BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB
April 03, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

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x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2005

¨ 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;

Class A common stock purchase warrants

(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 2005 were $849,562.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 27, 2006 was approximately $17,259,990 based on the closing sale price of the company s common stock on such date of U.S. $2.51 per share, as reported by the Nasdaq Capital Market (formerly known as the Nasdaq SmallCap Market).

As of March 27, 2006, there were 11,908,146 shares of the company s common stock outstanding.

Transitional Small Business Disclosure Format: Yes ¨ No x

EXPLANATORY NOTE

Readers of this Annual Report on Form 10-KSB should be aware that, included in the audited financial statements included herein, is a restatement of certain aspects of our unaudited financial statements for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005. Readers are therefore cautioned that our previously released financial statements for such periods as filed with the Securities and Exchange Commission should not be relied upon.

These quarterly financial statements were restated solely as a result of revised accounting treatment related to our issuance of financial instruments in February and May 2005 to Laurus Master Fund, Ltd. and to properly record the gain or loss resulting from the fair value adjustment of such financial instruments.

Our determination to make such restatements was made by our board of directors, as well as the audit committee of the board, on March 29, 2006, and was discussed with our independent registered public accounting firm.

In February 2005, we issued a $2.5 million convertible note and a warrant to purchase 350,000 shares of our common stock to Laurus as part of a financing transaction. In May 2005, we issued another $2.5 million convertible note and a warrant to purchase 483,871 shares of our common

stock to Laurus as part of a second financing transaction. Using the guidance in EITF 00-27, Application of EITF Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, we had previously accounted for the freestanding warrants and embedded beneficial conversion option associated with the convertible notes as equity.

As a result of our determination, the value of the warrants are now reflected as a financial instrument in the current liabilities section of the our balance sheet as a result of the application of EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock . We are also required to revalue the liability at each reporting period to reflect the current fair value of the financial instruments. The gain or loss associated with this revaluation is recorded as a component of income (loss) from continuing operations. The accounting changes had no cash flow impact on our company.

This change requires restatement of our unaudited quarterly financial information for the periods ending March 31, 2005, June 30, 2005 and September 30, 2005. No amendments have been made to our Quarterly Reports on Form 10-QSB for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005 as all relevant changes have been reflected in Footnote 14 to the audited financial statements included with this Report.

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NOTE ON FORWARD-LOOKING STATEMENTS

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

- our plans regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the Bioral® and BEMA technology platforms and any proposed formulations or products relating thereto;
- 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 Bioral® and BEMA technology platforms and our proposed formulations and products, including Emezine®;
- 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;
- our ability to receive federal, state, government or private grants; and
- the competition 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.

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PART I

Item 1. Description of Business.

Overview

We are a specialty biopharmaceutical company that is exploiting its licensed 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 such as:

- pain,
- nausea and vomiting,
- insomnia, and
- fungal infections

We also believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals. In addition to our Bioral® and BEMA platforms, we are also the exclusive U.S. licensee for Emezine®, a treatment of nausea and vomiting.

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 pay royalties or other fees to our licensors and/or third-party collaborators.

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

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 on a worldwide exclusive basis from Atrix Laboratories, Inc. (now a wholly-owned subsidiary of QLT Inc.), which we refer to herein as Atrix.

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. On July 15, 2005, we entered into a clinical development and licensing agreement with Clinical Development Capital, LLC, which we refer to herein as CDC, which will provide up to $7 million toward the Phase III clinical development of BEMA Fentanyl. On February 16, 2006, we announced that, as a result of our achievement of certain milestones called for under our CDC agreement, CDC made an initial $2 million payment to us, which will be followed by subsequent monthly payments through the BEMA Fentanyl Phase III program. We expect that the funds which we shall receive from CDC will represent a majority of the funds we will need to fund the BEMA Fentanyl Phase III clinical program.

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. We intend to enter clinical development with BEMA LA in the second quarter of 2006 and expect to finalize our Phase III program and prepare for Phase III trials in the fourth quarter of 2006.

A third product under development, BEMA Zolpidem, is a BEMA formulation of the most widely prescribed drug for the treatment of insomnia. We intend to submit an IND on BEMA Zolpidem during the fourth quarter of 2006.

We are also developing Emezine®, a formulation of prochlorperazine, which we believe will 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 New Drug Application, or NDA, on Emezine® and, on April 29, 2005, we submitted such NDA. The FDA accepted our NDA for filing on

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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. As of the date of this Report, we have requested a meeting with the FDA regarding their notification and will use the outcome of this meeting to evaluate the direction we intend to pursue regarding Emezine®. No assurances can be given that we will be able to satisfy any FDA concerns regarding Emezine®, and we may be forced to abandon this project. Despite the fact Emezine® represents a relatively small portion of our potential future revenues, the failure to achieve FDA approval of Emezine® could have a material adverse effect on our business. We do not, however, expect that such failure would seriously impair our overall potential future revenue growth. We licensed Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

Our Bioral® drug delivery technology encapsulates the selected drug 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 would have the potential for oral delivery of a drug that is currently only given by intravenous injection. Bioral® Amphotericin B is currently in the last stages of preclinical testing. Following the completion of this testing, we intend to submit an IND for Bioral® Amphotericin B in second or third quarter of 2006, which will immediately be followed by a Phase I clinical trial.

A second formulation for intranasal administration Amphotericin B to treat chronic rhinosinusitis, or CRS, is now in development. In April 2004, we licensed this second product 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 encochleation technology, including the creation of cochleate formulations of siRNA therapeutics, certain vaccines and important nutrients. In 2005, we entered into agreements with third parties for the evaluation of cochleate formulations of siRNA therapeutics. 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.

During 2005, we actively pursued strategic financing and related partnerships regarding certain of our proposed formulations and products as we attempt to move them through the development, approval and commercialization phases. The FDA non-approvable notification regarding Emezine® means that revenues we had previously projected as potentially being generated upon the launch of Emezine® in 2006 may be delayed or not generated at all. Therefore, in part to offset the potential loss of projected Emezine® revenue, we are continuing our strategic partnership initiatives in 2006 with equal vigor and hope to consummate one or more such transactions in 2006. In particular, we are likely to pursue strategic transactions, such as those with Sigma-Tau and CDC (each described in more detail below), which are designed around a particular product or products.

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Recent and Historical Events

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.

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 takes the form of a convertible note secured by certain of our assets. The note has a 3-year term and bears interest at a rate equal to prime plus 2% per annum. The note is 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 is now $2.46.

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.

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. Net proceeds from the May Laurus financing are to be 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 $2.46.

In addition, 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.

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Lastly, 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 have agreed to register the shares of common stock underlying the December 2005 Laurus warrants with the SEC, pursuant to a registration statement required to be filed by July 10, 2006.

CDC Development and Licensing Agreement

On July 15, 2005, we entered into a clinical development and license agreement with CDC pursuant to which CDC will provide, subject to certain conditions, up to $7 million in funding (including a $2 million upfront payment and subsequent monthly payments over a year) for the clinical development of our BEMA Fentanyl product. The total of the upfront payment and monthly payments shall not exceed, in the aggregate, the lesser of: (i) $7 million or (ii) the costs incurred in conducting the clinical development of BEMA Fentanyl, and such monthly amounts are subject to downward adjustment depending on the achievement by us of patient enrollment targets. All funds made available to us under our transaction with CDC must be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and therefore will be accounted for as a refundable deposit.

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, which will be followed by subsequent monthly payments over a year through the BEMA Fentanyl Phase III program.

Under the agreement, CDC is entitled to receive:

- as referenced above, a milestone fee equal to the lesser of $7 million or the actual amount provided by CDC for development of BEMA Fentanyl;
- 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.

Upon execution of the CDC agreement, 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.

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Royalties under the CDC agreement 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 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 CDC development agreement, 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, which interest terminates upon our payment to CDC of the milestone payment (due within sixty (60) days of FDA approval of BEMA Fentanyl) equal to the lesser of $7 million or the actual amount provided by CDC for development of BEMA Fentanyl.

Acquisition of Arius Pharmaceuticals, Inc.

On August 24, 2004, we consummated the acquisition of Arius Pharmaceuticals, Inc. Arius is 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 Atrix, 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 Senior Vice President of Product Development at BDSI. 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.

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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. As of the date of this Report, $1.45 million has been drawn under the Equity Line Agreement.

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.

2002 Initial Public Offering

In June 2002, we conducted our initial public offering which consisted of 2 million units, which we refer to herein as Units, with each Unit consisting of: (i) one share of our common stock and (ii) one Class A common stock purchase warrant, or Warrants. Each Warrant entitles the owner to purchase one share of our common stock at a price of $6.30 through June 24, 2007. The net offering proceeds we received were $8,571,397.

Subsequent Events

The following material events occurred subsequent to December 31, 2005:

On March 30, 2006, we amended our agreement with HCG to extend the commitment period of our $4.0 million equity line of credit agreement with HCG from March 31, 2006 to December 31, 2006. Except for the extension of the commitment period, no other terms or conditions of equity line of credit were amended.

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. As of the date of this Report, we have requested a meeting with the FDA regarding their notification and will use the outcome of this meeting to evaluate the direction we intend to pursue regarding Emezine®.

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On February 16, 2006, we announced that we had received the initial $2 million payment under our agreement with CDC.

On February 2, 2006, we announced our engagement of Addison Whitney, Inc. to develop the brand identity and brand strategy for our BEMA drug delivery technology and BEMA Fentanyl. We believe the branding process is a critical component of our BEMA commercialization strategy.

On January 9, 2006, we announced the appointment of Mark W. Salyer, a former executive with Altana Pharma AG and GlaxoSmithKline, to the newly created position of Executive Vice-President of Sales and Marketing. Mr. Salyer will be designing the commercial strategy around our proposed products and formulations, including BEMA Fentanyl and BEMA LA. He will also work to identify key partnerships including co-promotional agreements worldwide where they are deemed necessary to support our business strategy.

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

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. 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.

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 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,

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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, 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. As a result, doctors are familiar with the drug compounds and are accustomed to prescribing them. As with BEMA Fentanyl and Emezine®, 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:

Formulation/Product	Indication	Development Status	Commercial Status*
BEMA Fentanyl	Breakthrough cancer pain	Phase III	In-house commercialization for specialty indications
BEMA Long Acting Analgesic	Moderate and Severe Pain	IND Filed	In-house commercialization for specialty indications, primary care rights to be partnered
Bioral® Amphotercin B	Fungal infections	Pre-clinical	In-house commercialization
BEMA Zolpidem	Insomnia	Pre-clinical	In-house commercialization for specialty indications, primary care rights to be partnered
Emezine®	Nausea/Vomiting	FDA non-approvable received; Discussions	Partnered

with FDA ongoing

* Partnership options may be considered for certain of these products on a case by case basis.

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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 (the Phase III clinical development of which is being financed through our agreement with CDC), BEMA LA and Biora® Amphotericin B. After these programs, and depending on the availability of corporate resources, we hope to begin to fund the development of BEMA Zolpidem.

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

Licensed to us from a third party, 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 an excellent delivery system for time-critical conditions such as nausea, vomiting and breakthrough cancer pain, 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;

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Dissolve completely, leaving no residual product or waste unlike certain other systems; and

Have relatively inexpensive cost of goods, unlike certain other systems.

Current BEMA Formulations In Development

BEMA Fentanyl

The global market for pain medication is projected to generate $26 billion in 2006. It is estimated that between $2 billion and $4 billion is spent to treat breakthrough pain, and the market for breakthrough cancer pain (the proposed indicated for BEMA Fentanyl) is a subset of this market. The leading product for breakthrough cancer pain is the U.S. market is Actiq®, which had reported sales of $411.8 million in 2005. Cephalon s pain franchise (consisting of Actiq® and OraVescent fentanyl) is projected by Cephalon to obtain sales of $425-$475 million in 2006.

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.

We began preparing for Phase III clinical studies of BEMA Fentanyl in the fourth quarter of 2005 and in November 2005, we announced the results of a 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 addition, and also 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. Also, in February 2006, we received our initial $2 million payment from CDC to fund our BEMA Fentanyl Phase III trials. We estimate that the total development costs of this formulation will exceed $8 million.

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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.

BEMA Long Acting Analgesic

In addition to our lead BEMA product, BEMA Fentanyl, 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. We estimate that the total development costs of this formulation will be approximately $14 million.

The pain market is well established, with many pharmaceutical companies marketing innovative products as well as generic versions of older, non patent protected products. The global pain market is projected to generate $26 billion in 2006. 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.

BEMA LA contains a marketed opioid analgesic which has equal potency to morphine but with a lower propensity for adverse reactions and addiction. The lower potential for 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. This may help create a broader market opportunity for BEMA LA as doctors are able to call 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 for filling. Since the active ingredient in BEMA LA is a Schedule III controlled substance, physicians will be able to phone or fax in the prescription and also allow for refills to be included on the prescription, thus making chronic therapy easier for both the patient and the physician.

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 proposed BEMA formulation of this long acting analgesic is intended to meet the need for a new narcotic and will be ideally used for:

- Post-operative pain;
- Chronic pain, including lower back, osteoarthritis and rheumatoid arthritis; and
- Non-malignant breakthrough pain.

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 more convenient for physicians to prescribe, pharmacists to dispense, and patients to obtain,

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broad applicability across a wide spectrum of patients with varying types of moderate to severe pain 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.

Due to the ability of BEMA LA to potentially participate in the principal key pain markets (chronic pain, post-operative pain and breakthrough pain), we believe that BEMA LA has the potential to achieve a up to a 2% share of the total worldwide pain market, which is projected to grow to approximately $33 billion by 2014. 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 commence development of 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,

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- 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.

We expect to finalize a formulation for BEMA Zolpidem and file an IND by the end of the fourth quarter of 2006. This will allow us to enter Phase I clinical trials in the first quarter of 2007. Based on the outcome of several Phase I studies to determine the ideal strength and formulation of BEMA Zolpidem, we would anticipate entering into Phase III clinical trials. We estimate that the total development costs of this formulation will be approximately $9.4 million.

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.

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.

As of the date of this Report, we are mapping out our Emezine® defense strategy and hope to have our follow-up meeting with the FDA by no later than the end of May 2006. Although we plan to discuss and better understand the FDA concerns when we meet, no assurances can be given that we will be able to satisfy such concerns regarding Emezine®, and we may be forced to abandon this project. However, given the relatively small outlays we are actually making on this project, and given that our size

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of market projections regarding Emezine® are relatively small compared to other formulations in our pipeline, 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.

In December 2005, we announced the publication of a pharmacokinetic (PK) study in the Journal of Clinical Pharmacology showing that, in the PK study, plasma concentrations of Emezine® s active ingredient, prochlorperazine, were more than twice as high and less variable than those obtained from a standard oral tablet. In March 2005, we received notice from the FDA that it granted, under a small business exception, our request for a waiver of the FDA s human drug application fee in connection with our pending NDA for Emezine®. We believe this fee would have been approximately $672,000.

Anti-nausea, also known as anti-emetic, products are provided as injectable, oral and rectal formulations. Injectable products require that the patient be in a medical facility and have an intravenous injection line in place. Oral products have limitations because delayed gastric emptying that is associated with nausea and vomiting impedes the absorption of the product and actual product ingestion can be nauseating. Rectal suppositories are inconvenient as well as slow and unpredictable in onset. We believe, therefore, that an alternative delivery system is necessary for anti-emetic products, the market for which we estimate to be approximately $2 billion dollars in the United States. Based on our market research, we believe that the Emezine® buccal tablet formulation may be able to participate in the nausea and vomiting markets, including the separate markets for postoperative, chemotherapy induced and general nausea and vomiting. Such research and estimates indicate that Emezine® may be able to achieve peak sales of approximately $30 million annually, 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.

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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.

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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 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. We plan to submit an IND to the FDA and proceed into clinical trials in second or third quarter 2006.

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 Bioral® Amphotericin B, thereby facilitating commercial scale-up. Also, we have changed the ratio of PS to active molecules, thus improving the efficacy while moderating costs. We are currently investigating the pharmacology and toxicology in animals. We estimate that the total development costs of this formulation will be approximately $11 million.

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

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

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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 Bioral® Amphotericin B may be an appropriate treatment. Our market research indicates that Bioral® Amphotericin B 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 antifungals 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.

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.

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Licensing Opportunities and Other Projects

In addition to the foregoing, we have in the past dedicated resources to other projects. Given our limited resources, we decided during 2004 and 2005 to either focus exclusively on seeking licensing or similar collaborative opportunities for these projects and/or significantly scale back, outsource or place these projects on hold. These projects include:

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 2005, we entered into agreements with third parties for the evaluation of cochleate formulations of siRNA therapeutics, and we will likely continue to search for collaborators and strategic partners in this area. 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.

Bioral® Paclitaxel. Paclitaxel is one of the most commonly prescribed chemotherapies for solid tumors such as breast cancer. Paclitaxel is very insoluble in water and is currently available in either a cremophor formulation, which often has significant vehicle-related toxicities, or in a formulation composed as paclitaxel bound to albumin. Both are available as injections. We are working on an oral form of paclitaxel, making therapy for patients more convenient and reducing the risks associated with intravenous therapies. Evaluation of the formulation will be undertaken in collaboration with an academic center.

Bioral® NSAIDS. In early 2005, we announced that, in laboratory testing, we applied our licensed Bioral® nanocochleate drug delivery technology to aspirin and traditional NSAIDS that are not selective COX-2 inhibitors. We have contracted with an independent testing laboratory to test Bioral® formulations of aspirin and other NSAIDs in a well-established animal model of inflammation. These proof-of-principle animal studies have demonstrated that encochleated NSAIDS enabled a statistically significant reduction in gastro-intestinal toxicity (e.g., ulceration) compared to standard formulations at clinically-relevant high doses of these NSAIDs and aspirin while providing comparable anti-inflammatory effects. Due to limited corporate resources, however, this program has been deemphasized and no further development is anticipated at this point. The rights to this program are available for licensing to third parties.

Autologous HIV Therapy. We have developed and are investigating our patented autologous (patient-specific) HIV therapy for AIDS which uses a cochleate related (proteoliposome) delivery vehicle. In 2005, we investigated the potential cost for the research and administrative efforts that would be necessary to obtain an FDA approved IND necessary to continue this program. We have elected to de-emphasize this program to focus our later stage projects. We do not plan to utilize any resources on this program in the near term. The rights to this program are available for licensing to third parties.

Subunit HIV Vaccine. We are also developing, in conjunction with UMDNJ, a subunit HIV vaccine formulation with our cochleate technology that may have the ability to work following oral administration. This program is currently funded via an NIH grant which expired in January 2006 but was renewed in February 2006 through July 31, 2006. 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.

Bioral Nutrient Delivery, LLC. In January 2003, we formed Bioral Nutrient Delivery, LLC 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 suggest that, by using our

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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.

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, we 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, 2005, UMDNJ owned 139,522 shares (including shares issued under a research agreement) and warrants 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, 2005, Albany Medical College owned 2,222 shares of our common stock and warrants 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.

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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 $144,000 for the year, or $12,000 per month. 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 UNDNJ. These include two employees from UNDNJ for a total of approximately $119,880, a budget to purchase supplies and chemicals (adjusted to exact cost), and an indirect cost factor constituting 8% for 2001 (12% in 2002, 16% in 2003, 20% for 2004 and 24% for 2005) of the direct costs of the employee costs and chemicals.

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 to develop, market, and sell products incorporating Atrix s BEMA technology, including its BEMA Fentanyl product, and to use the BEMA trademark in conjunction therewith. The BEMA delivery technology consists of an easy to use, dissolvable, dime-sized polymer disc that is applied to the mucus membrane of the mouth. All research and development related to the BEMA technology, including three existing INDs, have been transferred to Arius in accordance with the Atrix license agreement.

Under the terms of the Atrix license agreement, we are required to pay Atrix: (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 Atrix 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. Atrix retains certain co-promotion rights to the BEMA Fentanyl product.

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.

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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.

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 2005. Working with Sigma-Tau s immunosuppressant compound, we were able during 2005 to undertake single and multiple dose in vivo efficacy studies versus a subcutaneous formulation of the compound. We anticipate that this Bioral® formulation will enter 28 day toxicology testing in 2006. If the results of this study meet expectation, we believe we will have achieved the next milestone in the collaboration, which is demonstration of proof of principal. If this occurs, a $250,000 payment to BDSI will be triggered, which payment will take the form of a purchase of our common stock by Sigma-Tau 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.

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.

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

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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.

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.

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

Public Health Research Institute of New York. To investigate our proposed Amphotericin B product and other anti-fungal applications of our drug delivery technology. This relationship may involve shared expense reimbursement and shared intellectual property with regard to joint inventions.

We also have agreements with entities that are affiliated with and partially-owned by key members of our board of directors and management to conduct research and license certain proposed drugs. See Certain Relationships and Related Transactions for affiliations with our management.

As of December 31, 2001, our board of directors appointed an audit committee consisting of independent directors. This committee, among other duties, is charged to review, and if appropriate, ratify all agreements and transactions which had been entered into with related parties, as well as review and ratify all future related party transactions. The audit committee independently ratified the agreements described below. At a subsequent meeting of independent board members, with Dr. O Donnell abstaining, and after seeking and reviewing advice from the audit committee and an independent valuation firm and inquiring about the details of the various transactions, the independent board members ratified the below-described related party transactions. During 2004, after compliance with our internal policies and procedures, we also entered into several new related party contracts, some of which were amended in 2005 in accordance with the same policies and procedures. The following are the related-party agreements entered into prior to our initial public offering and subsequently:

Accentia Biopharmaceuticals, Inc. We have several business relationships with Accentia Biopharmaceuticals, Inc. and its affiliates. HCG, 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, as well as all of our Series B Convertible Preferred Stock, 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.

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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.

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

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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.

TEAMM Pharmaceuticals, Inc. Under the distribution agreement with TEAMM, TEAMM: (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 TEAMM, at TEAMM 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.

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

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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 and Sigma-Tau 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 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 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.

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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 nine issued United States patents and five 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)

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Patent Number	Issued	Expires	Title	Owner
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)
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)
US04,871,488	10/03/1989	10/03/2006	Reconstituting viral glycoproteins into large phospholipid vesicles	Albany Medical College

Through Arius, we license from Atrix the following U.S. and 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)

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Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
09/069,703	US	04/29/1998	Pending			Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
09/684,682	US	10/04/2000	Pending			(same as above)
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	Pending		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)

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Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
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 formulations (including Emezine®) 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. 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 dose based on how the BEMA technology adheres to the buccal membrane and dissolves over a predetermined rate. We are aware that Access Pharmaceuticals is developing a technology which is similar to BEMA . We are exploring options in defense of our patent position in regard to this technology.

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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 lead product for this indication is Actiq , which generated $411.8 million in sales in 2005. Cephalon will license this product to Barr Laboratories upon approval of OraVescent Fentanyl. This product utilizes an effervescent tablet which is administered buccally. 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 Arakis, Ltd. are developing sublingual spray formulations of opioids for breakthrough pain. LAB International, Inc. and Delex Therapeutics, Inc 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.

BEMA LA will be positioned primarily 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 secondary 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 Oxycontin® from Purdue, Kadian® from Alpharma, Avinza® from 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, Oxymorphone IR/ER from Penwest/Endo, Remoxy from Pain Therapeutics/King Phamraceuticals, 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/ Pfizer), and gaboxadol (Lundbeck/Merck).

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Finally, there are also approved products development in special delivery technologies including zolpidem Flashdose® from Biovail, 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. and Nobex Corporation, each a privately-held company (although, according to its press releases, Nobex has recently filed for bankruptcy protection). 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.

Emezine®

The nausea and vomiting market is well established with many established pharmaceutical companies marketing products as well as generic versions of older, non patent protected products. The primary classes are the 5HT3 antagonists, the dopamine antagonists, the substance P antagonists, and the antihistamines. The 5HT3 antagonists account for the largest share of the market with GlaxoSmithKline s (NSYE:GSK) Zofran (tablets, injection and solution), which presently accounts for the largest share of the market. MGI Pharma s (NASDAQ:MOGN) Aloxi injection is the newest entry into the market and has gained significant share in a short period of time in the chemotherapy induced nausea and vomiting market. Merck s (NYSE:MRK) Emend tablet has the highest revenue of the non

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5HT3 drugs. Emend is available by tablet. The rest of the market is covered by the phenothiazines (dopamine antagonists) and antihistamines. These are generically available by injection, tablet or suppository. Emezine would be differentiated in this market due to the buccal route of administration.

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. Except as described below, we do not presently have manufacturing arrangements with respect to our intended products.

Emezine®. Under our licensing agreement with Reckitt, Emezine® will 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.

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.

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

Our marketing strategy, assuming completion of our drug delivery technologies, product and formulation development and regulatory approval, is to market and sell our approved formulations and products under the Bioral®, BEMA or other brand names which we either own or license from third parties. Our commercial efforts will be primarily focused on hospitals, oncologists and pain centers to maintain cost efficiency. We 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. 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 TEAMM Pharmaceuticals, a subsidiary of Accentia. TEAMM is responsible for the sales and marketing of Emezine®. 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

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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

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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 principal stage and involves studies in a limited patient population in order to:

Asses 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. One study was conducted in 2005 under the IND for BEMA Fentanyl. Multiple preclinical studies were conducted with Biora® Amphotericin B. No studies were conducted with BEMA LA in 2005. We expect that additional studies will be required in 2006 on these and, potentially, other 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.

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

International Approval

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country at this time has its own procedures and requirements.

Other Regulation

In addition to regulations enforced by the FDA, we are also subject to regulation under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Our research and development may involve the controlled use of hazardous materials, chemicals, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of any accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Employees

As of March 27, 2006, 13 full-time employees, of whom 5 are laboratory scientists and 8 are involved in our clinical and program development, operations, administration, accounting and information technology. Three of our scientists have Ph.D. degrees. 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.

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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 Related to Our Technologies

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. 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. As of the date of this Report, we have requested a meeting with the FDA regarding their notification and will use the outcome of this meeting to evaluate 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®. 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. Thus, any failure to obtain regulatory approvals, including those for Emezine®, could materially and adversely effect our business, results of operations and viability. See Business Government Regulation.

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.

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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. See Business Government Regulation.

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 effected. See Business Overview of Specialty Pharmaceuticals and the 505(b)(2) Regulatory Pathway.

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 (as well as a product, Emezine®) that we license from third parties such as the Universities, Atrix 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

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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. See Business Competition.

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, 2005, we have recorded accumulated losses totaling $23,574,501. As of December 31, 2005, we had working capital of $498,670. 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 earned some licensing-related revenue to date, we have not generated any revenue from the commercial sale of our proposed formulations or 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 we have more recently begun to focus on commercialization activities as well with the acquisition of Arius. We have not generated revenues to date other than research grants, limited licensing or royalty revenues and a $2.5 million sale of a royalty revenue stream to Accentia. This limited 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, and the proceeds from our October 2005 public offering and our agreement with CDC, that our current working capital and available financing will be sufficient to satisfy our contemplated cash requirements into approximately the first quarter of 2007, assuming that we do not accelerate the development of other

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opportunities available to us, have Laurus demand repayment of $2,500,000 of its loan 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 likely need to raise additional capital to fund our anticipated operating expenses and future expansion. Among other things, external financing will be required to 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 revenue from grants and collaborative agreements may not be sufficient to meet our 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 or our drug formulations or products;

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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 may exceed the maximum amounts CDC is required to fund us. In such a case, we will 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.

Our agreements with CDC are subject to several contingencies, and the funds provided for under such agreement may not be available to us if we fail to meet certain milestones.

Under our agreements with CDC, CDC s obligation to provide funding for the clinical development of BEMA Fentanyl is conditioned upon certain conditions. We achieved certain of these conditions in February 2006, which resulted in CDC making an initial payment to us of $2 million. However, if we do not meet these or other similar or related requirements, CDC can terminate their funding obligations and assume control of the BEMA Fentanyl project. 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. Our loss of the BEMA Fentanyl project would have a material adverse effect on our business.

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The funds we may receive from CDC must be paid back upon FDA approval of BEMA Fentanyl, and we may not be able to meet this obligation when due, which could result in our loss of BEMA Fentanyl.

Under our agreement with CDC, we must repay to CDC, as a milestone fee and within 60 days of FDA approval of BEMA Fentanyl, all funding previously provided to us by CDC. Assuming that CDC fully satisfies its funding commitment to us, of which no assurances can be given, this amount could be up to $7 million dollars. No assurances can be made that we will have funds available to us to meet this obligation. Our failure to make this payment would result in our loss of, and CDC s assumption of, the rights to BEMA Fentanyl and the right to continue development thereof. Our loss of the BEMA Fentanyl project would have a material adverse effect on our business.

If an event of default occurs under our convertible notes with Laurus, 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 to Laurus. The note and related agreements contain numerous events of default which include:

- failure to pay interest, principal payments or other fees when due;
- 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.

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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.

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We have a license agreement with the Universities in which they grant us exclusive license to conduct research and development of the encochleation drug delivery technology. Our research facilities are also located on the premises of the UMDNJ pursuant to a research agreement. In addition, our BEMA technology and Emezine® product are licensed from third parties.

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 the Universities 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. See Business Description of our Drug Delivery Technologies and Proposed Products and Formulations Relationship with the University of Medicine and Dentistry of New Jersey and Historical Relationship with Albany Medical College.

We currently lease our research facility from UMDNJ. Although, a new one year lease was signed with UMDNJ in December 2005 for this facility, no assurances can be given that we will be able to extend or renew the new lease beyond this one year extension, 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.

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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.

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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, using, 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

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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. Please see Business Description of our Drug Delivery Technologies and Proposed Products and Formulations for a description of our drug delivery technologies and related licenses.

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

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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 cochleate 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. For example, Aveva is our sole supplier of BEMA Fentanyl, and we currently purchase our lipid supplies only from Chemi, a subsidiary of Italfarmico, and from Lipoid GmbH. The reliance on a sole or limited number of suppliers could result in:

- potential delays associated with research and development and clinical and pre-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 timeframes, 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.

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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. See Business Manufacturing.

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 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.

If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, we will need to develop our own sales and marketing capabilities. Our experience in developing a fully integrated commercial organization is limited to previous experience of a single member of our management. 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. See Business Sales and Marketing.

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.

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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 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. See Business Competition.

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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.

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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 Messrs. James McNulty and Mark Salyer. 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 42.3% 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, our outstanding shares of Series B Preferred, all of which is held by HCG, an affiliate of Dr. O Donnell, or our

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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 Aveva) 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 Option 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 an executive officer, on our board of directors and also is a substantial beneficial owner of our securities, including all of our outstanding shares of Series B Preferred, 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. See Certain Relationships and Related Transactions.

General Risks Related to Our Company

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

Since our initial public offering in June 2002, there has only been a 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 the

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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 (formerly 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 note 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 December 31, 2005, there were 11,828,637 shares of common stock issued and 11,813,146 shares of common stock outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. We will likely, subject to the approval of our stockholders, increase the size of our option plan at our next annual meeting of stockholders. To the extent such options (including options under our larger, amended option plan) or warrants are exercised, the holders of our common stock may experience further dilution.

In addition, 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 principal applies to potential conversions of shares our Series A and Series B convertible preferred 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.

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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 A Non-Voting Convertible Preferred Stock and 941,177 shares of common stock issuable upon full conversion of shares of our Series B Convertible Preferred Stock, (ii) 2,185,595 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $4.43 per share, (iii) 2,085,000 shares of common stock issuable upon exercise of our outstanding publicly-traded warrants at a weighted average exercise price of $6.30 per share, (iv) 412,000 shares of common stock issuable upon exercise of our non-public warrants at a weighted average exercise price of $4.52 per share and 601,120 shares potentially issuable under the warrant issued to CDC at an exercise price of $3.50 per share, and (v) up to a maximum potential of 3,014,311 shares of common stock 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 warrants with Laurus. 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, 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.

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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 believe this space is presently adequate for use as our principal executive office.

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 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 2005. Historically, the payments for rent and supplies have averaged approximately $75,000 annually. The terms of the lease allows us flexibility of terminating the lease arrangement and relocating to a new space better suited for our long-term space requirements. Our ability to terminate is without a penalty provided that we give prior written notice. The lease was renewed in December 2005 for a term of one year at a cost of $144,000 for the year, or $12,000 per month. 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 us in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for us through an initial public offering. We have provided MAS Capital s counsel with copies of documents executed by either MAS Capital or its affiliates that we allege fully release our company. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that we allege fully release us, we have filed an Amended Answer asserting a claim for our attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. We filed a motion for summary judgment on June 9, 2005, and we presently expect a ruling thereon in the second quarter of 2006. We believe that the plaintiff s claims are without merit and we intend to continue to vigorously defend the lawsuit.

We may, from time to time, be involved in other actual or potential legal proceedings that we consider to be in the normal course of our business. We do not believe that any of these proceedings will have a material adverse effect on our business.

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

None.

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PART II

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

Our common stock and Class A warrants are listed for quotation on the Nasdaq Capital Market (formerly known as the Nasdaq SmallCap 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 2005, 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, 2005	$ 3.35	$ 3.06	$ 0.55	$ 0.55
June 30, 2005	$ 3.01	$ 2.87	$ 0.23	$ 0.23
September 30, 2005	$ 1.97	$ 1.66	$ 0.50	$ 0.50
December 31, 2005	$ 2.52	$ 2.41	$ 0.35	$ 0.35

As of March 27, 2006, 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	2,100,000	$ 4.49	
Equity compensation plans not approved by security holders	85,595	$ 3.03	
Total	2,185,595	$ 4.43	

Recent Sales of Unregistered Securities

(a) On February 22, 2005, we consummated a $2.5 million secured convertible debt financing with 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) and to support our research, development and commercialization opportunities and for general working capital purposes.

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The Laurus investment takes the form of a convertible note secured by substantially all of our assets. The note has a 3-year term and bears interest at a 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, but 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 is now $2.46. In connection with the 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.

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. Net proceeds from the May Laurus financing have been 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 $2.46.

We have registered the shares of common stock underlying the February and May 2005 Laurus notes and the warrants with the SEC.

The Laurus financing documents contain certain restrictions regarding the operation of our business while the note remains outstanding. Such restrictions include that, except with Laurus prior written consent (such consent not to be unreasonably withheld), we will not issue certain classes of debt securities or equity securities. In addition, so long as 25% of the note remains outstanding, the financing documents, among other things, prohibit us, except with Laurus prior written consent, from: (i) paying dividends or redeeming shares, and (ii) incurring additional debt in excess of five percent (5%) of the fair market value of our and our subsidiaries assets, other than debt incurred in connection with the purchase of assets in the ordinary course of business, or any refinancings or replacements thereof on terms no less favorable than the indebtedness being refinanced or replaced, so long as any lien relating thereto shall only encumber the fixed assets so purchased and no other assets of ours or our subsidiaries.

In addition, Laurus is not entitled to receive shares upon exercise of the warrant, upon payment of principal and interest on the note, or upon conversion of the note 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). Further, in accordance with Nasdaq Stock Market rules, the aggregate number of shares of common stock issuable by us and acquirable by Laurus pursuant to the terms of the note or the warrant shall not exceed an aggregate of 1,428,458 shares of common stock (representing 19.99% of our issued and outstanding shares of common stock on February 22, 2005, subject to appropriate adjustment for stock splits, stock dividends, or other similar recapitalizations affecting the common stock), unless the issuance of such excess amount of common stock is first approved by our stockholders. We sought and received stockholder approval of issuances in excess of this 19.99% limit at our 2005 annual meeting of stockholders.

(b) 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

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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.

(c) 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. As of the date of this Report, $1.45 million has been drawn on the HCG equity line.

The holders of the Series B Preferred will be entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred will be 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 ranks senior to shares of Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. Additionally, we have 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. HCG has no rights to cause the redemption or buy-back of the Series B Preferred shares.

Finally, the Certificate of Designations for the Series B Preferred provides that without the prior approval of our stockholders, in no event shall we issue shares of common stock at any time upon conversion of: (i) the first $1.25 million face value of Series B Preferred (representing 294,117 shares of Series B Preferred), plus (ii) any additional shares of Series B Preferred, the proceeds from the sale of which were used by us in connection with the acquisition Arius plus (iii) all shares of Series A Preferred, to the extent that the total aggregate number of shares of common stock issued or deemed to be issued at any time to any holder or all holders of the above mentioned preferred stock would exceed 19.99% of the issued and outstanding shares of common stock immediately prior to the effective time of the acquisition of Arius. We sought and received stockholder approval of issuances in excess of this 19.99% limit at our 2005 annual meeting of stockholders.

(d) As part of the acquisition of Arius in August 2004, we 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 our 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 us 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. We believe we have satisfied both of these conditions. The holders of the Series A Preferred enjoy certain other rights and privileges.

The terms of the Series A Preferred include a provision that if, at the time that any shares of Series A Preferred are converted, our common stock is listed for quotation on The Nasdaq Capital Market or The Nasdaq National Market, then, without the prior approval of our stockholders in accordance with

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the rules of Nasdaq, we shall be prohibited from issuing shares of our common stock to the extent that the total aggregate number of shares of common stock issued or deemed to be issued would exceed 19.99% of the issued and outstanding shares of common stock immediately prior to the effective time of the Arius acquisition. We sought and received stockholder approval of issuances in excess of this 19.99% limit at our 2005 annual meeting of stockholders.

Item 6. Management s Discussion and Analysis or Plan of Operation.

The following discussion and analysis of our financial condition and plan 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 2006. 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 have an additional grant of approximately $0.6 million which will be funded through July 2006.

We have a limited history of operations, and while we have received license revenues in 2003, 2004 and 2005 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.

For the Year Ended December 31, 2005 Compared to the Year Ended December 31, 2004

Sponsored Research Revenue. During the year ended December 31, 2005, we recognized sponsored research revenue of $0.4 million, compared to $0.8 million in the prior year. The sponsored research revenues were from our NIH grant which was completed in August 2004. We have a second NIH grant of $0.6 million, which was partially drawn ($0.01 million) in the year ended December 31, 2001, $0.01 million was funded in calendar 2004, $0.4 million was drawn in 2005 and the balance will be drawn through July 2006.

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License Fee, Milestone and Royalty Revenues. In 2004, Arius entered into a license agreement relating to Emezine® with TEAMM Pharmaceuticals, a subsidiary of Accentia, and earned a $1.0 million license fee. The revenues were recognized in full in the year ended December 31, 2004. During the year ended December 31, 2005, we recognized milestone revenue of $0.4 million relating to Emezine®. In addition, we recognized $0.06 million in royalty revenue in 2005 under our license agreement with Accentia relating to CRS.

Research and Development Expenses. During the years ended December 31, 2005 and 2004, research and development expenses totaled $6.5 million and $4.0 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, 2005 and 2004, general and administrative expenses totaled $3.6 million and $3.0 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, executive personnel costs, consulting fees, and business development costs. Furthermore, we incurred expenses in 2005 and 2004 of approximately $0.08 million and $0.2 million respectively, related to operating activities of our currently inactive Bioral Nutrient Delivery, LLC subsidiary that commenced in 2003. The increase in general and administrative expenses in 2005 is primarily due to increased staffing following the acquisition of Arius, and additional patent costs, partially offset by reduced costs associated with BND.

Stock-Based Compensation Expense. Stock-based compensation expenses of $0.03 million and $0.3 million were incurred in 2005 and 2004, respectively for stock options granted for services rendered by our underwriter and legal counsel. Employees stock option grants are treated under APB 25 through December 31, 2005. We intend to adopt FAS 123R in 2006 for new options granted to employees.

Other Income. We are parties to a License Agreement, dated April 12, 2004, with Accentia pursuant to which we licensed to Accentia a topical version of encochleated Amphotericin B. Accentia is currently a privately-held biopharmaceutical holding company partly-owned by HCG, which is partly-owned and controlled by our Chairman. In September 2004, we sold to Accentia a portion of the royalty revenue stream that is associated with the License Agreement in consideration of a cash payment of $2.5 million. The $2.5 million is included in other income in the financial statements for the year ended December 31, 2004.

Interest Income (Expense), Net. During the year ended December 31, 2005 we had net interest expense of $1.35 million, compared to $0.06 million in 2004. The increase in net interest expense is primarily due to amortization of debt discount and interest paid to Laurus for the two convertible notes.

Derivative Gain. Derivative gain in 2005 is related to the adjustment of derivative liabilities to fair value as of December 31, 2005. These derivatives relate to the Laurus financing (see Notes 7 and 8 to financial statements).

Income Tax Benefit. 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 $18.7 million at December 31, 2005 and also varying amounts 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 and 2004 totaling $4.5 million and $3.0 million, which generated cash of $0.5 million and $0.2 in 2005 and 2004, respectively. 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

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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 2004 and through 2005, we dedicated most of our corporate resources to the development of Emezine®, BEMA Fentanyl, Bioral® Amphotericin B and BEMA LA. Under our June 2005 agreement with CDC, up to $7 million will made available to us for the development of BEMA Fentanyl. As a result, we may use a small portion of our current cash to begin the development of BEMA Zolpidem, but due to our limited corporate resources, we are presently focusing mainly on these five projects, which are discussed in further detail below.

We believe that other projects which we have previously identified as being in our pipeline (Bioral® Paclitaxel, and Bioral® siRNA therapeutics) represent promising opportunities. However, we are consistently evaluating such opportunities as to whether or not (or how) to actively pursue them. 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 is currently funded by an NIH grant and does not utilize our corporate resources. We have decided not to pursue the Bioral® NSAID 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 prospectus 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 BEMA drug delivery technology on a worldwide exclusive basis from Atrix. We acquired this license when we acquired Arius in August 2004. 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. 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. 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 3 months from the receipt of the approval letter.

Through the end of 2005, we expended approximately $2.75 million on our efforts relating to BEMA Fentanyl. We currently estimate that the total development costs of BEMA Fentanyl will be approximately $8.3 million. 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 Atrix 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 mid-2008.

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The risks to our company associated with the BEMA Fentanyl project include: (i) failure to develop an adequate formulation; (ii) inability of our contract manufacturer to continue to make clinical supplies; (iii) slow patient enrollment in clinical trials; (iv) lack of funding to progress the program if it requires funding other than that committed by CDC; (v) failure to demonstrate efficacy in clinical trials; (vi) the development of safety issues with the product, (vii) the conclusion by the FDA that the risk benefit is inadequate; (viii) the conclusion by the FDA that our submission is inadequate and additional information is required; and (ix) 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. We license the BEMA drug delivery technology on a worldwide exclusive basis from Atrix. We acquired this license when we acquired Arius in August 2004. This formulation would 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 are proceeding to a Phase I trial in normal volunteers whereby we would measure the blood concentrations of the product in these patients. If these concentrations meet our objectives, we would then 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 pain condition will be acute requiring short term therapy (such as post surgical patients). The BEMA LA Phase II program will take approximately 3-6 months 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. 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, depending on the final indication 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.

Through the end of 2005, we expended approximately $0.2 million on our efforts relating to BEMA™ LA. We currently estimate that the future total development costs of this formulation will be approximately $14 million.

Due to the ability of BEMA LA being able to participate in all four of the key pain markets (chronic pain, post-operative pain, breakthrough malignant pain, breakthrough non-malignant 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 Atrix, although no assurances can be given of this estimation. We do not expect to generate any revenue from BEMA LA, if ever, until at least 2009.

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,

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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. We anticipate filing an IND on this product during the fourth quarter of 2006, 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 2005, we did not expend any resources on our efforts relating to BEMA Zolpidem. We currently estimate that the future total development costs of this formulation will be approximately $9.3 million.

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 Atrix, although no assurances can be given of this estimation. We do not expect to generate any revenue from BEMA Zolpidem, if ever, until at least 2010.

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 estimate that the filing of our IND on this oral formulation of amphotericin, which we expect will be for the treatment of esophageal candidiasis, will be made in the second or third quarter of 2006. If the FDA accepts our IND, we intend to begin Phase I studies in normal volunteers immediately. These studies will assess the oral absorption of amphotericin from our cochleate formulation. Following completion of Phase I trials, we would then move into a Phase II study in patients sometime in the late 2006-early 2007 and Phase III trials in late 2007. A Phase III program would run approximately 18-24 months after which we would spend approximately 3-6 months compiling and submitting the NDA. If the FDA accepts the NDA for filing, they will then have up to 10 months from the date the submission is accepted to decide whether the application is approvable. If we receive approval within this timeframe we would be prepared for a product launch within 3 months from this time. No assurances can be given that we will successfully complete any clinical phase of clinical trials.

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Since 2001, we have expended approximately $3.4 million on our efforts relating to encochleated Amphotericin B (including approximately $1.1 million in 2005). We are responsible for all costs and expenses on our Bioral® Amphotericin B product. We currently estimate that the total development costs of this formulation will be approximately $11.0 million. We have been awarded and received all funds under a grant totaling approximately $2.7 million from the NIH to support the development of this drug formulation.

Our market research indicates that 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 this estimation. We do not anticipate generating any revenue for Bioral® Amphotercin B, if ever, until at least late 2009.

The risks to our company associated with the Bioral® Amphotericin B 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 five 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 Bioral® Amphotericin B from a commercial perspective may be significant to us. The failure of this program or a failure of the product to meet commercial forecasts would have a 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 Bioral® Amphotericin B 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 transmucousally 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. During 2005, we expended approximately $0.9 million on our efforts relating to Emezine®.

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. As of the date of this Report, we have requested a meeting with the FDA regarding their notification and will use the outcome of this meeting to evaluate 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®. 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, TEAMM Pharmaceuticals, a subsidiary of Accentia, 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.

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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 TEAMM 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 TEAMM, 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, and the follow on offering in 2005, exercise of options, various licensing agreements, NIH grants, bank financing, and through the sale of a royalty stream asset to Accentia. From inception through March 31, 2002, we raised approximately $1.8 million, net of issuance costs, through private placements or convertible preferred stock and common stock financings. On April 1, 2001, we issued 137,300 shares of common stock in consideration for payment in full of the approximate $500,000 payable to the University of Medicine and Dentistry of New Jersey due through March, 2001. Our June 2002 public offering, net of offering costs of $2.4 million, and including the exercise of the underwriter s over-allotment option raised approximately $8.6 million. Our September 2005 follow-on offering, net of offering costs of $0.3 million, and including the underwriter s over-allotment option raised approximately $7.7 million. At December 31, 2005, we had cash and cash equivalents of $4.9 million. At December 31, 2004, we had cash and cash equivalents of $0.8 million. The adequacy of cash for our operations in continued research is dependent on, among other things, licensing opportunities we are able to negotiate in the coming year, as well as the funding of our equity line of credit, further described below, which had a balance remaining of $2.55 million at December 31, 2005.

In 2001, the National Institutes of Health awarded us a three-year Small Business Innovation Research Grant of $2.7 million which was used through 2004 to fund research and development efforts. In addition, we have a second grant from NIH for a total of $0.6 million, which has a remaining balance of $0.08 million at December 31, 2005.

We used $7.7 million of cash for operations in of the year ended December 31, 2005. This consisted of a net operating loss of $10.1 million, which was partially funded through the sale of our common stock during a follow-on offering in September 2005.

In the first quarter of 2003, we received a $1 million bank line of credit from Gold Bank, which was converted to a four year term loan, with a 75% loan to value ratio, at an interest rate of 7.5%, to be used in the purchase of laboratory and other equipment and facilities improvements in our Newark, New Jersey lab. The collateral was all equipment owned by us in our Newark facility. We drew 100% of these funds during 2003, all of which was utilized for our Newark laboratory needs. During 2004, with a loan balance of approximately $0.8 million, we were out of covenant with the bank, and paid down principal of $0.4 million. The loan was paid in full in February 2005.

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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, 2005, $1.45 million has 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 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 ranks senior to our common stock and our Series A Preferred Stock and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. Additionally, we have 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. 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.

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 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 $300,000 from the February Laurus financing to retire our secured equipment bank loan with Gold Bank in connection with the closing.

We have incurred significant net losses and negative cash flows from operations since our inception. As of December 31, 2005, we had stockholders equity of $7.4 million, versus $6.0 million at December 31, 2004.

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.

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We formed Bioral Nutrient Delivery, LLC as a majority-owned subsidiary in January 2003. We sub-license to BND, on an exclusive basis, our cochleate technology for use in the processed food and beverage and personal care product industries. The minority members are Class B founder shareholders with no cost basis and no obligation to fund deficits. Our business plan calls for BND to pay 8% royalties to BDSI, as BND transacts its business in the food and beverage industry. In February, 2003, we made an unsecured loan to BND in the amount of $0.5 million to cover organization expenses and initial working capital requirements. The loan accrues interest at a rate of 4.85% annually; with the principal to be paid back solely from 10% of any royalty revenue that may be received by BND, with payments first applied to interest, then to principal. We are under no obligation to make any capital contributions or any additional loan funds to BND beyond the initial $0.5 million. We also entered into a management services and administrative agreement with BND, pursuant to which certain of our officers and employees will provide services and office space to BND. This agreement provides that through 2004, we will not require repayment for allocated officer and employee salaries or certain other general and administrative costs. As a result of our decision to focus on other areas of our business in the near-term, we withdrew the pending registration statement relating to our proposed distribution to our stockholders of Class B interest in BND in February 2005 and did not renew the management services agreement. All of the transactions between us and BND eliminate in consolidation. BND is inactive at December 31, 2005.

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 operations and capital expenditures into approximately the first quarter of 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. 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.

Other Matters - Restatement of Quarterly Financials

The Laurus financings, discussed in Notes 7, 8, and 14 of the financial statements contained within this Report, included registration rights related to share settlement of the embedded conversion features and the warrants that have been determined to be not within our 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 in that the Laurus conversion price is adjusted at the point at the point we sell securities for a price less than

such conversion price. In these instances, authoritative literature (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.

During the fourth quarter of 2005, we reevaluated our accounting for the Laurus convertible note and warrant financing transactions discussed in Note 7 to the financial statements contained within this Report. During the three, six and nine months ended March 31, June 30 and September 30, 2005, we accounted for the freestanding warrants and embedded beneficial conversion option associated with the convertible notes as equity. We have determined that these derivatives should be recorded as liabilities at fair value and thereafter adjusted to fair value at each subsequent reporting period until certain conditions are met, at which time such derivative liabilities should be reclassified into equity. As such, the unaudited quarterly financial information as previously reported has been restated and is shown in tabular form in Note 14 to the financial statements contained within this Report.

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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-31 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.

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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 March 27, 2006 are as follows:

Name	Age	Position(s) Held
Francis E. O Donnell, Jr., M.D.	56	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	52	President, Chief Executive Officer and Director
Raphael J. Mannino, Ph.D.	59	Executive Vice President, Chief Scientific Officer and Director
Andrew L. Finn, Pharm.D.	56	Executive Vice President of Clinical Development and Regulatory Affairs
Mark W. Salyer	47	Executive Vice-President of Sales and Marketing
James A. McNulty	55	Chief Financial Officer, Secretary and Treasurer
L.M. Stephenson, Ph.D.	63	Director
William B. Stone	62	Director
John J. Shea	79	Director
William S. Poole	59	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 56, 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 52, 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 4 years in executive management.

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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 59, 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 56, has been our Executive Vice President of Clinical Development and Regulatory Affairs since September 2004. 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 his current position. 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.

Mark W. Salyer, age 47, has served as our Executive Vice-President of Sales and Marketing since January 2006. From 2002 until the time he joined our company, Mr. Salyer served in a dual role as Senior Vice-President, Sales and Marketing for the U.S. and Corporate Vice-President, Global Franchise Management-Respiratory for Altana Pharma AG. Prior to joining Altana, Mr. Salyer spent 17 years at GlaxoSmithKline in numerous leadership roles including Vice President, Global Commercial Strategy for Respiratory Products based in London, England; Director of Marketing for Respiratory and Migraine Brands in the U.S., and other strategic and financial roles. Mr. Salyer holds CPA licenses in North Carolina and Virginia, a BS in Accounting from Virginia Tech and a MBA from Duke University s Fuqua School of Business. Mr. Salyer is an active member of the Healthcare Advisory Board of Duke University s Fuqua School of Business.

James A. McNulty, age 55, 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

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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. 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.

L.M. Stephenson, Ph.D., age 63, is a member of our board of directors. Dr. Stephenson is currently Vice Provost for Research at Drexel University. He was associated with the University of Medicine and Dentistry of New Jersey from 1995 until 2003, serving as the Vice President for Research with responsibility over developing the research capability, research funding and intellectual property of New Jersey s medical science campuses, including three medical schools, dental, nursing and public health schools and a graduate school of biomedical sciences. He also served as the Acting Associate Dean for Research of the New Jersey Medical School, and served as the Director of Patents and Licensing of the University of Medicine and Dentistry of New Jersey where he was responsible for management of the Intellectual Property Assets, including marketing of patents and establishment of new ventures. His responsibilities at Drexel are closely similar. Dr. Stephenson is a graduate of the University of North Carolina where he earned a BS in Chemistry and was awarded the Venable Medal as the outstanding senior in chemistry. Dr. Stephenson earned his Ph.D. in Chemistry from the California Institute of Technology where he was an NSF Predoctoral Fellow and earned the Kodak Prize for outstanding graduate studies. Additionally, Dr. Stephenson was a Research Fellow at Harvard University. Dr. Stephenson has been a Fellow of both the Dreyfus Foundation and the Sloan Foundation. Dr. Stephenson also serves on the board of directors of University City Science Center and the Hepatitis B Foundation (both Non-Profit).

William B. Stone, age 62, 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 79, 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.

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William S. Poole, age 59, 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.

Director Independence

We believe that William B. Stone, L.M. Stephenson, John J. Shea and William S. Poole qualify as independent directors for Nasdaq Stock Market purposes. This means that our board of directors is composed of a majority of independent directors as required by the rules of the National Association of Securities Dealers, or NASD.

On September 15, 2005, we received a written deficiency notification from the staff of the Nasdaq Stock Market indicating the staff s view that Donald L. Ferguson was not independent under NASD Rule 4200(a)(15) and that, therefore, our board of directors was not composed of a majority of independent directors as required by NASD Rule 4350(c)(1). Accordingly, the NASD staff indicated its position that we did not meet the independent director requirement for continued listing on the Nasdaq Stock Market.

As a result of the NASD staff s determination, Mr. Ferguson and Alan Pearce, a director of the Company who was not independent, resigned from our board of directors effective September 15, 2005. We notified the NASD staff of this action and, as a result, the staff provided us with a written notification that we had regained compliance with NASD rules and that this matter is closed.

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, L.M. Stephenson and John J. Shea, all of whom are independent directors as defined by the rules of the NASD. 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 401(e) of Regulation S-B.

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The Audit Committee met six times during 2005. 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, L.M. Stephenson and John J. Shea. Mr. Shea serves as the chairman of the committee. Mr. Shea was named chairman of this committee on August 22, 2005. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The Nominating and Corporate Governance Committee was formed in May of 2004 and did not meet formally in 2005, although members of the committee were involved with interviews of William S. Poole prior to his joining the board of directors in April 2005. 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 2005, we did not pay any fees to any third parties to assist in the identification of nominees. During 2005, 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 S. Poole, who was named chairman of this committee effective August 22, 2005 (replacing Dr. O Donnell), L.M. Stephenson and William B. Stone. The compensation committee met one time during 2005.

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, William Stone and L.M. Stephenson. The investment committee as such did not meet during 2005.

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Scientific Advisory Board

We have a Scientific Advisory Board as an additional scientific and technical resource for our management team. Members of our advisory board have entered into consulting agreements that provide for expense reimbursements, 10,000 non-qualified stock options and cash compensation of $1,500 for attendance at each formal board meeting. The following is a short discussion of the backgrounds of our Scientific Advisory Board members:

Susan G. Bonitz, Ph.D., has served as a pharmaceutical business development consultant to numerous early-stage biotechnology companies. Dr. Bonitz currently serves as Director, Business Development for BDSI. She has an extensive research background in molecular biology, including DNA cloning, RNA characterization, and PCR analysis. She has conducted research at Genentech, Exxon Research and Engineering, Schering-Plough, and Cold Spring Harbor Laboratory. Because of her evaluations of a wide range of biotechnology companies, she has interacted with both the scientific and business pharmaceutical community. Dr. Bonitz has done extensive editing for two widely used technique publications-*Current Protocols in Molecular Biology* and *Current Protocols in Immunology*. She received her Ph.D. from Columbia University in mitochondrial research and has published articles in the field in peer-reviewed journals.

Floyd H. Chilton, Ph.D., is Founder, Director, President, Chief Executive Officer and Chief Scientific Officer of Pilot Therapeutics. Prior to joining Pilot Therapeutics as CEO and CSO in December 2000, Dr. Chilton was Director of Molecular Medicine, Professor of Physiology and Pharmacology, Professor of Internal Medicine (Section on Pulmonary and Critical Care Medicine) and Professor of Biochemistry at the Wake Forest University School of Medicine. Dr. Chilton is widely recognized in academia and industry for his leading work on the role of arachidonic acid metabolism in human diseases.

Jeff Katz, MD is an associate professor of anesthesiology at Northwestern University Medical School. He also serves as director of the Pain Clinic at the Veterans Healthcare Service Lakeside Division as well as associate director of the Section of Pain Medicine at Northwestern Hospital. Dr. Katz has published numerous chapters and papers on the subjects of acute and chronic pain as well as in the area of anesthesiology, and he continues to be active in clinical practice as well as teaching and research. Dr. Katz is on the Arius Scientific Advisory Board.

Celeste Lindley, Pharm. D, MS. FCCP, FASHP, BCPS, BCOP is an associate professor of Pharmacotherapy and Experimental Therapeutics in the School of Pharmacy and clinical associate professor of medical oncology in the School of Medicine at the University of North Carolina at Chapel Hill. Her professional service includes serving as Chair of the ASHP Commission on Therapeutics and Section of Clinical Specialists, Vice Chair of the BPS Oncology Advisory Board and member of advisory committees for the USP and American Society of Clinical Oncology. Her research interests include pharmacokinetics and drug metabolism, as well as clinical research in the management of pain, nausea and vomiting. She has over 150 publications including original research, reviews and book chapters. Dr. Lindley is on the Arius Scientific Advisory Board.

Arthur G. Lipman, Pharm. D,FASHP is a Professor of Pharmacotherapy in the College of Pharmacy, Adjunct Professor of Anesthesiology in the School of Medicine, and Director of Clinical Pharmacology at the University of Utah Hospitals and Clinics Pain Management Center. Dr. Lipman served on both the Acute Pain Management and Cancer Pain Management Guidelines Panel of the of the U.S. Public Health Service Agency for Health Care Policy and Research. His professional service includes being co-chair of the Arthritis Pain Management Clinical Guidelines Panel of the American Pain Society, the American Cancer Society National Advisory Group on Cancer Pain Relief, the American

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Pain Society Analgesic Regulatory Affairs Committee and the joint Ethics Task Force of the American Pain Society and American Academy of Pain Medicine. Lipman has over 100 publications and is the founding editor of the Journal of Pain and Palliative Care Pharmacotherapy. Dr. Lipman is on the Arius Scientific Advisory Board.

Bill McCarberg MD is Founder of the Chronic Pain Management Program for Kaiser Permanente in San Diego, California. He was on the board of directors of the American Pain Society. He is co-president of the Western Pain Society and Assistant Clinical Professor (voluntary) at the University of California at San Diego School Medicine. Dr McCarberg is a member of the American Academy of Family Physicians, the American Academy of Pain Medicine, the American Pain Society, and the International Association for the Study of Pain. He is the recipient of several awards, including the Shilling Compassionate Care Award, and in 1998 was named the Highest Rated Physician by Member Appraisal of Physician Services at Kaiser Permanente. He also received the Elizabeth Narcessian award for leader in the field of pain education from the American Pain Society. He has given more than 30 presentations on pain management issues and is the author or co-author of several publications. He is board certified by the American College of Pain Medicine, the American Board of Family Practice and additionally certified in Geriatrics. Dr McCarberg received his MD degree from Northwestern University Medical School in Chicago, Illinois. He completed a medical internship and a residency in family practice at Highland Hospital in Rochester, New York. Dr. McCarberg is on the Arius Scientific Advisory Board.

David S. Perlin, Ph.D., is Scientific Director of the Public Health Research Institute, a 63 year old biomedical research organization that specializes in infectious diseases research. His laboratory studies the molecular basis for clinical resistance to antifungal drugs and helps develop rapid diagnostic approaches for fungal pathogens, agents of bioterrorism, and new disease agents like the SARS coronavirus. As Scientific Director, Dr. Perlin has helped PHRI emerge as one of the foremost tuberculosis research organizations in the world. He also provided leadership for the development of the International Center for Public Health, a specialized center for infectious diseases research in Newark, NJ. Dr. Perlin was a consultant to the US Senate for their investigation of the Fall 2001 anthrax outbreak and he is an Executive Committee member of the Northeast Biodefense Center. He regularly serves on NIH review panels, is on the editorial board of a number of biomedical research journals, is a member of Senator Jon Corzine s New Jersey Healthcare Taskforce, and serves on the New York City Department of Health advisory panel on bioterrorism and emerging pathogens.

Leo A. Whiteside, M.D., is founder and President of Missouri Bone and Joint Center, Missouri Bone and Joint Research Laboratory, and Whiteside Biomechanics Inc. Dr. Whiteside is an internationally recognized arthritis surgeon and innovator, specializing in total replacement of the hip and knee. He has been the surgeon-inventor for three major hip replacement and two major knee replacement systems, and his company is involved with developing and marketing orthopedic surgical instruments and implantable devices. He is past president of the Hip Society. He is recipient of the Charnley award for excellence for research involving hip replacement surgery, the Volvo Award for innovative research involving the spine and the Ranawat Award for excellence in research involving knee replacement surgery. He is currently on the editorial board of The Journal of Arthroplasty and Clinical Orthopedics and Related Research.

Commercial Advisory Board

We also have a Commercial Advisory Board as an additional sales and marketing resource for our management team. The following is a short discussion of this advisory board member s background:

William O. Baicy has nearly 30 years of sales, marketing and general management experience in the pharmaceutical industry. Most recently Bill held the position of Executive Vice President of

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Commercial Development for Andrx Pharmaceutcials. Prior to holding this position Bill Baicy held several senior commercial management positions at Glaxo, Glaxo Wellcome and GlaxoSmithKline including Vice President of Marketing Cerenex Division; Vice President and General Manager of Care Management Division; Vice President of New Product Market Planning and Vice President of Business Development. Bill was also the President of HealthMatics, a joint venture between Glaxo Wellcome and Physicians Computer Newtwork, Inc. a developer and distributor of practice management systems to 100,000 physicians. Mr. Baicy began his career in the pharmaceutical industry as a Sales Representative for Syntex Laboratories.

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 2005, 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.

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.

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 ($)	All Other Compensation ($)
Francis E. O Donnell, Jr., M.D.	2005	$ 0				25,000		
	2004	117,962				35,000		
Chairman and Director	2003	145,962				35,000		
709 The Hampton Lane								
Chesterfield, MO 63017								
Mark A. Sirgo, Pharm.D.	2005	$ 202,366				77,929		
President and Chief Executive Officer	2004	62,596	31,177			5,147		
3100 Stone Gap Court	2003							
Raleigh, North Carolina 27612								

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		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 ($)	All Other Compensation ($)
Andrew L. Finn, Pharm.D.	2005	$ 192,471				57,929		
Executive Vice President of Clinical	2004	62,596	28,092			5,147		
Development and Regulatory Affairs	2003							
737 West Hargett Street								
Raleigh, NC 27603								
James A. McNulty,	2005	$ 113,670				36,189		
Chief Financial Officer, Secretary and	2004	105,866				3,235		
Treasurer	2003	141,769				18,616		
4419 W. Sevilla Street								
Tampa, FL 33629								
Raphael J. Mannino, Ph.D [2],	2005	$ 97,171		11,250		30,714		$ 3,543
Executive Vice President and Chief	2004	88,788		11,423		26,176		5,015
Scientific Officer	2003	90,000	52,500			111,449		5,015
UMDNJ New Jersey Medical School								
185 South Orange Avenue, Building 4								
Newark, NJ 07103								

* 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 $6,750 and 401(k) matching of $4,500 paid in 2005 as reflected in column (e) and (b) premiums paid on key-man life insurance has set forth in column (i). Excludes $114,690, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2005 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

Option Grants During Year Ended December 31, 2005

	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%($)
Francis E. O Donnell, Jr.	25,000	4%	$ 2.94	8/22/2015	$ 46,500	$ 116,750
Mark A. Sirgo	28,929	5%	$ 2.94	8/22/2015	$ 53,808	$ 135,098
	49,000	9%	$ 3.03	12/1/2015	$ 84,280	$ 215,100
Andrew L. Finn	8,929	2%	$ 2.94	7/252015	$ 16,608	$ 41,698
	49,000	9%	$ 3.03	12/1/2015	$ 84,280	$ 215,100
Raphael J. Mannino	30,714	5%	$ 2.94	8/22/2015	$ 57,128	$ 143,434
James A. McNulty	26,189	5%	$ 2.94	7/28/2015	$ 48,712	$ 122,303
	10,000	2%	$ 3.03	12/1/2015	$ 17,200	$ 43,900

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AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR

AND FY-END OPTION/SAR VALUES

Name and Principal Position (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)
Francis E. O Donnell, Jr., M.D.			130,000	$ 6,650
Mark A. Sirgo, Pharm.D.			21,715/61,361	
Andrew L. Finn, Pharm.D.			1,715/61,361	
Raphael J. Mannino, Ph.D.			274,557/24,315	$ 70,400
James A. McNulty			13,489/44,551	

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:

(a) Dr. Francis E. O Donnell, Chairman 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 candidate 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.

(b) 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. He was subsequently promoted twice and now holds the position of President and Chief Executive Officer of our company at an annual salary of $250,000. Dr. Sirgo also received a signing bonus in the amount of $31,177 at the signing of this agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(c) Andrew L. Finn, Pharm.D., Executive Vice President of Clinical Development and Regulatory Affairs 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 Clinical Development and Regulatory Affairs of our company at an annual salary of $220,000. Dr. Finn also received a signing bonus in the amount of $28,092 at the signing of this agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

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(d) 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 in June 2003) for a base salary of $185,000, reduced to $110,000 in June 2003, which agreement terminates on June 15, 2006. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(e) 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. Such expired on September 1, 2005, with the effect that, although Dr. Mannino is still an officer and director of our company in good standing, he currently is employed without an agreement.

(f) Mark W. Salyer, Executive Vice-President of Sales and Marketing On December 2, 2005, Mr. Salyer executed a one-year employment agreement to be our Executive Vice-President of Sales and Marketing beginning January 9, 2006 at an annual salary of $220,000. The term of this agreement automatically renews for successive one-year terms beginning December 31, 2006 unless terminated on 30-days advance written notice. 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 Option Plan

The purpose of the Amended and Restated 2001 Stock Option 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 Option Plan, we reserved 572,082 shares. The plan was approved by our stockholders at our October 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 Option Plan, to 2,100,000 shares, which was amendment and restatement was approved by our stockholders at the Annual Meeting in August 2003. Options to purchase 2,192,595 shares of common stock are outstanding as of December 31, 2005 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 issued in 2005 over the plan limits are subject to stockholder approval at the 2006 annual meeting of stockholders. We will likely seek to increase the overall size of our plan at such meeting. 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.

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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 3,492,740 shares of our common stock at prices ranging from $1.63 to $17.48 are outstanding at December 31, 2005. None of our options have been granted at less than 85% of the fair market value at the time of grant. Options issued during 2005 to employees and directors totaled 525,407 shares, at exercise prices ranging from $2.94 and $3.74. In addition, during 2005, we issued warrants to purchase 933,145 shares of common stock at an exercise price ranging from $0.001 and $3.88 to Laurus related to the principal note payment deferral. We also issued warrants to purchase 75,000 shares of common stock at an exercise price of $1.82 to Aveva in conjunction with our supply agreement with them.

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

The following table sets forth, as of March 27, 2006, 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 March 27, 2006
Hopkins Capital Group II, LLC [2]	3,652,756	30.7%
Francis E. O Donnell, Jr., M.D.[3]	3,986,212	33.5%
The Francis E. O Donnell, Jr. Irrevocable Trust #1[4]	3,820,256	32.1%
Pharmaceutical Product Development, Inc. [5]	690,000	5.8%
Jonnie R. Williams, Sr. [6]	3,744,288	31.4%
MOAB Investments, LP [7]	3,698,523	31.1%
Laurus Master Fund, Ltd. [8]	583,499	4.99%
Mark A. Sirgo, Pharm.D. [9]	41,515	*
Andrew L. Finn, Pharm.D. [10]	1,715	*
Raphael J. Mannino, Ph.D. [11]	429,566	3.6%
Mark W. Salyer [12]	-0-	*
James A. McNulty [13]	92,148	*
L.M. Stephenson, Ph.D [14]	155,500	1.3%
William B. Stone [15]	185,000	1.6%
John J. Shea [16]	105,000	1.0%
William S. Poole [17]	35,000	*
All Directors and Officers as a group (10 persons)	5,031,656	42.3%

* Less than 1%

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(1) Based on 11,908,146 shares of common stock outstanding as of March 27, 2006.

(2) Hopkins Capital Group II, LLC is owned one third by each of: (i) various trusts of the O Donnell family (see Note 4); (ii) John R. Williams, Sr. and his family trusts (see Note 6); and (iii) MOAB Investments, LP, which is beneficially owned by Dr. Dennis Ryll and members of his family (see Note 7). Hopkins Capital Group II, LLC also owns 341,176 shares of our Series B Convertible Preferred Stock, of which are presently convertible into shares of our common stock at March 31, 2006.

(3) Dr. O Donnell is our Chief Executive Officer, 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 of. 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 options to purchase 130,000 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 2), of which The Francis E. O Donnell, Jr. Irrevocable Trust #1 owns approximately 27%. The remaining 167,500 shares of common stock are held directly by this trust.

(5) PPDI s address is 3151 South Seventeenth Street, Wilmington, NC 28412.

(6) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2). Also includes 45,766 shares of common stock that are personally owned by Mr. Williams and an additional 45,767 shares owned by Mr. Williams wife. Mr. Williams address is 1 Starwood Lane, Manakin-Sabot, VA 23103.

(7) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2). MOAB Investments, LP is beneficially owned by Dr. Dennis Ryll and members of his family. The remaining 45,767 shares of common stock are personally owned by Dr. Ryll. The address for MOAB and Dr. Ryll is 2595 Red Springs Drive, Las Vegas, NV 89135.

(8) Up to a maximum potential of 3,014,311 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 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 825 Third Avenue, 14th Floor, New York, NY 10022.

(9) Includes 19,800 shares owned by Dr. Sirgo, our President and Chief Executive Officer. Dr. Sirgo also owns 797,414 shares of our Series A Convertible Preferred Stock, of which none are presently convertible into shares of our common stock. Includes options to purchase 20,000 shares of common stock, all of which are currently exercisable. Excludes options to purchase 61,361 shares of common stock which are not currently exercisable. Dr. Sirgo s address is 3100 Stone Gap Court Raleigh, North Carolina 27612.

(10) Dr. Finn is our Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn owns 797,414 shares of our Series A Convertible Preferred Stock, of which none are presently

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convertible into shares of our common stock. Excludes options to purchase 61,361 shares of common stock which are not currently exercisable. Dr. Finn s address is 737 West Hargett Street, Raleigh, NC 27603.

(11) Dr. Mannino is our Executive Vice President, Chief Scientific Officer and a Director. Includes 155,009 shares owned and options to purchase 274,557 shares of our common stock, all of which are currently exercisable. Excludes options to purchase 25,315 shares of common stock which are not currently exercisable.

(12) Mr. Salyer is our Executive Vice-President of Sales and Marketing. Excludes 100,000 options to purchase shares of our common stock, none of which are currently exercisable. His address is 205 Larkwood Lane, Cary, North Carolina 27511.

(13) Mr. McNulty is our Chief Financial Officer, Secretary and Treasurer. Includes 76,371 shares owned and options to purchase 13,489 shares of our common stock, all of which are currently exercisable. Includes 2,288 shares owned by his wife, as to which he disclaims beneficial interest of. Excludes options to purchase 44,551 shares of common stock which are not currently exercisable. Mr. McNulty s address is 4419 W. Sevilla Street, Tampa, FL 33629.

(14) Includes options to purchase 120,000 shares of our common stock, all of which are currently exercisable. Dr. Stephenson s address is 2401 Pennsylvania Ave., Apt. 5B, Philadelphia, PA 19130.

(15) Includes 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.

(16) Includes options to purchase 95,000 shares of our common stock, all of which are currently exercisable. Mr. Shea s address is 90 Poteskeet Trail, Kitty Hawk, NC 27949.

(17) Includes options to purchase 35,000 shares of our common stock, all of which are currently exercisable. Mr. Poole s address is 1301 Kings Grant Drive, Raleigh, NC 27614.

Item 12. Certain Relationships and Related Transactions.

We have several business relationships with Accentia and its affiliates. Hopkins Capital Group, 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, as well as all of our Series B Convertible Preferred Stock, is a significant stockholder of Accentia. In addition, Dr. Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, is the Secretary and Treasurer of Accentia, and 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.

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

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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.

Mr. James McNulty, our current Secretary, Treasurer and part-time Chief Financial Officer, is also the Chief Financial Officer of The Hopkins Capital Group II, LLC, which is affiliated with Dr. Francis E. O Donnell, our Chairman of the Board.

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 44,510 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 constitutes a majority as required by NASD rules. We believe that William B. Stone, L.M. Stephenson, John J. Shea and William S. Poole qualify as independent directors for Nasdaq Stock Market purposes.

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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)

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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)
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)

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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 requested 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)

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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 requested 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 requested 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)

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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 requested 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)

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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 December 2, 2005, between the Company and Mark W. Salyer (*)
10.83	Amendment, dated March 30, 2006, to Equity Line of Credit Agreement by and between the Company and Hopkins Capital Group II, LLC (*)
20.1	Code of Ethical Conduct of the Registrant (28)
21.1	Subsidiaries of the Registrant (*)
31.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
31.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)

* Filed herewith

** A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

(2) Previously filed with Form 10QSB, for the quarter ended March 31, 2001.
(3) Previously filed with Form 10KSB, for the fiscal year ended December 31, 2000 filed on August 15, 2001.
(5) Previously filed with Form 8K filed October 26, 2000 under our prior name of MAS Acquisition XXIII Corp.
(6) Previously filed with Form 10SB filed January 18, 2000 under our prior name of MAS Acquisition XXIII Corp.
(8) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(9) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.
(10) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.
(11) Previously filed with Form SB-2, Amendment No. 5, May 23, 2002.
(12) Previously filed with Form SB-2, Amendment No. 6, June 24, 2002.
(13) Previously filed with Form 10-QSB, November 15, 2002.
(14) Previously filed with Form 8-K, January 7, 2003.
(15) Previously filed with Form 8-K, February 26, 2003.
(16) Previously filed with Form 8-K, April 25, 2003.
(17) Previously filed with Form 10-QSB/A, September 2, 2003.
(18) Previously filed with Form 8-K, November 19, 2003.
(19) Previously filed with Form 8-K, June 4, 2004.
(20) Previously filed with Form 8-K, August 6, 2004.
(21) Previously filed with Form 8-K, August 12, 2004.

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(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.

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, 2005 and 2004, the review of the financial statements included in our Forms 10-QSB and consents issued in connection with BND s registration statement filings for 2003 totaled, respectively, $59,195 and $85,000. 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, 2005 and 2004 were $52,360 and $34,025, 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, 2005 and 2004 were $16,554 and $17,600, 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, 2005 and 2004 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

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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, 2005, and the related consolidated statements of operations, stockholders equity, 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, 2005, 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

March 31, 2006

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

DECEMBER 31, 2005

ASSETS	
Current assets:	
Cash and cash equivalents	$ 4,914,735
Due from related party	59,038
Prepaid expenses and other current assets	211,445
Total current assets	5,185,218
Equipment, net	647,677
Goodwill	2,715,000
Other intangible assets:	
Licenses	2,442,171
Non-compete agreements	500,000
Accumulated amortization	(647,608)
Total other intangible assets	2,294,563
Other assets	844,430
Total assets	$ 11,686,888
LIABILITIES AND STOCKHOLDERS EQUITY	
Current liabilities:	
Current maturities of convertible notes payable	$ 1,609,144
Accounts payable and accrued expenses	1,194,797
Due to related party	37,668
Deferred revenue	70,360
Dividends payable	87,553
Derivative liability	1,687,026
Total current liabilities	4,686,548
Convertible notes payable, less current maturities	1,623,144
Total liabilities	6,309,692
Commitments and contingencies (Notes 5 and 13)	
Stockholders equity:	
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, 11,828,637 shares issued; 11,813,146 shares outstanding	11,829
Additional paid-in capital	23,831,168
Treasury stock, at cost, 15,491 shares	(47,183)
Accumulated deficit	(23,574,501)

Total stockholders equity	5,377,196
Total liabilities and stockholders equity	$ 11,686,888

See notes to consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2005 AND 2004

	2005	2004
Sponsored research revenues	$ 364,225	$ 778,898
License fees, milestone and royalty revenues, related parties	422,342	1,000,000
Research fees	62,995	
	849,562	1,778,898
Expenses:		
Research and development:		
Related party	937,029	807,524
Other	5,526,833	3,180,513
General and administrative:		
Stock-based compensation	31,725	263,798
Related party	66,835	263,804
Other	3,501,561	2,747,087
	10,063,983	7,262,726
Loss from operations	(9,214,421)	(5,483,828)
Other income (expense):		
Sale of royalty rights, related party		2,500,000
Sale of tax loss carryforwards	451,590	216,674
Interest income (expense), net	(1,345,496)	(59,361)
Derivative gain	28,930	
	(864,976)	2,657,313
Net loss	(10,079,397)	(2,826,515