other companies such as Generex Biotechnology and Sosei Co. Ltd. are focusing on delivery using sublingual spray formulations. YM Biosciences, Akela/Janssen and Alexza/Endo are developing inhaled formulations of fentanyl for administration across the alveoli in the lungs. Javelin Pharmaceuticals, Inc. (OTC BB: JVPH.OB) is developing an intranasal morphine. 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, BEMA™ Fentanyl 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 will 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 and at least one product has been put on clinical hold. In the chart below find all competitors in development to BEMA™ Fentanyl and their development status.

Product	Company	Description	Status
Actiq®	Cephalon	Fentanyl lollipop, 2 generics	Marketed
Fentora™	Cephalon	Effervescent Buccal Tablet, irritation reported, dose capped at 800mcg	Marketed
BEMA™ Fentanyl	BDSI	Fentanyl Buccal Disc	NDA filed October 2007; PDUFA:8-31-08
Rapinyl™	Orexo/Endo	Sublingual Tablet	Phase III Initiated Fall 2005 NDA submission expected in 1H09
Instanyl	Nycomed	Fentanyl Nasal Spray	Phase III USA, Marketing application filed in EU
Nasalfent®	Archimedes	Fentanyl Nasal Spray	Phase III Initiated January 2007
Rylomine™	Javelin Pharmaceuticals	Morphine Nasal Spray	Phase III Post Operative Pain
AD923	Sosei	Sublingual Spray	Phase I USA, Phase III rest of world
Fentanyl TAIFUN®	Akela/ Janssen (EU)	Dry Powder Inhaler	Phase II
AeroLEF ™	YM Biosciences	Liposomal fentanyl delivered via nebulizer	Phase II FDA Placed on Clinical Hold (1/17/08)
Rapid Mist™ Fentanyl	Generex	Buccal Spray	Phase I
AZ003-Stacatto™ Fentanyl	Alexza/Endo	Aerosolized fentanyl for inhalation	Phase I

BEMA™ Buprenorphine will have several indications for the treatment of acute and chronic pain. It will be positioned as a first line therapy for post surgical patients. This would include hospital or outpatient surgeries. Market competitors for this indication include but are not limited to: non-steroidal anti-inflammatory (NSAIDs, e.g. ibuprofen), COX-2 inhibitors (Celebrex® from Pfizer), Tramadol (Ultracet® from Ortho McNeil) and potent opioids (hydrocodone and oxycodone combination products from various companies).

A second focus will be to position BEMA™ Buprenorphine as a step up from NSAIDs instead of Schedule II narcotics. Indications for such combination use with NSAIDs include pain associated with severe arthritis and lower back conditions. Marketed competitors for these indications include Tramadol (Ultram® ER from Biovail/Johnson and Johnson) and the potent opioids such as Opana™ from Penwest/Endo, OxyContin® from Purdue, Kadian® from Alpharma, Avinza® 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, such as Tramadol/NSAID and oxycodone/ibuprofen.

Finally, there are also products under development in special delivery technologies including Ralivia (tramadol once-daily) from Biovail, Tramadol extended release from Labopharm/Purdue, Remoxy™ from Pain Therapeutics/King Pharmaceuticals, Oxytrex™ from Pain Therapeutics and Chronogesic™ sufentanil transdermal system from Durect/Endo.

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 Novavax, Inc. (NASDAQ:NVAX), each a publicly-traded company, and CyDex, Inc., 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 Gilead’s AmBisome and Enzon’s Abelcet. Sales of liposomal amphotericin B products exceeded $260 million in 2006. 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 in Phase I development.

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 Pharmaceuticals Inc. (NASDAQ:ENZN), Flamel Technologies S.A. (NASDAQ:FLML), Nastech Pharmaceutical Company Inc. (NASDAQ: NSTK) and Inex Pharmaceuticals Corporation (TSX: INEX), each publicly-traded companies, which we believe may be seeking to develop technologies for cell-targeted delivery of drugs. In 2005, American Pharmaceutical Partners, Inc. (NASDAQ:APPX) received approval for Abraxane, which is a formulation of paclitaxel, which is bound to albumin. This provides for cellular delivery via the gp60 receptor. 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.

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.

- *BEMA™ Fentanyl*. Effective October 17, 2005, we entered into an agreement with Aveva Drug Delivery Systems, Inc. pursuant to which Aveva will supply BEMA™ Fentanyl product to us for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of BEMA™ Fentanyl for the United States and Canada.

  Effective December 15, 2006, we entered into a Process Development Agreement with LTS Lohmann Therapie-Systeme AG ("LTS"), pursuant to which LTS will undertake process development and scale up activities and supply BEMA™ Fentanyl product to us for clinical trials in Europe. Under the terms of this agreement, LTS is anticipated to be the sole supplier of BEMA™ Fentanyl 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 BDSI's Fentanyl product in the European Union.

- *Emezine®*. Under our licensing agreement with Reckitt, Emezine® would be manufactured by Reckitt in Hall, England. This facility has been inspected by the FDA and is currently used for the manufacture of other products sold in the U.S. Given the FDA non-approvable decision on this product in 2006 and our focus on other products in our pipeline, we plan to meet with our partners in 2008 to make a final determination regarding the future of the Emezine® project.

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, BEMA™ Fentanyl, with our U.S. and European partnership with Meda.

- Marketing and selling our approved formulations and products under the Bioral®, BEMA™ or other brand names which we either own or license from third parties. This approach would require us to build our own sales force, which we presently do not have and would be costly to implement.
- Using a contract sales organization to market and sell our products with the option to potentially convert these contract representatives to our employees at a future date. Although we would likely pay the costs associated with such a relationship, we would not bear the burden of having these individuals as BDSI employees.
- Using a co-promotion arrangement whereby we promote our product(s) along side our designated commercial partner. In such circumstances, it is not atypical to have the commercial partner pay for or subsidize the creation of a sales force. We have a co-promote option in our U.S. agreement with Meda for BEMA™ Fentanyl.

Significant progress was made in 2007 toward preparations for a commercial launch of BEMA™ Fentanyl. In Europe, commercial and development rights to BEMA™ Fentanyl were previously licensed to Meda in a licensing agreement announced in August 2006.

In September 2007, we secured an exclusive licensing and supply agreement with Meda for the commercialization rights for BEMA™ Fentanyl covering the United States, Canada and Mexico. This took place shortly following the acquisition of Medpointe Pharmaceutials of Somerset, New Jersey (now known as Meda Pharmaceuticals) by Meda, which provided Meda with a significant commercial presence in the United States. Under this agreement, Meda is responsible for the sales, marketing and distribution of BEMA™ Fentanyl 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 second full year of sales. The agreement specifies that BEMA™ Fentanyl 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 BEMA™ Fentanyl 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 BEMA™ Fentanyl in patients with breakthrough pain associated with other non-cancer related conditions such as back pain and osteoarthritis. In January 2008, we announced our intention to initiate this expanded clinical program for BEMA™ Fentanyl with Meda.

Meda is one of Europe’s leading specialty pharmaceutical companies. Meda has more than 1,000 employees in marketing and sales and covers all of Europe through its subsidiaries in more than 20 European countries. The U.S. division, Meda Pharmaceuticals, is a specialty pharmaceutical company that develops, markets, and sells branded prescription therapeutics. Although Meda Pharmaceuticals was founded in 2001, it draws upon a long history, entering the market through the acquisition of Carter-Wallace, Inc. Meda Pharmaceuticals has a sales force of over 400 representatives with a focus in specialty therapeutic areas including pain and central nervous system conditions. Meda Pharmaceuticals has established a track record of commercializing products with their top two products, Astelin® and the more recently launched Soma® 250 mg. Meda Pharmaceuticals has an experienced, well trained and highly regarded sales force. They have proven their ability to successfully launch products and sustain growth in highly competitive 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 Pharmaceuticals to also effectively compete in the transmucosal opioid market.

We believe that securing a commercial partner for two major global pharmaceutical markets will allow us to competitively launch BEMA™ Fentanyl 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 BEMA™ Fentanyl.

Beginning twenty-four months following approval of the BEMA™ Fentanyl NDA, we have the right to enter into a co-promotion with Meda in the United States. This co-promotion arrangement allows us to establish our own sales force to further efforts for BEMA™ Fentanyl, thereby enhancing our pain franchise by establishing a presence in the pain and specialty markets in support of potential future product entries, including BEMA™ Buprenorphine and Bioral® Amphotericin B.

Government Regulation

The manufacturing and marketing of any drug which we formulate with our licensed Bioral® or BEMA™ technologies and Emezine®, as well as our related research and development activities, are subject to regulation for safety, efficacy and quality by numerous 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.

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. No assurances can be given as to the ultimate outcome of such pre-clinical testing. 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.

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 I, 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 II 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 II evaluations, Phase III trials are undertaken to establish the confirm the clinical efficacy and establish the safety profile of the product within a larger population at geographically dispersed clinical study sites. Phase III 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. Two studies were conducted in 2004 under the Emezine® IND, although additional studies may be required should we decide to continue the Emezine® project (of which no assurances can be given).

Seven studies have been performed since 2005 under the IND for BEMA™ Fentanyl. Multiple preclinical studies were conducted with Bioral® Amphotericin B. One human pharmacokinetic study was conducted with BEMA™ Buprenorphine in 2006. We expect that additional studies in normal volunteers and potentially patients will be performed with BEMA™ Fentanyl, BEMA™ Buprenorphine and Bioral® Amphotericin B in 2008.

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.

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 can be no assurance that any approval will 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 IV) 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 various 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.

Employees

As of March 7, 2008, we have 21 full-time employees and 1 part-time employee. Four are laboratory scientists and 11 are involved in our clinical and program development and operations and six handle our administration, accounting and information technology. Advanced degrees of our staff include four Ph.D's, two Pharm.D's, one M.D., one J.D. 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 and administrative functions. We consider relations with our employees to be good. Each of our current scientific personnel has entered into confidentiality 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 or any amendment hereto, before deciding to buy or exercise our securities. If any of such 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 a limited operating history and have not generated any revenues from the sale of products to date, you cannot rely upon our limited historical performance to make an investment decision.

Since our inception in January 1997 and through December 31, 2007, we have recorded accumulated losses totaling approximately $75 million. As of December 31, 2007, we had working capital of approximately $2.8 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. No assurances can be given that we will be able 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 BEMA™ Fentanyl. This 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. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and derive material revenues from our proposed formulations or products in development.

As a result of our current lack of financial liquidity and negative stockholders' equity, 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 negative stockholders' equity, our auditors' report for our 2007 financial statements, which are included as part of this Report, contains a statement concerning our ability to continue as a "going concern." Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally. Our continuation as a "going concern" is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include negotiating up-front (and ultimately recognizing revenues from) milestone payments on pipeline products under development, and royalties from sales of our products which secure FDA approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. No assurances can be given, however, that we will be able to achieve these goals or that we will be able to continue as a going concern.

We may need to raise additional capital to continue our operations, and our failure to do so would impair our ability to fund our operations, develop our technologies 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 the sale of common and preferred stock and convertible debt to third parties and to a lesser degree from grants, loans and revenue from license and royalty fees. At December 31, 2007, we had cash and cash equivalents of approximately $13.8 million. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) 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 into approximately the third quarter of 2008, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events or contingencies, any of which could effect our cash requirements.

We expect to receive an additional $30 million milestone payment from Meda in connection with FDA approval and commercial launch of BEMA™ Fentanyl. If BEMA™ Fentanyl is not approved and we do not receive such payment, and given that our current cash on hand will not fully fund all development costs of our leading product formulations, we will need to raise additional capital to fund

our anticipated operating expenses and future expansion. If BEMA™ Fentanyl is not approved, we may be unable to find the needed capital to progress our business plan, and we cannot assure you that any financing, whether from external sources or related parties, will be available. 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 capital raising 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 limited operating history and business risks associated with our company. 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 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 formulations incorporating such technologies. We will require additional funds to conduct research and development, establish and conduct pre-clinical and clinical trials, secure commercial-scale manufacturing arrangements and provide for the marketing and distribution, especially if BEMA™ Fentanyl 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 have to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs or product launches or marketing efforts 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 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 and other professional 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. If adequate funds are not available, we may be required to significantly reduce or refocus our development and commercialization efforts with regard to our delivery technologies and our proposed formulations and products.

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 BEMA™ Fentanyl asset.

Under our agreements with CDC, if we do not meet certain conditions, CDC can assume control of the BEMA™ Fentanyl project and related intellectual property assets. For example, in the event that we do not diligently pursue the development and regulatory approval of BEMA™ Fentanyl or encounter certain specified negative circumstances regarding the development of BEMA™ Fentanyl, CDC has the right to require the assignment of our BEMA™ Fentanyl assets to CDC and to pursue development and commercialization of BEMA™ Fentanyl 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 BEMA™ Fentanyl 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. No assurances can be given that CDC will not seek to exercise the 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 customer acceptance of our proposed pharmaceutical 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;
- 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, 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, 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 and governmental agencies for both strategic and financial resources. Key among these agreements is our U.S. and European commercialization agreements with Meda and our supply agreement with Aveva relating to BEMA™ Fentanyl. 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. In addition, under our collaborative agreements with Meda, we are responsible for paying certain costs relating to BEMA™ Fentanyl. 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 we be sued, because we do not currently have product liability insurance above and beyond our general insurance coverage.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. Such claims may

be asserted against us. In addition, the use in our clinical trials of pharmaceutical formulations and products that our potential collaborators may develop 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 cannot assure you that we will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will 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 liquidity 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 drug product 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 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:

- cease selling, making, importing, incorporating or using any 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.

We are currently aware 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 can be no assurance 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, there can be no assurance that we would be able 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.

The mucoadhesive erodible drug delivery device technology space is congested, although we do not believe that our BEMA™ Fentanyl product is in conflict with or covered by external patents and do not believe that we require licenses under these patents for BEMA™ Fentanyl in the United States.

Although there can be no assurance that a court of law in the United States' might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our BEMA™ Fentanyl product. However, there can be no assurance that we would be able 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.

We have a been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by Lohmann Therapie Systeme to market the BEMA™ fentanyl product 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.

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. There can be no assurance that we would be able 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.

Most of the inventions claimed in our Bioral® patents were made with the United States government support. Therefore, the United States government has certain rights in the technology, and we have certain obligations to the United States government, which could be inconsistent with our plans for commercial development of products and/or processes. We believe to the extent the United States government would have rights in our licensed Bioral® technology due to their funding, we have to either obtain a waiver from the United States government relating to the United States government's rights in the technology, or have agreements with the United States government which would grant us exclusive rights.

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 protect such rights.

Our ability to license 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 patent, patent applications and licensed rights may not provide protection against competitive technologies or may be held invalid if challenged or 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 all 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 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 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 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 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;
- potential inability to timely obtain an adequate supply of required components; and
- potential for reduced control over pricing, quality and timely delivery.

Except for our agreement with Aveva, 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 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, 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 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 no equipment or facilities from which these activities could be performed. Therefore, we are dependent on third parties for our formulation development and manufacturing 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 commercial supplies to successfully launch and maintain the marketing of our products. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay 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.

Broad use of our proposed formulations and products and related drug delivery technologies 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 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 for all 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 enter into, extend or renew the lease, 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, other than through the Universities, 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.

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 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. No assurances can be given that we will be able 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, BEMA™ Fentanyl, on which we submitted an NDA in October 2007. Finally, although we have received a PDUFA date of August 31, 2008 for a decision by FDA on our BEMA™ Fentanyl NDA, 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:

- demonstrate benefit from delivery of each specific drug through our drug delivery technologies;
- demonstrate through pre-clinical and clinical trials that our drug delivery technologies are safe and effective; and
- establish 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 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.

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 commercialize 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 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 drug, 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 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, QLT and Reckitt. Although we have entered into agreements to purchase the BEMA™ technology from QLT, we may be unable to fulfill our obligations under such agreement. The loss of our key licenses 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 technology licenses 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 technology.

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

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

Our lead product candidates, most notably BEMA™ Fentanyl and BEMA™ Buprenorphine, contain 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 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. 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 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 without a new prescription.

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. No assurance can be given that the DEA review of such materials may not result in 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.

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 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.

We could be exposed to significant drug 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 $1 million limit per occurrence which does not provide coverage for product liability for commercial products. 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. We intend to seek additional insurance against such risks before our product sales commence, although there can be no assurance that such insurance will be available, or if it can be obtained at such time 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 BEMA™ Fentanyl, 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 current 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.

Risks Related to Our Management and Key Employees

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 success will depend to a significant degree upon the continued services of key management, technical, and scientific personnel, including Drs. Frank O'Donnell, Mark Sirgo, Andrew Finn, Raphael Mannino and Mr. James McNulty. 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, our success will 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 Chairman of the Board, Dr. Frank O’Donnell, 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 38.96% of our outstanding common stock. These figures do not reflect any future potential exercise of warrants (including those issued to Laurus Master Fund, Ltd., CDC and others) into shares of common stock or the increased percentages that our officers and directors may have in the event that they exercise any of the options granted to them under our Amended and Restated 2001 Stock Incentive Plan or if they otherwise acquire additional shares of common stock generally.

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. We have entered into a non-exclusive distribution agreement with Biotechnology Specialty Partners, Inc. Each of these business arrangements was approved (with Dr. O’Donnell abstaining) by our board of directors and our predecessor’s board of directors. In addition, Dr. Mannino is a member of the board of directors of Biovest International, Inc. (OTC BB:BVTI), 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.

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 can be no assurance that an active trading market in our securities will be 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.

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

We are authorized to issue 45 million shares of our common stock. As of March 7, 2008, there were 19,160,637 shares of common stock issued and 19,145,146 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 5,000,000 shares of authorized 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 presently have a significant number of convertible securities outstanding, including: (i) 2,907,177 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.88 per share, and (ii) 5,886,757 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.66 per share. If and when these securities are converted or 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 prospectus 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;
- 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. 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 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 2007. No assurances can be given that we will be able 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.

MAS Capital

On or about April 19, 2004, we were named as the defendant in an action commenced by MAS Capital in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks monetary damages from us in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for us through an initial public offering. We provided MAS Capital's counsel with copies of documents executed by MAS Capital and its affiliates that we alleged fully release them. Upon MAS Capital's refusal to dismiss the action, notwithstanding the documents that fully release all parties, we filed an Amended Answer asserting a claim for attorneys' fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. We also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital's claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on our claim for attorneys' fees and costs, but were unable to resolve this matter in light of MAS Capital's intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the Motion. Accordingly, the parties were to proceed until resolution of our counterclaim for attorneys' fees and costs and either party could appeal at that point in time. On August 6, 2007, the U.S. District Court entered a final judgment on our counterclaim pursuant to the parties' stipulation of dismissal. MAS Capital was required to initiate any appeal within thirty days of the entry of final judgment. MAS Capital has now filed its appeal with the Seventh Circuit Court of Appeals. The parties are now in the briefing stage of the appeal and await a decision from the Court of Appeals. We strongly believe that the District Judge's order will be upheld on appeal and, accordingly, no potential liability has been recorded.

CDC

On October 17, 2006, CDC filed an action against us in New York State Supreme Court seeking to enjoin the Company from entering into a financing transaction with a third party pursuant to CDC's purported ROFN granted to CDC under the SPA. On October 26, 2006, we entered into the Stipulation 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 the DRA with CDC pursuant to which we and CDC have terminated the previously instituted dispute resolution procedures between the parties relating to the Disputed Matters. The effect of the DRA is that CDC has withdrawn

its August 2006 claims to ownership of the BEMA™ Fentanyl asset, which had been asserted by CDC as part of the Disputed Matters, and we have withdrawn its 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 the Company and CDC's entry into the DRA, we and CDC 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 BEMA™ Fentanyl.

Concurrently with the parties' negotiation of the DRA, CDC alleged that we had violated the ROFN. Specifically, in January 2007, CDC alleged by written notice that certain transactions we had undertaken with Laurus Master Fund, Ltd. triggered the ROFN provisions. In order for us to avoid CDC's continued assertion of its alleged ROFN with respect to such transactions, 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 the New CDC Financing. The New CDC 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 transactions with Laurus.

On September 5, 2007, in connection with CDC's consent to the Meda U.S. licensing transaction, we and CDC entered into 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 the DRA II and its consent to the Meda transaction, we and CDC entered into the RPAA pursuant to which: (i) the ROFN was amended to covert such right into the ROFR and (ii) the Company granted CDC a 1% royalty on the Next BEMA Product.

We may also, from time to time, become involved in actual or potential legal proceedings that we consider to be routine, immaterial and in the normal course of our business.

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

None.

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 bid prices per share for our common stock for each fiscal quarter during 2007 and 2006, as reported by the Nasdaq Capital Market, is set forth below. The quotations merely reflect the prices at which transactions were proposed, and do not necessarily represent actual transactions.

Quarterly Common Stock Price Ranges

Fiscal Year 2007, Quarter Ended:	High	Low
March 31, 2007	$5.34	$5.20
June 30, 2007	$4.79	$4.05
September 30, 2007	$3.98	$3.90
December 31, 2007	$3.00	$2.71

Fiscal Year 2006, Quarter Ended:	High	Low
March 31, 2006	$3.48	$1.85
June 30, 2006	$2.95	$1.65
September 30, 2006	$2.60	$1.68
December 31, 2006	$3.53	$1.86

As of March 7, 2008, we had approximately 219 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 (c)
Equity compensation plans approved by security holders	2,907,177	$ 3.88	592,823
Equity compensation plans not approved by security holders	0	$ 0	—
Total	2,907,177	$ 3.88	592,823

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.

Limited Operating History; Background of Our Company

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 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.

In July 2006, we licensed commercialization rights in Europe for our lead product, BEMA™ Fentanyl, 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 BEMA™ Fentanyl in the U.S., Canada and Mexico. Our NDA for BEMA™ Fentanyl 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 are due when the FDA approves BEMA™ Fentanyl and the product is launched. The target date for FDA approval of BEMA™ Fentanyl is August 31, 2008, with Meda's expected launch in the fourth quarter of 2008, or within 90 days of expected approval. Assuming Meda's commercial launch of BEMA™ Fentanyl occurs as expected, we will begin receiving royalties from Meda from sales of BEMA™ Fentanyl in the fourth quarter 2008.

We expect to continue research and development of our drug delivery technologies, some of which will be funded by Meda under specific programs as described below. We will continue to seek additional license agreements, which may include up-front payments. For all other programs and products under development, revenues and payments (other than milestone payments under our Meda agreements) in 2008 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 limited history of operations, and while we have received: (i) up-front non-refundable license payments in 2006 and 2007 (which are classified as deferred revenues), (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 2007 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, 2007 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, 2007 was $6.47 million, net of accumulated amortization of $1.0 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. No goodwill impairment charges have resulted from this analysis for 2007 or 2006.

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 2007 or 2006.

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 2007, we assumed no dividend yield, risk-free interest rates ranging from 3.71% to 5.07%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor range between 50.43% to 65.78%, share prices ranging from $2.42 to $6.06, and option exercise prices ranging from $2.42 to $6.63.

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

We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements. When evaluating multiple element arrangements, we consider whether the components of the arrangement represents separate units of accounting as defined in Emerging Issues Task Force ("EITF") Issue No. 00-21, Revenue Arrangements with Multiple Deliverables ("EITF 00-21"). Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether it is separable from the other aspects of the contractual relationship.

License Arrangements

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

Non-refundable, upfront fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue over the established or estimated term of the license when the license arrangement commences and the licensed data, technology and/or product or supplies to manufacture the product is delivered. Such deliverables may include physical quantities of products, supplies, or design of the products, the conceptual framework and mechanism of actions taken by a third party, and rights to the patents or patents pending for such products.

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 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.

Sponsored Research

Sponsored research amounts are recognized as revenue when the research underlying such funding has been performed or when the grant funds have otherwise been properly utilized, such as for the purchase of operating assets. Grant revenue is recognized to the extent provided for under the related grant or collaborative research agreement. This is shown as sponsored research revenue on the accompanying consolidated statements of operations.

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 payments of $2.5 million in 2006 and $30.0 million in 2007 from Meda have been recorded as deferred revenue, and will be recognized over the license term 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, 2007 Compared to the Year Ended December 31, 2006

Sponsored Research Revenue. During the year ended December 31, 2006, we recognized sponsored research revenue of $0.08 million. As of September 2006, all grant funds available have been utilized, as such, there were no sponsored research revenues in 2007.

Royalty and Contract Revenues. We recognized $0.07 million in royalty revenue in each of 2007 and 2006, respectively, under our license agreement with Accentia relating to CRS. In addition, we also recognized $0.1 million of revenue related to various contractor agreements in each year presented.

License revenues. In accordance with GAAP and our revenue recognition policy, the Meda up-front payments of $2.5 million in 2006 and $30.0 million in 2007 from Meda have been recorded as deferred revenue, and will be recognized over the license term once commercialization revenues begin.

Research and Development Expenses. During the years ended December 31, 2007 and 2006, research and development expenses totaled $14.3 million and $9.3 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 BEMA™ Fentanyl. Funding of this research in 2006 and 2007 was obtained through deferred license revenue, sponsored research revenue, exercise of options by employees and directors, sales of securities (including the CDC conversion of its funding agreement to a common stock transaction, as further described under Liquidity and Capital Resources below) and funding of an equity line of credit from HCG II, which was converted to common stock in 2007. 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, 2007, and 2006, general and administrative expenses totaled $7.5 million and $5.1 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, executive personnel costs, consulting fees and business development costs. The increase in general and administrative expenses in 2007 is primarily due to increased professional and legal fees incurred in connection with our licensing transactions, increased patent costs, stock-based compensation (related to our adoption of FAS 123R) and investor relations.

Product Development Expense. Product development cost in 2007 and 2006 is related to warrant expense. In 2007, we issued 25,000 warrants valued at $0.03 million in connection of milestones achieved with our third-party manufacturer of BEMA™ Fentanyl. In 2006, we issued 601,120 warrants valued at $0.7 million in connection with the initial $2.0 million deposit transaction with CDC under the CDLA for BEMA™ Fentanyl.

Interest Income (Expense), Net. During the year ended December 31, 2007, we had net interest expense of $2.24 million, compared to $1.95 million in 2006. The increase in net interest expense is primarily due to amortization of debt discount and interest converted by Laurus for the two convertible notes. The Laurus debt was fully converted to common stock by April 2007. Interest income was $0.28 million in 2007 and nominal in 2006.

Derivative Gain (loss). Derivative gain in 2007 is related to the adjustment of derivative liabilities to fair value as of December 31, 2007. In 2006 the adjustment resulted in a loss. 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, which is treated for GAAP purposes as deferred revenue, we incurred net operating losses during both years presented, and we did not recognize any benefit associated with these losses. We had federal and state net operating loss carryforwards of approximately $50.8 million and $43.4 million at December 31, 2007, 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 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the company. 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 on an annual basis. The Company's annual limitation for utilizing this portion of the NOL is approximately $1.5 million.

Major Research and Development Projects

In 2007 and into 2008, we have and will continue to dedicate most of our corporate resources to the development of BEMA™ Fentanyl, CAMB and BEMA™ Buprenorphine. Substantially all of our financial resources spent in clinical development in 2007 were on BEMA™ Fentanyl and the BEMA™ technology. Under the CDLA with CDC, $7.0 million was made available to us for the development of BEMA™ Fentanyl. In February 2006, $2.0 million of this was paid to us and in May 2006, the remaining balance was converted to equity with all $7.0 million being transferred to us. In part due to the non-approval by the FDA of Emezine® in 2006 and the loss of its anticipated revenues, we delayed certain projects. As a result, we did not begin the development of BEMA™ Zolpidem and significantly slowed the development of BEMA™ Buprenorphine and CAMB. These and the other projects are discussed in further detail below.

We believe that other non-core projects which we have previously identified as being in our pipeline (such as 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 developments 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 no assurances can be given that such estimates will prove to be accurate.

BEMA™ Fentanyl. We licensed the US 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 BEMA™ Fentanyl, 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 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 BEMA™ Fentanyl. As a result of this guidance, we began our preparations for Phase III clinical studies in the fourth quarter of 2005. In early 2006, we began enrollment on the Phase III clinical studies. We projected that due to the nature of treating patients with breakthrough cancer pain, our patient recruitment process for the BEMA™ Fentanyl clinical program would take anywhere from 6 to 18 months. Subsequently, we completed enrollment in our efficacy study (FEN 201) and reported our findings in April 2007. The data demonstrated that our primary efficacy endpoint of the Summary of the Pain Intensity Difference at 30 minutes (SPID 30) was statistically significantly different from placebo (p value less than 0.0004). We completed the analysis and documentation of the results from our FEN 201 study as well as our FEN 202 safety study and submitted them as part of our NDA for BEMA™ Fentanyl on October 31, 2007. The FDA subsequently accepted our NDA for filing on December 31, 2007, and provided us with a PDUFA date of August 31, 2008, which is the date by which FDA is expected to provide us with a decision on the approvability of our NDA. If their decision is positive and an approval letter is granted, we anticipate our commercial partner Meda's launch of BEMA Fentanyl within 3 months from the receipt of the approval. It is possible, however, that FDA could take longer to review our NDA.

We believe that BEMA™ Fentanyl 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 peak sales of approximately $250 million, on which we will pay a royalty to CDC. No assurances can be given for this sales estimate. We do not expect to generate any royalty revenue from BEMA™ Fentanyl until into the fourth quarter of 2008.

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 BEMA™ Fentanyl to assess the efficacy and safety of the product for the treatment of breakthrough pain associated with other chronic pain conditions beyond cancer. Meda will be fully responsible for funding the expanded clinical development program in non-cancer breakthrough pain.

The risks to our company associated with the BEMA™ Fentanyl project include: (i) the FDA's issuance of a non-approval finding with respect to the product; (ii) claims of CDC against the intellectual property or otherwise; (iii) inability of our contract manufacturer to make commercial supplies or meet our commercial supply requirements; (iv) lack of funding to continue the program should the NDA not be approved by FDA on first submission; (v) the development of unexpected safety issues with the product, (vi) the conclusion by the FDA that the risk- benefit is inadequate; (vii) the conclusion by the FDA that our submission is inadequate and additional information is required; and (viii) failure of our commercial partner Meda to launch and sell the product. The failure of the BEMA™ Fentanyl 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 BEMA™ Fentanyl 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 our existing Meda agreements. We submitted an IND for BEMA™ Buprenorphine to the FDA in December 2005 which was accepted by the FDA. We conducted a Phase I trial in normal volunteers during 2006 which demonstrated that therapeutic blood concentrations of the active ingredient could be achieved in these healthy volunteers. Due to our focus on BEMA™ Fentanyl, we did not conduct any further work on BEMA™ Buprenorphine in 2007. We plan to complete our Phase I program by the third quarter of 2008 and then begin our Phase II program to evaluate its effectiveness in treating post-operative pain. The Phase II program will likely require 6 months to complete, including data analysis. If we meet our Phase II objectives, we would then move

into our Phase III program during the first half of 2009, under which we would be treating patients who have moderate to severe pain with the doses identified from our Phase II program. This pain condition may be either acute, requiring short term therapy (such as sprains and strains), or chronic (such as arthritis requiring chronic therapy). The BEMA™ Buprenorphine Phase III program may take from 12-24 months to complete, depending on the final indication for the patient population that we decide to evaluate and agreements with the FDA. After completing the Phase III program, it would likely take approximately 3 to 6 months to compile and submit our NDA to the FDA. After submission, the FDA will then have up to 10 months from the date the submission is accepted for filing 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 market for the opioid narcotics. This would translate into an estimated $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 2008, depending on our progress in our Phase I and Phase II programs, as described above.

The risks to our company associated with the BEMA™ Buprenorphine project include: (i) inability to develop a final formulation; (ii) inability of a contract manufacturer to produce clinical supplies; (iii) slow patient enrollment in clinical trials; (iv) lack of corporate funding to progress the program; (v) failure of clinical trials; (vi) product safety issues; (vii) clinical trial data that does not support an NDA submission; (viii) failure of or delay by the FDA to approve an NDA; (ix) failure to secure a commercial partner for the product or to develop our own internal commercial capability and (x) 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.

BEMA™ Zolpidem. This formulation would be our third BEMA™ following BEMA™ Fentanyl and BEMA™ Buprenorphine (although we may elect to pursue other BEMA™-formulated products depending on market conditions and other factors we deemed relevant). Based on the progress we make on BEMA™ Fentanyl and BEMA™ Buprenorphine and depending on the level of our corporate resources, we may not file an IND on this product in 2008. Once we file an IND on this product, it will be followed by our first Phase I trial in normal volunteers whereby we would measure the blood concentrations of the product in these patients. Based on the results of this first Phase I trial, one to two additional Phase I trials would be conducted. One of these studies would be conducted in a sleep laboratory. Based on the results of these studies, a final formulation would be chosen for initiating the Phase III program. The BEMA™ Zolpidem Phase III program may take from 12-24 months, depending on the final agreements with the FDA. After completing the Phase III program, it would likely take approximately 3 to 6 months to compile and submit our NDA to the FDA. After submission, the FDA will then have up to 10 months from the date the submission is accepted to render a decision on the approvability of our application. If the FDA approves the application we would anticipate launching the product within 3 months of that approval. During 2007, we did not expend any resources on BEMA™ Zolpidem.

Due to the potential ability of BEMA™ Zolpidem to induce sleep in 10-15 minutes versus the time for standard products (30-45 minutes) our market research indicates that BEMA™ Zolpidem has the potential to achieve a 5% share of the total worldwide insomnia market which currently exceeds $5 billion in the U.S. alone. This would translate into an estimated $250 million in peak annual sales, although no assurances can be given to this sales estimate. We do not expect to generate any revenue from BEMA™ Zolpidem, if ever, until at least 2012.

The risks to our company associated with the BEMA™ Zolpidem project include: (i) inability to develop a final formulation; (ii) inability of a contract manufacturer to produce clinical supplies; (iii) FDA fails to accept the IND upon first submission; (iv) slow patient enrollment in clinical trials; (v) lack of corporate funding to progress the program; (vi) failure of clinical trials; (vii) product safety issues; (viii) clinical trial data does not support an NDA submission; (ix) failure or delay by the FDA to approve the NDA; (x) failure to secure a commercial partner or to develop our own internal commercial capability and (xi) failure of a commercial partner or us to launch and sell the product. A technical failure of this product, or a failure of the product to meet commercial forecasts, 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 (CAMB). We license the encochleation drug delivery technology which we use in our Amphotericin B formulation from the Universities. We filed the IND on this oral formulation of Amphotericin, for the treatment fungal infections including esophageal candidiasis in the fourth quarter 2006. The IND was accepted by the FDA. We intend to begin Phase I studies in normal volunteers in the first half of 2008. These studies will assess the oral absorption and safety of Amphotericin from our cochleate formulation in normal volunteers. Following completion of Phase I trials, we would then move into a Phase II study in patients in the late 2008 or early 2009. Based on the outcome of our Phase II program our Phase III program could start sometime in 2009. A Phase III 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. No assurances can be given that we will successfully 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 peak sales of approximately $400 million annually, on which we will pay a royalty to UMDNJ. No assurances can be given regarding this estimate. We do not anticipate generating any revenue for CAMB, if ever, until at least late 2012.

The risks to our company associated with the CAMB project include: (i) inability of a contract manufacturer to produce clinical supplies; (ii) Phase I not showing significant oral absorption of product; (iii) failure of subsequent clinical trials, including if the Phase II 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.

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 CAMB 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 CAMB would, as it is our lead Bioral® product, likely validate the broader encochleation concept.

Emezine®. We are the exclusive U.S. licensee of Emezine®, a transmucousally delivered formulation of prochlorperazine, an anti-emetic product used for treating nausea and vomiting which

occurs after surgeries and chemotherapy. On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. We do not expect to spend material resources on the Emezine® project for the foreseeable future and in 2008, we expect to determine with our partners, Reckitt and Accentia, the disposition of this effort. Given the relatively small sales projections for Emezine®, we do not believe that our abandonment of this project, though potentially damaging to our reputation and stock price, would seriously impair our longer-term viability.

Liquidity and Capital Resources

From inception through August 2007, we financed our operations primarily from the private sales of our convertible preferred stock, convertible debt and common stock, our initial public offering in 2002 and follow-on 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 from 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 US$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 BDSI’s 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.

In early October 2005, we announced the consummation of a “follow on” public offering of 4,400,000 shares of our common stock, resulting in gross proceeds of $8.8 million to us. The public price per share for the offering was $2.00. The underwriters were granted an option to purchase up to an additional 660,000 shares of our common stock to cover over-allotments, which option was partially exercised in late October 2005, generating additional gross proceeds of $107,900.

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 BEMA™ Fentanyl was converted into shares of our common stock at a value of $3.50 per share. A s 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 BEMA™ Fentanyl.

In March 2007, we entered into a $1.9 million financing with CDC. This financing involves 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.

In September 2007, we received an up-front non-refundable payment in connection with our U.S commercialization agreement with Meda of $30.0 million.

At December 31, 2007, we had cash and cash equivalents of $16.6 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 generated $12.2 million of cash from operations in of the year ended December 31, 2007. This resulted from a net loss of $25.2 million, which included net non-cash charges of $5.8 million, as well as the Meda up-front payment with associated deferred revenue of $30.1 million and an increase in our accounts payable and accrued liabilities of $1.5 million.

We have incurred significant net losses and negative cash flows from operations since our inception. As of December 31, 2007, we had stockholders’ deficit of $18.8 million, versus $8.7 million at December 31, 2006.

We anticipate that cash used in operations and our investment in facilities will continue beyond our BEMA™ Fentanyl 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 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® cochleate 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 manufacturing and packaging equipment costs for BEMA Fentanyl. Our agreement with Meda requires all pre-launch marketing and commercialization costs for BEMA™ Fentanyl to be paid by Meda, as well as all required clinical costs associated with BEMA™ Fentanyl after FDA approval. Meda will pay for costs of Phase III-b and Phase IV studies which, although not required as part of our NDA, may be done to support the program with additional market data.

Our existing cash and cash equivalents, together with milestone revenue associated with our Meda European license, is considered by our management to be sufficient to finance the planned basic operations (minimal research and development activities beyond those covered under our Meda agreement) debt repayment obligations and capital expenditures into approximately the third quarter of 2008.

Under our existing Meda agreements, we expect to receive additional payments aggregating $30.0 million upon approval and launch of BEMA Fentanyl, for which we have a PADUFA date of August 31, 2008. Additional capital may be required in order to proceed with our support of the launch of BEMA™ Fentanyl, clinical development programs for BEMA™ Buprenorphine and CAMB (the scale of which is dependent in part on the success of BEMA™ Fentanyl 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. 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;
- public or private debt; and
- exercise of existing warrants.

There can be no assurance that additional capital will be available 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 2008 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.

As such, our auditors' report in our 2007 financial statements which is included as part of this Report, contains a statement concerning uncertainty about our ability to continue as a "going concern."

Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2007 are as follows:

	Payments Due by Period				
	Total	2008	2009	2010	thereafter
Long-term and short-term debt	$ 2,186,118	$ 2,186,118	$ —	$ —	$ —
Leases	589,454	101,567	114,073	117,496	256,318
Employment agreements	727,689	679,365	48,324	—	—
Total contractual cash obligations	$ 3,503,261	$ 2,967,050	$ 162,397	$ 117,496	$ 256,318

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 Aidman, Piser & Company, P.A., 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.

None.

Item 9A(T). Controls and Procedures.

Our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)

Internal control over financial reporting is promulgated under the Exchange Act as a process designed by, or under the supervision of, our CEO and CFO and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition or disposition of our assets that could have a material effect on the financial statements.

Readers are cautioned that internal control over financial reporting, no matter how well designed, has inherent limitations and may not prevent or detect misstatements. Therefore, even effective internal control over financial reporting can only provide reasonable assurance with respect to the financial statement preparation and presentation.

Our management, under the supervision and with the participation of our CEO and CFO, has evaluated the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) as of the end of the period covered by this Report based upon the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such evaluation, our management has made an assessment that our internal control over financial reporting is effective as of December 31, 2007.

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 in this Report.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of March 7, 2008 are as follows:

Name	Age	Position(s) Held
Francis E. O'Donnell, Jr., M.D.	58	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	54	President, Chief Executive Officer and Director
Raphael J. Mannino, Ph.D.	61	Executive Vice President, Chief Scientific Officer and Director
Andrew L. Finn, Pharm.D.	58	Executive Vice President of Product Development
James A. McNulty	57	Chief Financial Officer, Secretary and Treasurer
William B. Stone	64	Lead Director
John J. Shea	81	Director
William S. Poole	60	Director
Thomas W. D'Alonzo	64	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 58, 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 54, 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 20 years of experience in the pharmaceutical industry, including 16 years in clinical drug development; 7 years in marketing, sales, 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 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 61, has been our Executive Vice President and Chief Scientific Officer since October 2000, and a Director since October 2001. 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 58, 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 57, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis (estimated to constitute approximately 50% of his time) since October 2000. Beginning January 1, 2008, his position is 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 representing a vertically-integrated platform for 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 64, is a member of our board of directors and is our Lead Director. For thirty years, until his retirement in October 2000, Mr. Stone was employed with Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and Chief Information Officer for 16 years and 4 years, respectively. 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 81, is a member of our board of directors. He is currently the head of his own firm of John J. Shea & Associates and has also been a Quality Systems Adviser with Quintiles, a private consulting firm. Mr. Shea has been employed at J. Shea Inc. since 1989. 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 60, is a member 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 a solid management team and dramatically improving profitability. As President of these firms, Mr. Poole had total P&L responsibility and directly oversaw vice presidents in charge of manufacturing, research & development, sales, legal, marketing, finance, regulatory and human resources functions. 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 BDSI's subsidiary, Arius Pharmaceuticals. Currently, Mr. Poole is Acting President/CEO of Spherics, Inc., a biotechnology company focusing on unique delivery mechanisms of certain drugs for the treatment of CNS diseases. In addition Mr. Poole is a Board Member of Accentia BioPharmaceuticals Inc., and is Chairman of the Compensation Committee.

Thomas W. D'Alonzo, 64, was appointed to our Board of Directors on August 30, 2006. Mr. D'Alonzo's experience in the biopharmaceutical industry spans more than 30 years as a top-level pharmaceutical executive, and includes all major facets of pharmaceutical operations. From 1983-1993, Mr. D'Alonzo worked at Glaxo, Inc., the U.S. subsidiary of the former Glaxo Holdings P.L.C., rising to the position of President of Glaxo from 1988-1993. At Glaxo, he served on its board of directors and presided over 4,400 employees, including an 1,800 person sales force in a company that generated $3 billion dollars in annual revenues. From 1993 to 1996, Mr. D'Alonzo served as President and Chief Executive Officer of GenVec, Inc., a gene therapy biotechnology company. During his tenure at GenVec, two INDs were filed, Theragen, a separate gene therapy company, was acquired, and the company raised $20 million in funding. From 1996 to 1999, Mr. D'Alonzo served as President and Chief Operating Officer of Pharmaceutical Product Development, Inc., a multi-national clinical research organization. At PPDI, he oversaw 3,000 employees in a company that generated $300 million in revenues. In 1999, Mr. D'Alonzo received his Honorary Doctor of Pharmacy from Campbell University, Buies Creek, North Carolina. He received his BS in Business Administration from University of Delaware and his JD from University of Denver. Since 1999, he has served as a board member of other pharmaceutical companies, which currently includes, Salix Pharmaceuticals, Ltd., Amarillo Biosciences, Inc., and Dara Biosciences, Inc.

Director Independence

We believe that William B. Stone, John J. Shea, William S. Poole and Thomas D'Alonzo 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 Thomas D'Alonzo, 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 five times during 2007. 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, 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 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 and John J. Shea and Thomas D'Alonzo. 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 did not meet formally in 2007. 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 2007, we did not pay any fees to any third parties to assist in the identification of nominees. During 2007, 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 three times during 2007.

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 2007.

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.

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 2007, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, except that one Amended Form 5 was filed on February 26, 2008 by Mark A. Sirgo, our President and Chief Executive Officer, covering two "small acquisition" transactions as defined in SEC Rule 16a-6 (for an aggregate of 700 shares of our common stock), which acquisitions were not previously reported on a timely basis. Such transactions were unintentionally omitted from the original Form 5, filed on February 14, 2008.

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. The code of ethics is available at our website at www.bdsinternational.com.

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 this code of ethics by posting such information on our website, at the address specified above.

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, 2007 and 2006. 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, 2007.

SUMMARY COMPENSATION TABLE

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mark A. Sirgo,	2007	$286,169	0	0	$1,522,035	$ 44,770[1]	0	$ 32,404[2]	$1,885,378
Pharm.D. President,	2006	$252,617	0	0	$ 27,831	$ 21,574[1]	0	$ 12,668	$ 314,690
Chief Executive Officer and Director									
Andrew L. Finn,	2007	$236,941	0	0	$ 383,897	0	0	$ 9,838[3]	$ 630,677
Pharm.D. Executive Vice	2006	$223,902	0	0	$ 24,492	0	0	0	$ 248,394
President of Product Development									
James A. McNulty	2007	$114,400	0	0	$ 380,033	0	0	$ 17,714[4]	$ 512,147
Chief Financial Officer,	2006	$109,355	0	0	$ 12,245	0	0	0	$ 121,600
Secretary and Treasurer									
Raphael J. Mannino,	2007	$ 98,026	0	0	$ 40,580	$ 44,770[1]	0	$ 11,726[5]	$ 195,102
Ph.D Executive Vice President	2006	$ 97,841	0	0	$ 23,379	$ 21,574[1]	0	$ 11,123[5]	$ 153,914
and Chief Scientific Officer									

(1) The compensation disclosed in this item is comprised of 20,000 stock options granted as compensation for serving as a director.
(2) Includes: (a) vacation payout of $21,154 and 401(k) matching of $11,250 paid in 2007.
(3) Includes: 401(k) matching of $9,838 paid in 2007.
(4) Includes: (a) vacation payout of $11,423 and 401(k) matching of $6,291 paid in 2007.
(5) Includes: (a) a car allowance of $6,500 and 401(k) matching of $5,226 paid in 2007. Excludes $120,000, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2006 and 2007 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

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:

Dr. Francis E. O'Donnell, Chairman of the Board — On March 29, 2002, Dr. O'Donnell executed an employment agreement to be our full-time President and CEO at an annual salary of $150,000. Dr. O'Donnell's term of employment was to be no longer than three years or until another CEO is appointed. However, in January 2005, we entered into an amendment to Dr. O'Donnell's employment agreement pursuant to which: (i) he agreed to serve solely in the position of CEO and Chairman of the Board, (ii) the term of his employment was extended until March 22, 2008 and (iii) his annual salary was, effective February 1, 2005, reduced to $1.00. Dr. O'Donnell relinquished the title of Chief Executive Officer in August 2005 and now serves only as our Chairman of the Board.

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.

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.

We may terminate the 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 BDSI. Beginning January 1, 2008, Mr. McNulty devotes substantially all of his time to BDSI. 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 BDSI agreement, Mr. McNulty will receive base salary in 2008 of $198,000 per year and a target bonus of up to 50% of his base salary.

We may terminate the 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 the McNulty employment agreement for Good Cause (as defined in the employment agreement). Upon the termination of Mr. McNulty's employment for any reason, Mr. McNulty will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Mr. McNulty is terminated during the term of his employment agreement other than for Good Cause (as defined in the employment agreement), or if Mr. McNulty terminates his employment for Good Reason (as defined in the employment agreement), Mr. McNulty is entitled to a lump sum severance payment equal to 1 times the sum of his annual base salary plus a pro-rata annual bonus based on his target annual bonus. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Mr. McNulty will equal the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary, multiplied by 1.5. In addition, the employment agreement will terminate prior to its scheduled expiration date in the event of Mr. McNulty's death or disability.

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

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 the 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, 2007.

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.	20,000	—	—	$ 4.13	7/25/2017	—	—	—	—
		—	434,000(1)	$ 6.63	4/13/2017	—	—	—	—
	15,296	—	30,595(2)	$ 2.42	1/26/2017	—	—	—	—
	5,910	—	11,820(3)	$ 2.05	7/27/2016	—	—	—	—
	32,666	—	16,334(4)	$ 3.03	12/1/2015	—	—	—	—
	20,000	—	—	$ 2.94	8/22/2015	—	—	—	—
	5,952	—	2,977(5)	$ 2.94	7/28/2015	—	—	—	—
	5,147	—	—	$ 3.40	10/21/2014	—	—	—	—
Andrew L. Finn, Pharm.D.	—	—	100,000(1)	$ 6.63	4/13/2017	—	—	—	—
	12,402	—	24,807(2)	$ 2.42	1/26/2017	—	—	—	—
	5,201	—	10,402(3)	$ 2.05	7/27/2016	—	—	—	—
	32,666	—	16,334(4)	$ 3.03	12/1/2015	—	—	—	—
	5,952	—	2,977(5)	$ 2.94	7/28/2015	—	—	—	—
	5,147	—	—	$ 3.40	10/21/2014	—	—	—	—
James A. McNulty	—	—	100,000(1)	$ 6.63	4/13/2017	—	—	—	—
	11,369	—	22,740(2)	$ 2.42	1/26/2017	—	—	—	—
	5,201	—	10,402(3)	$ 2.05	7/27/2016	—	—	—	—
	6,666	—	3,334(4)	$ 3.03	12/1/2015	—	—	—	—
	17,458	—	8,731(5)	$ 2.94	7/28/2015	—	—	—	—
	3,235	—	—	$ 3.40	10/21/2014	—	—	—	—
	18,616	—	—	$ 3.83	8/14/2013	—	—	—	—
						—	—	—	—
Raphael J. Mannino, Ph.D.	20,000	—	—	$ 4.13	7/25/2017	—	—	—	—
	10,852	—	21,706(2)	$ 2.42	1/26/2017	—	—	—	—
	4,964	—	9,930(3)	$ 2.05	7/27/2016	—	—	—	—
	20,000	—	—	$ 2.05	7/27/2016	—	—	—	—
	20,000	—	—	$ 2.94	8/22/2015	—	—	—	—
	7,142	—	3,572(5)	$ 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	—	—	—	—
	60,000	—	—	$ 1.63	1/31/2008	—	—	—	—

(1) Of the unvested stock options, one third of the unvested stock options will vest on April 13, 2008, another third will vest on April 13, 2009 and the remaining third will vest on April 13, 2010.
(2) Of the unvested stock options, half of the unvested stock options will vest on January 26, 2008 and another half will vest on January 26, 2009.
(3) Of the unvested stock options, half of the unvested stock options will vest on July 27, 2008 and another half will vest on July 27, 2009.
(4) These unvested stock options will vest on December 1, 2008.
(5) These unvested stock options will vest on July 28, 2008.

Outstanding Equity Awards Narrative Disclosure

Amended and Restated 2001 Stock Incentive Plan

The purpose of the Amended and Restated 2001 Stock Incentive Plan is: (i) to align our interests and recipients of options under the 2001 Stock Option 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.

Our board of directors administers our stock option plan, selects the persons to whom options are granted and fixes the terms of such options.

Under our original 2001 Stock 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 2001 Stock Option Plan to increase the plan to 1,100,000 shares, and later, through an

amendment and restatement of the 2001 Stock 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 2,695,904 shares of common stock are outstanding as of December 31, 2007 under the Amended and Restated 2001 Stock Option Plan. All options were issued under our stock option plan, as the same may be amended. Options may be awarded during the ten-year term of the stock option plan to our employees (including employees who are directors), consultants who are not employees and our other affiliates. Our stock option plan provides for the grant of options intended to have been approved by our board of directors and 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.

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 stock option plan. The Amended and Restated 2001 Stock Option Plan provides for an initial grant of an option to purchase up to 20,000 shares of common stock to each director upon first joining our board of directors and subsequent grants of options to purchase 20,000 shares upon each anniversary of such director's appointment and an additional 10,000 option grant for serving as Lead Director. Additionally, directors will be granted 10,000 options for each committee chairmanship and 5,000 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 8,582,661 shares of our common stock at prices ranging from $0.001 to $6.63 are outstanding at December 31, 2007. None of our options have been granted at less than the fair market value at the time of grant. Options issued during 2007 to employees and directors totaled 1,402,917 shares, at exercise prices ranging from $2.42 and $6.63. 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.

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	$ 55,963	0	0	$ 55,963
William B. Stone [2]	$9,000	0	0	$ 123,118	0	0	$123,118
John J. Shea [3]	$8,000	0	0	$ 100,733	0	0	$100,733
William S. Poole [4]	$6,000	0	0	$ 89,540	0	0	$ 89,540
Thomas W. D'Alonzo [5]	$6,000	0	0	$ 78,348	0	0	$ 78,348

(1) As of December 31, 2007, the outstanding stock options held by Dr. O'Donnell total 145,000, all of which have vested.
(2) As of December 31, 2007, the outstanding stock options held by Mr. Stone total 205,000, all of which have vested.
(3) As of December 31, 2007, the outstanding stock options held by Mr. Shea total 148,700, all of which have vested.
(4) As of December 31, 2007, the outstanding stock options held by Mr. Poole total 110,000, all of which have vested.
(5) As of December 31, 2007, the outstanding stock options held by Mr. D'Alonzo total 65,000 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 20,000 options to purchase common stock for each year served as a director and an additional 10,000 options to purchase common stock per year for serving as Lead Director. Additionally, each director is granted 5,000 options to purchase common stock per year for serving on a committee of the board of directors and an additional 5,000 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 7, 2008, 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 7, 2008
Hopkins Capital Group II, LLC [2]	4,171,523	21.79%
Francis E. O'Donnell, Jr., M.D. [3]	4,478,788	23.39%
The Francis E. O'Donnell, Jr. Irrevocable Trust #1 [4]	4,339,023	22.66%
CDC IV, LLC [5]	3,505,120	18.31%
Laurus Master Fund. Ltd. [6]	955,137	4.99%
Mark A. Sirgo, Pharm.D. [7]	966,109	5.05%
Andrew L. Finn, Pharm.D. [8]	871,183	4.55%
Raphael J. Mannino, Ph.D. [9]	384,044	2.01%
James A. McNulty [10]	155,573	*
William B. Stone [11]	240,000	1.25%
John J. Shea [12]	175,000	*
William S. Poole [13]	118,190	*
Thomas D'Alonzo [14]	70,730	*
All Directors and Officers as a group (9 persons)	7,459,617	38.96%

* Less than 1%

(1) Based on 19,145,146 shares of common stock outstanding as of March 7, 2008.

(2) Includes 400,402 shares of our common stock which were converted from Series B Convertible Preferred Stock in January 2007.

(3) Dr. O'Donnell is our Chairman of the Board and a Director. Includes the shares 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 145,000 shares of our common stock, all of which is currently exercisable. Dr. O'Donnell's address is 709 The Hampton Lane, Chesterfield MO 63017.

(4) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 3). The remaining 167,500 shares of common stock are held directly by this trust.

(5) Includes 2,000,000 shares of common stock owned by CDC, IV. LLC and includes 1,505,120 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 2,559,138 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 844,443 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Includes options to purchase 120,266 shares of common stock, all of which are currently exercisable. Excludes options to purchase 528,879 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 797,413 shares owned by Dr. Finn. Includes options to purchase 73,770 shares of common stock, all of which are currently exercisable. Excludes options to purchase 181,400 shares of common stock which are not currently exercisable. Dr. Finn's address is 200 Royal Kings Lane, Raleigh, NC 27615.

(9) Dr. Mannino is our Executive Vice President, Chief Scientific Officer and a Director. Includes 212,609 shares owned by Dr. Mannino. Includes options to purchase 171,435 shares of our common stock, all of which are currently exercisable. Excludes options to purchase 24,356 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 79,371 shares owned by Mr. McNulty. Includes options to purchase 73,914 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 166,246 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 205,000 shares of our common stock, all of which are currently exercisable. Mr. Stone's address is 11120 Geyer Down Lane, Frontenac MO 63131.

(12) Mr. Shea is a Director. Includes 26,300 shares owned and options to purchase 148,700 shares of our common stock, all of which are currently exercisable. Mr. Shea's address is 290 Wax Myrtle Trail, Southern Shores, NC 27949.

(13) Mr. Poole is a Director. Includes 8,190 shares owned and options to purchase 110,000 shares of our common stock, all of which are currently exercisable. Mr. Poole's address is 7813 Hardwick Drive, Raleigh, NC 27615.

(18) Mr. D'Alonzo is a Director. Includes 5,730 shares owned and options to purchase 65,000 shares of our common stock, all of which are currently exercisable. Mr. D'Alonzo's address is 11896 Hedgestone Court Naples, FL 34135

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

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.

We also have several business relationships with Accentia and its affiliates. HCG II, which is controlled by Dr. Frank O'Donnell, 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. Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, is the Secretary and Treasurer of Accentia. Dr. Raphael J. Mannino, our Executive Vice President and Chief Scientific Officer, is a director of Biovest International, Inc. (OTC BB:BVTI), a subsidiary of Accentia. Mr. McNulty is also the CFO of HCG II.

- *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. The license agreement was amended effective June 1, 2004, then modified in September 2004 by our asset purchase agreement with Accentia, and 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. Given the FDA non-approvable decision on this product in 2006 and our focus on other products in our pipeline, we plan to meet with our partners, including Accentia, in 2008 to make a final determination regarding the future of the Emezine® project.
- 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™ disc 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's royalty purchase rights and, as consideration; we issued a warrant to HCG 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.

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. To the extent that such drugs utilize Bioral® cochleate technology, we will support drug development and will share in ten percent (10%) of all net revenue from such sales of Bioral® encapsulated drugs. 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, an emerging alliance of early stage biotechnology and specialty pharmaceutical companies. Biotech Specialty Partners, LLC is in its formative stage and 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%) discount to the wholesale price, which our 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 Biotech Specialty Partners, LLC.

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. 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 four independent directors which constitute a majority as required by Nasdaq Stock Market rules. We believe that William B. Stone, John J. Shea, William S. Poole and Thomas D'Alonzo 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 $60,000, 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 Aidman, Piser & Company, P.A. for professional services rendered for the audit of our annual financial statements for the years ended December 31, 2007 and 2006 and the review of the financial statements included in our Forms 10-QSB totaled $179,172 and $100,400, 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 Aidman, Piser & Company, P.A. for audit-related fees for the years ended December 31, 2007 and 2006 were $18,725 and $6,800, respectively.

Tax Fees. The aggregate fees billed by Aidman, Piser & Company, P.A. for professional services rendered for tax compliance, for the years ended December 31, 2007 and 2006 were $18,725 and $16,766, respectively.

All Other Fees. The aggregate fees billed by Aidman, Piser & Company, P.A. for products and services, other than the services described in the paragraphs captions “Audit Fees”, and “Tax Fees” above for the years ended December 31, 2007 and 2006 totaled zero for both years.

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 Aidman, Piser & Company, P.A. in 2007. 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 Aidman, Piser & Company, P.A.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Number	Description
1.1	Form of Underwriting Agreement for June 2002 initial public offering (11)
1.2	Form of Underwriting Agreement for September 2005 public offering (35)
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 (21)
2.2	Asset Purchase Agreement, dated September 8, 2004, by and between the Company and Accentia, Inc. (24)
3.1	Articles of Incorporation of the Company as an Indiana corporation (6)
3.2	Articles of Amendment of the Article of Incorporation as an Indiana corporation (5)
3.3	Bylaws of the Company as an Indiana corporation (6)
3.4	Articles of Incorporation of the Company after reincorporation merger into Delaware (8)
3.5	Bylaws of the Company after reincorporation merger into Delaware (8)
3.6	Secretary’s Certificate regarding amendments to Company’s Bylaws, dated August 23, 2005 (34)
4.1	Form of Class A Warrant Agreement with Forms of Class A Warrant Certificate (9)
4.2	Form of Representative’s Unit Purchase Option (11)
4.3	Form of Specimen of Unit Certificate (12)
4.4	Form of Specimen of Common Stock Certificate (12)

4.5	Form of Specimen of Warrant Certificate (12)
4.6	Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 20, 2004 (21)
4.7	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 25, 2004. (22)
4.8	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated September 2, 2004 (23)
4.9	Certificate of Designations of the Series B Convertible Preferred Stock of the Company, dated September 3, 2004 (23)
4.10	Secured Convertible Term Note, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.11	Common Stock Purchase Warrant, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.12	Common Stock Purchase Warrant (22,500 shares), dated June 29, 2005, by the Company in favor of Laurus Master Fund, Ltd. (32)
4.13	Common Stock Purchase Warrant (7,500 shares), dated June 29, 2005, by the Company in favor of Laurus Master Fund, Ltd. (32)
4.14	Common Stock Purchase Warrant, dated July 15, 2005, by the Company in favor of Clinical Care Development, LLC (33)
4.15	Common Stock Purchase Warrant, dated July 15, 2005, by the Company in favor of Aveva Drug Delivery Systems, Inc. (36)
4.16	Common Stock Purchase Warrant (39,574 shares), dated December 28, 2005, by the Company in favor of Laurus Master Fund, Ltd. (37)
4.17	Common Stock Purchase Warrant (29,700 shares), dated December 28, 2005, by the Company in favor of Laurus Master Fund, Ltd. (37)
4.18	Warrant, dated May 16, 2006, made by the Company in favor of CDC IV LLC (39)
4.19	Common Stock Purchase Warrant (62,887 shares), dated July 31, 2006, by the Company in favor of Laurus Master Fund, Ltd. (40)
4.20	Common Stock Purchase Warrant (47,113 shares), dated July 31, 2006, by the Company in favor of Laurus Master Fund, Ltd. (40)
4.19	Common Stock Purchase Warrant (943,305 shares), dated December 28, 2006, by the Company in favor of Laurus Master Fund, Ltd. (40)
4.20	Common Stock Purchase Warrant (556,695 shares), dated December 28, 2006, by the Company in favor of Laurus Master Fund, Ltd. (40)
4.21	Certificate of Designations, Preferences and Rights, of the Series C Non-Voting Convertible Preferred Stock of the Company, dated February 22, 2007 (45)
4.22	Common Stock Purchase Warrant, dated March 12, 2007, by the Company in favor of CDC (46)
10.1	Research Agreement with the University of Medicine and Dentistry of New Jersey (2)
10.2	Licensing Agreement with the University of Medicine and Dentistry of New Jersey (3)
10.3	Licensing Agreement with Albany Medical College (3)

10.4	License Agreement with BioKeys Pharmaceuticals, Inc. (8)
10.5	License Agreement with Tatton Technologies, LLC (8)
10.6	Addendum to License Agreement with Tatton Technologies, LLC (10)
10.7	License Agreement with RetinaPharma, Inc. (28)
10.8	Addendum to License Agreement with RetinaPharma, Inc. (9)
10.9	License Agreement with Biotech Specialty Partners, LLC (8)
10.10	National Institutes of Health Grant Letter (8)
10.11	Merger Agreement with BioDelivery Sciences, Inc., dated July 20, 2001 (2)
10.12	Settlement Agreement and Stock Purchase Agreement with Irving Berstein, et al. (2)
10.13	Employment Agreement with Christopher Chapman (2)
10.14	Employment Agreement with James A. McNulty (2)
10.15	Employment Agreement with Dr. Frank E. O'Donnell (10)
10.16	Confidentiality Agreement for Dr. Frank E. O'Donnell (10)
10.17	Covenant Not to Compete with Dr. Frank E. O'Donnell (10)
10.18	2001 Incentive Stock Option Plan (8)
10.19	Promissory Note for BioKeys Pharmaceuticals, Inc. dated August 22, 2001 (11)
10.20	Research Agreement with PharmaResearch Corporation (9)
10.21	Credit Facility Loan Agreement with Missouri State Bank (10)
10.22	Purchase Agreement between MAS Capital, Inc. and Hopkins Capital Group II, LLC (10)
10.23	Amendment to Purchase Agreement dated March 29, 2002 (10)
10.24	Agreement between Mr. Aaron Tsai and the Company (10)
10.25	Employment Agreement with Raphael Mannino (13)
10.26	Employment Agreement with Susan Gould-Fogerite (13)
10.27	Employment Agreement with James A. McNulty (13)
10.28	Sub-License Agreement, effective as of December 31, 2002, by and between the Company and Pharmaceutical Product Development, Inc. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (14)
10.29	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 (15)
10.30	Promissory Note, dated February 13, 2003, by Bioral Nutrient Delivery, LLC in favor of the Company (15)
10.31	First Amendment to Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, dated March 31, 2003 (17)
10.32	Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (17)

10.33	Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (17)
10.34	Distribution Agent Agreement, effective June 1, 2003, by and between Kashner Davidson Securities Corporation and Bioral Nutrient Delivery, LLC (17)
10.35	Amended and Restated Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated October 1, 2003, by the Company, as Managing Member (18)
10.36	First Amendment to Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (18)
10.37	License Agreement, dated effective April 12, 2004, between the Company and Accentia, Inc. (19)
10.38	Amendment to License Agreement, dated effective June 1, 2004, between the Company and Accentia, Inc. (19)
10.39	Facility Loan Agreement, dated effective August 2, 2004, between the Company and Hopkins Capital Group II, LLC (20)
10.40	Binding Letter of Intent and Termination Agreement, dated August 23, 2004, between Hopkins Capital Group II, LLC and the Company (22)
10.41	Registration Rights Agreement, dated August 24, 2004, by and among the Company and the former stockholders of Arius (22)
10.42	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.43	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.44	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.45	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.46	Voting Agreement, dated August 24, 2004, by Mark A. Sirgo and Andrew L. Finn in favor of the Company (22)
10.47	Voting Agreement, dated August 24, 2004, by certain stockholders of the Company in favor of the Company, Mark A. Sirgo and Andrew L. Finn (22)
10.48	Loan Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)
10.49	Security Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)
10.50	Limited Waiver and Forbearance Agreement, dated effective May 14, 2004, by and between the Company and Gold Bank (22)
10.51	Equity Line of Credit Agreement, dated September 3, 2004, by and between the Company and Hopkins Capital Group II, LLC (23)
10.52	Common Stock Purchase Agreement, dated January 20, 2005, between BDSI and Sigma Tau Finanziaria S.p.A. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (25)
10.53	Licensing Agreement, dated January 20, 2005, between the Company and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (25)

10.54	First Amendment to Employment Agreement, dated January 31, 2005, by and between the Company and Francis E. O'Donnell, Jr. (26)
10.55	Securities Purchase Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.56	Registration Rights Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.57	Subsidiary Guaranty, dated February 22, 2005, by Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.58	Master Security Agreement, dated February 22, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.59	Stock Pledge Agreement, dated February 22, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.60	Grant of Security Interest in Patents and Trademarks, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
10.61	Control Agreement Regarding Limited Liability Company Interests, dated February 22, 2005, by and among the Company and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.62	Letter Amendment to License Agreement, dated March 28, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (28)
10.63	Letter Amendment to License Agreement, dated April 25, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (28)
10.64	Consulting Agreement, executed as of April 14, 2005, by and between the Company and Susan Gould-Fogerite (29)
10.65	Termination Agreement and Release, dated April 14, 2005, by and between the Company and Susan Gould-Fogerite (29)
10.66	Non-Qualified Stock Option Agreement, dated April 14, 2005, between the Company and Susan Gould-Fogerite (29)
10.67	Securities Purchase Agreement, dated May 31, 2005, by and between the Company and Laurus Master Fund, Ltd. (30)
10.68	Secured Convertible Term Note, dated May 31, 2005, by the Company in favor of Laurus Master Fund, Ltd. (30)
10.69	Common Stock Purchase Warrant, dated May 31, 2005, by the Company in favor of Laurus Master Fund, Ltd. (30)
10.70	Registration Rights Agreement, dated May 31, 2005, by and between the Company and Laurus Master Fund, Ltd. (30)
10.71	Reaffirmation and Ratification Agreement and Amendment, dated May 31, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (30)
10.72	Grant of Security Interest in Patents and Trademarks, dated May 31, 2005, by the Company in favor of Laurus Master Fund, Ltd. (30)
10.73	Letter Amendment to License Agreement, dated June 6, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (31)

10.74	Amendment, dated June 29, 2005, to February 22, 2005 Laurus Master Fund, Ltd. financing documents (32)
10.75	Amendment, dated June 29, 2005, to May 31, 2005 Laurus Master Fund, Ltd. financing documents (32)
10.76	Clinical Development and License Agreement, dated as of July 14, 2005, among Clinical Development Capital LLC, the Company and Arius Pharmaceuticals, Inc. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (33)
10.77	Form of Security Agreement to be entered into by and among the Company, Arius Pharmaceuticals, Inc and Clinical Development Capital LLC (33)
10.78	Registration Rights Agreement, dated as of July 14, 2005, by and between the Company and Clinical Development Capital LLC (33)
10.79	Supply Agreement, dated October 17, 2005, by and between Aveva Drug Delivery Systems, Inc., Arius Pharmaceuticals, Inc. and the Company (36)
10.80	Second Amendment, dated December 28, 2005, to February 22, 2005 Laurus Master Fund, Ltd. financing documents (37)
10.81	Amendment, dated December 28, 2005, to May 31, 2005 Laurus Master Fund, Ltd. financing documents (37)
10.82	Employment Agreement, dated January 9, 2006, between the Company and Mark W. Salyer (38)
10.83	Amendment, dated March 30, 2006, to Equity Line of Credit Agreement by and between the Company and Hopkins Capital Group II, LLC (38)
10.84	Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC IV, LLC (39)
10.85	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 (39)
10.86	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. (39)
10.87	Amended and Restated Registration Rights Agreement, dated as of May 16, 2006, by and between the Company and CDC IV, LLC (39)
10.88	Third Amendment to February 22, 2005 Laurus Master Fund, Ltd. financing documents, dated July 31, 2006 (40)
10.89	Third Amendment to May 31, 2005 Laurus Master Fund, Ltd. financing documents, dated July 31, 2006 (40)
10.90	Registration Rights Agreement, dated July 31, 2006, between the Company and Laurus Master Fund, Ltd. (40)
10.91	Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT USA, Inc. and Arius Two, Inc. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.92	Secured Promissory Note dated August 2, 2006, by Arius Two, Inc. in favor of QLT USA, Inc. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)

10.93	Security Agreement, dated August 2, 2006, between Arius Two, Inc. and QLT USA, Inc. (41)
10.94	Patent and Trademark Security Agreement, dated August 2, 2006, between Arius Two, Inc. and QLT USA, Inc. (41)
10.95	Guaranty, dated August 2, 2006, by the Company in favor of QLT USA, Inc. (41)
10.96	Assignment of Patents and Trademarks, dated August 2, 2006, by QLT USA, Inc. in favor of Arius Two, Inc. (41)
10.97	BEMA Acquisition Consent, Amendment, and Waiver, dated August 2, 2006, by and between Arius Pharmaceuticals, Inc., Arius Two, Inc. and CDC IV, LLC. (41)
10.98	Letter agreement, dated August 2, 2006 between the Company, Arius Pharmaceuticals, Inc. and Arius Two, Inc. (41)
10.99	Consent and Waiver Agreement, dated August 2, 2006, by and among Laurus Master Fund, the Company, Arius Pharmaceuticals, Inc. and Arius Two, Inc. (41)
10.100	Second Amendment Agreement, dated August 2, 2006, between QLT USA, Inc. and Arius Pharmaceuticals, Inc. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.101	BEMA License Agreement, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.102	First Amendment Agreement, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.103	License and Development Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.104	BEMA Fentanyl Supply Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.105	Sublicensing Consent, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.106	Sublicensing Consent and Amendment, dated August 2, 2006, by the Company, Arius Pharmaceuticals, Inc. and CDC IV, LLC (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (41)
10.107	Letter agreement, dated August 2, 2006, between Meda AB, Arius Pharmaceuticals, Inc, Arius Two, Inc. and the Company (41)
10.108	Notice of Breach and Demand for Dispute Resolution, sent August 30, 2006, from the Company to CDC IV, LLC (42)
10.109	Notice of Breach and Termination, received August 30, 2006, from CDC IV, LLC to the Company (43)
10.110	Fourth Amendment to February 22, 2005 Laurus Master Fund, Ltd. financing documents, dated December 28, 2006 (44)
10.111	Fourth Amendment to May 31, 2005 Laurus Master Fund, Ltd. financing documents, dated December 28, 2006 (44)

10.112	Amended and Restated Registration Rights Agreement, dated December 28, 2006, between the Company and Laurus Master Fund, Ltd. (44)
10.113	Process Development Agreement, effective December 15, 2006, between LTS Lohmann Therapie-Systeme AG and the Company (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)(48)
10.114	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Mark A. Sirgo (45)
10.115	Amendment No. 1 to Employment Agreement, dated February 22, 2007, between the Company and Andrew L. Finn (45)
10.116	Employment Agreement, dated February 22, 2007, between the Company and Raphael J. Mannino (45)
10.117	Employment Agreement, dated February 22, 2007, between the Company and James A. McNulty (45)
10.118	Dispute Resolution Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (46)
10.119	Amendment to Clinical Development and License Agreement, dated March 9, 2007, between the Company and CDC IV, LLC (46)
10.120	Promissory Note, dated March 12, 2007, by the Company in favor of CDC IV, LLC (46)
10.121	Registration Rights Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (46)
10.122	Subscription Agreement, dated March 12, 2007, between the Company and CDC IV, LLC (46)
10.123	Cooperative Research and Development Agreement, dated June 7, 2006 between the Company and Walter Reed Army Institute of Research (48)
10.124	Promissory Note, dated April 2, 2007, by the Company in favor of Hopkins Capital Group II, LLC (47) (confidential treatment granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2) (48)
10.125	Fifth Amendment to May 31, 2005 Laurus Master Fund, Ltd. financing documents, dated April 10, 2007 (48)
10.126	Common Stock Purchase Warrant, dated April 10, 2007, issued by the Company in favor of Laurus Master Fund, Ltd. (48)
10.127	Second Amended and Restated Registration Rights Agreement, dated April 10, 2007, between the Company and Laurus Master Fund, Ltd. (48)
10.128	Common Stock Purchase warrant (475,000 shares), dated September 5, 2007, by the Company in favor of HCG II (49)
10.129	Registration Rights Agreement, dated September 5, 2007, by and among the Company and CDC II (49)
10.130	License and Development Agreement, dated September 5, 2007, between the Company, Arius Pharmaceuticals, Inc.and Meda AB (49) (confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.131	Bema Fentanyl Supply Agreement, dated September 5, 2007, between the Company and Meda AB (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.132	Sublicensing Consent dated September 5, 2007, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)

10.133	License Agreement dated, September 5, 2007, by and between Arius Two, Inc., and Arius Pharmaceuticals, Inc. (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.134	Intellectual Property Assignment Agreement dated, September 5, 2007 by and between QLT USA, Inc. and Arius Two, Inc. (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.135	Amended and Restated Patent and Trademark Agreement, dated as of September 5, 2007, by and between Arius Two, Inc., and QLT USA, Inc. (49)
10.136	Amended and Restated Security Agreement dated September 5, 2007, by and among Arius Two, Inc., and QLT USA, Inc. (49)
10.137	Assignment of Patent and Trademarks, dated September 5, 2007 (49)
10.138	Termination Agreement dated September 5, 2007, by and among Arius Pharmaceuticals, Inc., QLT USA, Inc. and CDC IV, LLC (solely as third party beneficiary) (49)
10.139	Patent and Trademark Security Agreement, dated as of September 5, 2007, between Arius Two, Inc., and QLT USA, Inc. (49)
10.140	Security Agreement, dated as of September 5, 2007, between Arius Two, Inc., and QLT USA, Inc. (49)
10.141	Second Amendment Agreement dated September 5, 2007, by Arius Two, Inc. and Arius Pharmaceuticals, Inc. (49)
10.142	Secured Promissory Note, dated September 5, 2007, between Arius Two, Inc., and QLT USA, Inc. (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.143	Guaranty, dated as of September 5, 2007, made between BioDelivery Sciences International, Inc. and in favor of QLT USA, Inc. (49)
10.144	Bema Acquisition Consent, amendment and waiver, dated September 5, 2007, between the Company and CDC IV, LLC (49)
10.145	Sublicensing Consent and Amendment, dated September 5, 2007, between the Company, its wholly-owned subsidiary Arius Pharmaceuticals, Inc, CDC IV, LLC and Meda AB (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.146	Royalty Purchase and Amendment Agreement, dated as of September 5, 2007 between BioDelivery Sciences International, Inc., and CDC IV, LLC (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.147	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. (49) (Confidential treatment has been requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2)
10.148	Dispute Resolution Agreement, dated September 5, 2007 by and between the Company and CDC IV, LLC (49)
10.149	Promissory Note, dated September 4, 2007, between the Company and Southwest Bank of St. Louis (49)
10.150	Security Agreement, dated September 4, 2007, between the Company and Southwest Bank of St. Louis (49)

10.151	Continuing Contract of Guarantee, dated September 4, 2007, between the Company and Southwest Bank of St. Louis (49)
10.152	Hypothecation Agreement, dated September 4, 2007, between Hopkins Capital Group, LLC and Southwest Bank of St. Louis (49)
10.153	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 (49)
10.154	Side Letter Agreement, dated September 5, 2007, between CDC IV, LLC and QLT USA, Inc. (49).
10.155	Side Letter Agreement, dated September 5, 2007, between CDC IV, LLC, the Company, Arius Pharmaceuticals, Inc., and Arius Two, Inc. (49)
10.156	Side Letter Agreement, dated September 5, 2007, between MEDA AB and QLT USA, Inc. (49).
10.157	Allonge, effective date, September 5, 2007, between the Company and CDC IV, LLC (49)
10.158	Promissory Note, dated September 11, 2007, by the Company in favor of Meda AB (50)
20.1	Code of Ethical Conduct of the Registrant (28)
21.1	Subsidiaries of the Registrant (*)
31.1	Certification of the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
31.2	Certification of the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.1	Certification of the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.2	Certification of the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)

* Filed herewith

** A signed original of this written statement 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.

(2) Previously filed with Form 10QSB, for the quarter ended March 31, 2001.
(3) Previously filed with Form 10KSB, for the fiscal year ended December 31, 2000 filed on August 15, 2001.
(5) Previously filed with Form 8K filed October 26, 2000 under our prior name of MAS Acquisition XXIII Corp.
(6) Previously filed with Form 10SB filed January 18, 2000 under our prior name of MAS Acquisition XXIII Corp.
(8) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(9) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.
(10) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.
(11) Previously filed with Form SB-2, Amendment No. 5, May 23, 2002.
(12) Previously filed with Form SB-2, Amendment No. 6, June 24, 2002.
(13) Previously filed with Form 10-QSB, November 15, 2002.
(14) Previously filed with Form 8-K, January 7, 2003.
(15) Previously filed with Form 8-K, February 26, 2003.
(16) Previously filed with Form 8-K, April 25, 2003.
(17) Previously filed with Form 10-QSB/A, September 2, 2003.
(18) Previously filed with Form 8-K, November 19, 2003.

(19) Previously filed with Form 8-K, June 4, 2004.
(20) Previously filed with Form 8-K, August 6, 2004.
(21) Previously filed with Form 8-K, August 12, 2004.
(22) Previously filed with Form 8-K, August 26, 2004.
(23) Previously filed with Form 8-K, September 8, 2004.
(24) Previously filed with Form 8-K, September 8, 2004.
(25) Previously filed with Form 8-K, January 24, 2005.
(26) Previously filed with Form 8-K, February 3, 2005.
(27) Previously filed with Form 8-K, February 25, 2005.
(28) Previously filed with Form 10-K/A, April 29, 2005.
(29) Previously filed with Form SB-2/A, April 29, 2005.
(30) Previously filed with Form 8-K, June 3, 2005.
(31) Previously filed with Form 10-K/A, June 10, 2005.
(32) Previously filed with Form 8-K, June 30, 2005.
(33) Previously filed with Form 8-K, July 21, 2005.
(34) Previously filed with Form 8-K, August 24, 2005.
(35) Previously filed with Form SB-2/A, September 23, 2005.
(36) Previously filed with Form 10-QSB, November 10, 2005.
(37) Previously filed with Form 8-K, January 1, 2006.
(38) Previously filed with Form 10-K, April 1, 2006.
(39) Previously filed with Form 8-K, May 22, 2006.
(40) Previously filed with Form 8-K, August 4, 2006.
(41) Previously filed with Form 8-K, August 9, 2006.
(42) Previously filed with Form 8-K, August 31, 2006.
(43) Previously filed with Form 8-K, August 31, 2006.
(44) Previously filed with Form 8-K, December 28, 2006.
(45) Previously filed with Form 8-K, February 22, 2007.
(46) Previously filed with Form 8-K, March 16, 2007.
(47) Previously filed with Form 8-K, April 6, 2007.
(48) Previously filed with Form 10-KSB, April 17, 2007.
(49) Previously filed with Form 8-K, September 10, 2007.
(50) Previously filed with Form 8-K, September 12, 2007.

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors

BioDelivery Sciences International, Inc.

We have audited the accompanying consolidated balance sheets of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2007, and 2006 and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2007 and 2006, and the consolidated results of their operations and their cash flows for each of the years then ended 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 financials statements, the Company incurred cumulative net losses of approximately $47.6 million during the two years ended December 31, 2007 and has a stockholders' deficit of approximately $18.8 million as of December 31, 2007. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards 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 or the amounts and classification of liabilities that might arise from the outcome of this uncertainty.

/s/ Aidman, Piser & Company, P.A.

Tampa, Florida
March 7, 2008

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2007 AND 2006

ASSETS

	2007	2006
Current assets:		
Cash and cash equivalents	$ 13,797,093	$ 2,172,104
Certificate of deposit	2,800,000	—
Accounts receivable	305,497	42,118
Due from related party	14,414	8,523
Prepaid expenses and other current assets	160,704	180,863
Total current assets	17,077,708	2,403,608
Equipment, net	222,806	379,654
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	542,171	2,442,171
Acquired product rights	6,900,000	2,000,000
Accumulated amortization	(974,208)	(561,767)
Total other intangible assets	6,467,963	3,880,404
Deposits on equipment	1,344,311	—
Other assets	15,937	463,268
Restricted cash	144,000	—
Total assets	$ 27,987,725	$ 9,841,934
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Notes payable, related party	$ 1,296,164	$ —
Notes payable	90,834	1,000,000
Accounts payable and accrued liabilities	4,109,402	2,032,765
Due to related parties	2,083,166	1,001,177
Deferred revenue, current	120,121	70,360
Dividends payable	—	152,803
Derivative liability (Note 9)	6,543,571	7,795,931
Total current liabilities	14,243,258	12,053,036
Convertible notes payable, less current maturities	—	4,003,250
Deferred revenue, long-term	32,532,252	2,500,000
Total liabilities	46,775,510	18,556,286
Commitments and contingencies (Notes 3 and 14)	—	—
Stockholders' deficit:		
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 0 and 1,647,059 shares issued and outstanding in 2007 and 2006, respectively	—	3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 0 and 341,176 shares issued and outstanding in 2007 and 2006, respectively	—	1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized, 19,101,037 and 14,048,637 shares issued; 19,085,546 and 14,033,146 shares outstanding in 2007 and 2006, respectively	19,101	14,049
Additional paid-in capital	56,267,563	32,132,609
Treasury stock, at cost, 15,491 shares, 2007 and 2006	(47,183)	(47,183)
Accumulated deficit	(75,027,266)	(45,969,710)
Total stockholders' deficit	(18,787,785)	(8,714,352)
Total liabilities and stockholders' deficit	$ 27,987,725	$ 9,841,934

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2007 AND 2006

	2007	2006
Revenues:		
Sponsored research revenues	$ —	$ 75,717
Royalty revenue, related party	74,988	65,061
Research fees	127,000	135,000
Total revenues	201,988	275,778
Expenses:		
Research and development	8,468,983	6,718,638
Related party research and development	5,832,154	2,550,058
Product development costs	25,603	746,591
General and administrative	7,497,319	4,947,506
Related party general and administrative	37,802	124,505
Total expenses	21,861,861	15,087,298
Loss from operations	(21,659,873)	(14,811,520)
Other income, net	—	7,663
Interest expense, net	(2,239,360)	(1,948,264)
Derivative gain (loss)	2,307,433	(1,013,142)
Loss on extinguishment of debt	(3,595,169)	(4,629,946)
	(3,527,096)	(7,583,689)
Net loss	(25,186,969)	(22,395,209)
Preferred stock dividends	—	(65,250)
Constructive dividend-preferred stock	(3,870,587)	—
Loss attributable to common stockholders	$(29,057,556)	$(22,460,459)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (1.64)	$ (1.67)
Weighted average common stock shares outstanding – basic and diluted	17,771,055	13,435,091

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2007 AND 2006

	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, 2006	1,647,059	$ 3,705,883	341,176	$ 1,450,000	—	—	11,828,637	$ 11,829	$23,831,168	$ (47,183)	$ (23,574,501)	$ 5,377,196
Stock based compensation	—	—	—	—	—	—	—	—	576,627	—	—	576,627
Issuance of stock, net of offering costs	—	—	—	—	—	—	2,000,000	2,000	6,973,900	—	—	6,975,900
Issuance of warrants for product development	—	—	—	—	—	—	—	—	51,205	—	—	51,205
Conversion of notes payable to common stock	—	—	—	—	—	—	213,363	213	522,524	—	—	522,737
Conversion of interest to common stock	—	—	—	—	—	—	6,637	7	20,768	—	—	20,775
Reclassification of derivative liability to equity	—	—	—	—	—	—	—	—	221,667	—	—	221,667
Series B Preferred dividends	—	—	—	—	—	—	—	—	(65,250)	—	—	(65,250)
Net loss	—	—	—	—	—	—	—	—	—	—	(22,395,209)	(22,395,209)
Balances, December 31, 2006	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)

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2007 AND 2006

	2007	2006
Operating activities:		
Net loss	$(25,186,969)	$(22,395,209)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of common stock	209,155	20,775
Expenses paid through the issuance of warrants	609,711	988,185
Depreciation	262,482	277,569
Amortization of intangible assets	412,440	414,161
Derivative gain (loss)	(2,307,433)	1,013,142
Loss on extinguishment of debt	3,595,169	4,629,946
Accretion of debt discount	1,971,531	1,425,363
Stock-based compensation expense	1,066,532	576,627
Changes in assets and liabilities:		
Accounts receivable	(263,379)	—
Prepaid expenses and other assets	309,823	30,580
Accounts payable and accrued liabilities	1,455,682	837,970
Deferred revenue	30,082,013	2,500,000
Net cash flows from operating activities	12,216,757	(9,680,891)
Investing activities:		
Purchase of equipment	(74,438)	(9,546)
Deposits on equipment	(736,545)	—
Purchase of certificate of deposit	(2,800,000)	—
Purchase of intangible assets	(3,000,000)	(1,000,000)
Net cash flows from investing activities	(6,610,983)	(1,009,546)
Financing activities:		
Proceeds from issuance of common stock	250,000	6,975,900
Proceeds from exercise of stock options	692,547	—
Advances from related parties	2,003,103	971,906
Proceeds from exercise of common stock warrants	3,235,437	—
Proceeds from notes payable	4,000,000	—
Payment on notes payable	(4,161,872)	—
Net cash flows from financing activities	6,019,215	7,947,806
Net change in cash and cash equivalents	11,624,989	(2,742,631)
Cash and cash equivalents at beginning of year	2,172,104	4,914,735
Cash and cash equivalents at end of year	$ 13,797,093	$ 2,172,104

See notes to consolidated financial statements

SUPPLEMENTAL CASH FLOW INFORMATION

Non-cash Financing and Investing activities

The Company converted $4,305,760 and $522,737 of convertible notes payable through the issuance of 1,757,454 and 213,363 shares of common stock during the years ended December 31, 2007 and 2006, respectively.

The Company reclassified derivative liabilities of $5,175,700 and $221,667 from debt to equity during the years ended December 31, 2007 and 2006, respectively, as a result of the conversions of notes payable to which the derivatives related.

The Company paid $152,802 of accrued dividends payable through the issuance of 59,227 shares of common stock during the year 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 year ended December 31, 2007.

The Company purchased insurance policies (prepaid insurance) with proceeds from notes payable in the aggregate amount of $254,300 during the year ended December 31, 2007.

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006

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

Organization:

BioDelivery Sciences International, Inc. ("BDSI" or the "Company") was incorporated in the State of Indiana on January 6, 1997 and later reincorporated as a Delaware corporation in 2002. BDSI and its subsidiaries are collectively referred herein to as the "Company."

BDSI is a specialty biopharmaceutical company that is exploring its licensed and patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, clinically-significant new formulations of proven therapeutics targeted as "acute" treatment opportunities such as pain and infections. The Company's drug delivery technologies include: (i) the patented BEMA™ (transmucosal or mouth) drug delivery technology and (ii) the patented Bioral® nanocochleate technology, designed for a potentially broad base of applications.

Principles of consolidation:

The financial statements include the accounts of BDSI 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"), which is currently an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Cash and cash equivalents:

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. The Company's cash and cash equivalents are placed in high credit quality institutions, but amounts on deposit significantly exceed federally insured limits.

Revenue Recognition

The Company recognizes revenue in accordance with the SEC's Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements. When evaluating multiple element arrangements, the company considers whether the components of the arrangement represents separate units of accounting as defined in Emerging Issues Task Force ("EITF") Issue No. 00-21, Revenue Arrangements with Multiple Deliverables ("EITF 00-21"). Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether it is separable from the other aspects of the contractual relationship.

License Arrangements

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

Non-refundable, upfront fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue over the established or estimated term of the license when the license arrangement commences and the licensed data, technology and/or product or supplies to manufacture the product is delivered. Such deliverables may include physical quantities of products, supplies, or design of the products, the conceptual framework and mechanism of actions taken by a third party, and rights to the patents or patents pending for such products.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006

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

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, the Company defers the milestone payments and recognizes them as revenue over the estimated period of performance under the contract as the Company completes its 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.

Sponsored Research

Sponsored research amounts are recognized as revenue when the research underlying such funding has been performed or when the grant funds have otherwise been properly utilized, such as for the purchase of operating assets. Grant revenue is recognized to the extent provided for under the related grant or collaborative research agreement. This is shown as sponsored research revenue on the accompanying consolidated statements of operations.

Royalty and Contract Revenues

Royalty revenue amounts are recognized as revenue on a monthly basis based on net sales under the Company’s license agreement with Accentia relating to chronic rhinosinusitis (“CRS”). This is shown as royalty revenue, related party on the accompanying consolidated statements of operations. In accordance with generally accepted accounting principles, or GAAP, and the Company’s revenue recognition policy, the Meda up-front payments of $2.5 million in 2006 and $30.0 million in 2007 from Meda have been recorded as deferred revenue, and will be recognized over the license term once commercialization revenues begin.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006

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

Research Revenues

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

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.

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 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 2007 or 2006.

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

	Estimated Useful Lives
Licenses	12 years
US Product rights	11 years
EU Product rights	10 years

The Company incurred amortization expense on other intangible assets of approximately $.4 million for each of the years ended 2007 and 2006. Estimated aggregate future amortization expenses for other intangible assets for each of the next five years and thereafter are as follows:

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006

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

Goodwill and other intangible assets (continued):

Year ending December 31,	
2008	641,056
2009	641,056
2010	641,056
2011	641,056
2012	641,056
Thereafter	3,262,683
	$ 6,467,963

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 2007 or 2006.

Restricted cash:

Restricted cash consists of amounts held by a bank restricted by the Company's new 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.

Income taxes:

Deferred income tax assets and liabilities are determined based on differences between the financial statement and tax bases of assets and liabilities as measured by the enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

Use of estimates in financial statements:

The preparation of the accompanying financial statements conforms with accounting 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 financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006

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

Net loss per common share:

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:

	2007	2006
Options and warrants to purchase common stock	8,582,661	8,604,469
Preferred stock convertible to common stock	—	1,988,235
Convertible debt	—	1,757,453

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

	2007	2006
Numerator:		
Net loss attributable to common stockholders	$(29,057,556)	$(22,460,459)
Denominator:		
For basic loss per share – weighted average shares	17,771,055	13,435,091
Effect of dilutive securities	—	—
Weighted average shares for dilutive loss per share	17,771,055	13,435,091
Net loss per share attributable to common stockholders, basic and dilutive	$ (1.64)	$ (1.67)

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. 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006

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

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

	2007	2006
Expected price volatility	50.43%-65.78%	51.68-62.78%
Risk-free interest rate	3.71%-5.07%	4.60%-4.98%
Weighted average expected life in years	5-6 years	5-6 years
Dividend yield	0	0

Financial instruments

Financial instruments, as defined in Financial Accounting Standard No. 107 Disclosures about Fair Value of Financial Instruments (FAS 107), consist of cash, evidence of ownership in an entity and contracts that both (i) impose on one entity a contractual obligation to deliver cash or another financial instrument to a second entity, or to exchange other financial instruments on potentially unfavorable terms with the second entity, and (ii) conveys to that second entity a contractual right (a) to receive cash or another financial instrument from the first entity or (b) to exchange other financial instruments on potentially favorable terms with the first entity. Accordingly, the Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, notes payable, amounts due/from related party, and derivative financial liabilities.

The Company estimated fair values of cash and cash equivalents, certificates of deposit, accounts receivable, accounts payable, accrued liabilities, and amounts due/from related party approximate their carrying values due to their current nature. The Company carries notes payable, related party at historical cost less discounts attributable to the concurrent issuance of detachable warrants. However, fair values of these debt instruments are estimated for disclosure purposes based upon the present value of the estimated cash flows at market interest rates applicable to similar instruments (see Note 5). Derivative liabilities are reported at fair value.

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2007 AND 2006

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

high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company's income will reflect the volatility in these estimate and assumption changes.

Recent accounting pronouncements

In December 2007, the FASB issued Statement No. 141 (revised), Business Combinations (SFAS No. 141(R)). The standard changes the accounting for business combinations including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for pre-acquisition gain and loss contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. Management is currently evaluating the effect, if any, the adoption will have on the Company's financial position and results of operations.

In December 2007, the FASB issued Statement No. 160, Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51 (SFAS No. 160). The standard changes the accounting for noncontrolling (minority) interests in consolidated financial statements including the requirements to classify noncontrolling interests as a component of consolidated stockholders' equity, and the elimination of "minority interest" accounting in results of operations with earnings attributable to noncontrolling interests reported as part of consolidated earnings. Additionally, SFAS No. 160 revises the accounting for both increases and decreases in a parent's controlling ownership interest. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. Management is currently evaluating the effect, if any the adoption will have on the Company's financial position and results of operations.

In February 2007, the FASB issued Statement No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities, including and amendment of FASB Statement No. 115" ("FAS 159"). FAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. FAS 159 is effective for fiscal years beginning after November 15, 2007. Management is currently assessing the adoption of FAS 159, and the effect, if any, on the Company's financial position or results of operations.

In September 2005, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 157 (FAS 157). This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is a relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current valuation and accounting practices. For fiscal years beginning after November 15, 2007, the Company will be required to implement FAS 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 in the financial statements. FAS 157 implementation for other non-financial assets and liabilities has been deferred to fiscal years beginning after November 15, 2008. Earlier application is permitted provided that the reporting entity has not yet issued financial statements for that fiscal year. Management is currently assessing the effect, if any, adoption of FAS 157 will have on the Company's financial position and results of operations.

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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, research fees and sponsored research revenues in 2006 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.

Significant funding in 2006 consisted of:

- $7,000,000 sale of Common Stock in 2006, consisting of 2 million shares of Common Stock issued to CDC IV, LLC, as successor in interest to Clinical Development Capital, LLC (collectively "CDC").

Significant financing or commitments in 2007 consisted of:

- $1,900,000 loan from CDC (see Note 5);
- $1,000,000 loan from Hopkins Capital Group II, LLC ("HCG II") (see Note 5);
- $250,000 received from the sale of Common Stock to Sigma Tau Industrie Farmaceutiche Riunite S.p.A ("Sigma-Tau") in January 2007 pursuant to a previously executed Stock Purchase Agreement;
- Approximately $693,000 from the exercise of Common Stock options;
- Approximately $3,200,000 from the exercise of Common Stock warrants held by Laurus Master Fund, Ltd. ("Laurus");
- $3,000,000 loan from Southwest Bank of St. Louis (which was also repaid in 2007);
- $30,000,000 up-front, non-refundable payment under a license agreement with Meda AB ("Meda" see Note 7);

The Company's existing cash and cash equivalents are considered by management to be sufficient to finance the Company's operations, capital expenditures and debt obligations into the third quarter of 2008.

While the Company expects that significant additional payments will be received in 2008 under the Meda license agreement, (see Note 7), the receipt of such payments is conditioned upon, among other things, FDA approval of the Company's BEMA™ Fentanyl new drug application. As such

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

no assurance can be given that such payments will be received in 2008, if at all. Accordingly, additional outside capital may be required in order to support the Company's 2008 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. The Company believes that it will be able to secure such funding at levels sufficient to support planned operations. However, there can be no assurance that additional capital 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 expanded 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. The financial statements do not include any adjustment that may arise as a result of these uncertainties.

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 under a non-cancelable operating lease agreement which expired on December 31, 2005. The Company is currently leasing space on a month to month basis. The Company incurred approximately $0.1 million and $0.1 million of research expense in connection with this agreement in the years ended December 31, 2007 and 2006 respectively. Amounts due to UMDNJ at December 31, 2007 and 2006 are approximately $.04 million and $0.2 million, respectively.

The Company has an agreement with Pharmaceutical Product Development, Inc., a Company stockholder, for research work in connection with a product under development. The Company incurred research expense of $5.6 million and $2.3 million under this agreement in 2007 and 2006 respectively. Amounts due to PPD at December 31, 2007 and 2006 are approximately $1.9 million and $0.7 million, respectively.

The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia Biopharmaceuticals, Inc., a related party (two of the Company's officers are also officers in Accentia), and shares three employees, with personnel costs paid based on the approximate time spent on Company activities. Rent payments to Accentia were $0.02 million in 2007 and 2006 respectively, and are included in general and administrative costs, related party. Amounts due to Accentia at December 31, 2007 and 2006 are approximately $0.0 million and $0.01 million, respectively.

The Company pays business-related costs for aircraft travel to a company that is partially-owned by the Company's Chairman. Payments of $0.0 million and $0.01 million were made in 2007 and 2006 respectively and are included in general and administrative costs, related party.

See Note 5 regarding related party notes payable.

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4. Equipment:

Equipment consists of the following:

	December 31, 2007	December 31, 2006
Office and laboratory equipment	$ 2,011,934	$ 1,906,300
Less accumulated depreciation	(1,789,128)	(1,526,646)
	$ 222,806	$ 379,654

Depreciation expense for each year ended December 31, 2007 and 2006 was approximately $0.3 million.

5. Note payable, related party:

Note payable, related party consists of the following:

	December 31, 2007
Note payable, CDC (stockholder) (1)	1,900,000
Less unamortized discount	(603,836)
Total at December 31 2007	$ 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 is required to file a registration statement with the Securities and Exchange Commission to register the shares of Common Stock underlying the New CDC Warrant by March 12, 2008. CDC was also granted "piggyback" registration rights with respect to such shares of Common Stock which come into effect only after March 12, 2008. The New CDC Warrant contains "weighted average" anti-dilution protection. The fair value of note payable, related party at December 31, 2007 is $1.9 million.

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, 2007, consist of insurance premium financing. The short-term financing from First Insurance Funding Corp., at 7.7% per annum is payable monthly through May 25, 2008. December 31, 2006 note payable represented amounts due QLT USA, Inc. ("QLT") (Note 7).

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7. 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 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. In addition to the purchased BEMA intellectual property rights, QLT granted to the Company the option, for a period of 12 months, to purchase the intellectual property rights owned by QLT related to its BEMA™ technology for the United States territory. If such option is exercised, the purchase price for the United States territory would be $7.0 million, which would be paid over time.

On August 2, 2006, the Company, Arius One and Meda AB, a Swedish Company (“Meda”) entered into a License and Development Agreement pursuant to which the Company and Arius One granted Meda an exclusive license to develop and sell the Company’s BEMA™ Fentanyl product in Europe in exchange for an upfront payment of $2.5 million, milestone payments, and a royalty on sales. Milestone payments, totaling an additional $7.5 million, shall be received by the Company upon the achievement of certain future milestones. As part of this transaction, Meda, the Company and Arius One have also entered into a BEMA™ Fentanyl Supply Agreement pursuant to which Meda shall acquire, and the Company and Arius One shall supply (directly or indirectly through third party contractors), all of Meda’s requirements of BEMA™ Fentanyl product. The Company has recorded the $2.5 million payment received as deferred revenue (see Note 1 for revenue recognition policy).

On September 5, 2007, the Company exercised a previously granted 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 (the “BEMA™ U.S. Rights”). 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 million, consisting of $3 million in cash and a promissory note, secured by the purchased assets, in the principal amount of $4 million. Payments under such note are due as follows: (i) $2 million within ten (10) business days of FDA approval of a product based on the BEMA™ technology 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.

The Company has recorded the $3 million payment as additional acquired product rights in the accompanying December 31, 2007 consolidated balance sheet. Management deems the $4 million

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7. Acquired product rights and license agreements (continued):

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 allocated the remaining license amounts for BEMA™ to acquired product rights.

On September 5, 2007, the Company entered into a definitive License and Development Agreement (the "License Agreement") with Meda, and the Company's Arius subsidiary pursuant to which the Company and Arius agreed to grant to Meda an exclusive commercial license to manufacture, market, sell, and, following regulatory approval, continue development of the Company's BEMA™ Fentanyl product in the United States, Mexico and Canada.

Pursuant to the License Agreement, the Company did or will receive:

- $30 million milestone payment upon closing (which was received on September 14, 2007).
- An additional $30 million milestone payment concurrently with receipt of approval of BEMA™ Fentanyl by the FDA, unless the Company has not, at such time, manufactured stocks of BEMA™ Fentanyl, in bulk or finished form, sufficient for commercial launch of BEMA™ Fentanyl in the U.S., in which case $15 million will be paid upon FDA approval and $15 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 BEMA™ Fentanyl. The Company anticipates that it will have sufficient launch stocks of BEMA™ Fentanyl product concurrently with FDA approval of BEMA™ Fentanyl.
- A significant double digit royalty on net sales of BEMA™ Fentanyl 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 the Company during the second through seventh years following the product's first commercial sale.
- Sales milestones: A total of $30 million payable at:
  - $10 million when and if annual sales exceeds $75 million;
  - $10 million when and if annual sales exceeds $125 million; and
  - $10 million when and if annual sales exceeds $175 million

Also, pursuant to the License Agreement, the Company has been granted certain rights to co-promote BEMA™ Fentanyl using its own sales force, with financial support by Meda. Per agreement with Meda, this financial support will not begin for a period of time following FDA approval of BEMA™ Fentanyl. In addition, Meda is subject to certain minimum sales call and

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7. Acquired product rights and license agreements (continued):

advertising and promotional expenditure requirements under the License Agreement, and has agreed to support costs of clinical development undertaken following FDA approval to pursue approval of additional indications for BEMA™ Fentanyl.

The Company has recorded the $30 million payment received as deferred revenue (see Note 1 for revenue recognition policy).

8. Convertible notes payable:

During February and September, 2005, the Company consummated an aggregate $5.0 million secured convertible debt financing from Laurus Master Fund, Ltd. (“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 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.

From June 2005 through July 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

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.

On September 20, 2006, the Company issued Laurus a common stock purchase warrant to purchase up to 33,000 shares of common stock at an exercise price of $3.00 per share that expire September 20, 2011. This warrant was issued in satisfaction of penalties arising under registration rights agreements. Except for the exercise price of the warrants, the warrants issued in September 2006 are substantially similar to the warrants issued in February and May, 2005.

On December 28, 2006, the Company entered into fourth amendments to the February and May 2005 financing agreements with Laurus. Under the fourth amendments, Laurus agreed to defer payments by the Company of certain monthly principal amounts under the February and May 2005 notes, as well as certain other previously postponed principal amounts due under such notes, until the first business day of January 2008.

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8. Convertible notes payable (continued):

In consideration of Laurus' agreement to enter into the fourth amendments, the Company issued to Laurus warrants to purchase 1,500,000 shares of the Company's common stock (the "December 2006 Warrants"). The December 2006 warrants are exercisable into shares of Company common stock at an exercise price of $3.05 per share and expire on December 28, 2013. Other than the exercise price, the December 2006 warrants are substantially similar to the warrants issued to Laurus in February and May, 2005, June 29, 2005, December 28, 2005 and July 31, 2006.

The Company applied the provisions of EITF 06-06, "Debtor's Accounting for Modification (or exchange) of Convertible Debt Instruments" to the amendments dated December 28, 2006. Since the post-modification present value of the cash flows to the lender, including the approximately $4,380,000 fair value of the December 2006 warrants, exceeded such cash flows before the modification by more than 10%, the debt modification was accounted for as a debt extinguishment, and as such, the debt was adjusted to its fair value; the $249,496 excess of that fair value over the then carrying value of the debt, and the $4,380,000 fair value of the December 2006 warrants was recorded as a loss on extinguishment of debt.

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

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8. Convertible notes payable (continued):

the proceeds between the various instruments and the derivative elements carried at fair value. 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 closing	2,556,095
Accretion of discount (interest expense) through December 31, 2005 using effective interest method	847,693
Conversion of debt to equity through December 31, 2005	(171,500)
Carrying value at December 31, 2005	3,232,288
Accretion of discount (interest expense) during 2006	1,044,203
Conversion of debt to equity during 2006	(522,737)
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	$ —

9. Derivative Financial Instruments:

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

	2007	2006
Embedded beneficial conversion option in the Laurus convertible debt	$ 0	$ 1,993,655
Free standing warrants	6,543,571	5,802,276
Total	$ 6,543,571	$ 7,795,931

	2007	2006
Shares into which derivative liability can be settled:		
Embedded beneficial conversion option	0	1,757,453
Free standing warrants	4,622,265	2,313,394
Total	4,622,265	4,070,847

	2007	2006
Derivative income (expense) in the accompanying statement of operations is related to the individual derivatives as follows:		
Embedded derivative instruments	$(3,430,698)	$ (702,202)
Free standing derivatives (principally warrants)	5,738,131	(310,940)
Total	$ 2,307,433	$(1,013,142)

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10. Income taxes:

The Company has no income tax expense or benefit for 2007 or 2006 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,	
	2007	2006
Federal statutory income tax rate	34.00%	34.00%
State taxes, net of federal benefit	3.45	3.45
Permanent difference—compensation expense	(4.59)	(2.83)
Research and development ("R&D") credit	0.79	4.74
Other	(0.01)	(0.05)
Valuation allowance	(33.64)	(39.32)
	— %	— %

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

	December 31,	
	2007	2006
Deferred tax assets (liabilities)		
Deferred revenue	$ 993,361	$ 962,646
Basis difference in equipment	(30,357)	(89,678)
Basis difference in debt	(87,557)	—
Basis difference in intangibles	(1,244,232)	(1,950,382)
Accrued liabilities and other	442,867	115,168
R&D credit	1,489,421	1,249,148
Stock options	159,945	—
Derivative liabilities	1,853,035	1,733,998
Net operating loss carry-forward (NOL)	18,765,169	12,111,365
Less: valuation allowance	(22,341,652)	(14,132,265)
Net deferred tax	$ —	$ —

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10. Income taxes (continued):

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.

The Company has a federal net operating loss of approximately $50.8 million and a State net operating loss of $43.4 million as of December 31, 2007. These loss carryforwards expire principally beginning in 2020 through 2026 for federal and 2028 for state purposes. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the company. 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.

11. Stockholders' equity:

Preferred stock:

The Company has authorized five million shares of $.001 par value preferred stock. At December 31, 2006, 2,588,236 shares were designated as follows: Series A Preferred Stock of 1,647,059 shares and Series B preferred Stock of 941,177 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.

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11. Stockholders' equity (continued):

Stock options:

The Company has a stock option 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 option plan to Company employees, directors, consultants and other affiliates.

Stock option activity for the years ended December 31, 2007 and 2006 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2006	2,185,595	$ 4.43	
Granted in 2006:			
Officers and Directors	235,000	2.08	
Others	241,255	2.32	
Exercised	—	—	
Forfeitures	(638,146)	6.39	
Outstanding at December 31, 2006	2,023,704	$ 3.04	$1,099,052
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

Options outstanding at December 31, 2007 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 – 5.00	1,912,159	7.70	$ 2.92	
$ 5.01 – 10.00	783,745	9.06	$ 6.45	
	2,695,904			$606,414

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11. Stockholders' equity (continued):

Options exercisable at December 31, 2007 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 – 5.00	1,472,209	7.70	$ 2.78	
$ 5.01 – 10.00	45,000	9.06	$ 5.34	
	1,517,209			$443,120

The weighted average grant date fair value of options granted during 2007 and 2006 whose exercise price is equal to the market price of the stock at the grant date was $3.68 and $2.08, 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 2006 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, 2007, 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, 2007	396,651		
Granted	1,400,932		
Vested	(519,668)		
Forfeited	(99,219)		
Nonvested at December 31, 2007	1,178,696	$ 2.77	$163,293

As of December 31, 2007, there was approximately $3.2 million of unrecognized compensation cost related to unvested shares-based compensation awards granted. These costs will be expensed over the next three years.

Warrants:

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

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11. Stockholders' equity (continued):

Warrants outstanding at December 31, 2007 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	5,186,757	5.56	$ 3.42	
$ 5.01 – 10.00	700,000	3.79	$ 5.45	
	5,886,757			$336,387

Warrants exercisable at December 31, 2007 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 – 5.00	5,161,766	5.56	$ 3.43	
$ 5.01 – 10.00	700,000	3.79	$ 5.45	
	5,861,766			$308,637

12. 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% that a participant contributes to the plan. The Company made contributions of approximately $0.8 million in each of 2007 and 2006.

13. National Institutes of Health Grant:

In 2002, the National Institutes of Health ("NIH") awarded the Company a Small Business Innovation Research Grant (the "SBIR"), for $0.6 million, which has been utilized in research and development efforts.

During the years ended December 31, 2007 and 2006, the Company incurred approximately $0 million and $0.07 million, respectively, of costs related to this agreement and received and recognized corresponding revenue from this grant for the corresponding year ended December 31. All available funds have been drawn from this grant at December 31, 2007.

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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, 2007 are $0.7 million and $0.05 million for the years ended December 31, 2008 and 2009, 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 $0.1 million for both years ended December 31, 2007 and 2006.

The future minimum commitments on all operating leases at December 31, 2007 are as follows:

Years ending December 31,	
2008	$101,567
2009	114,073
2010	117,496
2011	121,021
2012	124,651
Thereafter	10,646
	$589,454

Royalty commitment:

Upon its formation, BDSI originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, BDSI 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 BDSI proceeds); or (c) BDSI sales (3% of revenue). Amounts due to these universities at December 31, 2007 and 2006 for royalties are both approximately $.06 million. Royalty expense was $0.0 million for each of the years ended December 31, 2007 and 2006.

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, 2007 which would trigger any liability under the agreement.

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14. Commitments and contingencies (continued):

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 total payments of $711,650 and has outstanding invoices of $607,766 pursuant to a purchase order (classified as deposits on equipment in the accompanying December 31, 2007 balance sheet) towards the total cost, which is $2,372,165. Payments will be made in separate increments during the production of the equipment. The equipment is expected to be delivered by the third quarter of 2008.

Litigation:

On or about April 19, 2004, the Company was named as the defendant in an action commenced by MAS Capital Inc. in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company has provided MAS Capital's counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleges fully release them. Upon MAS Capital's refusal to dismiss the action, notwithstanding the documents that fully release the Company; the Company filed an Amended Answer asserting a claim for attorneys' fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital's claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on the Company's claim for attorneys' fees and costs, but were unable to resolve in light of MAS Capital's intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the Motion. Accordingly, the parties were to proceed until resolution of the Company's counterclaim for attorneys' fees and costs and either party could appeal at that point in time. On August 6, 2007, the U.S. District Court entered a final judgment on the Company's counterclaim pursuant to the parties' stipulation of dismissal. MAS Capital was required to initiate any appeal within thirty days of the entry of final judgment. MAS Capital has now filed its appeal with the Seventh Circuit Court of Appeals. The parties are now in the briefing stage of the appeal and await a decision from the Court of Appeals. The Company strongly believes that the District Judge's order will be upheld on appeal and, accordingly, no potential liability has been recorded.

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 BEMA™ Fentanyl product. Pursuant to the

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
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14. Commitments and contingencies (continued):

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 BEMA™ Fentanyl. The Security Agreement terminates at the time of FDA approval of BEMA™ Fentanyl. As such, until such approval, CDC retains the right to reclaim the BEMA™ Fentanyl-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 seven $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 one percent (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 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.

BEMA Fentanyl Supplier Concentration

Key components used in the manufacture of the Company's BEMA™ Fentanyl product 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 agreement with Aveva, the manufacturer of the BEMA™ Fentanyl product, by distribution in the U.S. under the Company's distribution agreement with Meda, the Company does not have long-term agreements with any of its 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 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 needs. This could delay Aveva'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.

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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 7, 2008

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 7, 2008
/s/ Mark A. Sirgo Mark A. Sirgo	President and Chief Executive Officer (Principal Executive Officer)	March 7, 2008
/s/ James A. McNulty James A. McNulty	Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)	March 7, 2008
/s/ Raphael J. Mannino Raphael J. Mannino	Executive Vice President, Chief Scientific Officer and Director	March 7, 2008
/s/ William B. Stone William B. Stone	Director	March 7, 2008
/s/ John J. Shea John J. Shea	Director	March 7, 2008
/s/ Thomas D'Alonzo Thomas D'Alonzo	Director	March 7, 2008
/s/ William S. Poole William S. Poole	Director	March 7, 2008

Exhibit 21.1

Subsidiaries of the Registrant

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

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

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a)

I, Mark A. Sirgo, hereby certify that:

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

Date: March 7, 2008

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

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, James A. McNulty, hereby certify that:

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

Date: March 7, 2008

/s/ James A. McNulty

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

Exhibit 32.1

CERTIFICATION

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

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

(1) The Annual Report on Form 10-K for the year ended December 31, 2007 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 7, 2008

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

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

Exhibit 32.2

CERTIFICATION

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

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

(1) The Annual Report on Form 10-K for the year ended December 31, 2007 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 7, 2008

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

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