BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB
April 17, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

¨ 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 0-28931

BioDelivery Sciences International, Inc.

(Name of small business issuer in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2501 Aerial Center Parkway, Suite 205	
Morrisville, NC	**27560**
(Address of principal executive offices)	**(Zip Code)**

Issuer s telephone number: (919) 653-5160

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
Class A common stock purchase warrants	NASDAQ-Capital Market

(Title of class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act ¨

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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of issuer s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. ¨

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

Issuer s revenues for fiscal year 2006 were $2,775,778.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of April 13, 2007 was approximately $69,831,096 based on the closing sale price of the company s common stock on such date of U.S. $6.03 per share, as reported by the Nasdaq Capital Market.

As of April 13, 2007, there were 16,666,777 shares of the company s common stock outstanding.

Transitional Small Business Disclosure Format: Yes ¨ No x

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, partnering, 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, which we refer to herein as the FDA, 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 sublicense partners to commercially exploit our drug delivery platforms and our ability to enter into sublicenses and to receive royalty and other payments from parties to whom we have sublicensed our technologies;
- 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 biopharmaceutical company that is utilizing its licensed, owned and proprietary patented 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 membrane) drug delivery technology, and
- the patented Bioral® nanocochleate 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. Our lead product, currently in Phase III clinical trials, is BEMA Fentanyl. We intend to announce the results of the Phase III efficacy study for BEMA Fentanyl in April 2007 and submit a New Drug Application, or NDA, to the FDA regarding BEMA Fentanyl with an indication for the treatment of breakthrough cancer pain as soon as possible thereafter.

We also believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals and also to other therapeutics such as small interfering RNA, or siRNA,

We currently generate revenue from licensing milestone payments and royalties, and have generated revenue from grants. Ultimately, if we secure approval from the FDA for our licensed and/or proprietary products and formulations, our goal will be to augment these revenues from sales of such products and formulations, on which we will also 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 licensed technologies to existing therapeutics to create our own proprietary formulations, which we will then seek to obtain FDA approval for and subsequently commercialize,
- licensing and joint venture arrangements with third parties, including pharmaceutical companies whose own proprietary pharmaceutical products may benefit from our drug delivery technologies,

partnering with pharmaceutical companies to assist in the distribution of our products for which we will receive milestone and royalty payments, and

proceeds raised from our public and private financings and strategic transactions.

BEMA Technology and Products in Development

Our BEMA drug delivery technology consists of a small, dissolvable polymer disc for application to mucosal (inner lining of cheek) membranes. BEMA discs deliver a rapid, reliable dose of drug across mucous membranes for time-critical conditions like breakthrough cancer pain (i.e., episodes of severe pain which break through the medication used to control the persistent pain), or trauma cases where intravenous lines or injections are unavailable or not practical. We license the BEMA drug delivery technology in the United States on an exclusive basis from Atrix Laboratories, Inc. (now a wholly-owned subsidiary of QLT 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. This agreement includes an exclusive option to purchase the U.S. rights within 12 months of the effective date of this agreement. After purchasing the intellectual property rights from QLT, we will not owe any future milestone payments or royalties.

Our lead BEMA product under development is BEMA Fentanyl, a treatment for breakthrough cancer pain. This 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. At such meeting, we received confirmation from the FDA regarding the process being undertaken for the BEMA Fentanyl program. In January 2007 we announced that the results of the Phase III efficacy trial and an update on the program status will be available in April 2007.

On July 15, 2005, we entered into a clinical development and licensing agreement (which agreement we refer to herein as the CDLA) with Clinical Development Capital, LLC, which we refer to herein as CDC, under which CDC has provided $7 million toward the Phase III clinical development of BEMA Fentanyl. The CDLA was subsequently assigned to CDC IV, LLC, an affiliate entity of Clinical Development Capital, LLC. On February 16, 2006, we announced that, as a result of our achievement of certain milestones called for under the CDLA, CDC made an initial $2 million payment to us.

On May 17, 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. As a result of this transaction, CDC was issued 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 $7 million milestone payable to CDC upon the approval by the FDA of BEMA Fentanyl which had been required under the CDLA.

In August 2006, we entered into a definitive agreement with Meda AB, or Meda, to license the European development and commercial rights to BEMA Fentanyl to Meda AB. We received an upfront license payment of $2.5 million, are eligible to earn up to $7.5 million more upon achievement of certain milestones and will receive a double digit royalty on net sales of BEMA Fentanyl in Europe.

A second product under development, BEMA Long Acting Analgesic, which we refer to herein as BEMA LA, is a BEMA formulation of an already approved product in the U.S. that will target a broader range of pain conditions including post operative and, potentially, chronic pain due to osteoarthritis, lower back disorders and rheumatoid arthritis. In early December 2005, we submitted an Investigational New Drug Application, or IND, with FDA for BEMA LA. In mid-2006, we conducted our first Phase I study with BEMA LA in normal volunteers. The data from this study confirmed that we can deliver the active ingredient of BEMA LA at therapeutic plasma (blood) concentrations based on other work done in other deliver forms of the active ingredient. We therefore expect that we will be able to demonstrate efficacy with BEMA LA for the treatment of certain types of pain. Additional formulation work with BEMA LA is ongoing and we project to start Phase II trials by the end of 2007 or early in 2008.

A third product under development, BEMA Zolpidem, is a BEMA formulation of the most widely prescribed drug for the treatment of insomnia. Given funding constraints and our focus on applying the majority of our resources to the Phase III BEMA Fentanyl program, the initiation of the BEMA Zolpidem program was delayed in 2006. The timing of the restart of this program will be evaluated in 2007.

Bioral® Technology and Products in Development

Our Bioral® (cochleate) drug delivery technology encapsulates (encochleates) the selected drug or therapeutic in a nanocrystalline 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 given the time and resources we have spent in developing the technology. 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. If financing permits, we expect to begin this program in 2007.

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 the use in the treatment of CRS and asthma. Certain of our officers and directors 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. In 2005 and 2006, we entered into agreements with third parties for the evaluation of cochleate formulations of siRNA therapeutics. The results of one of these collaborations demonstrated that the Bioral® technology showed the potential to deliver the siRNA resulting in the knock down of the targeted enzyme (meaning the siRNA positively effected the enzyme in question in such a way so as to potentially achieve a therapeutic effect). This was established in two sets of experiments (which we announced in August 2006) in a mouse model of influenza where intra-nasally and intravenously administered Bioral® siRNAs reduced the viral titer significantly. We believe this may represent a significant opportunity to deliver these therapeutics, which are normally difficult to use and which are easily destroyed in the plasma by the body s natural enzymes, to patients. We have an ongoing evaluation agreement with a major companies 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®

We have also been developing Emezine®, a formulation of prochlorperazine, which we believe would be the first drug to be delivered transmucousally for treatment of nausea and vomiting. In February 2005, we announced that we completed the clinical studies required for our Emezine® NDA, and on April 29, 2005, we submitted such NDA. The FDA accepted our NDA for filing on June 30, 2005. On February 28, 2006, however, 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. On May 17, 2006, we met with the Gastroenterology Division of the FDA to discuss the nonapprovable letter we received for Emezine®. The FDA s position was that while a 505(b)(2) submission is still an acceptable regulatory pathway for Emezine®, additional clinical trials would be required to support the use of Emezine® in the target population of the proposed indication. The FDA further suggested that a Special Protocol Assessment could potentially fulfill the remaining requirements. Based on the FDA feedback, on July 14, 2006, we submitted two draft pharmacokinetic protocols for review as a Special Protocol Assessment along with a proposal as to how the data from these protocols would address the deficiencies noted in the nonapprovable letter. We are currently involved in discussions with clinical consultants to determine how and whether we will proceed with the continued development of Emezine® based on the feedback we received from FDA on the information we submitted on July 14, 2006. Given the opportunity that the BEMA Fentanyl and BEMA LA products currently present to us in terms of potential commercial value, any continued spending on Emezine® based on the challenges of meeting FDA s requirements for the ultimate approval of Emezine® may not be warranted. We therefore plan to continue to monitor, but not spend material resources, on the Emezine® project for the foreseeable future. Despite the fact Emezine® represents a relatively small portion of our potential future revenues, the failure to ultimately achieve FDA approval of Emezine® could have an adverse effect on our business. We do not, however, expect that such failure would seriously impair our overall potential future revenue growth. We license Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

During 2006, we actively pursued strategic financings and related partnerships regarding certain of our proposed formulations and products as we attempt to move them through the development,

approval and commercialization phases. Unfortunately, the FDA non-approvable notification regarding Emezine® meant that revenues we had previously projected as potentially being generated upon the launch of Emezine® in 2006 were not realized. Therefore, in part to offset the potential loss of projected Emezine® revenue but primarily due to our interest in securing distribution partners for our products, we aggressively pursued these types of transactions in 2006 and will continue to do so in 2007. As a result, we were able to execute a European transaction involving the distribution rights of BEMA Fentanyl with Meda (European based pharmaceutical company with a focus in pain) that included a signing milestone payment of $2.5 million. We are currently in discussions with several companies regarding the same distribution rights for BEMA Fentanyl in the U.S.

Recent and Historical Events

Laurus Financings

On February 22, 2005, we consummated a $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., which we refer to herein as Laurus. Net proceeds from the financing were used primarily to retire our secured equipment loan with Gold Bank (on which approximately $300,000 was owed and was paid at the closing of the Laurus transaction), to support our research and development opportunities and for general working capital purposes.

The February Laurus investment took the form of a convertible note secured by certain of our assets. The note had a 3-year term and an interest rate equal to prime plus 2% per annum. The note was convertible, under certain conditions, into shares of our common stock at a price equal to $3.10 per share. As a result of the anti-dilution provisions of the February Laurus note and the pricing of our October 2005 public offering, the conversion price of the February Laurus note was lowered to $2.45.

Due to the exercise by Laurus from time to time of its right to convert its note into shares of our common stock, the February 2005 Laurus note has been fully converted into shares of our common stock as of the date of this Report.

In connection with this financing, we also issued Laurus a common stock purchase warrant to purchase up to 350,000 shares of our common stock at a price equal to $3.88 per share. A registration statement we filed with the SEC to register the shares of common stock underlying the February Laurus note and the warrant was declared effective on June 20, 2005. This warrant was exercised on April 10, 2007. See Subsequent Events below.

On May 31, 2005, we closed an additional $2.5 million secured convertible debt financing from Laurus. As with the February 2005 Laurus financing, this financing takes the form of a secured convertible note and a warrant to purchase 483,871 shares of our common stock. This warrant was exercised on April 10, 2007. See Subsequent Events below. Net proceeds from the May Laurus financing were used to support our research, development and commercialization opportunities and for general working capital purposes. As a result of the anti-dilution provisions of the May Laurus note and the pricing of our October 2005 public offering, the conversion price of the May Laurus note is now $2.45.

On June 29, 2005, we entered into two separate amendments to our February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by us of principal under the February and May 2005 Laurus notes until December 1, 2005. In consideration of Laurus agreement, we issued to Laurus two warrants, one to purchase 22,500 shares of our common stock (in connection with the February amendment) and a second to purchase 7,500 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of our common stock at an exercise price of $.001 per share and expire on June 29, 2012. Except for the exercise price of the warrants, the warrants issued to Laurus in connection with the foregoing amendments are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005. We agreed to register the shares of common stock underlying the May note and warrant and the June warrants with Laurus with the SEC, which registration statement was declared effective on July 11, 2005.

On December 28, 2005, we entered into two separate second amendments to our February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by us of certain monthly principal amounts, as well as all of the previously postponed principal amounts due to Laurus addressed in our June 29 amendments, until July 1, 2006. In consideration of Laurus agreement to postpone such payments, we issued to Laurus two additional warrants, one to purchase 39,574 shares of our common stock (in connection with the February amendment) and a second to purchase 29,700 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of our common stock at an exercise price of $.001 per share and expire on December 28, 2012. Except for the exercise price of the warrants, the warrants issued to Laurus in December 2005 are substantially similar to the warrants issued to Laurus on February, May and June 29, 2005. We agreed to register the shares of common stock underlying the warrants issued in connection with these amendments, which registration statement was declared effective on May 16, 2006.

On July 31, 2006, we entered into two separate third amendments to our February and May 2005 financing agreements with Laurus. Under the third amendments, Laurus has agreed to defer payments by us of certain monthly principal amounts under the Laurus notes ($909,096 in the aggregate), as well as certain other previously postponed principal amounts due under such notes ($1,280,945 in the aggregate), until the first business day of January 2007. In consideration of Laurus agreement enter into the third amendments, we issued to Laurus two warrants, one to purchase 62,887 shares of our common stock (in connection with the February amendment) and a second to purchase 47,113 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of common stock at an exercise price of $3.00 per share and expire on July 31, 2013. Except for the exercise price, these warrants are substantially similar to the warrants issued to Laurus on February 22, 2005, May 31, 2005, June 29, 2005 and December 28, 2005. We have agreed to register the shares of common stock underlying the July 2006 warrants with the Securities and Exchange Commission pursuant to a registration statement required to be filed by no later than May 25, 2007.

On December 28, 2006, we entered into two separate fourth amendments to our February and May 2005 financing agreements with Laurus. Under the fourth amendments, Laurus has agreed to defer payments by us of certain monthly principal amounts under the Laurus notes ($1,818,192 in the aggregate), as well as certain other previously postponed principal amounts due under such notes ($2,018,541 in the aggregate), until the first business day of January 2008. In consideration of Laurus agreement enter into the third amendments, we issued to Laurus two warrants, one to purchase 943,305 shares of our common stock (in connection with the February amendment) and a second to purchase 556,695 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of common stock at an exercise price of $3.05 per share and expire on December 28, 2013. Except for the exercise price, these warrants are substantially similar to the warrants issued to Laurus on February 22, 2005, May 31, 2005, June 29, 2005, December 28, 2005 and July 31, 2006. We have agreed to register the shares of common stock underlying the July 2006 warrants with the Securities and Exchange Commission pursuant to a registration statement required to be filed by no later than May 25, 2007.

During the first quarter of 2007, Laurus exercised its right to convert an additional $3.044 million of aggregate principal and $0.119 million of interest under its two notes with us into 1,290,861 shares of common stock. On April 10, 2007, Laurus agreed to defer all remaining principal to July 1, 2008. As of the date of this report, the remaining principal due to Laurus is $1.262 million. See Subsequent Events below.

CDC Clinical Development and Licensing Agreement

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 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. As a result of this transaction, CDC was issued 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 $7 million milestone payable to CDC upon the approval by the FDA of BEMA Fentanyl which had been required under the CDLA.

Under the CDLA, CDC is entitled to receive:

- royalties based on net sales of BEMA Fentanyl (including minimum royalties); and
- a portion of any licensing revenue received by us prior to FDA approval of BEMA Fentanyl, which will be credited against our initial milestone payment to CDC.

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 data, information, and intellectual property rights concerning BEMA Fentanyl were exclusively licensed to CDC, subject to CDC s return grant of an exclusive license for us to utilize all such information and rights. Further, CDC shall own 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, 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. CDC retains the right to reclaim the assets in the event of a default under the CDLA as long as payments are due as royalties. Events of default would include failure to pay royalties, acceleration of a debt in excess of $1.0 million, judgment of $500,000, or 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 BEMATM 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. These matters were settled in March 2007. See Subsequent Events below.

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 797,414 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. See Subsequent Events below.

Hopkins Capital Group Equity Line of Credit

On September 3, 2004, we entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC, which we refer to herein as HCG, a principal stockholder of our company which is controlled and partially-owned by Dr. Francis E. O Donnell, Jr., our Chairman of the Board. Pursuant to the Equity Line Agreement, HCG will, at our request, invest up to $4.0 million in our company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock, or Series B Preferred. On March 30, 2006, we amended our agreement with HCG to extend the commitment period from March 31, 2006 to December 31, 2006. This agreement with HCG expired on December 31, 2006 and all shares of Series B Preferred have subsequently converted by HCG into shares of our common stock.

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® nanocochleate 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 2006. Working with Sigma-Tau s immunosuppressant compound, we were able during 2006 to undertake additional 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. BDSI received a $250,000 payment which took the form of a purchase of our common stock by Sigma-Tau as described above.

Subsequent Events

The following material events occurred subsequent to December 31, 2006:

CDC

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 is that CDC has withdrawn 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 is 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 financing right of first refusal (which we refer to as the 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. As described above, 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 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 to 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.

Laurus

On April 10, 2007, we entered into a fifth amendment to our 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 our common stock, resulting in cash proceeds of $3,183,567 to us and (ii) to defer all principal payments under our May 2005 note with Laurus (which currently stands at $1.262 million) until the first business day of July 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 a registration statement registering the shares underlying such warrant by May 25, 2007.

Sigma Tau

In January 2007, under our development agreement with Sigma Tau, we were paid a milestone payment of $.25 million for which we issued 73,964 shares of common stock at $3.38.

Other

On April 13, 2007, the Compensation Committee of our board of directors awarded the following options to the following senior executives of our company: Mark Sirgo: 434,000 options; James McNulty: 100,000 options; and Andrew Finn 100, 000 options. All of the foregoing options vest in three equals installments beginning on the first anniversary of the grant date (April 13, 2008) and have an exercise price of $6.63 per option share.

On March 30, 2007, HCG funded a $1.0 million unsecured, non-interest bearing note, due June 30, 2007. As consideration for the loan made by HCG, we granted HCG 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 can be demanded by either us or HCG at any time before September 30, 2007, is $5.0 million. The

royalty is to be paid based on low single digit, tiered percentage of net sales of BEMA Fentanyl, once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, we would issue 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). No assurances can be given the either we or HCG will elect to enter into the royalty purchase agreement.

On February 22, 2007, we designed the Series C Stock. Concurrently with the creation of the Series C Stock, we exchanged all 1,647,059 outstanding shares of our Series A Stock with the holders thereof for an aggregate of 1,647,059 shares of Series C Stock. Following such exchange, all shares of Series A Stock were cancelled. The designation of the Series C Stock and the exchange were undertaken in light of the significant contributions of Drs. Sirgo and Finn to our company.

The rights associated with the Series C Stock are identical to those associated with the Series A Stock in all material respects except that the Series C Stock has different terms of conversion into shares of our common stock. Shares of Series A Stock were convertible into shares of our common stock upon the earliest to occur of: (i) (30) days written notice by a holder thereof to us following the occurrence of the Conversion Event (as defined below); (ii) the first approval by the FDA for the marketing and sale by us or any of our subsidiaries of any of the following products: Emezine®, BEMA Fentanyl, BEMA Sumitriptan or any product which primarily incorporates technology similar to the foregoing for the buccal delivery of pharmaceuticals; or (iii) August 24, 2009. The term Conversion Event meant our failure to provide at least $3,000,000 to Arius as required to: (i) pay Atrix Laboratories, Inc. $1,000,000 by August 24, 2004 and (ii) fund, in a total amount of no less than $2,000,000, the operations of Arius in accordance with an agreed upon business plan. Since the triggers for a Conversion Event have been satisfied, the term is not associated with the Series C Stock.

Shares of Series C Stock are 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.

As a result of certain previous issuances by us of our securities at prices below the then current market price of our common stock (including a warrant to issued to Laurus in April 2007 as described above), the exercise price of our publicly-traded warrants was, effective April 10, 2007, adjusted downward from $6.30 to $6.11 pursuant to the terms of the warrant agreement entered into in connection with our June 2002 initial public offering. Our publicly-traded warrants expire on June 24, 2007.

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 2005 and 2006 as we continued development of our principal products and formulations toward regulatory submissions.

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 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 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 drugs, as well as extending existing drug patent protections. 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 for which there is an established medical need but an opportunity to introduce a new form of delivery of that product in order to meet an unmet treatment 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 previously established. Consequently, we believe that our clinical trials would primarily need to show that our Bioral® or BEMA technologies deliver the drug without harming the patient or changing the clinical attributes of the drug. Focusing on drug delivery compared to drug discovery should allow us to 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	Phase III	Partner being sought in US, certain rights to be retained. Partnered in EU with Meda AB
BEMA Long Acting Analgesic	Moderate and Severe Pain	Phase I	In-house commercialization for specialty indications, 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, 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, including certain of those discussed under Licensing Opportunities and Other Projects below, we are presently dedicating most of our corporate resources toward the development and commercialization of BEMA Fentanyl, BEMA LA 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 developments 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 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 such as pain, nausea, vomiting or trauma cases where intravenous lines or injections are unavailable or not practical. 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;

Dissolve completely, leaving no residual product or waste; and

Have relatively inexpensive cost of goods.

The U.S. rights to the BEMA technology are licensed from QLT and the non-U.S. rights are owned by us, having been acquired (subject to scheduled payments) from QLT in August 2006. We have an option to purchase the U.S. rights of the BEMA technology from QLT, which option expires on August 2, 2007. 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 pain medication will generate $30 billion in 2008. The market in the U.S. for breakthrough cancer pain (the proposed indicated for BEMA Fentanyl) is projected to grow to over $1.5 billion in the next 5 years. The leading fentanyl product for the treatment of breakthrough cancer pain is the U.S. market is Actiq® which is marketed by Cephalon. Cephalon introduced a second fast dissolving fentanyl product, Fentora in 2006. The reported combined sales of these products in 2006 was $659 million.

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

	Actiq®	**Fentora®**	**Rapinyl®**	**BEMA Fentanyl**
	buccal lozenge	**buccal tab**	**sublingual tab***	**buccal disc***
Attribute	**(Cephalon)**	**(Cephalon)**	**(Endo)**	**(BDSI)**
Strengths	200 1600 µg	100 800 µg	100 1200 µg	200 1200 µg
Dose Linearity	Yes	Up to 800 µg	TBD	Yes
Taste issue potential	Yes	Higher	Higher	Low
Irritation	Occurred in >1% of patients in long term study	10% of all patients		
		3% of all patients with ulcerations	TBD	Low

* projected as neither product is marketed

We believe there is a clear need and growing market for additional narcotic agents in alternative dosage forms to provide rapid 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 applied with 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;

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.

In March 2005, we announced that we received confirmation from the U.S. Food and Drug Administration that we will be able to utilize the FDA s 505(b)(2) process for regulatory approval consideration of our licensed BEMA Fentanyl formulation. In September 2006, we announced that we had conducted a second meeting with the FDA regarding the BEMA Fentanyl development program and the program is progressing towards a NDA submission.

In November 2005, we announced the results of a key 12 subject study comparing BEMA Fentanyl and Actiq®. The results showed that the BEMA Fentanyl formulation showed greater bioavailability (absorption), higher maximum plasma concentrations (Cmax) and faster concentrations of fentanyl in the plasma (t-first and t-max) compared to Actiq®.

In April 2006, we announced the results from two key pharmacokinetic studies regarding BEMA Fentanyl. The first was a 12 subject study comparing three doses of BEMA Fentanyl. The results showed that increasing the dose of BEMA Fentanyl from 200 mcg to 1,200 mcg resulted in a proportionate increase in maximum and total plasma concentrations meaning the dosage form is maintaining linear pharmacokinetics. This is important from the standpoint that our BEMA dosage form delivered a reliable and consistent plasma concentration of fentanyl each time that it is given and as one increases the dose or strength. In other words, a 400 mcg dose provides approximately twice the plasma concentration of a 200 mcg dose and an 800 mcg dose provides approximately twice the plasma concentration of a 400 mcg dose. This represents an important finding for the BEMA technology. Among other things it means that BEMA Fentanyl should provide a reliable level of fentanyl as patients titrate to an acceptable strength or dose to control their pain.

The second study, announced in May 2006, was also a 12 subject study comparing the effects of multiple doses of BEMA Fentanyl. The results of the study showed that a 600mcg dose given on two different days demonstrated reproducible plasma concentrations. This demonstrates dose to dose reliability or reproducibility within the same patient. Additionally, when three 600mcg doses were given 1 hour apart the peak plasma concentration was proportionate to the increased dose.

We began preparing for Phase III clinical studies of BEMA Fentanyl in the fourth quarter of 2005. Enrollment in the program was initiated in early 2006. In February 2007, we announced an update on the progress of the clinical program. In this announcement, we disclosed that the data from the Phase III efficacy program and an update on the entire program will be available in April 2007.

In November 2005, we announced that we entered into a supply agreement with Aveva Drug Delivery Systems, Inc., or Aveva, under which Aveva will prepare clinical supplies for our Phase III BEMA Fentanyl trials and provide commercial manufacturing for BEMA Fentanyl in the United States. Effective December 15, 2006, we entered into a Process Development Agreement with LTS Lohmann Therapie-Systeme AG, or LTS, pursuant to which LTS will undertake process development and scale up activities and supply 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.

Commercially, in 2006 we disclosed that we will pursue one of three approaches or a

combination thereof to marketing BEMA Fentanyl. We may consider licensing the products to appropriate partners so that they can market and distribute the products for us. This would allow us to avoid building the commercial infrastructure required to do so and the associated risks particularly around launching ones first product. Alternatively, we may consider marketing and selling BEMA Fentanyl ourselves. If we pursue this route, our commercial efforts will be primarily focused on hospitals, oncologists and pain centers to maintain cost efficiency. We would plan to initiate the sales organization around the launch of BEMA Fentanyl with 75-100 representatives focused on physicians, hospitals and groups who treat cancer patients. These representatives may be our employees. A third option is to use a contract sales organization to market and sell our products. Although we would have the costs associated with such a relationship we would not bear the burden of having these individuals as BDSI employees. These contracts can also be written to allow for termination of the effort if sales are not going as planned or to convert these employees to permanent BDSI employees at a future time where a good deal of the risk of the product launch and the early years of distribution has passed. A final option is to use a mix of BDSI employees and a contract sales organization with an option again to convert these contract representatives to BDSI employees at a future date.

Outside of the U.S., we expect to create distribution partnerships with suitable partners such as our August 2006 agreement Meda AB of Sweden. Meda, a large European specialty pharmaceutical company with a focus in pain, licensed BEMA Fentanyl for an upfront payment of $2.5 million and additional payments that could total up to $10 million. Meda will be responsible for development of the product in Europe and will pay us a double digit royalty on net sales of BEMA Fentanyl in Europe.

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 Long Acting Analgesic

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 LA 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 LA. In August 2006, we announced the completion of the initial Phase I study for BEMA LA. The results of this study demonstrated achievement of plasma concentrations that are associated with analgesia. This data potentially indicates that BEMA LA 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 LA through scale up of manufacturing and pursuit of further clinical studies working towards an NDA. However, due to financial constraints in 2006 and our focus on BEMA Fentanyl, we did not progress BEMA LA into Phase II. We do plan to begin that program in the second half of 2007 and based on those results proceed into Phase III.

BEMA LA contains 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 LA as a Schedule III controlled substance versus the majority of the other potent opioids, such as morphine and oxycodone, which are Schedule II. It is our belief that this attribute will help create a broader market opportunity for BEMA LA as many doctors are reluctant to prescribe narcotics particularly on a chronic basis for the fear of addiction. In addition, physicians are able to

phone Schedule III prescriptions into the pharmacy whereas the prescription for a Schedule II controlled substance must be obtained by the patient from the doctor s office which the patient then must take to the pharmacy. Since the active ingredient in BEMA LA is a Schedule III controlled substance, physicians will be able to phone or fax in 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. Consequently, we believe that BEMA LA will have the potency of a product such as morphine but with the attributes afforded a Schedule III narcotic.

The FDA-approved compound which forms the basis of BEMA LA 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 LA will be an ideal next step product for patients with incomplete pain relief on non-narcotic analgesics.

Our BEMA LA 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 LA will be differentiated based on the following features:

- efficacy equivalent to morphine but unlike morphine is a Schedule III narcotic making it less addicting 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 either used in combination with less potent analgesics such as nonsteroidal anti-inflammatory drugs, or NSAIDS, or used as sole therapy,
- a longer half life which allows for less frequent dosing, thus potentially increasing patient compliance,
- an established safety profile compared to the 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 $7 billion are for opioid therapies. The total market for pain treatment is projected to grow to approximately $33 billion by 2014.

Due to the ability of BEMA LA to potentially participate in the principal key pain markets (chronic pain as well as acute and post-operative pain), we believe that BEMA LA 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 intend to 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 global market for insomnia treatments has been projected to be approximately $3.6 billion for 2005 and is estimated to grow to approximately $5.2 billion by 2009 and to approximately $5.5 billion in 2014. 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® is the world s best selling product for insomnia with 2005 sales of $1.5 billion. Lunesta ®, which contains a different active ingredient and was launched in 2005, achieved sales of $329 million in 2005.

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 every time it is used.

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, BDSI strategically decided to focus primarily on the continued development of BEMA Fentanyl in 2006. Subsequently, we did not initiate the development of the BEMA Zolpidem program in 2006. In 2007, financial and human resources permitting we plan to finalize a formulation for BEMA Zolpidem and file an IND. This will allow us to enter Phase I clinical trials in 2008. Based on the outcome of several Phase I studies to determine the ideal strength and formulation of BEMA Zolpidem, we would then anticipate entering into Phase II clinical trials.

Due to the rapid onset characteristics of BEMA Zolpidem, our market research indicates that BEMA Zolpidem has the potential to achieve a 5% share of the total worldwide insomnia market which has a 2010 projected value of approximately $5 billion. 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

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. If financial and human resources are available to us, we plan to scale up manufacturing and conduct an initial Phase I study late in 2007.

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.

According to market research firm Visiongain, the global antifungal market was approximately $6 billion in 2003 and is projected to grow to as much as $8 billion by 2009. 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, 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. Further, 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. We have an ongoing evaluation agreement with one of the major companies developing siRNA therapeutics and we are seeking 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 apply at this time any internal resources to these programs. Due to this de-emphasis, no progress on these programs was made in 2006. 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, 2006.

Emezine®

We have licensed the U.S. rights to 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.

On May 17, 2006, we met with the Gastroenterology Division of the FDA to discuss the nonapprovable letter we received for Emezine®. The FDA s position was that while a 505(b)(2) submission is still an acceptable regulatory pathway for Emezine®, additional clinical trials would be required to support the use of Emezine® in the target population of the proposed indication. The FDA further suggested that a Special Protocol Assessment could be a potential way to fulfill the remaining requirements. Based on the FDA feedback, on July 14, 2006, we submitted two draft pharmacokinetic protocols for review as a Special Protocol Assessment along with a proposal as to how the data from these protocols would address the deficiencies noted in the nonapprovable letter. We are currently involved in discussions with clinical consultants to determine how and whether we will proceed with the continued development of Emezine® based on the feedback we received from FDA on the information we submitted on July 14, 2006. However, there are no assurances that we will continue with the development of Emezine®.

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 the failure 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, 2006, UMDNJ owned 139,522 shares (including shares issued under a research agreement) and options to purchase 9,951 shares of our common stock at $3.06 and 75,000 options to purchase our common stock at a price per share of $2.37. As of December 31, 2006, Albany Medical College owned 2,222 shares of our common stock and options to purchase 9,951 shares of our common stock at $3.06 and 75,000 options to purchase our common stock at a price per share of $2.37. 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 located on their campus pursuant a lease agreement ending December 31, 2005. The monthly rent was $3,340 for 2001, $3,840 for 2002, $4,340 for 2003, $4,840 for 2004 and $5,340 for 2005. The lease was renewed in December 2005 for a term of one year at a cost of $64,080 for the year, or $5,340 per month. We are currently negotiating the lease for 2007 with UMDNJ but anticipate that the monthly rent will not change from 2006 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 universities, government agencies, corporate partners, and contractors. 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:

Atrix Laboratories, Inc. On May 27, 2004, prior to its acquisition by us, Arius entered into a worldwide, exclusive royalty-bearing license agreement with Atrix (now a subsidiary of QLT Inc.) 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.

QLT. Under the terms of the license agreement with QLT, we are required to pay: (i) an upfront licensing fee of $1 million, which was paid in August 2004, (ii) additional cash payments upon achievement of certain developmental and regulatory milestones, (iii) for reimbursement for research and development support, and (iv) royalties on commercial sales of all BEMA products. A joint development management committee composed of representatives of our company and QLT oversees product development. We are responsible for the research and development of the products, including costs and expenses, and for their sale, marketing, manufacture and distribution. QLT retains certain co-promotion rights to the BEMA Fentanyl product.

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. Besides the rights to the BEMA technology outside of the U.S., the agreement granted us an option to purchase the U.S. BEMA technology patents within 12 months ending August 2, 2008. 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. These payments will also be paid over time. After purchasing the intellectual property rights from QLT, we will not owe any future milestone payments or royalties.

Meda AB (Sweden). In August 2006, we announced a collaboration with Meda AB to develop and commercialize BDSI s flagship BEMA Fentanyl product 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 all of Europe. Upon regulatory approval, Meda will exclusively commercialize BEMA Fentanyl in Europe. BDSI retains all development and commercial rights in the U.S., Japan, Australia and other territories outside of Europe.

Aveva Drug Delivery Systems. 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. 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 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.

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

We continued to work with Sigma-Tau on this project during 2006. Working with Sigma-Tau s immunosuppressant compound, we were able during 2006 to undertake additional 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 proof of principle. 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.

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.

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 shall 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. We can give no assurances that the agreement will not be terminated by Reckitt or us.

National Institutes of Health. To investigate the properties of new antifungal cochleate formulations, 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. No assurances can be given that NIAID will proceed with or actually pay for this testing.

Other Bioral® Collaborations. In 2006, we entered into additional collaborations to combine the Bioral® technology with other companies intellectual property in the form of Evaluation and Material Transfer Agreements. If positive, these may turn into license 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. Hopkins Capital Group (HCG), which is controlled by Dr. Francis E. O Donnell, Jr., our Chairman of the Board and which owns a significant percentage of our common stock as of the date of this Report, is a significant stockholder of Accentia. In addition, Dr. O Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, is the Treasurer of Accentia and 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.

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 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.

Arius/TEAMM 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 is a specialty

pharmaceutical company and 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. In 2005, we received $300,000 from TEAMM upon the acceptance by the FDA of the Emezine® NDA for filing. TEAMM now operates as Accentia Pharmaceuticals.

Analytica International Market Studies. During 2004, Analytica International, a provider of research, commercialization, and communications services to the pharmaceutical and biotechnology industries and a subsidiary of Accentia, performed two market studies for us. We paid Analytica $47,800 for these reports, some of which we paid in 2005.

RetinaPharma Technologies, Inc. We previously entered into a license agreement with this development-stage biotechnology company to use our delivery technology in connection with their proposed nutraceutical product with potential application for macular degeneration and retinitus 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, one of our significant stockholders, and Dr. Francis E. O Donnell, Jr., our Chairman of the Board, are affiliated as stockholders and a director of RetinaPharma.

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:

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.

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 an initial milestone payment and shall in the future pay to us certain additional milestone payments upon achievement of certain developmental and regulatory milestones, (iii) shall support our clinical development costs with respect to such product, and (iv) 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 $300,000 milestone payment with the acceptance of the NDA filing for Emezine® by FDA in 2005.

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 interest in the 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 frequently considered to be uncertain and involve complex legal and technical issues. There is considerable uncertainty regarding the breadth of claims allowed in such cases and the degree of protection afforded under such patents. 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 patent applications will be

successful or that our current or future intellectual property will afford us the desired 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 drugs.

Other parties could have patent rights which may block our products. We are aware of two issued United States patents dealing with lipid formulations of Amphotericin B products. The first of these patents, United States Patent No. 4,978,654, claims an Amphotericin B liposome product. We do not believe that our patent or technology are in conflict with this existing patent, although there can be no assurance that a court of law in the United States patent authorities might determine otherwise. Our belief is based upon the fact that our cochleate product does not contain liposomes, which is required by the issued claims of this patent. The second of these patents, United States Patent No. 5,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our Bioral® nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we require a license under this patent.

We are also aware of United States Patent No. 6,585,997, related to mucoadhesive erodible drug delivery devices. We do not believe that our BEMA Fentanyl product is in conflict with the existing patent, at least because there are limitations recited in the issued claims that are not met by our product. Accordingly, we do not believe that we require a license under this patent for BEMA Fentanyl. We are further aware of U.S. Patents Nos. 5,948,430, 6,177,096 and 6,284,264, and European Patent No. 0 949 925, which are owned by LTS Lohmann and which also relate to mucoadhesive erodible drug delivery devices. Under our December 2006 Process Development Agreement with LTS, LTS has granted us a license to European Patent No. 0 949 925 in regard to BEMA Fentanyl in the European Union. This agreement has an option for LTS to exclusively manufacture clinical trial and commercial supplies of BEMA Fentanyl in the European Union. Freedom to operate searches and analyses have not been completed for other proposed BEMA based products.

If a court were to determine that we infringe any of these patents and that these patents are valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B and/or our 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, there may be a material adverse effect upon our business plan to commercialize these products.

Most of the inventions claimed in our cochleate 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 U.S. 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.

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 protect our intellectual property.

Cochleate Technology

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 owned by the parties listed in the chart below. 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. Our intellectual property strategy is intended to maximize our potential patent portfolio, license agreements, proprietary rights and any future licensing opportunities we might pursue. With regard to our Bioral® cochleate technology, we intend to 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. Below is a table summarizing patents we believe are currently important to our business and technology position.

Patent Number	**Issued**	**Expires**	**Title**	**Owner**
EUR0722338	07/25/2001	09/30/2014	Protein- and peptide cochleate vaccines methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,165,502	12/26/2000	09/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	(same as above)
US06,153,217	11/28/2000	01/22/2019	Nanocochleate formulations, process of preparation and method delivery of pharmaceutical agents	BioDelivery Sciences International, Inc., The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,592,894	07/15/2003	01/22/2019	(same as above)	(same as above)
AUS722647	11/23/2000	09/02/2017	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,994,318	11/30/1999	11/24/2015	Cochleate delivery vehicles	(same as above)
EUR 812209	05/06/2004	02/22/2016	Cochleate delivery vehicles for biologically relevant molecules	(same as above)
CA 2,246,754	10/22/2002	02/21/2017	Cochleate delivery vehicles	(same as above)
US05,840,707	11/24/1998	11/24/2015	Stabilizing and delivery means of biological molecules	(same as above)

Patent Number	Issued	Expires	Title	Owner
US05,834,015	11/10/1998	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	(same as above)
AUS689505	02/02/1998	09/30/2014	Protein- or peptide-cochleate immunotherapeutics and methods of immunizing using the same	(same as above)
US05,643,574	07/01/1997	07/01/2014	(same as above)	(same as above)
CA 2,169, 297	08/02/2005	09/30/2014	Protein- or peptide-cochleate immunotherapeutics and methods of immunizing using the same	(same as above)
AUS753008	01/23/2003	02/22/2016	Cochelate Delivery Vehicles	(same as above)
US04,871,488	10/03/1989	10/03/2006	Reconstituting viral glycoproteins into large phospholipid vesicles	Albany Medical College

Through Arius, we license from QLT USA, Inc. the following U.S. and, and we own the following foreign 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
10/706,603	US	11/12/2003	Pending			Adhesive Bioerodible Ocular Drug Delivery System
US04/026531	PCT	08/16/2004	N/A	N/A	N/A	Adhesive Bioerodible Transmucosal Drug Delivery System
US97/18605	PCT	10/16/1997	N/A	N/A	N/A	Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
9747574	Australia	10/16/1997	729516	05/17/2001	10/16/2017	(same as above)
200138924	Australia	10/16/1997	769500	05/13/2004	10/16/2017	
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)
US99/09378	PCT	04/29/1999	N/A	N/A	N/A	(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.

Emezine®

With respect to Emezine®, we license from Reckitt U.S. Patent No. 4,717,723, issued January 5, 1988, entitled Pharmaceutical Compositions.

Competition

The biopharmaceutical industry in general is competitive and subject to rapid and substantial technological change. 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 TransOral Pharmaceuticals, Inc., 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 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. Cephalon s first product for this indication is Actiq®, which generated $629 million in sales in 2006. Cephalon licensed a generic to this product to Barr Laboratories upon approval of Fentora , formerly known as OraVescent Fentanyl. This product utilizes an effervescent tablet which is administered buccally. Fentora was approved and launched in 2006 generating $30 million in sales. Endo has licensed Rapinyl, which is a polymer formulated sublingual fentanyl tablet indicated for breakthrough cancer pain, from Orexo AB. This product is administered sublingually. Generex Biotechnology and Sosei Co. Ltd. (formerly Arakis, Ltd.) are developing sublingual spray formulations of opioids for breakthrough pain. LAB International, Inc. and YM Biosciences (formerly Delex Therapeutics) are developing inhaled formulations of fentanyl for administration either nasally or across the alveoli in the lungs. Javelin Pharmaceuticals, Inc. (OTC BB: JVPH.OB) is developing an intranasal morphine and Nycomed, a private company from Denmark is developing a Fentanyl Nasal Spray. 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. 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	Phase III NDA in 2007
Rapinyl	Orexo/Endo	Sublingual Tablet	Phase III Initiated Fall 2005 NDA delayed to 1H 2008
Instanyl	Nycomed	Fentanyl Nasal Spray	Phase III Initiated May 2006
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 TAIRFUN®	LAB	Dry Powder Inhaler	Phase IIB (Recruiting)
AeroLEF	YM Biosciences	Liposomal fentanyl delivered via nebulizer	Phase IIB (Post Operative Pain)
Rapid Mist Fentanyl	Generex	Buccal Spray	Phase I
AZ003-Stacatto Fentanyl	Alexza Pharmaceuticals	Aerosolized fentanyl for inhalation	Phase I

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BEMA LA 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 LA as a step up from an NSAID 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 (formerly Ligand) and Duragesic® from Johnson & Johnson.

Other competition includes multiple new chemical entities with different mechanisms of action. These include a glutamate antagonist from Neurocrine, a mixed delta/mu antagonist from Enhance Biotech/Alza and multiple COX-2 products from GSK, Sanofi-Aventis, Novartis and Sankyo.

Finally, there are also products under development in special delivery technologies including Tramadol flash dose from Biovail, Tramadol extended release from Labopharm/Purdue, Remoxy from Pain Therapeutics/King Pharmaceuticals, Oxytrex from Pain Therapeutics and sufentanil transdermal patch from Durect/Endo.

BEMA Zolpidem will compete in the insomnia market with an indication for the short term treatment of insomnia. Zolpidem is the active ingredient in Ambien®. Ambien® is the world s best selling product for insomnia with 2005 sales of $1.5 billion. BEMA Zolpidem will be positioned primarily as a first line therapy for insomnia patients. This would include hospital and primary care applications. Market competitors for this indication include but are not limited to: Ambien® and Ambien CR® (Sanofi-Aventis), Lunesta® (Sepracor), Rozerem® (Takeda) and Sonata® (King Pharmaceuticals).

Other competition includes multiple new chemical entities. These include indiplon (Neurocrine), and gaboxadol (Lundbeck/Merck).

Finally, there are also approved products development in special delivery technologies including zolpidem Flashdose® from Biovail, Zolpidem Oral Spray from Novadel and Sonata® ER from King Pharmaceuticals.

Cochleate 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 using 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., each 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.

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 Valentis Inc. (NASDAQ:VLTS), 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 agreements. 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, 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.

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

Assuming completion of our drug delivery technologies, product and formulation development and regulatory approval, we will pursue one of three approaches or a combination thereof to marketing our products. We may consider licensing the products to appropriate partners so that they can market and distribute the products for us. This would allow us to avoid building the commercial infrastructure required to do so and the associated risks particularly around launching ones first product. Alternatively, we may consider 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. If we pursue this route, our commercial efforts will be primarily focused on hospitals, oncologists and pain centers to maintain cost efficiency. We would plan to initiate the sales organization around the launch of BEMA Fentanyl with 75-100 representatives focused on physicians, hospitals and groups who treat cancer patients. These representatives may be our employees. A third option is to use a contract sales organization to market and sell our products. Although we would have the costs associated with such a relationship we would not bear the burden of having these individuals as BDSI employees. These contracts can also be written to allow for termination of the effort if sales are not going as planned or to convert these employees to permanent BDSI employees at a future time where a good deal of the risk of the product launch and the early years of distribution has passed. A final option is to use a mix of BDSI employees and a contract sales organization with an option again to convert these contract representatives to BDSI employees at a future date.

For sales and marketing into primary care and geographies outside of the United States, we will explore a wide range of potential arrangements, such as licensing, direct sales, co-marketing, joint venture and other arrangements. Such arrangements may be with large or small pharmaceutical companies, general or specialty distributors, biotechnology companies, physicians or clinics, or otherwise.

We have licensed the commercial rights to Emezine® to Accentia. Accentia is responsible for the sales and marketing of Emezine®.

In Europe, we have licensed the commercial and development rights to BEMA Fentanyl to Meda AB. We have a non-exclusive distribution arrangement with Biotech Specialty Partners, LLC, an early-stage alliance of specialty pharmaceutical and biotechnology companies, although BSP has waived its rights with respect to Arius products.

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 formulation 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 and will take a number of years and involve the expenditure of substantial resources.

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

1. Laboratory and 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 product and establish its safety and efficacy 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 intend to largely rely upon 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, dosage tolerance, metabolism, bio-distribution, excretion and pharmacodynamics (clinical pharmacology). 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 indicator; and

Identify possible adverse side effects 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 clinical efficacy and 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 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 based on the non-approvable letter we received from the FDA on Emezine® in late February 2006.

Five studies were started in 2006 under the IND for BEMA Fentanyl. Multiple preclinical studies were conducted with Bioral® Amphotericin B. One study was conducted with BEMA LA in 2006. We expect that additional studies will be required in 2007 on these and other proposed products and formulations.

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 for approval to market and sale of 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. 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 a New Drug Application 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 if problems occur following initial marketing. Post approval studies may be conducted to explore further intervention, new indications or new product uses.

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 April 13, 2007, we have 12 full-time employees and 4 part-time employees; 4 are laboratory scientists and 12 are involved in our clinical and program development, operations, administration, accounting and information technology. Advanced degrees of our staff include four Ph.D s, two Pharm.D s, on R.Ph. 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 before deciding to buy or exercise our securities. If any of the following risks actually materialize, our business and prospects could be seriously harmed, the price and value of our securities could decline and you could lose all or part of your investment.

Risks Relating to Our Business

Since we have 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, 2006, we have recorded accumulated losses totaling approximately $43.5 million. As of December 31, 2006, we had negative working capital of approximately $9.6 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.

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, although since 2005 we have shifted our focus towards 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.

We will 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. 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 available financing will be sufficient to satisfy our contemplated cash requirements into approximately the first 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. Thereafter, 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. Among other things, external financing will be required to allow us to pay, by March 31, 2007 (which we paid March 30, 2007), $1 million to QLT in connection with our August 2006 acquisition of the non-U.S. BEMA® assets and also cover the further development of our product formulations and other operating costs. While we expect that we will be able to find the needed capital to progress our business plan, we cannot assure you that 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 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 will not be sufficient to meet our present and future capital requirements. We do not know when this will change. We have expended and will continue to expend substantial funds in the research, development and clinical and pre-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 clinical and pre-clinical trials, commercial-scale manufacturing arrangements and to provide for the marketing and distribution. While we expect that we will have access to financial resources so that we will be able to progress with our business plan, 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 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 regards to our delivery technologies and our proposed formulations and products.

Additionally, investors are cautioned that the total projected development costs for BEMA® Fentanyl will exceed the maximum amounts CDC has funded to us. As a result, we have and will continue to require additional financial resources to complete the development of BEMA® Fentanyl, which resources may not be available to us.

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

The additional financings which we have undertaken and which we will require have and may in the future 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.

CDC has claimed that we have breached the CDLA and has sought to gain control of our BEMA® Fentanyl asset.

In August 2006, CDC provided us with a written notice in which they claimed that we had materially breached the CDLA. Such notice also contained a demand that we transfer to CDC all rights associated with BEMA® Fentanyl. Although we settled this dispute in March 2007, such resolution was without prejudice to CDC s or our claims, and no assurances can be given however that CDC will not in the future make similar or additional claims against us. Our dispute with CDC has forced us to spend corporate resources in our defense and has distracted management s attention from key projects. Moreover, 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 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. In addition to the time and cost associated with defending ourselves from CDC, which have negatively impacted us, if CDC were to prevail, our loss of BEMA® Fentanyl to CDC would have a material adverse effect on our business.

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

Under our May 2006 Securities Purchase Agreement, until such time as we achieve a market capitalization of $85 million, 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 60 days. If no terms are agreed to, we may pursue a financing with a third party for 120 days, but only on terms superior and similar in structure to those offered by CDC. CDC has exercised this right of first negotiation to our detriment in the past, and the right of first negotiation was the subject of a now settled litigation between us and CDC in October 2006. No assurances can be given that CDC will not seek to exercise the right again in the future. The existence of CDC s right of first negotiation, or CDC s exercise thereof, 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.

If an event of default occurs under our convertible notes with Laurus Master Fund, Ltd., it could seriously harm our operations.

On February 22, 2005 and May 31, 2005, we issued two separate $2.5 million secured convertible term notes with Laurus. The notes and related agreements contain numerous events of default which include:

- failure to pay interest, principal payments or other fees when due (pursuant to certain amendments to our notes, we will owe Laurus an aggregate of $1,262,093 in deferred principal payments on the first business day of July 2008; no assurances can be given that we will have the resources to make such payments);
- breach by us of any material covenant or term or condition of the notes or any agreements made in connection therewith;
- breach by us of any material representation or warranty made in the notes or in any agreements made in connection therewith;
- default on any indebtedness exceeding, in the aggregate, $100,000, to which we or our subsidiaries are a party;
- assignment for the benefit of our creditors, or a receiver or trustee is appointed for us;
- bankruptcy or insolvency proceeding instituted by or against us and not dismissed within 30 days;
- money judgment entered or filed against us for more than $100,000 and remains unresolved for 30 days;
- common stock suspension for 10 consecutive days or 10 days during any 30 consecutive days from a principal market, provided that we are unable to cure such suspension within 30 days or list our common stock on another principal market within 60 days; and

loss, damage or encumbrance upon collateral securing the Laurus debt which is valued at more than $100,000 and is not timely mitigated.

If we default on the notes and the holder demands all payments due and payable, the cash required to pay such amounts would most likely come out of working capital, which may not be sufficient to repay the amounts due. In addition, since we rely on our working capital for our day to day operations, such a default on the note could materially adversely affect our business, operating results or financial condition to such extent that we are forced to restructure, file for bankruptcy, sell assets or cease operations. Further, our obligations under the notes are secured by substantially all of our assets. Failure to fulfill our obligations under the notes and related agreements could lead to loss of these assets, which would be detrimental to our operations.

Certain restrictions on our activities contained in the Laurus financing documents could negatively impact our ability to obtain financing from other sources.

So long as 25% of the principal amount of either of the February and May Laurus notes are outstanding, the Laurus financing documents restrict us from obtaining additional debt financing without Laurus approval and subject to certain specified exceptions. To the extent that Laurus declined to approve a debt financing that does not otherwise qualify for an exception to the consent requirement, we would be unable to obtain such debt financing. In addition, subject to certain exceptions, we have granted to Laurus a right of first refusal to provide additional financing to us in the event that we propose to engage in additional debt financing or to sell any of our equity securities. Laurus right of first refusal could act as a deterrent to third parties which may be interested in providing us with debt financing or purchasing our equity securities. To the extent that such a financing is required for us to conduct our operations, these restrictions could materially adversely impact our ability to achieve our operational objectives.

Low market prices for our common stock could result in greater dilution to our stockholders, and could negatively impact our ability to convert the Laurus debt into equity.

The market price of our common stock significantly impacts the extent to which the Laurus debt is convertible into shares of our common stock. The lower the market price of our common stock as of the respective times of conversion, the more shares we will need to issue to Laurus to convert the principal and interest payments then due. If the market price of our common stock falls below certain thresholds, we will be unable to convert any such repayments of principal and interest into equity, and we will be required to make such repayments in cash. Our operations could be materially adversely impacted if we are required to make repeated cash payments on the unrestricted portion of the Laurus debt.

The Laurus financing documents prohibit the payment of dividends by us. You should not invest in our securities on the expectation that you will receive dividends.

So long as 25% of the principal amount of either of the February or May Laurus notes are outstanding, we will be prohibited from paying dividends without the prior consent of Laurus. Moreover, we have not paid dividends on our common stock in the past, and we do not anticipate paying any such dividends for the foreseeable future. You should not invest in our securities on the expectation that you will receive dividends.

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 universities, governmental agencies, manufacturers, contract research organizations and corporate partners for both strategic and financial resources. Our inability to secure such relationships as needed, or the loss of or failure to perform by us or our partners under any applicable agreements or arrangements, may 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.

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 lease expired December 31, 2005. We are currently leasing the space on a month to month basis, but are in negotiations to renew the lease. 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.

We may be unable to obtain, or elect not to pursue, extensions of our NIH grants and we may not be able to secure new NIH or similar grants in the future, which could deny us important funding.

In 2001, the NIH awarded us a Small Business Innovation Research Grant, or SBIR, which we utilized in our research and development efforts relating to our Bioral® Amphotericin B formulation. We have received all anticipated funding under this grant to date, and this grant expired in August 2004.

In 2002, the NIH awarded us a second SBIR grant which we have utilized in our research and development efforts relating to a proposed encochleated HIV subunit vaccine. This grant expired in December 2005 but was extended by the NIH in February 2006 until July 31, 2006, and we believe this

will be the final extension for this grant. As a result of this extension, we expect to receive approximately $74,000 in additional funds from the NIH for this project. In 2005, we subcontracted the responsibilities under the NIH grant for this project to UMDNJ.

Also, 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 encochleated Amphotericin B. No assurances can be given that NIAID will proceed with or actually pay for this testing.

Moreover, although we may seek additional NIH funding for either of these or other programs, we may choose not to seek such funding or such funding may be unavailable to us even should we desire it. The absence of additional funding from the NIH could impair our ability to further develop our Bioral® Amphotericin B formulation or other projects. Furthermore, as a result of these expirations, we incurred a decline in sponsored research revenue with associated NIH grant expenditures in 2005.

We are exposed to product liability, clinical and pre-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 with 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.

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 payors 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, payors 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 may be sued by third parties who claim that our drug formulations or products infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents.

We may be exposed to future litigation by third parties based on claims that our technologies, formulations, products or activities 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 medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. 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. In addition, intellectual property litigation or claims could 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.

Other parties could have patent rights which may block our products. We are aware of two issued United States patents dealing with lipid formulations of Amphotericin B products. The first of these patents, United States Patent No. 4,978,654, claims an Amphotericin B liposome product. We do not believe that our patent or technology are in conflict with this existing patent, although there can be no assurance that a court of law in the United States patent authorities might determine otherwise. Our belief is based upon the fact that our cochleate product does not contain liposomes, which is required by the issued claims of this patent. The second of these patents, United States Patent No. 5,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our Bioral® nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we require a license under this patent.

We are also aware of United States Patent No. 6,585,997, related to mucoadhesive erodible drug delivery devices. We do not believe that our BEMA Fentanyl product is in conflict with the existing patent, at least because there are limitations recited in the issued claims that are not met by our product. Accordingly, we do not believe that we require a license under this patent for BEMA® Fentanyl. We have not, however, conducted any patent searches with respect to our other proposed BEMA®-based products. We are further aware of U.S. Patents Nos. 5,948,430, 6,177,096 and 6,284,264, and European Patent No. 949 925, which are owned by LTS Lohmann and which also relate to mucoadhesive erodible drug delivery devices.

If a court were to determine that we infringe any of these or other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B and/or our 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 U.S. 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 obtain license to 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 to access the patents. Without these licenses, the technologies would be protected from our use and we would not be able to even conduct research without prior permission from the patent holder. Therefore, any disruption in access to the technologies could substantially delay the development of our technologies.

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 applications and any issued and licensed patents 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, and that all inventions arising out of the individual s relationship with us shall be our exclusive property. 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 our information and techniques, 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 the patents is a significant factor in the development and commercialization of our drug delivery technologies. Aside from the general body of scientific knowledge from other drug delivery processes and lipid technology, these patents, to the best of our knowledge and based upon our current scientific data, are 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 our rights for 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.

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 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 once our drug formulations or products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost.

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, once our proposed formulations or products are approved for commercial sale, we will need to establish, most likely through third parties, the capability to commercially manufacture our formulations or products in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our formulations or products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our proposed formulations or products. We presently plan to rely on third party contractors to manufacture part or all of our proposed formulations or products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanic shut downs, employee strikes, or any other unforeseeable acts that may delay production.

Due to the fact that we must build our marketing, sales, managed care, and distribution infrastructure and channels, we may be unsuccessful in our efforts to sell our formulations or products.

Except for our non-exclusive distribution agreement with BioTech Specialty Partners, Inc., a development-stage company affiliated with Dr. Francis E. O Donnell, a member of our management and significant beneficial owner of our securities, and the agreement between us and TEAMM Pharmaceuticals, also an affiliate of Dr. O Donnell, relating to Emezine®, we have yet to establish marketing, sales or distribution capabilities for our proposed formulations or products. Even though our proposed formulations or products have not been approved by the regulatory authorities, we devote meaningful time and resources in this regard. At the appropriate time, we intend to enter into agreements with third parties to sell our proposed formulations or products, or we may (in the future, resources permitting) develop our own sales and marketing force. 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. In particular, our inability to secure a commercial partner for our lead product, BEMA® Fentanyl, would seriously compromise our ability to bring this product to market.

If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, especially our lead product BEMA® Fentanyl, we will need to develop our own sales and marketing capabilities. Given the late stage of the clinical development of BEMA® Fentanyl, it is highly unlikely that we will have the time or resources to develop such capabilities with respect to such product and will have to rely on securing a commercial partner. Moreover, even if we were to develop our own sales and marketing capability, our experience in developing a fully integrated commercial organization is very limited. If we choose to establish a fully integrated commercial organization, we may incur substantial additional 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.

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.

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.

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. 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.

For example, on February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. We subsequently have had interactions with the FDA regarding Emezine®, and at the present time, given our level of resources and our focus on other initiatives, it is not likely that we will proceed with Emezine® in the foreseeable future.

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. The loss of these 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® LA, 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 the active ingredient in BEMA® LA, are listed by the DEA as Schedule II or III substances 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 payors, 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 payors 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 payors 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 clinical and pre-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 clinical or pre-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 are commenced, although there can be no assurance that such insurance can be obtained at such time, or even if it is available, that the cost will be affordable. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs. The cost and availability of such insurance are unknown. 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. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. 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.

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. Francis 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, our President and Chief Executive Officer, Dr. Mark Sirgo, or any of our other executive officers. 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 30.5% of our outstanding common stock. These figures do not reflect any conversion or exercise of our outstanding shares of Series A Preferred, the vast majority of which is held by Drs. Sirgo and Finn, or our convertible

notes with Laurus. Additionally, these figures do not reflect any future potential exercise of our Class A warrants or other outstanding warrants (including those issued to Laurus, 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 and director stockholders may differ from the interests of other stockholders. As a result, these current officer and director stockholders would 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, has a financial interest in a number of other companies which have business relationships with us. These companies include Accentia, RetinaPharma Technologies, Inc., Biotechnology Specialty Partners, Inc, and American Prescription Providers, 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 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 Publicly-Traded Securities

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.

In 2004, according to rules of the Nasdaq Capital Market (then known as the Nasdaq SmallCap Market), our shares of common stock were subject to potential delisting from such market because we did not meet certain requirements. Also, on September 15, 2005, the Nasdaq Stock Market informed us of its view that we did not meet continuing listing requirements as a result of the non-independent status of Donald L. Ferguson, a former director of our company. These issues have been resolved and we believe that we are currently in compliance with Nasdaq listing requirements. Although, as of the date of this Report, our shares are still listed on the Nasdaq Capital Market, in the future, 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.

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 National Association of Securities Dealers, Inc. s electronic bulletin board. As a consequence of any such delisting, an event of default may be called under our Laurus notes and, regardless of whether such an event of default is called, a stockholder 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 April 13, 2007, there were 16,682,268 shares of common stock issued and 16,666,777 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, as in the case of our February and May 2005 financings with Laurus, 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. This same principle applies to potential conversions of shares of our Series C Stock.

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) 1,647,059 shares of common stock, issuable upon full conversion of shares of our Series C Stock, (ii) 2,732,787 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $2.96 per share, and (iii) 7,594,129 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $4.27 per share and (iv) 2,085,000 shares underlying our publicly-traded warrants, which expire on June 24, 2007 currently have an exercise price at $6.11 per share (originally $6.30 per share, but adjusted downward because of issuances of our securities at below the market price on the date of the issuance). 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, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one year holding period 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. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a two year holding period. 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, our bylaws and Delaware law contain provisions that preserve our current management.

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

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 early 2005, we relocated our principal executive offices to Arius offices in Morrisville, North Carolina. Arius lease for this approximately 2000 square foot space terminates in September 2007. Rental payments due on this space are: (i) from February 1, 2005 through September 30, 2005, $2,733.50 per month; (ii) from October 1, 2005 through September 30, 2006, $2,816.33 per month; and (ii) from October 1, 2006 through September 30, 2007, $2,900.82 per month. The landlord for this space is Pizzagalli Properties, LLC. We are currently exploring whether this space is adequate as our principal executive office location.

We conduct our research operations a single site located on the campus of UMDNJ. Pursuant to a five year lease agreement with UMDNJ ending December 31, 2005, we occupy a total of approximately 8,000 square feet. The monthly rent was $3,340 in 2001, $3,840 in 2002, $4,340 in 2003, $4,840 in 2004 and is $5,340 in 2005 and 2006 plus agreed payments for graduate student assistants, two of our executives and supplies used by us. The payments to UMDNJ for certain executive salaries totaled approximately $119,880 for 2006. Historically, the payments for rent and supplies have averaged approximately $75,000 annually. Our lease ended December 31, 2005 and we are currently leasing month to month. We are in negotiations to renew the lease. 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.

Item 3. Legal Proceedings.

On or about April 19, 2004, we were 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 us through an initial public offering. We have provided MAS Capital s counsel with copies of documents executed by MAS Capital and its affiliates that we allege fully release us. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that fully release us, 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 our 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 are to proceed until resolution of our counterclaim for attorneys fees and costs and either party could appeal at that point in time. The parties are in the discovery phase with regard to the counterclaim for attorneys fees and costs and no hearing date has yet to be scheduled on said counterclaim. We believe that the plaintiff s claims are without merit and we intend to continue to vigorously defend the lawsuit.

On August 21, 2006, we filed an action in New York State Supreme Court against CDC seeking: (i) to enjoin CDC from filing a Schedule 13D filing with the Securities and Exchange Commission without first giving us an opportunity to review the proposed Schedule 13D filing for potential disclosures of our confidential information in violation of the CDLA and (ii) to compel CDC to adhere to the dispute resolution mechanisms set forth in the CDLA. Our motion for a preliminary junction enjoining the filing of CDC of the Schedule 13D was denied on August 22, 2006.

On August 30, 2006, we delivered to CDC the BDSI Notice pursuant to the CDLA. In the BDSI Notice, 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 the BDSI 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 us 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 granted to CDC under the Securities Purchase Agreement, dated May 16, 2006, between us and CDC. On October 26, 2006, we entered into a stipulation with CDC to settle this case without prejudice pursuant to which we and CDC agreed to follow a procedure regarding the right of first negotiation as modified by the stipulation.

On March 12, 2007, we entered into a Dispute Resolution Agreement (the DRA) with CDC. Pursuant to the DRA, 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 Disputed Matters). The effect of the DRA is that CDC has withdrawn its claims to ownership of our 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 is without prejudice to the Disputed Matters of both ours and CDC. As such, no assurance can be given that CDC will not make similar or additional claims against the Company. Simultaneously with our and CDC s entry into the DRA, we and CDC entered into an amendment to CDLA, us. 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. Under the CDLA, the Company must meet certain conditions or CDC can assume control of the BEMA™ Fentanyl project and related intellectual property assets. Concurrently with the parties negotiation of the DRA, CDC alleged that we had violated CDC s financing right of first refusal (as amended, the ROFN) provided for in the May 2006 Securities Purchase Agreement between the parties. Specifically, in January 2007, CDC alleged by written notice that our December 2006 note deferral agreements with Laurus Master Fund Ltd. (the Laurus Deferral Transaction) triggered the ROFN provisions.

In order for the 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 to a $1.9 million financing with CDC (the New CDC Financing). The New CDC 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 (the New CDC 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 with the Securities and Exchange Commission to register the shares of our common stock underlying the New CDC 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. The New CDC Warrant contains weighted average anti-dilution protection. The proceeds from the New CDC Financing will be used for general corporate purposes and for the continued development of BEMA Fentanyl.

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 and Class A warrants are listed for quotation on the Nasdaq Capital Market under the symbols BDSI and BDSIW respectively. Also, such securities are listed on the Boston Stock Exchange under the symbols BDS and BDS&W. The range of reported high and reported low bid prices per share for our common stock and warrants for each fiscal quarter during 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/Warrant Price Ranges

	Common Stock		Warrants	
Quarter Ended:	**High**	**Low**	**High**	**Low**
March 31, 2006	$ 3.48	$ 1.85	$ 0.79	$ 0.26
June 30, 2006	$ 2.95	$ 1.65	$ 0.47	$ 0.20
September 30, 2006	$ 2.60	$ 1.68	$ 0.42	$ 0.24
December 31, 2006	$ 3.53	$ 1.86	$ 0.35	$ 0.05

As of April 13, 2007, we had approximately 226 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.

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	2,023,704	$ 3.04	1,476,296
Equity compensation plans not approved by security holders	0	$ 0	
Total	2,023,704	$ 3.04	1,476,296

Recent Sales of Unregistered Securities

(a) On April 10, 2007, we entered into a fifth amendment to our May 2005 convertible note with Laurus. Pursuant to the fifth amendment, Laurus agreed: (i) to exercise and 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 $3.2 million to us and (ii) to defer all principal payments under our May 2005 note with Laurus (which currently stands at $1.262 million). 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 a registration statement registering the shares underlying such warrant by May 25, 2007.

(b) On March 12, 2007, we entered into a $1.9 million financing with CDC. 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.

(c) 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. As a result of this transaction, CDC was issued 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 $7 million milestone payable to CDC upon the approval by the FDA of BEMA™ Fentanyl which had been required under the CDLA.

(d) Simultaneously with our entry into a licensing agreement with Sigma-Tau Pharma in January 2005, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of US$250,000 from, Sigma-Tau Finanziaria S.p.A., or 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 filing of product INDs by Sigma-Tau Pharma for one or more of the four subject encochleated compounds. Such additional unregistered shares will be issued at the lesser of: (i) $4.25 and (ii) the average of the closing trade price of our common stock for the ten (10) trading days through and including the applicable payment date, with an absolute floor $3.38 per share. 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 January 2007, we received a second non-refundable payment of US$250,000 from Sigma-Tau. This payment was made in consideration of unregistered shares of our common stock at $4.25 a share.

(e) In August 2004, we entered into an Equity Line Agreement with HCG under which, at our request, HCG will invest up to $4 million in our company in consideration of a newly-created class of preferred stock, the Series B Preferred. The Equity Line Agreement with HCG was amended on March 30, 2006 to extend the commitment period from March 31, 2006 through December 13, 2006. $1.45 million was been drawn on the HCG equity line and the equity line terminated on December 31, 2006. On January 10, 2007, HCG converted all of its Series B Preferred stock into common stock at a value of $4.25 per share. Accrued dividends under the Series B Preferred were converted at the closing market price on January 10, 2007. As a result of the conversion, HCG will receive 400,402 shares of our unregistered common stock. HCG has certain piggyback registration rights with respect to such shares of common stock.

Item 6. 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

Until 2002, we were a development stage company. Our first license agreement was funded in 2003 in the amount of $2 million, and we had an additional license funded in 2004 for $1 million, as part of our acquisition of Arius. We expect to continue research and development of our drug delivery technologies, and while we are seeking additional license agreements, which may include up-front payments, we anticipate nominal royalty revenues from the sale or commercialization of our products under development (other than license fees) during 2007. We anticipate that funding for the next several years will come primarily from the sale of securities, collaborative research agreements, including pharmaceutical companies, grants from public service entities and government entities, and potential exercises of our warrants.

In 2001, the National Institutes of Health awarded us a three-year $2.7 million Small Business Innovation Research Grant, which was fully funded through 2004, and which was utilized in our research and development efforts. We had an additional grant of approximately $0.6 million which was funded through July 2006. No additional funds are available on this grant.

We have a limited history of operations, and while we have received license revenues in 2003, 2004, 2005 and 2006 for licensing our technology, we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future. We believe 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 encountered by companies maturing in commercialization of their technologies, particularly companies in new and rapidly evolving 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 drugs, which may not occur. We may not be able to appropriately address these risks and difficulties. We may require additional funds to complete the development of our technology and to fund expected operations in the next several years.

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. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated period of benefit, ranging from eleven to thirteen years.

Our carrying value of goodwill at December 31, 2006 was $2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements. Our carrying value of other, amortizing intangible assets at December 31, 2006 was $3.88 million, net of accumulated amortization of $.6 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test has two steps. The first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired and the second step is not necessary. If the carrying value exceeds the fair value, the second step calculates the possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded. No goodwill impairment charges have resulted from this analysis for 2006 or 2005.

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 2006 or 2005.

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 the Company s 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 2006, we assumed no dividend yield, risk-free interest rates ranging from 4.5% to 4.7%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor range between 54.5% to 89.5%, share prices ranging from $2.05 to $2.69, and option exercise prices ranging from $2.05 to $2.69.

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.

For the Year Ended December 31, 2006 Compared to the Year Ended December 31, 2005

Sponsored Research Revenue. During the year ended December 31, 2006, we recognized sponsored research revenue of $0.08 million, compared to $0.4 million in the prior year.

License Fee, Milestone and Royalty Revenues. During the year ended December 31, 2006, we recognized license revenue of $2.5 million relating to BEMA Fentanyl. No license revenues were received in 2005. During the year ended December 31, 2005, we recognized milestone revenue of $0.4 million relating to Emezine®. In addition, we recognized $0.07 million and $0.06 million in royalty revenue in 2006 and 2005, respectively, under our license agreement with Accentia relating to CRS.

Research and Development Expenses. During the years ended December 31, 2006 and 2005, research and development expenses totaled $9.3 million and $6.5 million, respectively. Our scientific staff continued to work toward increased development and application of our BEMA and Bioral ® cochleate technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options by directors, sales of securities and funding of an equity line of credit from HCG. 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, 2006 and 2005, general and administrative expenses totaled $5.1 million and $3.6 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, executive personnel costs, consulting fees, and business development costs. Product development cost in 2006 is warrant expense related to a securities purchase agreement. Furthermore, we incurred expenses in 2005 of approximately $0.08 million related to operating activities of our currently inactive Bioral Nutrient Delivery, LLC subsidiary that commenced in 2003. There were no expenses related to this subsidiary in 2006. The increase in general and administrative expenses in 2006 over the prior year is primarily due to increased professional and legal fees incurred in connection with legal due diligence associated with licensing transactions, increased patent costs, stock-based compensation (related to our adoption of FAS 123R), and investor relations.

Product Development Expense. In 2006, we issued 601,120 warrants valued at $0.7 million in connection with the initial $2.0 million deposit transaction with CDC Clinical Development Licensing Agreement for BEMA Fentanyl. We had no such expense in 2005.

Interest Income (Expense), Net. During the year ended December 31, 2006 we had net interest expense of $1.95 million, compared to $1.35 million in 2005. The increase in net interest expense is primarily due to amortization of debt discount and interest paid to Laurus for the two convertible notes. Interest income for years ending 2006 and 2005 was nominal.

Derivative Gain (loss). Derivative loss in 2006 is related to the adjustment of derivative liabilities to fair value as of December 31, 2005 and subsequent changes in fair value in 2006. These derivatives relate to the Laurus financing (see Notes 1and 7 to financial statements) and warrants issued to CDC.

Debt extinguishment (loss). During the year ended December 31, 2006, 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 sale of state tax loss carryforwards. We incurred net operating losses during both years presented, and we did not recognize any benefit associated with these losses. We had federal net operating loss carryforwards of $33.0 million at December 31, 2006 and $25.5 million of state carryforwards. The federal net operating loss carryforwards expire beginning in 2020, if not utilized. We sold New Jersey state tax credits and net operating losses in 2005 of $4.5 million, which generated cash of $0.5 million in 2005. The state operating loss carryforwards expire beginning in 2008, if not utilized. 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.

Major Research and Development Projects

In 2006 and into 2007, we have and will continue to dedicate most of our corporate resources to the development of BEMA Fentanyl, CAMB and BEMA LA. Approximately 85% of our financial resources spent in clinical development in 2006 were on BEMA Fentanyl and the BEMA technology generally. Under the CDLA with CDC, up to $7 million will be made available to us for the development of BEMA Fentanyl. In February 2006, $2 million of this was paid to us and in May 2006, the remaining balance was converted to equity with all $7 million being transferred to us. In part due to the non-approval of Emezine® and the loss of its anticipated revenues, we decided to delay certain projects. As a result, we did not begin the development of BEMA Zolpidem and significantly slowed the development of BEMA LA 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 or not (or 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. The Subunit HIV Vaccine program was previously funded by a NIH grant and did not utilize our corporate resources. We have decided not to pursue the Bioral® NSAID, Bioral® Paclitaxel, or the Autologous HIV Vaccine programs further at this time. Presently, all such opportunities are available for licensing by third parties.

Readers of this Report are advised that the projected dates for filing INDs or 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 best judgments given their previous experiences, but no assurances can be given that such estimates will prove to be accurate.

BEMA Fentanyl. We license 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 and have an option to buy the U.S. rights within 12 months of the non-U.S. purchase. 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 will be able to 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. Due to the nature of treating patients with breakthrough cancer pain, our patient recruitment process for the BEMA Fentanyl clinical program may take anywhere from 6 to 18 months. We project that enrollment will be complete and the results from the Phase III efficacy study will be available by April 2007. At such time, we will be in a better position to project the timing of the submission of our NDA. Recruitment for the safety study required as part of the NDA will continue until we meet the number of patients that the FDA has requested. It is the conclusion of this study that will dictate the timing of the submission of our NDA. When patient recruitment is complete, it will likely take an additional 3 to 6 months, approximately, to submit our NDA. If the FDA accepts the NDA for filing, they will have up to 10 months from the date of

acceptance of filing to render a decision on the approvability of our application. If their decision is positive and an approval letter is granted, we anticipate launching the product within 3 months from the receipt of the approval letter. When the Phase III efficacy results are released in April 2007, we will update the time lines for the entire program including the NDA submission.

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 QLT and to CDC, although no assurances can be given of this estimation. We do not expect to generate any revenue from BEMA Fentanyl, if ever, until at least the second half of 2008.

The risks to our company associated with the BEMA Fentanyl project include: (i) failure to develop an adequate formulation; (ii) claims of CDC against the intellectual property or otherwise; (iii) inability of our contract manufacturer to continue to make clinical supplies; (iv) slow patient enrollment in clinical trials; (v) lack of funding to progress the program; (vi) failure to demonstrate efficacy in clinical trials; (vii) the development of safety issues with the product, (viii) the conclusion by the FDA that the risk benefit is inadequate; (ix) the conclusion by the FDA that our submission is inadequate and additional information is required; and (x) failure to maintain a manufacturer that can meet our commercial supply requirements. The failure of the BEMA Fentanyl project or a failure of the product to meet commercial forecasts would seriously impair our potential future revenues, as well as investor confidence and potentially our public stock price, as we believe it would be the first of our formulations with a significant market opportunity to reach market.

BEMA Long Acting Analgesic (BEMA LA). BEMA LA will be our second BEMA analgesic product after BEMA Fentanyl. We submitted an IND for BEMA LA to the FDA in December 2005 which was accepted by the FDA 30 days later. 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. We plan to move into our Phase II program in which we would be treating patients who have moderate to severe pain in order to determine the optimal dose of BEMA LA. The BEMA LA Phase II program will take approximately 3-12 months to complete depending on the final indication for the patient population we decide to evaluate and agreements with the FDA. If we meet our Phase II objectives, we would then move into our Phase III program, 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 LA 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 LA to participate in the key pain markets (chronic pain, acute pain, post-operative pain), we believe that BEMA LA has the potential to achieve up to a 2% share of the total worldwide pain market which is projected to grow to $33 billion by 2014. This would translate into an estimated $500 million in peak annual sales, on which we will pay a royalty to QLT until the time we exercise the U.S. rights to the BEMA technology, although no assurances can be given to this peak sales estimation. We do not expect to generate any revenue from BEMA LA, if ever, until at least 2010.

The risks to our company associated with the BEMA LA project include: (i) our inability to

develop a final formulation; (ii) the 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, including if the Phase III study does not show efficacy; (vi) if the product encounters safety issues; (vii) if overall composite of data from clinical trials does not support NDA submission; and (viii) even if an NDA is submitted, the failure of the FDA to approve such NDA or a delay in the approval process because the FDA requires additional information. A failure of this product, or a failure of the product to meet commercial forecasts, would have a pronounced effect on our future revenue stream and could also negatively affect investor confidence in our company and potentially our public stock price.

BEMA Zolpidem. This formulation would be our third BEMA product after BEMA Fentanyl and BEMA LA. Based on the progress we make on BEMA Fentanyl and BEMA LA and depending on the level of our corporate resources, we may file an IND on this product during the fourth quarter of 2007, and this 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 2006, we did not expend any resources on our efforts relating to BEMA Zolpidem.

Due to the potential ability of BEMA Zolpidem being able 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 has a projected year 2010 value of $5 billion. This would translate into an estimated $250 million in peak annual sales, on which we will pay a royalty to QLT until we execute the option to purchase the US rights to the BEMA technology, although no assurances can be given to this peak sales estimation. We do not expect to generate any revenue from BEMA Zolpidem, if ever, until at least 2011.

The risks to our company associated with the BEMA Zolpidem project include: (i) our inability to develop a final formulation; (ii) the inability of a contract manufacturer to produce clinical supplies; (iii) if the 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, including if the Phase III study does not show efficacy; (vii) if the product encounters safety issues; (vii) if overall composite of data from clinical trials does not support NDA submission; and (ix) even if an NDA is submitted, the failure of the FDA to approve such NDA or a delay in the approval process because the FDA requires additional information. A failure of this product, or a failure of the product to meet commercial forecasts, would have a pronounced effect on our future revenue stream and could also negatively affect investor confidence in our company and potentially our public stock price.

Bioral® Amphotericin B. We license the encochleation drug delivery technology which we use in our Amphotericin B formulation from the Universities. We filed the IND on this oral formulation of amphotericin, for the treatment fungal infections including esophageal candidiasis in the fourth quarter 2006. The IND was accepted by the FDA. Finances permitting, we intend to begin Phase I studies in normal volunteers in late 2007. 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 sometime in the late 2007 and Phase III trials in 2008. 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 time frame 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 based on an indication for the treatment of 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, although no assurances can be given of meeting this estimation. We do not anticipate generating any revenue for CAMB, if ever, until at least late 2010.

The risks to our company associated with the CAMB project include: (i) if the FDA fails to accept the IND upon first submission; (ii) the inability of a contract manufacturer to produce clinical supplies; (iii) Phase I studies do not show significant oral absorption of product; (iv) failure of clinical trials, including if the Phase II study shows drug is ineffective in treating the fungal infection in question; (v) if the product encounters safety issues; and (vi) lack of corporate funding to progress the program. Of the four major programs to which we are currently dedicating material 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 upside 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 serious impact on long term corporate revenue and could also negatively affect other encochleation projects and investor confidence in our company (and potentially our public stock price) generally, as CAMB is our lead Bioral® product and is likely viewed as a way to validate the broader encochleation concept.

Emezine®. We are the exclusive U.S. licensee of Emezine®, a transmucously delivered formulation of prochlorperazine, an anti-emetic product used for treating nausea and vomiting which occurs after surgeries and chemotherapy. Arius licensed Emezine® from Reckitt and we acquired this license with the Arius acquisition in August 2004.

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. In May 2006, we met with the FDA to discuss their issues with the NDA package. As a result of the meeting, we submitted a revised program including two PK studies under a Special Protocol Assessment (SPA). Under the SPA, an agreement is reached with the FDA to what specifically must be done to achieve the endpoints needed to gain approval. As of the date of this Report, we have not made a final decision to the direction we intend to pursue regarding Emezine®. No assurances can be given that we will be able to satisfy any concerns the FDA may have regarding Emezine® or that we will have the corporate resources to do so. Therefore, we may be forced to abandon the Emezine® project and any revenues that we had hoped to generate from Emezine® would not be achieved.

If ultimately approved by the FDA, of which no assurances can be given, we anticipate an approximate 3 month period before our marketing partner, Accentia Pharmaceuticals, will have the product in the various distribution channels for sale. This 3 month period is used to distribute product samples, provide sales training to sales staff and prepare final marketing and advertising materials based on the final labeling the FDA allows for the product. Reckitt will be responsible for manufacturing the product for distribution in the U.S.

Based on our market research, we believe that Emezine® may be able to achieve peak sales of

approximately $30 million annually, on which we will receive a royalty from Accentia Pharmaceuticals, our commercialization partner (and on which we will pay a royalty to Reckitt), although no assurances can be given of this estimation.

The risks to our company associated with the Emezine® project include: (i) failure to receive FDA approval or significant delay in the approval process because the FDA requires additional information; (ii) if Reckitt, our manufacturing partner, fails to fulfill its obligations under their licensing and supply agreement with us; (iii) if Accentia, our commercial partner, fails to fulfill their contractual obligations to us (including funding obligations) and (iv) if the product fails to meet sales forecasts. However, 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, we do not presently believe that the failure of this project, though damaging to our market reputation and our stock price, among other matters, would seriously impair our overall potential future revenue growth.

Liquidity and Capital Resources

Since inception, we financed our operations primarily from the private sales of our convertible preferred stock, convertible debt and common stock, our initial public offering, the follow-on offering in 2005, exercise of options, various strategic and licensing agreements (including the CDLA), NIH grants, bank financing, and through the sale of a royalty stream asset to Accentia. At December 31, 2006, we had cash and cash equivalents of $2.2 million. The adequacy of cash for our operations in continued research is dependent on, among other things, licensing and additional equity or debt financing opportunities we are able to negotiate in the coming year.

We used $9.7 million of cash for operations in of the year ended December 31, 2006. This resulted from a net loss of $20 million, which included non-cash charges of $9.3 million.

In September 2004, we entered into an Equity Line of Credit Agreement with HCG, an affiliated entity which is controlled and partially-owned by our Chairman, Pursuant to the Equity Line Agreement, as amended March 30, 2006, HCG will, as requested by us, 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 has been 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 any time as of or after April 1, 2006, or earlier upon a change of control of our company, in each case at a price equal to $4.25 per share. The Series B Preferred ranked senior to our common stock and our Series A Preferred Stock and had certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. Additionally, we had the right, in our discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. Finally, HCG had no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

On January 10, 2007, HCG 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 also acquired 59,226 shares of common stock pursuant to the conversion of accrued and unpaid dividends on the Series B Preferred Stock. In February 2007, all of the shares of our Series A Preferred Stock were exchanged with the holders thereof for shares of newly designated Series C Non-Voting Convertible Preferred Stock. The rights associated with the Series C Stock are identical to those associated with the Series A Stock in all material respects except that the Series C Stock has different terms of conversion into shares of our common stock.

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. As a result of this transaction, CDC was issued 2 million shares of our common stock and 904,000 warrants at $3.50 in return for accelerating the funding of the $4.2 million balance of $7 million of aggregate commitment under the CDLA and for eliminating the $7 million milestone payable to CDC upon the approval by the FDA of BEMA™ Fentanyl which had been required under the CDLA.

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 BDSI 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. Sigma-Tau, through other holding entities, is currently a stockholder of BDSI. In addition to the milestone payments, BDSI will receive a royalty on future sales of each of the four products which may arise from the encochleated compounds. In January 2007, under our development agreement with Sigma Tau, we were paid a milestone payment of $.25 million for which we issued 73,964 shares of common stock at $3.38.

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. We also used approximately $0.3 million from the February Laurus financing to retire our secured equipment bank loan with Gold Bank in connection with the closing. The February 2005 Laurus debt has been fully converted into shares of our common stock. The balance of the May 2005 Laurus Note ($1.262 million) is due as of the first business day of July 2008.

We have incurred significant net losses and negative cash flows from operations since our inception. As of December 31, 2006, we had stockholders deficit of $6.2 million, versus $5.4 million at December 31, 2005.

We anticipate that cash used in operations and our investment in facilities will increase significantly in the future as we research, develop, and, potentially, manufacture our proposed drug formulations. 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, and not on the marketing, production or sale of FDA approved products.

Our existing cash and cash equivalents, together with available financing, including the remaining balances of our existing equity line of credit and grant, and potential new license revenue, is considered by our management to be sufficient to finance the planned basic operations (minimal research and development activities) and capital expenditures into approximately the first quarter of 2008. Additional capital will be required in order to proceed with our expanded BEMA™ Fentanyl development activities, the scale of which is dependent on the BEMA™ Fentanyl Phase III efficacy study results which is expected in April 2007. 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

redemption and/or exercise of existing public 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.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of December 31, 2006 are as follows;

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-term and short-term debt	$ 5,305,761	$ 1,000,000	$ 4,305,761	$	$
Leases	47,258	33,799	13,459		
Employment agreements	2,400,000	800,000	1,600,000		
Total contractual cash obligations	$ 7,753,019	$ 1,833,799	$ 5,919,220	$	$

Off Balance Sheet Arrangements

We are not a party to any balance sheet arrangements.

Item 7. 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 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 8A. Controls and Procedures.

Our Chief Executive Officer and Chief Financial Officer, referred to in this context as the certifying officers, are responsible for establishing and maintaining our disclosure controls and procedures. Such officers have concluded (based on their evaluation of these controls and procedures as of a date within 90 days of the filing of this Report) that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in this Report is accumulated and communicated to our management, including our principal executive officers as appropriate, to allow timely decisions regarding required disclosure. The certifying officers also have indicated that there were no significant changes in our internal controls or other factors that could significantly affect such controls subsequent to the date of their evaluation, and there were no corrective actions with regard to significant deficiencies and material weaknesses.

We are continuing the process to complete a thorough review of our internal controls as part of its preparation for compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires our management to report on, and our external auditors to attest to, the effectiveness of our internal control structure and procedures for financial reporting. As a non-accelerated filer under Rule 12b-2 of the Exchange Act, our first report under Section 404 will be contained in our Form 10-KSB for the fiscal year ended December 31, 2007.

PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance With Section 16(a) of the Exchange Act.
Our directors and executive officers and their ages as of April 13, 2007 are as follows:

Name	Age	Position(s) Held
Francis E. O Donnell, Jr., M.D.	57	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	53	President, Chief Executive Officer and Director
Raphael J. Mannino, Ph.D.	60	Executive Vice President, Chief Scientific Officer and Director
Andrew L. Finn, Pharm.D.	57	Executive Vice President of Product Development
James A. McNulty	56	Chief Financial Officer, Secretary and Treasurer
William B. Stone	63	Director
John J. Shea	80	Director
William S. Poole	60	Director
Thomas W. D Alonzo	63	Director

There are no family relationships between any director, executive officer, or person nominated or chosen to become a director or executive officer.

Francis E. O Donnell, Jr., M.D., age 57, 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. which now includes Tatton Technologies, LLC, and a co-founder of Biotech Specialty Partners, LLC, an alliance of specialty pharmaceutical and biotechnology companies. 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 53, was appointed President and Chief Executive Officer in July of 2005. This followed his appointment as President and Chief Operating Officer in January 2005. He joined the company in August 2004 upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder and Chief Executive Officer, in the capacity of Senior Vice President of Commercialization and Corporate Development, and, prior to being named our President, was promoted to Executive Vice President, Corporate and Commercial Development and 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 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 60, 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 57, has been our Executive Vice President of Product Development since January 2007. He joined the company in August 2004 upon our acquisition of Arius, of which he was a co-founder, in the capacity of Senior Vice President of Product Development and was subsequently promoted to the position of Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn has more than 20 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 56, 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. 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 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 63, is a member of our board of directors. For thirty years, until his retirement in October 2000, Mr. Stone was employed with Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and Chief Information Officer for 16 years and 4 years, respectively. 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 80, 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 John J. Shea Associates 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.

Thomas W. D Alonzo, 63, 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 to 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 to 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 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 the rules of the National Association of Securities Dealers, or NASD.

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 each operate under a charter that has been approved by the board.

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. 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.

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-B. The Audit Committee met five times during 2006. 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 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 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-KSB 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. Mr. Shea was named chairman of this committee on August 22, 2005. T he 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 2006, although members of the committee were involved with interviews of Mr. D Alonzo prior to his joining the board of directors in September 2006. 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 NASD. 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 2006, we did not pay any fees to any third parties to assist in the identification of nominees. During 2006, 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. The members of the compensation committee are William B. Stone and William S. Poole, who was named chairman of this committee effective August 22, 2005 (replacing Dr. O Donnell). The compensation committee met one time during 2006.

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 Stone. The investment committee as such did not meet during 2006.

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 2006, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons.

Code of Ethics

On March 24, 2003 our board of directors adopted a code of ethics that applies to our principal executive and financial officers. We intend to file amendments, changes or waivers to the code of ethics as required by SEC rules.

Item 10. Executive Compensation.

The following table sets forth information concerning all compensation paid to our named executive officers for services rendered during our fiscal year ended December 31, 2006, 2005 and 2004.

SUMMARY COMPENSATION TABLE*

		Annual Compensation[1]			Long Term Compensation Awards		Payouts	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)
Name and Principal Position	**Year**	**Salary ($)**	**Bonus ($)**	**Other Annual Compensation ($)**	**Restricted Stock Award(s) ($)**	**Securities Underlying Options/ SARs (#)**	**LTIP Payouts ($)**	**All Other Compensation ($)**
Mark A. Sirgo, Pharm.D.	2006	$ 252,617				37,730		
	2005	202,366				77,929		
President and Chief Executive Officer	2004	62,596	31,177			5,147		
1203 Clematis Street								
Knightdale, NC 27545								
Andrew L. Finn, Pharm.D.	2006	$ 223,902				15,603		
	2005	192,471				57,929		
Executive Vice President of Product Development	2004	62.596	28,092			5,147		
200 Royal Kings Lane								
Raleigh, NC 27615								
James A. McNulty,	2006	$ 109,355				15,603		
	2005	113,670				36,189		
Chief Financial Officer, Secretary and Treasurer	2004	105,866				3,235		
4419 W. Sevilla Street								
Tampa, FL 33629								
Raphael J. Mannino, Ph.D [2],	2006	$ 97,841		11,123		34,894	$	
	2005	97,171		11,250		30,714		3,543
Executive Vice President and Chief Scientific Officer	2004	88,788		11,423		26,176		5,015
518 Lannon Lane								
Glen Gardner, NJ 08826								
Francis E. O Donnell, Jr., M.D.	2006	$				25,000		
	2005					25,000		
Chairman and Director	2004	117,962				35,000		
709 The Hamptons								
Chesterfield, MO 63017								

* Salary reflects total compensation paid to these executives.

(1) Except as reflected in column (e) with respect to Dr. Mannino, the annual amount of perquisites and other personal benefits, if any, did not exceed the lesser of $50,000 or 10% of the total annual salary reported for each named executive officer and has therefore been omitted.

(2) Includes: (a) a car allowance of $6,500 and 401(k) matching of $4,623 paid in 2006 as reflected in column (e) and (b) premiums paid on key-man life insurance has set forth in column (i). Excludes $120,000, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2006 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

Option Grants During Year Ended December 31, 2006

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term	
	(a)	(b)	(c)	(d)	(e)	(f)	(g)
Name	Number of Securities Underlying Options/ SARs Granted(#)	Percent of Total Options/ SARs Granted to Employees in Fiscal Year	Exercise or Base Price ($/Sh)	Expiration Date	5%($)	10%($)
Mark A. Sirgo	37,730	8%	$ 2.05	7/27/2016	$ 48,294	123,377
Andrew L. Finn	15,603	3%	$ 2.05	7/27/2016	$ 19,972	$ 51,022
James A. McNulty	15,603	3%	$ 2.05	7/27/2016	$ 19,972	$ 51,022
Raphael J. Mannino	34,894	7%	$ 2.05	7/27/2016	$ 44,664	$ 114,103
Francis E. O Donnell, Jr.	25,000	5%	$ 2.05	7/27/2016	$ 32,000	$ 81,750

AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR

AND FY-END OPTION/SAR VALUES

Name (a)	Shares Acquired On Exercise(#) (b)	Value Realized($) (c)	Number of Securities Underlying Unexercised Options/SARs At Fiscal Year-End(#) Exercisable Unexercisable (d)	Value of Unexercised Unexercisable In-The-Money Options/SARs At Fiscal Year-End($) Exercisable Unexercisable (e)
Mark A. Sirgo, Pharm.D.			62,740 /58,066	31,157 / 26,927
Andrew L. Finn, Pharm.D.			22,740 /55,939	3,357 /24,502
James A. McNulty			32,834 /40,809	2,716 / 23,219
Raphael J. Mannino, Ph.D.			214,560 /24,096	170,093 / 18,765
Francis E. O Donnell, Jr., M.D.			146,991	66,250

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. 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.

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 twice 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. 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 2 times the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary. 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. 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 2 times the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary. 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 Although he is a part-time CFO, Mr. McNulty 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. Under his employment agreement, Mr. McNulty is required to spend no less than 50% of his working time on company matters. Mr. McNulty is also employed by Accentia Biopharmaceuticals, Inc. Under the terms the agreement, Mr. McNulty will receive base salary of $114,000 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 1.5 times the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary. 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 1.5 times the sum of his then current annual base salary plus an amount equal to fifty percent (50%) of his then current annual base salary. 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).

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 2,023,704 shares of common stock are outstanding as of December 31, 2006 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. 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 8,604,469 shares of our common stock at prices ranging from $1.63 to $17.48 are outstanding at December 31, 2006. None of our options have been granted at less than 85% of the fair market value at the time of grant. Options issued during 2006 to employees and directors totaled 484,624 shares, at exercise prices ranging from $2.05 and $2.69. In addition, during 2006, we issued warrants to purchase 1,643,000 shares of common stock at an exercise price ranging from $3.00 and $3.50 to Laurus related to the principal note payment deferral and stale registration statement. We issued warrants to purchase 601,120 and 904,000 shares of common stock at an exercise price of $2.91 and 3.00 respectively to CDC in conjunction with a license agreement with them. We also issued warrants to purchase 2,500 shares of common stock at an exercise price of $2.90 to a law firm in consideration of delayed payment.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth, as of April 13, 2007, 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., 2501 Aerial Center Parkway, Suite 205, Morrisville, North Carolina 27560.

Name of Beneficial Owner	Number of Shares of Common Stock Owned[1]	Percentage of Class as of April 13, 2007
Hopkins Capital Group II, LLC [2]	3,711,982	22.3%
Francis E. O Donnell, Jr., M.D.[3]	4,040,014	24.2%
The Francis E. O Donnell, Jr. Irrevocable Trust #1[4]	3,879,482	23.3%
CDC IV, LLC [5]	3,505,120	21.0%
Laurus Master Fund. Ltd. [6]	832,000	4.99%
Mark A. Sirgo, Pharm.D. [7]	97,836	*
Andrew L. Finn, Pharm.D. [8]	35,412	*
Raphael J. Mannino, Ph.D. [9]	362,598	2.2%
James A. McNulty [10]	120,574	*
William B. Stone [11]	185,000	*
John J. Shea [12]	140,000	*
William S. Poole [13]	75,000	*
Thomas D Alonzo[14]	30,000	*
All Directors and Officers as a group (9 persons)	5,086,164	30.5%

* Less than 1%

(1) Based on 16,666,777 shares of common stock outstanding as of April 13, 2007.

(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) and 45,767 shares of common stock, owned by his wife, as to which Dr. O Donnell disclaims beneficial interest. 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 120,000 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 3,306,406 shares of common stock are issuable upon full conversion or exercise, as the case may be, of our February and May 2005 notes and warrants and our June and December 2005 and December 2006 warrants with Laurus. However, the terms of the convertible notes and warrants issued by us to Laurus provide that Laurus is not entitled to receive shares upon exercise of the warrants, upon payment of principal and interest on the notes, or upon conversion of the notes if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% 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 19,800 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Dr. Sirgo also owns 797,414 shares of our Series C Convertible Preferred Stock, of which none are presently convertible into shares of our common stock. Includes options to purchase 78,036 shares of common stock, all of which are currently exercisable. Excludes options to purchase 522,661 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. Dr. Finn owns 797,414 shares of our Series C Convertible Preferred Stock, of which none are presently convertible into shares of our common stock. Includes options to purchase 35,142 shares of common stock, all of which are currently exercisable. Excludes options to purchase 180,746 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 152,609 shares owned and options to purchase 209,989 shares of our common stock, all of which are currently exercisable. Excludes options to purchase 45,802 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 74,083 shares owned and options to purchase 44,203 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. Excludes options to purchase 163,549 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 150,000 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 10,000 shares owned and options to purchase 130,000 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 5,000 shares owned and options to purchase 70,000 shares of our common stock, all of which are currently exercisable. Mr. Poole s address is 7813 Hardwick Drive, Raleigh, NC 27615.

(14) Mr. D Alonzo is a Director. Includes options to purchase 30,000 shares of our common stock, all of which are currently exercisable. Mr. D Alonzo s address is 9048 Falling Leaf Drive, Bonita Springs, FL 34135.

Item 12. Certain Relationships and Related Transactions.

We have several business relationships with Accentia and its affiliates. HCG, 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. James A. McNulty, our Secretary, Treasurer and part-time 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. McNutty is also the CFO of HCG and Biovest International.

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 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 is a specialty pharmaceutical company and 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.

Analytica International Market Studies. During 2004, Analytica International, a provider of research, commercialization, and communications services to the pharmaceutical and biotechnology industries and a subsidiary of Accentia, performed two market studies for us. We paid Analytica $47,800 for these reports, some of which we paid in 2005.

On April 2, 2007, we obtained a $1.0 million financing from HCG 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, we granted HCG the right, for a period of six months, to enter into a royalty purchase agreement with us. The consideration to be paid by HCG upon exercise of the right, which can be demanded by us or HCG in our respective discretion at any time before September 30, 2007, is $5.0 million in cash. If the royalty purchase agreement is entered into, the royalty to be paid to HCG shall be based on a low, single digit, tiered percentage of net sales of BEMA™ Fentanyl, once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, we would issue 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). No assurances can be given the either we or HCG will elect to enter into the royalty purchase agreement.

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, 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.

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 NASD 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 13. Exhibits and Reports on Form 8-K.

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 requested 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 requested 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 requested 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 requested 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 requested 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 requested 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 requested 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 requested 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 (*)+
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 (*)
10.124	Promissory Note, dated April 2, 2007, by the Company in favor of Hopkins Capital Group II, LLC (47)+
10.125	Fifth Amendment to May 31, 2005 Laurus Master Fund, Ltd. financing documents, dated April 10, 2007 (*)
10.126	Common Stock Purchase Warrant, dated April 10, 2007, issued by the Company in favor of Laurus Master Fund, Ltd. (*)
10.127	Second Amended and Restated Registration Rights Agreement, dated April 10, 2007, between the Company and Laurus Master Fund, Ltd. (*)

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.

\+ Confidential treatment is requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.

(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-KSB/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-KSB/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-KSB, 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.
* Filed herewith.
+ Confidential treatment is requested for portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.

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, 2006 and 2005 and the review of the financial statements included in our Forms 10-QSB respectively, $100,400 and $59,195. 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, 2006 and 2005 were $6,800 and $52,360, 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, 2006 and 2005 were $16,766 and $16,554, 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, 2006 and 2005 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 2005. 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 or their designee has been designated by the Audit Committee to approve any services arising during the year that were not pre-approved by the 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.

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 sheet of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2006, and the related consolidated statements of operations, stockholders deficit, and cash flows for each of the two years in the period 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 auditing 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, 2006, and the consolidated results of their operations and their cash flows for each of the two years in the period then ended in conformity with accounting principles generally accepted in the United States of America.

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

Tampa, Florida

April 16, 2007

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

DECEMBER 31, 2006

ASSETS	
Current assets:	
Cash and cash equivalents	$ 2,172,104
Accounts receivable	42,118
Due from related party	8,523
Prepaid expenses and other current assets	180,863
Total current assets	2,403,608
Equipment, net	379,654
Goodwill	2,715,000
Other intangible assets:	
Licenses	2,442,171
Acquired product rights	2,000,000
Accumulated amortization	(561,767)
Total other intangible assets	3,880,404
Other assets	463,268
Total assets	$ 9,841,934
LIABILITIES AND STOCKHOLDERS DEFICIT	
Current liabilities:	
Note payable	$ 1,000,000
Accounts payable and accrued expenses	2,032,765
Due to related party	1,001,177
Deferred revenue	70,360
Dividends payable	152,803
Derivative liability	7,795,931
Total current liabilities	12,053,036
Convertible notes payable	4,003,250
Total liabilities	16,056,286
Commitments and contingencies (Notes 6 and 12)	
Stockholders deficit:	
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, issued and outstanding	3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized,14,048,637 shares issued; 14,033,146 shares outstanding	14,049
Additional paid-in capital	32,132,609
Treasury stock, at cost, 15,491 shares	(47,183)

Accumulated deficit	(43,469,710)
Total stockholders deficit	(6,214,352)
Total liabilities and stockholders deficit	$ 9,841,934

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2006 AND 2005

	2006	2005
Sponsored research revenues	$ 75,717	$ 364,225
Milestone and royalty revenues, related parties	65,061	422,342
License fees, European	2,500,000	
Research fees	135,000	62,995
	2,775,778	849,562
Expenses:		
Research and development	6,718,638	5,526,833
Related party research and development	2,550,058	937,029
Product development	746,591	
General and administrative	4,947,506	3,533,286
Related party general and administrative	124,505	66,835
	15,087,298	10,063,983
Loss from operations	(12,311,520)	(9,214,421)
Other income, net	7,663	
Other expense:		
Sale of tax loss carryforwards		451,590
Interest expense, net	(1,948,264)	(1,345,496)
Derivative gain (loss)	(1,013,142)	28,930
Loss on extinguishment of debt	(4,629,946)	
	(7,591,352)	(864,976)
Net loss	(19,895,209)	(10,079,397)
Preferred stock dividends	(65,250)	(65,250)
Loss attributable to common stockholders	$ (19,960,459)	$ (10,144,647)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (1.49)	$ (1.21)
Weighted average common stock shares outstanding:		
Basic and diluted	13,435,091	8,353,346

See notes to consolidated financial statements.

SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2006 AND 2005

	Series A Preferred Stock		Series B Preferred stock							
	Shares	Amount	Shares	Amount	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity
Balances, January 1, 2005	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,245,863	$ 7,246	$ 14,619,701	$ (303,894)	($ 13,495,104)	$ 5,983,832
Stock-based compensation							11,724			11,724
Conversion of notes payable to common stock					70,000	70	171,430			171,500
Issuance of treasury stock							(99,711)	256,711		157,000
Shares issued for cash, net of offering costs					4,512,774	4,513	7,901,253			7,905,766
Reclassification of equity to derivative liability							(624,593)			(624,593)
Reclassification of derivative liability to equity							1,610,929			1,610,929
Issuance of warrants for financing costs							305,685			305,685
Series B Preferred Dividends							(65,250)			(65,250)
Net loss									(10,079,397)	(10,079,397)
Balances, December 31, 2005	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 expense							51,205			51,205
Conversion of notes payable to common stock					213,363	213	522,524			522,737

Expense paid through the issuance of 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									(19,895,209	(19,895,209)
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)	($ 43,469,710)	($ 6,214,352)

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2006 AND 2005

	2006	2005
Operating activities:		
Net loss	$ (19,895,209)	$ (10,079,397)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of treasury stock		57,000
Expenses paid through the issuance of common stock	20,775	
Expenses paid through the issuance of warrants	988,185	
Depreciation	277,569	281,392
Amortization of deferred finance costs and intangible assets	795,321	435,950
Accretion of interest on convertible debentures	1,044,203	1,054,846
Derivative loss (gain)	1,013,142	(28,930)
Loss on extinguishment of debt	4,629,946	
Stock-based compensation expense	576,627	31,725
Changes in assets and liabilities:		
Prepaid expenses and other assets	30,580	31,392
Accounts payable and accrued expenses	837,970	558,883
Deferred revenue		(52,950)
Net cash flows from operating activities	(9,680,891)	(7,710,089)
Investing activities:		
Purchase of equipment	(9,546)	(33,776)
Purchase of intangible assets	(1,000,000)	
Net cash flows from investing activities	(1,009,546)	(33,776)
Financing activities:		
Proceeds from issuance of common stock and sale of warrants	7,000,900	8,163,322
Offering cost paid from issuance of Common Stock and Sale of Warrants	(25,000)	(257,556)
Proceeds from convertible debentures		5,000,000
Proceeds from (repayment of) related party borrowings	971,906	(156,265)
Cash paid for loan costs		(507,500)
Payment on notes payable		(333,333)
Net cash flows from financing activities	7,947,806	11,908,668
Net change in cash and cash equivalents	(2,742,631)	4,164,803
Cash and cash equivalents at beginning of year	4,914,735	749,932
Cash and cash equivalents at end of year	$ 2,172,104	$ 4,914,735

See notes to consolidated financial statements

SUPPLEMENTAL CASH FLOW INFORMATION

The Company paid interest of $0.5 million and $0.3 million during 2006 and 2005, respectively.

Non-cash Financing and Investing activities

The Company accrued $0.07 million and $0.07 million in annual cumulative dividends in connection with its Series B Preferred stock during 2006 and 2005 respectively.

The Company converted $522,737 and $171,500 of convertible notes payable through the issuance of 213,363 and 70,000 shares of common stock during 2006 and 2005 respectively.

The Company reclassified derivative liabilities of $221,667 and $1,610,929 from debt to equity during 2006 and 2005 respectively.

During 2005, the Company reclassified the $624,593 fair value of a beneficial conversion option from equity to liabilities at the point that the conversion price became variable.

During 2005, the Company issued common stock warrants for $305,685 of deferred financing costs.

During 2006, the Company issued common stock warrants of $51,205 for product development costs.

The Company purchased certain intangible assets for $2,000,000, including a $1,000,000 promissory note during the year ended December 31, 2006.

See notes to consolidated financial statements.

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, anxiety, nausea and vomiting, 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:

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.

License fees are payments for the initial license of and access to the Company s technology. For nonrefundable license fees received at the initiation of license agreements for which the Company as an ongoing research and development commitment, the Company defers these fees and recognizes them ratably over the period of the related research and development.

In addition to license fees, the Company may also generate revenue from time to time in the form of milestone payments. Milestone payments are only received and recognized as revenues if the specified milestone is achieved and accepted by the customer and continued performance of future research and development services related to that milestone are not required. The Company, for arrangements where non-refundable upfront fees

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

exist and there are further payments due upon achieving certain milestones, recognizes such revenue pursuant to Emerging Issues Task Force 00-21, Revenue Arrangements with Multiple Deliverables, whereby multiple deliverables are evaluated to determine whether such deliverables should be considered a single unit of accounting.

Research and development:

Research and development expenses are charged to operations as incurred. Research and development expenses principally include contractor research, consulting fees and testing of compounds under investigation, and salaries and benefits of employees engaged in research and development activities.

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:

Other intangible assets include licenses and noncompete agreements, which are accounted for based on Financial Accounting Standard Statement No. 142 Goodwill and Other Intangible Assets (FAS 142).

The Company periodically reviews intangible assets and equipment 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 or equipment in 2006 or 2005.

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

	Estimated Useful Lives
Licenses	13 years
Product rights	11 years

The Company incurred amortization expense of other intangibles of $414,160 and $435,950 for the years ended 2006 and 2005 respectively. Estimated aggregate future amortization expenses for other intangible assets with finite lives for each of the next five years and thereafter are as follows:

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

Year ending December 31,	
2007	366,279
2008	366,279
2009	366,279
2010	366,279
2011	366,279
Thereafter	2,049,009
	$ 3,880,404

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 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 2006 or 2005.

Other assets

Other assets consist of deferred finance costs.

Deferred finance costs will be amortized over the term of the related financial instrument. Approximate future amortization of deferred finance costs are as follows:

Year ending December 31,	
2007	$ 381,176
2008	82,092
	$ 463,268

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.

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:

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

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

	2006	2005
Numerator:		
Net loss attributable to common stockholders	$ (19,960,459)	$ (10,144,647)
Denominator:		
For basic loss per share weighted average shares	13,435,091	8,353,346
Effect of dilutive securities		
Weighted average shares for dilutive loss per share	13,435,091	8,353,346
Net loss per share attributable to common stockholders, basic and dilutive	$ (1.49)	$ (1.21)

The effect of common stock equivalents are not considered in the calculation of diluted loss per share because the effect would be anti-dilutive. They are as follows:

	2006	2005
Options and warrants to purchase common stock	8,604,469	5,615,740
Preferred stock convertible to common stock	1,988,235	1,988,235
Convertible debt	1,757,453	1,970,694

Stock-based compensation:

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (FAS 123(R)) using the modified-prospective-transition method. Under this transition method, employee compensation cost in 2006 includes cost for options granted prior to but not vested as of December 31, 2005, and options vested in 2006. Therefore, results for prior periods have not been restated.

The adoption of SFAS No. 123(R) lowered net income by approximately $0.6 million for the year ended December 31, 2006, compared to continued accounting for share-based employee compensation using the intrinsic value method under APB No. 25, Accounting for Stock Issued to Employees.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 in the year ended December 31, 2005. For the purposes of this pro forma disclosure, the value of the options is estimated using a Black-Scholes option-pricing model and amortized to expense over the options vesting periods.

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

	Year ended December 31, 2005
Loss-attributable to common stockholders, as reported	$ (10,144,647)
Stock-based employee compensation, as reported	11,724
Stock-based employee compensation under fair value method	(721,244)
Pro forma loss attributable to common stockholders under fair value method	$ (10,854,167)
Loss attributable to common stockholders basic and diluted:	
As reported	$ (1.21)
Pro forma under fair value method	$ (1.30)

As of December 31, 2006, there was approximately $820,000 of unrecognized compensation cost related to unvested share-based compensation awards granted. That cost is expected to be recognized over the next three years. Options were granted to certain employees during July 2006 at prices equal to the market value of the stock on the dates the options were granted. The options granted have a term of 10 years from the grant date and granted options for employees vest ratably over a three year period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the option and each vesting date. The Company has estimated the fair value of all stock option awards as of the date of the grant by applying the Black-Scholes pricing valuation model. The application of this valuation model involves assumptions that are judgmental and sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted during the periods ended December 31, 2006 and 2005 are as follows:

	Year ended December 31, 2006	Year ended December 31, 2005
Expected price volatility	62.78%	75.00%
Risk-free interest rate	5.00%	5.00%
Weighted average expected life in years	6 years	5 years
Dividend yield	0	0

Fair value of financial instruments:

Fair value of cash and cash equivalents, accounts receivable, due from related party and accounts payable approximate their carrying amount due to their short maturity. The fair value of the convertible notes payable approximates the carrying value due to the adjustment of the carrying value to fair value in December 2006 as the result of the debt extinguishment discussed in Note 7. Notes payable and due to related party carrying value approximate fair value due to the short term nature of these liabilities.

The Company evaluates each of its financial instruments to determine if such instruments

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

qualify as derivative instruments in accordance with FASB Statement No. 133 Accounting for derivative instruments and hedging activities and EITF 00-19, Accounting for derivative financial instruments indexed to, and potentially settled in, a Company s own stock .

The Company estimates fair values of derivative financial instruments using various techniques (and combinations thereof) that are considered to be consistent with the objective of measuring fair values. In selecting the appropriate techniques(s), management considers, among other factors, the nature of the instrument, the market risks that it embodies and the expected means of settlement. The Company generally uses the Black-Scholes option valuation technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary to fair value instruments. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the Company s trading market price which has high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company s income will reflect the volatility in these estimate and assumption changes.

The following tabular presentation reflects the components of derivative financial instruments on the Company s balance sheet at:

	Number of shares into which derivative liability can be settled	
Embedded derivative instruments that have been bifurcated	1,757,453	$ 1,993,655
Freestanding derivatives (principally warrants)	2,313,394	5,802,276
	4,070,847	$ 7,795,931

Derivative income (expense) in the accompanying statement of operations is related to the individual derivatives as follows:

	Year Ending December 31,	
	2006	2005
Embedded derivative instruments	($ 702,201)	($ 294,344)
Freestanding derivatives (principally warrants)	(310,941)	323,274
	($ 1,013,142)	$ 28,930

Recent accounting pronouncements

The Financial Accounting Standards Board (FASB) has recently announced a new interpretation, FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which will be effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes . FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 is not expected to result in any changes to the beginning stockholders deficit and the Company s financial position.

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

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157). SFAS 157 clarifies the definition of fair value, describes methods used to appropriately measure fair value, and expands fair value disclosure requirements. This statement is effective for fiscal year beginning after November 15, 2007. The Company is currently in the process of assessing the impact that SFAS 157 will have on the consolidated financial statement.

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities . SFAS 159 permits entities to choose to measure financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The decision to elect the fair value option may be applied instrument by instrument, is irrevocable, and is applied to the entire instrument and not to only specified risks, specific cash flows or portions of that instrument. An entity is restricted in choosing the dates to elect the fair value option for an eligible item. Adoption of SFAS 159 is effective for the Company on January 1, 2008. Early adoption is permitted, provided the entity also elects to apply the provisions of SFAS 157, Fair Value Measurements . Management of the Company is currently evaluating the potential impact of SFAS 159 on the Company s financial condition, results of operations, and liquidity.

2. Bioral Nutrient Delivery, LLC corporate structure:

On January 8, 2003, the Company formed BND as a majority-owned subsidiary. BND presently has two classes of equity interests: Class A Shares and Class B Shares. As of the date of this report, BDSI owns approximately 94.5% of BND s Class B Shares and all 708,587 of BND s Class A Shares.

During 2003, BND filed a registration statement on Form SB-1 on behalf of BDSI. In connection therewith, the Company made plans to distribute to BDSI stockholders 3,545,431 of BND s Class B Shares, or approximately 43% of BND s outstanding equity interests, including the Class A Shares. After having reevaluated this strategic opportunity, the Company decided in early 2005 to forego the planned distribution of Class B Shares and presently have no intention of effecting any such distribution. BND is substantially inactive at December 31, 2006.

3. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from convertible notes, through short-term borrowings, which were subsequently repaid, and from funded research arrangements. The Company has not generated revenue from the sale of any product but has generated revenues from licensing arrangements and sponsored research in 2006 and 2005. The Company intends to finance its research and development efforts and its working capital needs from existing cash, new sources of financing and licensing agreements.

On September 3, 2004, the Company entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC (HCG), a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman. Pursuant to the Equity Line Agreement as amended, HCG will, at the Company s request, invest up to $4.0 million in the Company from August 23, 2004 through December 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock, or Series B Preferred. As of December 31, 2006, $1.45 million had been drawn under the Equity Line Agreement. The equity line and all accrued interest was converted to 400,402 shares of common stock at $4.25 per share on January 12, 2007.

In February and May 2005, the Company consummated two separate $2.5 million secured convertible debt financings from Laurus Master Fund, Ltd., a Cayman Islands corporation (Laurus). Net proceeds from the financing were used primarily to retire the secured equipment

3. Liquidity and management s plans (continued):

loan with Gold Bank (on which approximately $300,000 was owed and was paid at the closing of the Laurus transaction) and were used to support research and development opportunities and for general working capital purposes. See Note 7 below for further information on the Laurus financings.

On May 16, 2006, the Company consummated a transaction with CDC pursuant to which $7 million in funds previously committed by CDC under the CDLA to fund the Company s clinical development of BEMA Fentanyl was converted into shares of the Company s common stock at a value of $3.50 per share. As a result of this transaction, CDC was issued 2 million shares of the Company s common stock and 904,000 common stock warrants at $3.00 each 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 payable to CDC upon the approval by the FDA of BEMA Fentanyl which had been required under the CDLA.

During March and April 2007 (see Note 13), the Company secured additional financings as follows:

HCG:

$1,000,000 non-interest bearing note payable which matures in June 2007.

$5,000,000 right and commitment by HCG to purchase a royalty from the Company related to BEMA Fentanyl. The Company s option to require the purchase and HCG s right to purchase expires in September 2007.

CDC:

$1,900,000 note payable bearing interest at 10.25%, due March 2008.

Additionally, the Company generated approximately $3,485,000 from the sale of Common Stock as the result of:

$3,235,000 from the exercise of warrants by Laurus Master Fund, Ltd. in April 2007

$250,000 from the sale of common stock to Sigma-Tau Pharma in January 2007

Finally, Laurus Master Fund, Ltd. converted approximately $3.04 million of principal of its convertible notes and $0.119 million of interest into common stock from January through April 2007 and also, on April 10, 2007, extended the maturity date of the $1.262 million balance of convertible notes until July, 2008.

The Company s existing cash and cash equivalent together with available financing and common stock sale proceeds discussed in the preceding paragraph is considered by management to be sufficient to finance the Company s basic operations (minimal research and development activities), capital expenditures and debt obligations into approximately the first quarter of 2008.

Additional capital will be required in order to proceed with the Company s planned expanded BEMA Fentanyl development activities, the scale of which is dependent upon the results of the BEMA Fentanyl Phase III efficacy study, which are expected in late April 2007. Management is currently negotiating with a number of funding sources and believes they will be successful in securing such funding at levels sufficient to support planned expanded operations. However, there can be no assurance that additional capital will be available at favorable terms, if at all. In addition, the Company is talking to a number of potential commercial partners in regards to the distribution rights for BEMA Fentanyl. It is believed that should a distribution partnership be consummated it is anticipated that the costs for the expanded program would be paid in full or in part by the distribution partner. If adequate funds either through a financial or distribution partner are not available, the Company would be required to significantly reduce or refocus its planned expanded operations (conduct only the basic operations as discussed in the preceding paragraph) 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 in 2008 and beyond.

4. Research and development arrangements and related party transactions:

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). The amendment to the agreement on December 16, 2002 also provided for the granting of options to purchase 75,000 shares of the

4. Research and development arrangements and related party transactions (continued):

Common Stock to each of the two universities.

During 2004, the Company entered into a license agreement with TEAMM Pharmaceuticals, Inc., a subsidiary of Accentia Biopharmaceuticals, Inc. (Accentia), in which BDSI s Chairman is a significant stockholder. The license agreement granted exclusive rights to Emezine® to the Company recognized revenues which aggregated $1.0 million in 2004, which was earned upon satisfaction of milestones specified in the agreement. During the year ended December 31, 2005, BDSI recognized revenue of approximately $0.35 million in milestone payments. There were no revenues recognized in 2006 related to this product. BDSI will earn future royalties when and if the FDA approves the product. On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. We subsequently have had interaction with the FDA regarding Emezine®, and at the present time, given our level of resources and our focus on other initiative, it is not likely that we will proceed with Emezine® in the foreseeable future.

In addition, the Company earned $0.07 million and $0.07 million from Accentia under the Accentia License Agreement in 2006 and 2005, respectively.

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 BDSI 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 12, 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 in negotiations to renew the lease. The Company incurred approximately $.2 million and $.5 million of research expense in the years ended December 31, 2006 and 2005 respectively. Amounts due to UMDNJ at December 31, 2006 are approximately $.2 million.

The Company has a license agreement with Albany Medical College (AMC), an entity that is also a Company stockholder, under which BDSI pays AMC royalty payments for licensed patents or technology. Amounts due to AMC at December 31, 2006 are approximately $.06 million.

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 $2.3 million and $0.4 million under this agreement in 2006 and 2005 respectively. Amounts due to PPD at December 31, 2006 are approximately $.7 million.

The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia, and shares three employees, with costs paid based on the approximate time spent on Company activities. Rent payments to Accentia were $0.02 million and $0.02 million in 2006 and 2005 respectively, and are included in general and administrative costs, related party. Amounts due to Accentia at December 31, 2006 are approximately $.01 million.

The Company pays business-related costs for aircraft travel to a company that is partially-owned by the Company s Chairman. Payments of $0.1 million and $0.05 million were made in 2006 and 2005 respectively and are included in general and administrative costs, related party.

See Note 9 regarding related party equity line of credit agreement.

5. Equipment:

Equipment consists of the following at December 31, 2006:

Office and laboratory equipment	$ 1,906,300
Less accumulated depreciation and amortization	(1,526,646)
	$ 379,654

Depreciation expense related to equipment for the years ended December 31, 2006 and 2005 was approximately $0.3 million and $0.3 million, respectively.

6. Note payable, acquired property rights and European licensing revenues:

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

Management deems the last $1.0 million payment a contingent liability and therefore will not record the $1.0 million as a liability or intangible asset until the conditions occur which would trigger the requirement to make this payment. 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 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.

7. Convertible notes payable:

On February 22, 2005, the Company consummated a $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., which we refer to herein as Laurus. The February Laurus investment takes the form of a convertible note secured by certain of the Company s assets. The note has a 3-year term and is payable in monthly installments of $75,758 plus interest at prime plus 2%, with a floor of 7.5%. The note is convertible, under certain conditions, into shares of common stock at a price equal to $3.10 per share. As a result of the anti-dilution provisions of the February Laurus note and the pricing of an October 2005 public offering, the conversion price of the February Laurus note is now $2.45.

In connection with this financing, the Company also issued Laurus a common stock purchase warrant to purchase up to 350,000 shares of common stock at a price equal to $3.88 per share. A registration statement filed with the SEC to register the shares of common stock underlying the February Laurus note and the warrant was declared effective on June 20, 2005.

On May 31, 2005, the Company closed an additional $2.5 million secured convertible debt financing from Laurus. As with the February 2005 Laurus financing, this financing takes the form of a secured convertible note and a warrant to purchase 483,871 shares of common stock. The note has a 3-year term and is payable in monthly installments of $75,758 plus interest at prime plus 2%, with a floor of 8%. As a result of the anti-dilution provisions of the May Laurus note and the pricing of the October 2005 public offering, the conversion price of the May Laurus note is now $2.45.

From June 2005 through July 2006, the Company entered into amendments to the February and May 2005 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 issued to Laurus were substantially similar to the warrants issued on February 22 and May 31, 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 to Laurus in September 2006 are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005.

7. Convertible notes payable (continued):

On December 28, 2006, the Company entered into two separate fourth amendments to the February and May 2005 financing agreements with Laurus. Under the fourth amendments, Laurus has agreed to defer payments by the Company of certain monthly principal amounts under the Company s February and May 2005 Convertible Notes with Laurus ($1,818,192 in the aggregate), as well as certain other previously postponed principal amounts due under such notes ($2,018,541 in the aggregate), until the first business day of January 2008. During the first quarter of 2007, Laurus exercised its right to convert $2.4 million of principal and $0.1 million of interest, and as such the amount due at January 1, 2008 is $1.5 million.

In consideration of Laurus agreement to enter into the fourth amendments, the Company issued to Laurus two warrants, one to purchase 943,305 shares of Company common stock (in connection with the February amendment) and a second to purchase 556,695 shares of Company common stock (in connection with the May amendment) (such warrants collectively, the December 2006 Warrants). In each case, 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. The December 2006 warrants are substantially similar to the warrants issued to Laurus on February 22, 2005, May 31, 2005, June 29, 2005, December 28, 2005 and July 31, 2006. The Company has agreed to register the shares of common stock underlying the December 2006 Warrants with the Securities and Exchange Commission pursuant to a registration statement required to be filed by no later than July 31, 2007.

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, changed 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.

The Laurus financings included registration rights related to share settlement of the embedded conversion features and the warrants which the company has determined not to be within its control.

In addition, certain features associated with the financings, such as anti-dilution protection afforded to Laurus render the number of shares issuable under the financings to be variable, (only when and if the Company sells stock for an amount less than the otherwise fixed conversion price). In these instances, EITF 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock , requires allocation of 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:

7. Convertible notes payable (continued):

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) through December 31, 2006	1,044,203
Conversion of debt to equity through December 31, 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

The discount to the debt instruments resulting from the original allocation of the debt proceeds was amortized through periodic charges to interest expense using the effective interest method. Effective interest rates used to amortize the Laurus financing discounts amounted to 33.3%, and 46.6% for the February and May financings, respectively.

Future maturities of convertible note payable are as follows:

Year Ended December 31,	
2008	$ 4,305,761
Less unamortized discount	(302,511)
	$ 4,003,250

8. Income taxes:

The Company has no income tax expense or benefit for 2006 or 2005 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,	
	2006	2005
Federal statutory income tax rate	34.00%	34.00%
State taxes, net of federal benefit	3.45	3.45
Permanent difference compensation expense	(3.19)	(2.90)
Research and development (R&D) credit	5.34	
Other	(0.05)	
Valuation allowance	(39.55)	(34.55)
	%	%

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,	
	2006	2005
Deferred tax assets (liabilities)		
Deferred revenue	$ 26,351	$
Basis difference in equipment	(89,678)	(152,184)
Basis difference in intangibles	(1,950,382)	(1,490,743)
Accrued liabilities and other	115,168	34,590
R&D Credit	1,249,148	186,631
Derivative	1,733,998	
Net operating loss carry-forward	12,111,365	6,749,171
Less: valuation allowance	(13,195,970)	(5,327,465)
Net deferred tax	$	$

In 2005, the Company sold New Jersey net operating loss carryforwards and R&D credits for aggregate proceeds of $0.5 million. No R&D credits were sold in 2006. As a result of this sale in 2005, $7.5 million in New Jersey state tax operating loss carryforwards are no longer available. The Company has a federal net operating loss of approximately $33.0 million and a State net operating loss of $25.5 million as of December 31, 2006. These loss carryforwards expire principally beginning in 2021 and 2028 for federal and state purposes, respectively.

9. 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:

Convertible Preferred Shares:	
Series A	1,647,059
Series B	941,177
	2,588,236

As part of the acquisition of Arius in August 2004, the Company issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of convertible preferred stock. The newly-created Series A Preferred is convertible (upon the satisfaction of certain conditions) into shares of common stock on a one for one basis. Shares of Series A Preferred are eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first proposed product (ii) 30 days notice to the Company of a Conversion Event (hereinafter defined) or (iii) five (5) years from the closing date of the acquisition. The term Conversion Event is defined in the Certificate of Designation of the Series A Preferred to mean our failure to provide at least $3.0 million to Arius as required to: (i) pay Atrix $1.0 million by August 24, 2004 pursuant to the terms of a license agreement between Arius and Atrix and (ii) fund, in a total amount of no less than $2.0 million, the operations of Arius. The Company believes they have satisfied both of these conditions. The holders of the Series A Preferred enjoy certain other rights and privileges.

On August 23, 2004, the Company entered into a private, unregistered Equity Line Agreement with HCG, a principal stockholder of the Company, whereby HCG will, as requested by the Company, invest up to $4.0 million in the Company from August 23, 2004 through December 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock of BDSI (the Series B Preferred). As of December 31, 2006 and 2005, $1.45 million had been drawn under the Equity Line Agreement. The holders of the Series B Preferred are entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred is convertible into shares of Common Stock at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to shares of the Company s Common Stock and the Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. HCG is an affiliated entity of the Company which is controlled and partially-owned by the Company s Chairman.

Additionally, the Company has the right, in its discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. Furthermore, the Certificate of Designations for the Series B Preferred provides for certain limitations on the conversion of the Series B Preferred into shares of Common Stock without the prior approval of the Company s stockholders. Finally, HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

9. Stockholders equity (continued):

Common Stock:

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

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.

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2005	1,861,480	$ 5.03	
Granted in 2005:			
Officers and Directors	417,761	2.96	
Others	142,703	4.60	
Exercised			
Forfeitures	(236,349)	5.44	
Outstanding at December 31, 2005	2,185,595	$ 4.43	$ 165,608
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

Options outstanding at December 31, 2006 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	1,858,653	7.03	$ 2.72	
$ 5.01 10.00	147,889	0.75	$ 5.75	
$10.01 15.00	8,581	0.87	$ 11.80	
$15.01 20.00	8,581	0.87	$ 17.48	
	2,023,704			$ 1,099,052

9. **Stockholders equity (continued):**

Options exercisable at December 31, 2006 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	1,461,532	7.03	$ 2.75	
$ 5.01 10.00	141,889	0.75	$ 5.76	
$10.01 15.00	8,581	0.87	$ 11.80	
$15.01 20.00	8,581	0.87	$ 17.48	
	1,620,583			$ 863,245

The weighted average grant date fair value of options granted during 2006 and 2005 whose exercise price is equal to the market price of the stock at the grant date was $2.08 and $2.97, respectively. The weighted average grant date fair value of options granted during 2005 whose exercise price is greater than the estimated market price of the stock at the grant date is $3.10. There were no options granted during 2006 whose exercise price is greater than the estimated market price of the stock at the grant date.

Warrants:

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

Activity is as follows and includes 2,085,000 warrants issued in connection with the 2002 public offering of securities. Warrants outstanding at December 31, 2006 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	4,270,765	6.43	$ 3.11	
$ 5.01 10.00	2,310,000	0.67	$ 6.20	
	6,580,765			$ 999,683

Warrants exercisable at December 31, 2006 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	4,245,765	6.19	$ 3.11	
$ 5.01 10.00	2,310,000	0.67	$ 6.20	
	6,555,765			$ 965,433

10. 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 and $0.8 million in 2006 and 2005, respectively.

11. 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, 2006 and 2005, the Company incurred approximately $0.07 million and $0.3 million of costs related to this agreement and received and recognized revenue of $0.07 million and $0.4 million, from this grant for the year ended December 31, 2006 and 2005, respectively. All available funds have been drawn from this grant at December 31, 2006.

12. 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, 2006 are $0.8 million, $0.8 million and $0.8 million for the years ended December 31, 2007, 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, 2006. The Company is currently in negotiations to renew the lease. Lease expense for the years ended December 31, 2006 and 2005 was approximately $0.1 million and $0.06 million, respectively. Related party rent expense was $0.01 million for each year presented.

The future minimum commitments on all operating leases at December 31, 2006 are as follows:

Years ending December 31,	
2007	$ 33,799
2008	7,691
2009	5,768
	$ 47,258

12. Commitments and contingencies (continued):

Indemnifications:

The Company indemnified its officers and directors 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. As of December 31, 2006, the Company has not recorded a liability for any obligations arising as a result of these indemnifications as the cause thereof is deemed nominal.

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 allege fully release them. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that fully release the Company; they 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 their 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 are to proceed until resolution of the Company s counterclaim for attorneys fees and costs and either party could appeal at that point in time. The parties are in the discovery phase with regard to the counterclaim for attorneys fees and costs and no hearing date has yet to be scheduled on said counterclaim. The Company believes that the plaintiff s claims are without merit and intend to continue to vigorously defend the lawsuit. No liability, if any, that may result form this matter has been recorded in the financial statements.

On August 21, 2006, The Company filed an action in New York State Supreme Court against Clinical Development Capital, LLC (CDC) seeking: (i) to enjoin CDC from filing a Schedule 13D filing with the Securities and Exchange Commission without first giving the Company an opportunity to review the proposed Schedule 13D filing for potential disclosures of their confidential information in violation of the Clinical development and licensing agreement (CDLA) and (ii) to compel CDC to adhere to the dispute resolution mechanisms set forth in the CDLA. The Company s motion for a preliminary junction enjoining the filing of CDC of the Schedule 13D was denied on August 22, 2006.

12. Commitments and contingencies (continued):

On August 30, 2006, the Company delivered to CDC the BDSI Notice pursuant to the CDLA. In the BDSI Notice, the Company claimed that CDC breached the CDLA and damaged them when it acted or failed to act in accordance with or in contravention of the terms of the CDLA. In the BDSI Notice, the Company reserved the right to make additional claims against CDC. Also on August 30, 2006, the Company received written notice from CDC of CDC s claim of termination of the CDLA. In its notice, CDC alleged that the Company 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 the Company seeking to enjoin them from entering into a financing transaction with a third party pursuant to a purported right of first negotiation provision granted to CDC under the Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC. On October 26, 2006, the Company entered into a stipulation with CDC to settle this case without prejudice pursuant to which BDSI and CDC agreed to follow a procedure regarding the right of first negotiation as modified by the stipulation.

See Note 13 for resolutions of the CDC litigation.

13. Subsequent Events:

On January 10, 2007, Hopkins Capital Group II, LLC, (HCG) converted 341,176 shares of Series B Convertible Preferred Stock of the Company (the 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 also acquired 59,226 shares of Common Stock pursuant to the conversion of accrued and unpaid dividends on the Series B Convertible Preferred Stock.

On January 24, 2007, Sigma Tau acquired 73,964 shares of the Company s Common Stock at a price of $3.38 per share in accordance with their Stock Purchase Agreement. The Stock Purchase dated January 20, 2005 provides for certain development milestones and purchases of stock thereof. No other consideration was paid.

On February 22, 2007, all 1,647,059 shares of the Company s Series A Preferred Stock were exchanged with the holders thereof for an identical number of shares of newly designated Series C Non-Voting Convertible Preferred Stock. The rights associated with the Series C Preferred Stock are identical to those associated with the Series A Preferred Stock in all material respects except that the Series C Preferred Stock has different terms of conversion into shares of Common Stock.

On March 12, 2007, the Company entered into a Dispute Resolution Agreement (the DRA) with CDC IV, LLC. Pursuant to the DRA, the Company 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 Disputed Matters). The effect of the DRA is that CDC has withdrawn its claims to ownership of the Company s BEMA Fentanyl asset, which had been asserted by CDC as part of the Disputed Matters, and the Company has withdrawn its claims against CDC. The Company has previously rejected CDC s August 2006 allegations and demands. The resolution of the disputes under the DRA is without prejudice to the Disputed Matters of both the Company and CDC. As such, no assurance can be given that CDC will not make similar or additional claims against the Company. Simultaneously with the Company and CDC s entry into the DRA, the Company and CDC entered into an amendment to their Clinical Development and License Agreement, dated July 14, 2005 (as amended, 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. Under the CDLA, the Company must meet certain conditions or CDC can assume control of the BEMA Fentanyl project and related intellectual

13. Subsequent Events (continued):

property assets. Concurrently with the parties negotiation of the DRA, CDC alleged that the Company had violated CDC s financing right of first refusal (as amended, the ROFN) provided for in the May 2006 Securities Purchase Agreement between the parties. Specifically, in January 2007, CDC alleged by written notice that the Company s December 2006 note deferral agreements with Laurus Master Fund Ltd. (the Laurus Deferral Transaction) triggered the ROFN provisions.

In order for the Company 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, the Company enter into to a $1.9 million financing with CDC (the New CDC Financing). The New CDC Financing is intended to resolve CDC s January 2007 ROFN claims, notwithstanding the Company s 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 (the New CDC Warrant) to purchase 1 million shares of Company common stock with an exercise price of $3.80. The Company is not required to file a registration statement with the Securities and Exchange Commission to register the shares of Company common stock underlying the New CDC 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. The New CDC Warrant contains weighted average anti-dilution protection. The proceeds from the New CDC Financing will be used for general corporate purposes and for the continued development of BEMA Fentanyl.

The holder of convertible notes payable, Laurus, has converted $3.044 million of principal and $0.119 million of interest into 1,290,861 shares of common stock from January 1, 2007 through April 10, 2007.

On March 30, 2007, HCG funded a $1.0 million unsecured, non-interest bearing note, due June 30, 2007. As consideration for the loan made by HCG, the Company granted HCG 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 can be demanded by either the Company or HCG at any time before September 30, 2007, is $5.0 million. The royalty is to be paid based on a low, single digit tiered percentage of net sales of the BEMA Fentanyl once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, the Company would issue a warrant to HCG to purchase 475,000 shares of Common Stock at $5.55 per share (the closing price on April 2, 2007). No assurances can be given that either the Company or HCG will elect to enter into the royalty purchase agreement.

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 and aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of Common Stock, resulting in cash proceeds of $3,183,567 to the Company and (ii) to defer all principal payments under the Company s May 2005 note with Laurus (which currently stands at $1.262 million) 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 agreed to file a registration statement registering the shares underlying such warrant by July 31, 2007.

On April 13, 2007, the Compensation Committee of the Company s board of directors awarded the following options to the following senior executives of the Company: Mark Sirgo: 434,000 options; James McNulty: 100,000 options; and Andrew Finn 100,000 options. All of the foregoing options vest in three equal installments beginning on the first anniversary of the grant date (April 13, 2008) and have an exercise price of $6.63 per option share.

As a result of certain previous issuances by the Company of its securities at prices below the then current market price of the Common Stock (including a warrant issued to Laurus in April 2007 as described above), the exercise price of the Company s publicly-traded warrants was, effective April 10, 2007, adjusted downward from $6.30 to $6.11 pursuant to the terms of the warrant agreement entered into in connection with the Company s June 2002 initial public offering. The Company s publicly-traded warrants expire on June 24, 2007.

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: April 16, 2007

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	April 16, 2007
/s/ Mark A. Sirgo Mark A. Sirgo	President and Chief Executive Officer (Principal Executive Officer)	April 16, 2007
/s/ James A. McNulty James A. McNulty	Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)	April 16, 2007
/s/ Raphael J. Mannino Raphael J. Mannino	Executive Vice President, Chief Scientific Officer and Director	April 16, 2007
/s/ William B. Stone William B. Stone	Director	April 16, 2007
/s/ John J. Shea John J. Shea	Director	April 16, 2007
/s/ Thomas D Alonzo Thomas D Alonzo	Director	April 16, 2007
/s/ William S. Poole William S. Poole	Director	April 16, 2007