BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB/A
April 29, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB/A

(Amendment No. 1)

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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, 2004

¨ 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)

UMDNJ Medical School

185 South Orange Avenue, Bldg. #4

Newark, New Jersey 07103

(Former name, former address and former fiscal year, if changed since last report)

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. x

Issuer s revenues for fiscal year 2004 were $1,778,898.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 22, 2005 was approximately $8,648,748.20 based on the closing sale price of the company s common stock on such date of U.S. $3.70 per share, as reported by the Nasdaq SmallCap Market.

Transitional Small Business Disclosure Format: Yes ¨ No x

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INTRODUCTORY NOTE

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 and other similar expressions. In addition, any statements that refer to expectations, projections 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 and development 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 and status of our filings with the U.S. Food and Drug Administration, which we refer to herein as the FDA;
- our ability to generate commercial viability and acceptance of our Bioral® and BEMA technology platforms and our proposed formulations and products;
- the protection and control afforded by our interest in licensed patents, or our ability to enforce our rights under such licenses;
- the ability of our sublicense partners to commercially exploit our drug delivery platforms;
- our ability to enter into sublicenses and to receive royalty and other payments from Accentia and other 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/or attract capital; and
- the competition that may arise in the future.

The foregoing does not represent an exhaustive list of risks. Other sections of this Report include additional risks which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. 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, or partner with third parties on, clinically-significant new formulations of proven therapeutics, nutraceuticals and micronutrients. Our drug delivery technologies include: (i) the patented Bioral® nanocochleate technology, designed for a potentially broad base of applications, and (ii) the patented BEMA (transmucosal, or applied to the inner cheek membrane) drug delivery technology being developed by our Arius Pharmaceuticals, Inc. subsidiary, which we acquired in August 2004 and which we refer to herein as Arius. Arius is developing products for acute treatment opportunities such as pain, anxiety, nausea and vomiting.

Our Bioral® drug delivery technology encapsulates the selected drug in a nanocrystalline structure termed a cochleate cylinder. We also believe this technology can be applied to micronutrients for use in processed foods and beverages and personal care products. 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 drug or micronutrient. Our Bioral® drug delivery technology was developed in collaboration with The University of Medicine and Dentistry of New Jersey and the Albany Medical College (which we refer to herein as the Universities) that have each 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. A second formulation for intranasal administration Amphotericin B to treat chronic rhinosinusitis is now in development. In April 2004, we licensed this second product to Accentia Biopharmaceuticals, Inc., or Accentia, for the use in the treatment of chronic rhinosinusitis, or CRS, and asthma. We have also explored the creation of cochleate formulations of important nutrients, which we have prepared in kilogram quantities using standard manufacturing processes. We believe these preparations may stabilize the encochleated micronutrients during food processing and may enhance the shelf life of the end product.

Our BEMA drug delivery technology consists of a dissolvable, dime-sized 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, or trauma cases where intravenous lines or injections are unavailable or not practical. Our lead BEMA product under development is BEMA fentanyl, a treatment for breakthrough cancer pain. This product is projected to enter into Phase III trials for breakthrough cancer pain in the second half 2005. A follow on product, BEMA Long Acting Analgesic, is also under development. This 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 chronic pain due to osteoarthritis, lower back disorders and rheumatoid arthritis. We intend to submit an Investigational New Drug Application, or IND, and enter BEMA Long Acting Analgesic into clinical trials in the second half of 2005. Arius licenses 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.

Through Arius, we are also developing Emezine®, which we believe is the first drug to be delivered transmucousally for rapid treatment of nausea and vomiting. In February 2005, we announced that we completed the clinical studies required for our pending New Drug Application, or NDA, on Emezine®. We anticipate filing of the Emezine® NDA in April of this year. Through Arius, we license Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

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Our development strategy focuses on the utilization of the FDA 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 efficient and less time consuming than other FDA approval methods.

In addition to developing and commercializing our drug delivery technologies and initial Bioral® and BEMA products, we are presently in the process of determining the cost and timing of progressing with our autologous HIV therapy to an IND. This technology is being developed as a patient specific, or autologous, therapy for treatment following HIV infection. Our autologous HIV therapy is based upon a patented proteoliposome technology, which we believe facilitates uptake by cells responsible for stimulating immune responses. We believe that the ongoing research and development of this technology will require significant time and resources and we intend to primarily rely upon the availability of grants and corporate support to largely finance further development of this technology, and we may elect not to continue this program. We are also developing 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 a National Institutes of Health, or NIH, grant which expires during 2005. We plan on evaluating a potential extension of this grant in 2005.

We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through: (i) 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 and (ii) licensing and joint venture arrangements with pharmaceutical companies, whose own proprietary pharmaceutical products may benefit from our drug delivery technologies. We also have and may continue to raise additional funding from other sources, including debt financing and equity financing. While there can be no assurance that such sources will provide adequate funding for our operations, management believes such sources will be available to us.

In early 2005, we moved our principal executive offices to Arius offices in North Carolina. The new address of our principal executive offices is 2501 Aerial Center Parkway, Suite 205, Morrisville, North Carolina 27560 and our phone number there is (919) 653-5160. Our principal research facilities are in Newark, New Jersey. We also have an administrative office in Tampa, Florida. In this Report, unless the context specifically requires otherwise, the terms BDSI, we, us, our and similar terms refer to BioDelivery Sciences International, Inc., a Delaware corporation, together with its consolidated subsidiaries, Arius and Bioral Nutrient Delivery, LLC, which we refer to herein as BND.

Historical and Recent Events

Public Offering and Financing

On June 24, 2002, the Securities and Exchange Commission, or SEC, declared our Registration Statement on Form SB-2, Registration No. 333-72877, effective. Commencing on June 25, 2002, and pursuant to such Registration Statement, we conducted an offering consisting of 2 million units, which we refer to herein as Units, with each Unit consisting of: (i) one share of common stock, par value $.001 per share, 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 was $8,226,758. As of the fiscal year ended December 2004, we had exhausted substantially all of the proceeds from our public offering.

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Acquisition of Arius Pharmaceuticals, Inc.

On August 24, 2004, we consummated the acquisition of Arius. As a result of this acquisition, Arius was reorganized with and into a newly formed, wholly-owned subsidiary, which we renamed Arius Pharmaceuticals, Inc. following the closing. 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. rights to a transmucousally delivered tablet formulation of Emezine®, an anti-nausea and vomiting medication. Through Arius, we license Emezine® from Reckitt.

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 to the position of Executive Vice President and Chief Operating Officer of our company and, in early 2005, was named President 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.

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 and CEO. 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. As of December 31, 2004, $1.45 million has been drawn under the Equity Line Agreement.

Subsequent Events

The following material events occurred subsequent to December 31, 2004:

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 Finanziaria S.p.A., or Sigma-Tau, a holding company of The Sigma-Tau Group. 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 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.

Laurus Financing

On February 22, 2005, we consummated a $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., a Cayman Islands corporation (referred 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) and will be used to support our research and development opportunities and for general working capital purposes.

The 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. 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. We have agreed, pursuant to a registration rights agreement, to register the shares of common stock underlying the Laurus note and the warrant.

Overview of Specialty Pharmaceuticals

Since our inception, we have focused primarily on research and development of our licensed encochleation technology and the application of such technology to specific drugs and nutraceuticals. 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 have begun 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. We are currently seeking to capitalize on the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of new these formulations of previously approved therapeutics which incorporate our licensed drug delivery technologies.

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

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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
Emezine®	Nausea/Vomiting	Pre-registration	Partnered
BEMA Fentanyl	Breakthrough pain	Clinical Trials	In-house commercialization
BEMA Long Acting Analgesic	Pain	Preclinical	In-house commercialization
Bioral® Amphotericin B	Fungal infections	Preclinical	In-house commercialization
Bioral® NSAID	Pain/inflammation	Preclinical	Available for licensing
Bioral® Paclitaxel	Oncology	Preclinical	Available for licensing
Bioral® siRNA therapeutics	Infectious disease/cancer	Preclinical	Available for licensing
Subunit HIV Vaccine	Encochleated HIV vaccine	Preclinical	Available for licensing
Autologous HIV Vaccine	Therapeutic vaccine for HIV	Preclinical	Available for licensing

We are presently dedicating most of our corporate resources toward the development and commercialization of Emezine®, BEMA Fentanyl, Bioral® Amphotericin B and BEMA Long Acting Analgesic.

Description of Our Drug Delivery Technologies and Proposed Formulations and Products

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.

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Our licensed Bioral® cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our Bioral® cochleate technology are phosphatidylserine, or PS, and calcium. Phosphatidylserine 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 that we are aware of) 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 nontoxic nature, today phosphatidylserine isolated from soybeans is sold in health food stores as a nutritional supplement.

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

Potential Advantages

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

All-natural ingredients. Our Bioral® drug delivery technology uses phosphatidylserine, which can be sourced from soy beans, and calcium. Phosphatidylserine from soybeans is available commercially as a nutritional supplement with FDA-allowed health promotion claims.

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

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

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

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

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Stability. Our Bioral® drug delivery technology employs cochleates which consist of multi-layered structures of large, continuous, solid, lipid bilayer sheets, either stacked or rolled up in a spiral, with little or no internal aqueous space. We believe that our cochleate preparations can be stored in cation-containing buffer, or dried, by freezing in a high vacuum environment, to a powder, which is then stored at room temperature and reconstituted with liquid prior to administration. Our cochleate preparations have been shown to be stable for more than two years in cation-containing buffer, and at least one year as a powder at room temperature.

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

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

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

Initial Bioral® Products in Development

We plan a diverse pipeline of products to 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 and nutraceutical 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.

Bioral® Amphotericin B

Systemic fungal infections continue to be a major domestic and international health care problem. In the mid-1990s, Amphotericin B was the most commonly used drug to treat these infections in the United States. Amphotericin B is an established drug which is delivered intravenously. 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 late 2005. In the last year, we have successfully sourced phosphatidylserine, or 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

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toxicology in animals. Accordingly, we estimate that the submission of our IND will be made in the fourth quarter of 2005. We estimate that the preclinical and clinical development costs of this formulation will be approximately $7.0 million.

Amphotericin B is an established drug which is used to a disease that frequently strikes patients with AIDS. 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.

According to Visiongain, a market research firm, in 2003, the global antifungal market was approximately $6 billion and is projected to grow to as much as $8 billion by 2009. 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 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. The license agreement was amended effective June 1, 2004, then modified in September 2004 by the asset purchase agreement with Accentia describe below, and was twice amended again in 2005 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 estimates that annual prescription cost for its CRS product will be approximately $1,000 per patient. 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 the 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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Encochleated HIV Subunit Vaccine

Very few vaccine formulations have the ability to work following oral administration. Cochleates have demonstrated the capability in mice to orally deliver DNA, protein immunogens and also small molecules. They have been shown to be effective vehicles for inducing immune responses when administered by parenteral or mucosal routes. Our scientists are working to develop a safe and effective prophylactic/therapeutic HIV subunit vaccine (i.e., a vaccine that creates a bodily immunity to a virus from whose DNA the vaccine is made). The advantages of this potential vaccine may be:

- oral administration because of safety, convenience, lower cost, and the potential to induce systemic and mucosal immunity;
- stability at room temperature;
- induced protective, HIV-specific, antibody and cell mediated immunity; and
- induced systemic and mucosal immune responses.

This program is currently funded via an NIH grant which expires during 2005. We plan on evaluating a potential extension of this grant in 2005.

Bioral® NSAIDS

We have targeted inflammation disorders, such as arthritis, for development of Bioral® products, based upon accepted, unpatented, over-the-counter and prescription anti-inflammatory drugs such as generic aspirin or ibuprofen. Various types of over-the-counter anti-inflammatory compounds are currently available. Nonsteroidal anti-inflammatory drugs, or NSAIDS, significantly decrease inflammation at higher dosages. We believe that Bioral® cochleates may be used to effectively deliver anti-inflammatory drugs with reduced side effects. The primary advantages which we are seeking for our proposed Bioral® anti-inflammatory products include reduced gastrointestinal side effects, reduced required dosage and improved cellular uptake. Anti-inflammatories formulated within cochleates are inside a multi-layered solid particle which we believe may enhance the safety and efficacy profiles and could potentially transform the compounds into an entirely new class of improved anti-inflammatory drugs.

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 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.

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.

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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 early 2005, we established a collaborative research agreement with a major pharmaceutical company to explore the use of our cochleate delivery technology for systemic and oral delivery of siRNA.

Other Bioral® Projects. We previously targeted the application of our licensed encochleation technology to pharmaceuticals for the treatment of tuberculosis and hereditary lysosomal storage diseases, in particular to Gaucher Disease. We have also pursued collaborative studies with a university for the purpose of determining the feasibility of applying our encochleation technology to create an oral formulation of Apo-A1, a component of HDL. As we are presently focusing our efforts on formulations which are further along in the pre-clinical and clinical stage, we decided in 2004 to place these programs on hold.

BEMA™ Technology Overview

Licensed from a third party to us through our Arius subsidiary, BEMA™ stands for bioerodible mucoadhesive. BEMA™ discs are the size of a dime 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 IV lines or injections are unavailable or not practical. The BEMA™ system permits control of two critical factors allowing for better dose to dose reproducibility: (i) the contact area for mucosal drug delivery, and (ii) the time the drug is in contact with that area, known as residence time.

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

- Adhere to mucosa in seconds and dissolve in minutes;
- Permit absorption to be determined by the product, with patients not being required to swish or move the product around in the mouth for absorption;
- Have a narrow, reproducible delivery rate, not susceptible to varying or intermittent contact with mucus membranes;
- Dissolve completely, leaving no residual product or waste unlike certain other systems; and
- Cost of goods are relatively inexpensive unlike certain other systems.

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Emezine® and Current BEMA™ Formulations In Development

Emezine®

Through Arius, we have licensed the U.S. rights to a transmucousally delivered formulation of Emezine®, an anti-nausea and vomiting medication used for treating nausea and vomiting which occurs after surgeries and chemotherapy. 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.

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.

We believe that our licensed Emezine® tablet:

- Will be the first transmucousally delivered anti-emetic in U.S. market place;
- May offer predictability and speed of onset similar to intravenous injections; and
- Will avoid the discomfort of injections and the inconvenience of suppositories.

Postoperative nausea and vomiting, or PONV, occurs in approximately 30% of patients undergoing operative procedures. Many factors influence the risk and severity of PONV. These include patient specific factors (age, gender), operative procedure (type and duration of procedure) anesthetic related factors (type and duration) and postoperative factors (presence of pain, oral intake). Although significant progress has been made in the prevention of symptoms, patients continue to have difficulty with PONV. Vomiting can result in dehydration, electrolyte imbalances, prolonged recovery room stay, hospital admissions and loss of work.

Anti-emetic, agents are most effective when given prior to the surgical procedure or at cessation of anesthesia and frequently must be continued for several hours after the operative procedure. Products commonly employed for prevention and treatment of PONV are limited to dopamine receptor antagonists (droperidol, prochlorperazine) and serotonin receptor antagonists (ondansetron, granisetron, dolasetron, palonosetron). Dopamine receptor antagonists were the first agents used for PONV and remain the most effective agents.

Chemotherapy induced nausea and vomiting, or CINV, occurs in 70% to 80% of patients receiving different regimes of chemotherapy. CINV is classified five (5) different ways:

Anticipatory: nausea and vomiting occurring as a conditional response from previous chemotherapy;

Acute: acutely within the first 24 hours of the patient receiving their chemotherapy regimen;

Delayed: nausea and vomiting occurring 24 hours after chemotherapy administration (may begin as early as 16 hours after chemotherapy);

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Breakthrough: nausea and vomiting occurring despite preventative therapy; and

Refractory: nausea and vomiting occurring during subsequent cycles of chemotherapy when anti-emetic prophylaxis or rescue therapy (or both) has failed in earlier cycles.

Various classes of drugs have efficacy against acute emetogenic chemotherapy and radiotherapy. These include dopamine receptor antagonists, cannabinoids, corticosteroids and the serotonin (5-HT3) receptor antagonists. Emezine® s active ingredient has activity against Acute, Delayed and Breakthrough CINV. Nausea and vomiting also occur in relation to other conditions such as migraine, vertigo, viral illness and the use of opiod analgesics. Dopamine receptor antagonists are utilized to treat nausea and vomiting caused by many of these conditions.

Based on our market research, we believe that Emezine® may be able to participate in the CINV, PONV and the general nausea and vomiting markets. Such research indicates that Emezine® may be able to achieve peak sales of approximately $25 million annually, although no assurances can be given of this estimation.

In February 2005, we announced that we completed the clinical studies required for our pending FDA new drug application on Emezine®, which we expect to file in the second quarter of 2005. In addition, in March 2005, we received notice from the FDA that it granted, under a small business exception, Arius 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.

BEMA™ Fentanyl

The global market for pain medication generates annual sales of over $24 billion. Between $2 billion and $4 billion is spent to treat breakthrough pain. Breakthrough episodes of pain are the flares of pain which break through the medication used to control the persistent pain. The leading product for breakthrough cancer pain is the U.S. market is Actiq, which had reported sales of $345 million in 2004 and is projected to exceed sales of $400 million in 2005. 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 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:

Post-operative patients following step-down from intravenous narcotics;

Hospitalized patients or outpatients without intravenous access; and

Emergency room patients where available intravenous lines are limited or impractical.

We recently 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. As a result of this guidance, we plan to enter BEMA fentanyl into Phase III clinical studies in the second half of 2005. We estimate that the

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clinical development costs of this formulation will be approximately $5.35 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, although no assurances can be given of this estimation.

BEMA Long Acting Analgesic

In addition to our lead BEMA product, fentanyl, we are also developing a second analgesic product with a longer duration of action suited for a broad range of pain conditions. We are working with this FDA-approved compound that 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 long acting analgesic 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; and
- Chronic pain, including lower back, osteoarthritis and rheumatoid arthritis.

We expect to submit an IND for BEMA Long Acting Analgesic in the second half of 2005. Entrance into clinical trials will follow immediately thereafter. We estimate that the clinical development costs of this formulation will be approximately $5.5 million.

Due to the ability of BEMA Long Acting Analgesic 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 Long Acting Analgesic has the potential to achieve a 1-2% share of the total worldwide pain market which is valued at approximately $24 billion. This would translate into an estimated $250-500 million in peak annual sales, although no assurances can be given of this estimation.

Other Projects

Autologous HIV Therapy

As part of our research and development activities, we have developed and are investigating our patented autologous (patient-specific) HIV therapy for AIDS which uses a cochleate related (proteoliposome) delivery vehicle. This immunotherapeutic is autologous meaning that it contains the specific patient s virus or membrane protein. Our autologous HIV therapy is intended to boost or alter the immune response in patients already infected with HIV.

We are currently investigating the potential cost for the research and administrative efforts that would be necessary to obtain an FDA approved IND necessary to continue this program. If these costs turn out to be prohibitively high, we may elect to not pursue this program or seek a development and commercial partner. We believe that the time, expense and risk to market for this program is substantial and uncertain, particularly when compared to that which we anticipate for the potentially broad-base of pharmaceuticals and vaccines which may ultimately be encapsulated in our cochleate drug delivery technology.

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Bioral Nutrient Delivery, LLC

On January 8, 2003, we formed Bioral Nutrient Delivery, LLC, a Delaware limited liability company, as a majority-owned subsidiary. BND presently has two classes of equity interests: Class A Shares and Class B Shares. As of the date of this Report, we own approximately 94.5% of BND s Class B Shares and all 708,586 of BND s Class A Shares. During 2003, we made plans to distribute to our stockholders 3,545,431 of BND s Class B Shares, or approximately 43% of BND s currently outstanding equity interests, including the Class A Shares. In early 2005, after having reevaluated this strategic opportunity, we decided to forego the planned distribution of Class B Shares and withdrew the registration statement relating to the distribution from the SEC. We presently have no intention of effecting any such distribution.

Effective April 1, 2003, we entered into an agreement with BND pursuant to which BND sublicenses from us, on an exclusive world-wide perpetual basis, our proprietary encochleation technology for use in processed food and beverages and personal care products. BND s early-stage business opportunity is based solely upon our licensed encochleation technology platform, which we utilize as a drug delivery system. Our preliminary findings suggest that, by using our encochleation technology, a variety of nutrients, which are substances with potentially beneficial properties, might be protected from degradation during the manufacturing process and delivered with substantially all of the characteristics of the nutrient intact, although no assurances can be given that we will be able to accomplish this on a large-scale basis. BND was formed to identify licensees who will apply our sublicensed technology to nutrients, and BND will seek to commercialize our delivery technology through a combination of licensing programs to manufacturing, marketing and distribution companies within food, beverage and personal care product industries. BND does not intend to manufacture market or distribute products itself.

In consideration of the sublicense grant, BND shall pay us a royalty of 8% on all revenue which BND receives from third parties. Among other things, failure to make the payment of the royalties on a timely basis shall be cause for termination of the sublicense. In addition, we may terminate the sublicense subsequent to BND s entering into sublicenses in consideration of a payment equal to six (6) times our trailing twelve (12) months gross revenues. We also reserve the right to use the technology in all ways except those covered by our sublicense agreement with BND. In order to keep our operating expenses manageable, effective April 1, 2003, BND entered into a management services and administrative agreement with us, under which we provided BND with certain resources, including use of our office in Tampa, Florida. The management services agreement with BND terminated on December 31, 2004, and given that the BND opportunity is not presently a high priority for us, we opted not to renew such agreement.

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.

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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, 2004, UMDNJ owns 139,522 shares (including shares issued under a research agreement) and warrants to purchase 8,951 shares of our common stock at $3.05 and 75,000 options to purchase our common stock at a price per share of $2.37. As of December 31, 2004, Albany Medical College owns 2,222 shares of our common stock and warrants to purchase 9,951 shares of our common stock at $3.05 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 UNDNJ s facilities until December 31, 2005. We also agreed to provide UNDNJ with progress and data updates and allow its researchers to publish certain projects. We lease our research facilities totaling approximately 8,000 square feet located on their campus pursuant a lease agreement ending December 31, 2005. The monthly rent was $3,340 for 2001, $3,840 for 2002, $4,340 for 2003, $4,840 for 2004 and $5,340 for 2005. We plan to enter into discussions with UMDNJ during 2005 regarding a possible extension or renewal of this lease. No assurances can be given that we will be able to extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations.

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 $209,811.45, 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. Our relationships include:

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Atrix Laboratories, Inc. On May 27, 2004, 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 Investigational New Drug Applications, have been transferred to Arius in accordance with the Atrix license agreement.

Under the terms of the Atrix license agreement, Arius is 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 comprised of representatives of Arius and Atrix oversees product development. Arius is responsible for the research and development of the products, including costs and expenses, and for their sale, marketing, manufacture, and distribution, provided that, under the terms of a clinical supply agreement between Atrix and Arius entered into pursuant to the license agreement, Atrix shall provide Arius with certain supplies of BEMA fentanyl product for clinical trials for a limited period of time, at Arius expense. 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, Arius is 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. Arius will be responsible for the development of the product, including costs and expenses, and for its sale, marketing, and distribution in the United States. In addition, Arius shall be required to obtain from Reckitt, and Reckitt shall be required to supply to Arius, at Arius expense, all product to be sold under the license.

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.

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PPDI. On December 31, 2002, we entered into an agreement with 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.

Potential siRNA Partner. We have entered into a pre-evaluation agreement with a major pharmaceutical company focusing on siRNA targets. The goal of the agreement is to generate proof of concept of the ability of our nanochocleates to successfully formulate the siRNA targets. After proof of concept is achieved, the agreement has an option to progress these targets to therapeutics at which time royalties will be discussed.

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

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 to review all agreements and transactions which have been entered into with related parties, as well as all future related party transactions. At the meeting the independent board members, with Dr. O Donnell abstaining, and after seeking and reviewing advice from an independent valuation firm and inquiring about the details of the various transactions, ratified all prior related party transactions. Subsequent to this meeting, the audit committee independently ratified these agreements. During 2004, after compliance with our internal policies and procedures, we also entered into several new related party contracts. 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. Frank O Donnell, our Chairman and CEO 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, Alan Pearce, a member of our board of directors, is the CFO of Accentia and James A. McNulty, our Secretary, Treasurer and CFO, is the Treasurer and Corporate Secretary 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 Mayo Foundation for Medical Education and Research for the treatment of CRS and asthma on a worldwide basis. The technology consists of using low-dose topical antifungals to control the debilitating symptoms of CRS and asthma. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indications of CRS and asthma on a worldwide basis, including expenses associated with the 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., 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.

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 Chief Executive Officer and Chairman, are affiliated as stockholders and a director of RetinaPharma.

Biotech Specialty Partners, LLC. We have entered into a non-exclusive distribution agreement with Biotech Specialty Partners, LLC, or BSP, a development-stage distribution company, to market and distribute our proposed products once we have completed the commercialization of our products. Our financial arrangement with BSP requires us to sell to BSP all of our proposed products, as and when purchased by with 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

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(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. HCG, which is affiliated with Dr. Francis E. O Donnell, Jr., our Chairman and CEO, are affiliated as stockholders, and a member of the management, of

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 and asthma 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 Arius 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 Arius certain additional milestone payments upon achievement of certain developmental and regulatory milestones, (iii) shall support Arius clinical development costs with respect to such product, and (iv) shall pay royalties to Arius based on the sales of such product. In addition, Arius 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 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.

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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 new drug delivery technologies and our HIV therapies, 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. If a court were to determine that we infringe any of these patents and that these patents are valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B and/or our BEMA products. There can be no assurance that we would be able to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

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

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We rely on trade secrets and confidentiality agreements with collaborators, advisors, employees, consultants, vendors and other service providers. We cannot assure you 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	The University of Medicine and Dentistry of New Jersey and Albany Medical College
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	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
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

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Patent Number	Issued	Expires	Title	Owner
US05,994,318	11/30/1999	11/24/2015	Cochleate delivery vehicles	The University of Medicine and Dentistry of New Jersey and Albany Medical College
EUR 812209	05/06/2004	02/22/2016	Cochleate delivery vehicles for biologically relevant molecules	The University of Medicine and Dentistry of New Jersey and Albany Medical College
CA 2,246,754	10/22/2002	02/21/2017	Cochleate delivery vehicles	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,840,707	11/24/1998	11/24/2015	Stabilizing and delivery means of biological molecules	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,834,015	11/10/1998	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
AUS689505	02/02/1998	09/30/2014	Protein - or peptide - cochleate immunotherapeutics and methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,643,574	07/01/1997	07/01/2014	Protein - or peptide - cochleate immunotherapeutics methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US04,871,488	10/03/1989	10/03/2006	Reconstituting viral glycoproteins into large phospholipid vesicles	Albany Medical College
US04,663,161	05/05/1987	04/22/2005	Liposome methods and compositions	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

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Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
09/144,827	US	09/01/1998	6,159,498	12/12/2000	10/18/2006	(same as above)
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)
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
60/495,356	US	08/15/2003				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
4757497	Australia	10/16/1997	729516	05/17/2001	10/16/2017	(same as above)
2,268,187	Canada	10/16/1997	Pending		10/16/2017	(same as above)
2001508037	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)
3967899	Australia	04/29/1999	746339		04/29/2019	(same as above)
2,329,128	Canada	04/29/1999	Pending		04/29/2019	(same as above)
2002512950	Japan	04/29/1999	Pending		04/29/2019	(same as above)
99922753	EP	04/29/1999	1079813	02/09/05	04/29/2019	(same as above)
10/121,430	US	04/11/2002	Pending			Process for Loading a Drug Delivery Device
US03/11313	PCT	04/11/2003	N/A	N/A	N/A	(same as above)

* Validated in the following European countries: Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Greece, Ireland, Italy, Netherlands, Sweden.

Emezine®

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

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BEMA Trademark

In addition, in March 2005, we received notification from Atrix, from whom we license the trademark BEMA , that Atrix received an office action from the U.S. Patent and Trademark Office rejecting their application for such mark. Based on our discussions with Atrix, we believe it may be possible to overcome any objections that the trademark examiner may have, and we have requested that Atrix continue to pursue the mark aggressively. No assurances can be given, however, that Atrix will be able to overcome such objections, and if such objections are not resolved to the examiner s satisfaction, we may be denied federal trademark protection for this mark.

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, proposed drug formulations (including Emezine®) and HIV therapies 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.

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. 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

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Inc. (NASDAQ: VLTS) and Enzon Pharmaceuticals Inc. (NASDAQ: ENZN), both publicly traded companies, and Flamel Technologies and Inex Pharmaceuticals Corporation, both of which are privately-held companies, which we believe may be seeking to develop technologies for cell-targeted delivery of drugs. American Pharmaceutical Partners (NASDAQ: APPX) has recently 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.

BEMA

Included among the companies which we believe are developing potentially competitive technologies to BEMA are Hollis Eden (NASDAQ: HEPH), a publicly traded company, and TransOral Pharmaceuticals, a privately-held company. We believe that these potential competitors are seeking to develop and commercialize technologies for the buccal 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.

For BEMA fentanyl, in the breakthrough cancer pain area, we believe the most advanced competitors are Cephalon (NASDAQ: CEPH) and Endo Pharmaceutical Holdings (NASDAQ: ENDP) both publicly traded companies. Cephalon s lead product for this indication is Actiq which generated $345 million in sales in 2004. 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, from Orexo Pharmaceuticals AB, Rapinyl, which is a polymer formulated sublingual fentanyl tablet indicated for breakthrough cancer pain. 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. 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 fentanyl will have intra-dose variability.

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

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GlaxoSmithKline s (NSYE: GSK) Zofran(tablets, injection and solution), which presently accounts for the largest share of the market. MGI Pharma s (NASDAQ: MOGN) Aloxiinjection is the newest entry into the market and has gained significant share in a short period of time in the CINV market. Merck s (NYSE: MRK) Emendtablet has the highest revenue of the non 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 will be differentiated in this market due to the buccal route of administration.

Autologous HIV Therapy

In terms of our Autologous HIV therapy, we believe that competitors may also be working on patient-specific therapies for cancer. However, we are not aware of any competitors currently attempting to develop patient-specific therapies for HIV. This does not, however, mean that there are not any now or that there will not be in the future. Vaccines can be used for prophylactic (prevention of infection), or therapeutic (treatment following infection) applications. The patient-specific therapeutic, which we are attempting to develop, is intended to boost or alter the immune response in patients already infected with HIV. For the most part, HIV vaccines in development, about which we are aware, are being targeted specifically to prevent infection. However, some of these vaccines may also prove useful for therapeutic applications. As such, these could prove to be competitive with our autologous therapeutic. We are aware of a product in development, EradicAide, by Adventrx Pharmaceuticals (AMEX: ANX) which utilizes a similar mechanism to elicit a cellular based response to attack HIV infected cells. We believe our therapeutic HIV vaccine is superior due to it being tailored to each patient. With the advent of multiple mutations giving the virus resistance to conventional HIV therapies, our product is intended to be tailored to attack that particular virus potentially, thus potentially allowing for a higher degree of efficacy through this specificity.

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. Except as provided for under our license agreement with Reckitt for Emezine®, we do not presently have manufacturing arrangements with respect to our intended product. 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. The formulation for BEMA fentanyl development, and initial clinical trial material for the manufacturer, will be done by Dow Pharmaceutical Sciences and Atrix, respectively. We are in the process of finalizing an agreement for the manufacture of large scale clinical trial suppliers and a NDA stability batch with a commercial scale manufacturer that currently produces products for the US market on identical equipment to that planned for BEMA manufacture. As our intended products near market introduction, we intend to outsource manufacturing to third party manufacturers, which comply with the FDA s applicable Good Manufacturing Practices. While we believe that such commercial manufacturing arrangements may be available, no such relationships have been establish to date.

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, are to market and sell our approved formulations and

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products under the Bioral®, BEMA or other brand names which we either own or license from third parties through our Arius subsidiary. The Arius commercial efforts will be primarily focused on the hospital/oncology/surgery areas 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 or nutraceutical which we formulate with our licensed encochleation or BEMA technologies, our autologous HIV therapeutic and Emezine®, as well as our related research and development activities, are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. We anticipate that these regulations will apply separately to each drug formulation with our drug delivery technologies. We believe that complying with these regulations will involve a considerable level of time, expense and uncertainty.

In the United States, drugs are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our drugs. Drug development and approval within this regulatory framework is difficult to predict and will take a number of years and involve the expenditure of substantial resources.

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

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

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

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

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

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

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

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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 assurance can be given as to the ultimate outcome of such pre-clinical testing. The results of pre-clinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of clinical trials. Unless the FDA objects to an IND, clinical studies may begin thirty (30) days after the IND is submitted.

We intend to largely rely upon contractors to perform pre-clinical trials.

Clinical Trials

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

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the product into healthy human subjects, the drug is tested for safety (adverse side effects), absorption, dosage tolerance, metabolism, bio-distribution, excretion and pharmacodynamics (clinical pharmacology). Phase II is the proof of 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 (2) studies were conducted in 2004 under the Emezine® IND. Multiple studies will be conducted in 2005 under the IND for

BEMA fentanyl and for Bioral® Amphotericin B.

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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 preclinical and clinical testing, the NDA applicant must submit detailed information about chemistry, manufacturing and controls that will describe how the product is made. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Consequently, there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may deny a New Drug Application if applicable regulatory criteria are not satisfied, require additional testing or information or require post-marketing testing (Phase IV) and surveillance to monitor the safety of a company s product if it does not believe the NDA contains adequate evidence of the safety and efficacy of the drug. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Post approval studies may be conducted to explore further intervention, new indications or new product uses.

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

International Approval

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

Other Regulation

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

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Employees

As of March 21, 2005, we had 22 full-time employees, of which 10 are laboratory scientists and 12 are involved in our operations, administration, accounting and IT. Eight of our scientists have Ph.D. degrees and two have medical 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.

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

The failure to complete development of our drug delivery technologies, obtain government approvals, including required FDA approvals, or to comply with ongoing governmental regulations 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, clinical trials and regulatory approval can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources.

In order to be commercially viable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute formulations or products incorporating our technologies. For each drug or nutraceutical that we formulate with our drug delivery technologies and for our HIV therapies, as the case may be, we must successfully 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 and our HIV therapies are safe and effective; and

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establish a viable Good Manufacturing Process capable of potential scale-up.

The time-frame necessary to achieve these developmental milestones may be long and uncertain, and we may not successfully complete these milestones for any of our proposed formulations or products in development.

In addition to the risks previously discussed, our HIV immunotherapeutic is subject to additional developmental risks, which include the following:

uncertainties arising from the rapidly growing scientific aspects of HIV and potential treatments;

uncertainties arising as a result of the broad array of potential treatments related to HIV;

anticipated expense and time believed to be associated with the development and regulatory approval of treatments for HIV; and

availability of corporate resources to dedicate to this project and the potential that this project will not be a priority for us.

In order to conduct clinical trials that are necessary to obtain approval by FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do not follow the FDA s requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell any drug or medical device for human consumption without FDA approval.

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

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.

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Competitors in the drug development industry may develop competing technology.

Drug companies and/or other technology companies may seek to develop and market nanoencapsulation or mucosal adhesive 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.

Our HIV therapies may not gain FDA approval in clinical trials or be effective as a therapeutic against the HIV virus which could affect our future profitability.

In order to obtain regulatory approvals of our autologous and subunit HIV therapies, we must demonstrate that these procedures are safe and effective for use in humans and function as therapeutics against the HIV virus. We may not be able to demonstrate that our proposed HIV therapies are safe or effective in advanced clinical trials that involve human patients. We are also not able to assure that the results of the clinical trials already conducted and which we intend to conduct will support our applications for regulatory approval. As a result, our HIV therapy programs may be curtailed, redirected or eliminated at any time. The HIV virus is very complex and may be prone to genetic mutations. These mutations have produced strains of HIV that are resistant to currently approved therapeutics. Even if we gain regulatory approval for our autologous or subunit HIV therapies, the virus may develop similar resistance to our treatment. This could have a material adverse effect on our business, financial condition and results of operations.

Moreover, to date, we have only conducted a pilot study pursuant to Institutional Review Board oversight in anticipation of our initial FDA submission for our autologous HIV therapy. We are currently investigating the potential cost for the research and administrative efforts that would be necessary to obtain the FDA approved IND necessary to continue this program. If these costs turn out to be prohibitively high, we may elect to not pursue this program. In addition, our subunit HIV vaccine program is currently funded via an NIH grant which expires during 2005. We plan on evaluating a potential extension of this grant in 2005. We may be unsuccessful is securing additional grant money or other funds to continue this program.

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, 2004, we have recorded accumulated losses totaling $13,495,104. As of December 31, 2004, we had a working capital deficit of $357,000. 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 or any drugs or nutraceuticals to which we have applied our technologies. 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.

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We will need to raise additional capital to continue our operations or we may be unable to fund our operations, promote our formulations or products or develop our technologies.

Our operations have relied almost entirely on external financing to fund our operations. Such financing has historically primarily come from the sale of common and preferred stock and convertible debt to third parties and to a lesser degree from 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 subsequent to December 31, 2004, that our current working capital will be sufficient to satisfy our contemplated cash requirements at least through December 31, 2005. We will need to raise additional capital to fund our anticipated operating expenses and future expansion. Among other things, external financing will be required to cover our operating costs. We cannot assure you that financing whether from external sources or related parties will be available if needed or on favorable terms. 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 because of 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, potentially, our autologous HIV immunotherapeutic. 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. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from any available source, 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.

During 2004, we exhausted substantially all of the proceeds from our June 2002 initial public offering. Our long term capital requirements are expected to depend on many factors, including:

- number of potential formulations 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 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 or nutraceutical formulations or products;

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costs involved in establishing manufacturing capabilities for commercial quantities of our drug or nutraceutical formulations or products;

competing technological and market developments;

market acceptance or our drug or nutraceutical formulations or products;

costs for recruiting and retaining employees and consultants; and

costs for training physicians.

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.

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 or will effectively dilute 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.

We currently rely on the facilities of the University of Medicine and Dentistry of New Jersey for all of our research and development activities, 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 University of Medicine and Dentistry of New Jersey and Albany Medical College for this purpose, as well as third party providers of testing and trial services. Additionally, the Universities own certain of the patents to our encochleation drug delivery technology. Our inability to conduct research and development, or our inability to find suitable third party providers of research and development services on an outsourcing basis, may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technologies, formulations and products.

We plan to enter into discussions with UMDNJ during 2005 regarding a possible extension or renewal of this lease. No assurances can be given that we will be able to extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations. 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

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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 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 rely upon numerous collaborative agreements with universities, governmental agencies, manufacturers, contract research organizations and corporate partners. The loss of or failure to perform under any of these arrangements, by any of these entities, may substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials. This loss may also increase our expenses and materially harm our business, financial condition and results of operation.

We have a license agreement with the University of Medicine and Dentistry of New Jersey and Albany Medical College 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 University of Medicine and Dentistry of New Jersey pursuant to a research agreement. In addition, our BEMA technology and Emezine® product are licensed from third parties.

To date, almost all of our funding for research and operations have come from grants and other types of funding from corporate sponsors and the NIH. We will continue to be dependent upon the NIH, in particular, to develop our Bioral® Amphotericin B. Furthermore, we anticipate that research and development of our HIV therapy will primarily depend on funding from the federal government.

Our two National Institutes of Health grants have either expired or are set to expire, which could deny us important funding.

In 2001, the National Institutes of Health awarded us a Small Business Innovation Research Grant (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 our encochleated HIV subunit vaccine. We have received anticipated funding under this second grant to date, and the grant is set to expire on July 31, 2005. Although we may seek additional NIH funding for either of these programs, we may choose not to seek such funding or such funding may be unavailable to us. The absence of additional funding from the NIH could impair our ability to further develop our Bioral® Amphotericin B formulation or our encochleated HIV subunit vaccine. Furthermore, as a result of these expirations, we are anticipating a decline in sponsored research revenue with associated NIH grant expenditures in 2005.

We are exposed to product liability, clinical and preclinical 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

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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, and we maintain liability insurance relating only to clinical trials on Emezine®. 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 or nutraceutical 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 technologies;
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our proposed formulations or products; and
- our ability to market our formulations or products.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our proposed formulations or products. If we are unable to obtain regulatory approval, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

We may be sued by third parties who claim that our drug or nutraceutical 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,

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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. If a court were to determine that we infringe any of these patents and that these patents are valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B and/or our BEMA products. There can be no assurance that we would be able to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

Most of the inventions claimed in our 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.

In addition, in March 2005, we received notification from Atrix, from whom we license the trademark BEMA , that Atrix received an office action from the U.S. Patent and Trademark Office rejecting their application for such mark. Based on our discussions with Atrix, we believe it may be possible to overcome any objections that the trademark examiner may have, and we have requested that Atrix continue to pursue the mark aggressively. No assurances can be given, however, that Atrix will be able to overcome such objections, and if such objections are not resolved to the examiner s satisfaction, we may be denied federal trademark protection for this mark.

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As of the date of this Report, and except as discussed above, we have not engaged in discussions, received any communications, nor do we have any well-founded reason to believe that any third party is challenging or has the right proper legal authority to challenge our intellectual property rights or those of the actual patent holders.

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 a license to access the patents. Without this license, the technologies would be protected from our use and we would not be able to even conduct research without prior permission from the patent holder. Therefore, any disruption in access to the technologies could substantially delay the development of our technologies.

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

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements provide that all materials and confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual s relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology.

Although our trade secrets and technical know-how are important, our continued access to the patents is a significant factor in the development and commercialization of our drug delivery technologies. Aside from the general body of scientific knowledge from other drug delivery processes and lipid technology, these patents, to the best of our knowledge and based upon our current scientific data, are the only intellectual property necessary to develop and apply our Bioral® and BEMA drug delivery systems to the drugs or nutraceuticals to which we are attempting to apply them. We do not believe that we are violating any other patents in developing our technologies.

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.

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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, we currently purchase our lipid supplies from Chemi, a subsidiary of Italfarmico. 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.

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 or nutraceutical 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 the capability to commercially manufacture our formulations or products in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our formulations or products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our proposed formulations or products.

We presently plan to rely on third party contractors to manufacture part or all of our proposed formulations or products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanic shut downs, employee strikes, or any other unforeseeable acts that may delay production.

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Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our formulations or products, enter into relationships with third parties or develop a direct sales organization.

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 Arius 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. Until such time as our proposed formulations or products are further along in the regulatory process, we will not devote any 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. We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force on a cost effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our formulations or products;
- cease operations with little or no notice to us; or
- offer, design, manufacture or promote competing formulations or products.

If we fail to develop sales, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

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

Broad use of our 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.

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If an event of default occurs under the convertible note issued to Laurus, it could seriously harm our operations.

On February 22, 2005, we issued a $2.5 million secured convertible term note 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 note or any agreement made in connection therewith;
- breach by us of any material representation or warranty made in the note or in any agreement 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;
- failure to timely deliver shares of common stock when due upon conversions of the note;
- 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 note 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 note are secured by substantially all of our assets. Failure to fulfill our obligations under the note and related agreements could lead to loss of these assets, which would be detrimental to our operations.

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The 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 the Laurus note is 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 would result in greater dilution to our shareholders, 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.

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 HIV therapeutics, 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.

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The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or products, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies, formulations and products to receive widespread acceptance if commercialized.

If users of our proposed formulations or products are unable to obtain adequate reimbursement from third-party payors, or if new restrictive legislation is adopted, market acceptance of our proposed formulations or products may be limited and we may not achieve revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our proposed formulations or products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

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

The testing, manufacture, marketing and sale of our proposed drug or nutraceutical 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. 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 Emezine® formulation, 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

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available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our drug delivery technology. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products.

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

In connection with our research and development activities and our manufacture of materials and drugs, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development may in the future involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. The current hazardous chemicals that we currently use, which may change as our research progresses, are chloroform and methanol. We are authorized to use these and other hazardous chemicals in our facilities through our affiliation with the University Medicine and Dentistry of New Jersey. The university also disposes these chemicals from our premises as part of our agreement to use the facilities and carries general liability insurance in this regard.

Although we believe that our safety procedures for storing, handling and disposing of such materials will comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Our Management and Key Employees

We depend upon key personnel who may terminate their employment with us at any time, and we will need to hire additional qualified personnel.

Our success will depend to a significant degree upon the continued services of key management, technical, and scientific personnel, including Drs. Francis O Donnell, Mark Sirgo, Andrew Finn, Raphael Mannino and Mr. James McNulty. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, our success will depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all.

We have key man life insurance policy for Dr. Raphael Mannino in the amount of $2.0 million. This insurance may not adequately compensate us for the loss of Dr. Mannino s services. Additionally, neither our Chairman and CEO, Dr. Frank O Donnell, our President and Chief Operating Officer, Dr. Mark Sirgo, nor any of our other executives currently has this coverage. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

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Executive officers, directors and entities affiliated with them have substantial control over, 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 principal stockholders, together with their affiliates, will beneficially own, in the aggregate, approximately 68.0% of our outstanding common stock. These figures do not reflect 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 convertible note with Laurus. Additionally, these figures do not reflect any future potential exercise of our Class A warrants or other outstanding warrants 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 control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

election of directors;

adoption of or amendments to stock option plans;

amendment of charter documents;

issuance of blank check preferred stock; or

approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets.

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 Partners, Inc. We have entered into license agreements with Accentia and RetinaPharma International, Inc. with regard to proposed products incorporating our Bioral® technology. We have entered into a non-exclusive distribution 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. These agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and Dr. O Donnell.

Risks Related to Our Publicly-Traded Securities

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

Since our initial public offering in June 2002, there has only been a limited public market for our securities and there can be no assurance that an active trading market in our securities will be maintained. In addition, the overall market for securities in recent years has experienced extreme price and volume

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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 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 SmallCap 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 SmallCap Market, our shares of common stock were subject to potential delisting from such market because we did not meet certain requirements. Although, as of the date of this prospectus, our shares are still listed on the Nasdaq SmallCap Market, in the future, we may not be able to meet the listing maintenance requirements of the Nasdaq SmallCap Market and Nasdaq rules, which require, among other things, minimum stockholders equity of $2.5 million. 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.

The redemption of our public warrants may adversely affect potential investors.

Our publicly-traded warrants, which expire on June 24, 2007, are redeemable, in whole or in part, for $.10 per warrant upon 30 days written notice to the warrant holder; provided that: (i) there is then an effective registration statement under the Securities Act covering the shares issuable upon exercise of the warrants and (ii) the average closing sale price of our common stock equals or exceeds $7.87 for the 10 trading days prior to the date of the notice of redemption.

Notice of redemption of the warrants could force holders to exercise the warrants and pay the exercise price therefore at the time when it may be disadvantageous for them to do so, sell the warrants at the current market price when they might otherwise wish to hold the warrants or accept the redemption price which is likely to be substantially less than the market value of the warrants at the time of redemption.

Current prospectus and state blue sky registration required to exercise warrants.

Holders of our warrants will be able to exercise their warrants only if a current registration statement relating to such shares is then in effect and only if the shares are qualified for sale under the securities laws of the applicable state or states. We do not currently have an effective registration statement covering the shares of common stock issuable upon exercise of the warrants. The warrants may be deprived of any value if the a registration statement covering the shares underlying the warrants is not effective and available or such underlying shares are not or cannot be registered in the applicable states.

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

We are authorized to issue 45 million shares of our common stock. As of December 31, 2004, there were 7,245,863 shares of common stock issued and 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. To the extent such options or warrants are exercised, the holders of our common stock may experience further dilution. In addition, as in the case of the Laurus financing, 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.

In addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5 million shares of authorized preferred stock, the terms of which may be fixed by our Board. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

Shares eligible for future sale may adversely affect the market.

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, 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 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.

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These provisions could allow our board of directors to affect your rights as a stockholder since our board of directors can make it more difficult for common stockholders to replace members of the board. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team.

Item 2. Description of Property.

In early 2005, we relocated our principal executive offices to Arius offices in Morrisville, North Carolina. Arius lease for this approximately 2000 square foot space terminates in September 2007. Rental payment 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 BDSI executives and supplies used by us. The payments to UMDNJ for certain executive salaries totaled $211,747 for 2004. 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. We plan to enter into discussions with UMDNJ during 2005 regarding a possible extension or renewal of this lease. No assurances can be given that we will be able to extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations.

Item 3. Legal Proceedings.

On or about April 19, 2004, we were named as the defendant in an action commenced by MAS Capital Inc., or MAS Capital, in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, plaintiff seeks monetary damages from us in the amount of $1.575 million based upon the allegation that MAS Capital, at our request, procured an underwriter to raise capital for us through an initial public offering. We have removed the action from the Indiana state court to the U.S. District Court for the Southern District of Indiana. We have also answered the complaint, denying the material allegations asserted by plaintiff. The case is presently in the pre-trial discovery stage. We believe that plaintiff s claims are without merit and intend 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 SmallCap Market under the symbols BDSI and BDSIW respectively. Also, such securities are listed on the Boston Stock Exchange under the same symbols. The range of reported high and reported low bid prices per share for our common stock and warrants for each fiscal quarter during 2004, as reported by the Nasdaq SmallCap 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, 2004	$ 4.34	$ 2.52	$ 1.06	$ 0.50
June 30, 2004	$ 4.60	$ 2.79	$ 1.24	$ 0.80
September 30, 2004	$ 3.00	$ 1.52	$ 0.99	$ 0.20
December 31, 2004	$ 4.25	$ 2.56	$ 0.94	$ 0.48

As of March 21, 2005, 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**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance**
	(a)	**(b)**	**(c)**
Equity compensation plans approved by security holders	1,861,480	$ 4.79	238,520
Equity compensation plans not approved by security holders			
Total	1,861,480	$ 4.79	238,520

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 will be used to support our research, development and commercialization opportunities and for general working capital purposes.

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

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note is convertible, under certain conditions, into shares of our common stock at a price equal to $3.10 per share. 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. We have agreed, pursuant to a registration rights agreement, to register the shares of common stock underlying the Laurus note and the warrant.

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 at an average price below $3.10 per share 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.

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

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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 intend to seek stockholder approval of issuances in excess of this 19.99% limit at our upcoming 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 SmallCap Market or The Nasdaq National Market, then, without the prior approval of our stockholders in accordance with 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 intend to seek stockholder approval of issuances in excess of this 19.99% limit at our upcoming 2005 annual meeting of stockholders.

Use of Proceeds From Registered Securities

On June 24, 2002, the SEC declared our Registration Statement on Form SB-2, Registration No. 333-72877, effective. Commencing on June 25, 2002, and pursuant to such Registration Statement, we conducted an offering consisting of 2.0 million Units, with each Unit consisting of (i) one share of common stock, par value $.001 per share, and (ii) one Class A common stock purchase Warrant. 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, after deducting the offering expenses, was $8,226,758. Proceeds from such offering were used for research and development and general working capital purposes. We exhausted substantially all of the proceeds from our public offering during 2004.

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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 2005. The funding will come primarily from the sale of securities, collaborative research agreements, including pharmaceutical companies, grants from public service entities and government entities, and the potential exercise 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 2005.

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, 2004 Compared to the Year Ended December 31, 2003

Sponsored Research Revenue. During the year ended December 31, 2004, we recognized sponsored research revenue of $0.8 million, compared to $0.9 million in the prior year. Except for $0.01 million in 2003 from collaborative research agreements, the sponsored research revenues were from the National Institutes of Health 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, and the balance will be drawn through August 2005.

License Fee 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 December 2002, we entered into a

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licensing agreement with a company (which is a stockholder), which included a non-refundable payment of $2 million. We recognized $ 2 million license income in 2003 over the period of the related research and development commitment.

Research and Development Expenses. During the years ended December 31, 2004 and 2003, research and development expenses totaled $4.0 million and $2.6 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, 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. For more detail on expenditures related to our major projects currently under development, see Major Research and Development Projects below.

General and Administrative Expenses. During the years ended December 31, 2004 and 2003, general and administrative expenses totaled $3.0 million and $2.6 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, executive personnel costs, consulting fees, and business development costs. Furthermore, we incurred expenses in 2004 and 2003 of approximately $0.2 million and $0.5 million respectively, related to operating activities of our Bioral Nutrient Delivery, LLC subsidiary that commenced in 2003, approximately $0.2 million of which related to offering costs associated with a registration statement that was pending throughout the latter half of 2003 and most of 2004 until it was withdrawn in early 2005. The increase in general and administrative expenses in 2004 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 $0.3 million and $0.2 million were incurred in 2004 and 2003, 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, 2004. We intend to adopt FAS 123 in 2005 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 and Chief Executive Officer. 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, 2004 we had net interest expense of $0.06 million, compared to net interest income of $0.07 million in 2003. The decrease in net interest income is primarily due to reduction of invested liquid funds which we used to fund our operations. We borrowed funds to purchase laboratory equipment and to make leasehold improvements in 2003. Our bank note terms with Gold Bank called for interest-only through October 2003 and amortization of principal over 48 months beginning in November 2003. Such note was paid in February 2005, as further discussed below.

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 and state net operating loss carryforwards of $10.4 million and $7.2 million at December 31, 2004. The federal net operating loss carryforwards expire beginning in 2020, if not utilized. We sold New Jersey state tax credits in 2004

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totaling $3.3 million, which generated cash of $0.2 million. The state operating loss carryforwards expire beginning in 2008, if not utilized. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Major Research and Development Projects

In 2004, we dedicated most of our corporate resources to the development of Emezine®, BEMA Fentanyl, Bioral® Amphotericin B and BEMA Long Acting Analgesic. We believe that the other projects which we have identified as currently being in our pipeline (Bioral® NSAID, Bioral® Paclitaxel, Bioral® siRNA therapeutics, Subunit HIV Vaccine and Autologous HIV Vaccine) represent promising opportunities. However, we are consistently evaluating such opportunities as to whether or not (or how) to actively pursue them. As a result, due to our limited corporate resources, we are presently focusing mainly on the following four projects:

Emezine®. Through Arius, we have licensed the U.S. rights to a transmucously delivered formulation of Emezine®, 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 2004, we expended approximately $0.514 million on our efforts relating to Emezine®. In March 2005, we received notice from the FDA that it granted, under a small business exception, Arius 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. This one-time exemption represents a considerable savings to our company.

Once the NDA for Emezine® is submitted, the FDA has 60 days during which to accept the application for filing. If accepted, following Prescription Drug User Fee Act, guidelines, the FDA will have up to 8 months (10 months total) from the date of submission to review and render a decision on the application as to whether it is approvable or not. If they render it non approvable, it is likely we will have additional work to complete before resubmitting. If approved by the FDA, 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.

Based on our market research, we believe that Emezine® may be able to achieve peak sales of approximately $25 million annually, on which we will receive a royalty from TEAMM Pharmaceuticals, our commercialization partner (who will also pay a royalty to Reckitt), although no assurances can be given of this estimation. We do not expect to generate any revenue from Emezine®, if ever, until at least mid 2006, if not later.

The risks to our company associated with the Emezine® project include: (i) failure of the FDA to approve our NDA or a 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 potentially damaging to our market reputation and our stock price, among other matters, would seriously impair our potential future revenue growth.

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BEMA Fentanyl. Through Arius, 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. We recently 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 anticipate entering BEMA fentanyl into Phase III clinical studies in the second half 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 submission 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.

During 2004, we expended approximately $0.26 million on our efforts relating to BEMA fentanyl. We estimate that the clinical development costs of BEMA fentanyl will be approximately $5.35 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, 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, if not later.

The risks to our company associated with the BEMA fentanyl project include: (i) failure to develop an adequate formulation; (ii) inability of Atrix, our contract manufacturer, or another manufacturer, to make clinical supplies; (ii) slow patient enrollment in clinical trials; (iii) lack of funding to progress the program; (iv) failure to demonstrate efficacy in clinical trials; (v) the development of safety issues with the product, (vi) the conclusion by the FDA that the risk benefit is inadequate; (vii) the conclusion by the FDA that our submission is inadequate and additional information is required; and (viii) failure to identify 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.

Bioral® Amphotericin B. We license the encochleation drug delivery technology which we use in our Amphotericin B formulation from UMDNJ. 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 fourth quarter of 2005. 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 second half of 2006 and Phase III trials in late 2006 or 2007. A Phase III program would run approximately 18-24 months after which we would spend 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 of submission 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.

Since 2001, we have expended approximately $2.25 million on our efforts relating to encochleated Amphotericin B (including approximately $0.75 million in 2004). We are responsible for all costs and expenses on our Bioral® Amphotericin B product. We estimate that the preclinical and

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clinical development costs of this formulation will be approximately $7.0 million. 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.

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® Amphoteracin B, if ever, until late 2008, if not later.

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 for contract manufacturer to make clinical supplies; (iii) Phase I studies do not show significant oral absorption of product; (iv) failure of clinical trials, including if the Phase II study shows drug is ineffective in treating the fungal infection in question; (v) if the product encounters safety issues; and (vi) lack of corporate funding to progress the program. Of the four major programs to which we are currently dedicating material resources, we believe this program has the highest risk because of the early-stage and more complex nature of the Bioral® technology (as opposed to BEMA). However, due to the large market for anti-fungal projects, we believe the upside potential of 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.

BEMA Long Acting Analgesic. Through Arius, 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 expect to submit an IND for BEMA Long Acting Analgesic in the second half of 2005. In the event that the FDA accepts this IND, we would proceed with 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 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 Long Acting Analgesic 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 of submission to render a decision on the approvability of our application. If FDA approves the application we would anticipate launching the product within 3 months of that approval.

During 2004, we did not expend any resources on our efforts relating to BEMA Long Acting Analgesic. We estimate that the future clinical development costs of this formulation will be approximately $5.5 million.

Due to the ability of BEMA Long Acting Analgesic 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 Long Acting Analgesic has the potential to achieve a 1-2% share of the total worldwide pain market which is valued at approximately $24 billion. This would translate into an estimated $250-500 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 Long Acting Analgesic, if ever, until at least late 2008, if not later.

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The risks to our company associated with the BEMA Long Acting Analgesic project include: (i) our inability to develop a final formulation; (ii) the inability of contract manufacturer to make 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.

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, 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. At December 31, 2004, we had cash and cash equivalents of $0.8 million. At December 31, 2003 we had cash and cash equivalents totaling approximately $2.6 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 $2.6 million at December 31, 2004.

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 $0.4 million at December 31, 2004.

We used $2.9 million of cash for operations in of the year ended December 31, 2004. This consisted of a net operating loss of $2.8 million, which was funded through liquidation of our investments of $2.0 million, and we acquired cash of $.06 million in our August 2004 acquisition of Arius Pharmaceuticals. We purchased equipment of $0.1 million in calendar 2004. We do not anticipate any material capital expenditures in 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 is 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.

During the second quarter of 2003, we, as authorized by our Board of Directors, repurchased 100,000 shares of our common stock with a per share price between $2.80 and $3.20 for a total cost of $303,894.

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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 and CEO. Pursuant to the Equity Line Agreement, HCG will, as requested by us, invest up to $4.0 million in our company from through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock. As of December 31, 2004, $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 $3.54 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.

On February 22, 2005, we closed a $2.5 million secured convertible debt financing from Laurus. Net proceeds from the financing will be used primarily to support our research, development and commercialization opportunities and for general working capital purposes. We also used approximately $300,000 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. The initial public offering allowed us to pay all of our outstanding debts, including all bank debt, and outstanding obligations resulting from a dispute with a former shareholder and officer. As of December 31, 2004, we had stockholders equity of $6.0 million, versus $3.1 million at December 31, 2003.

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 in the next 18 months is 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.

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 through at least December 31, 2005. 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.

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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-24 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.

Item 8B. Other Information.

On November 29, 2004, we engaged the investment banking firm of Ferris, Baker Watts, Incorporated, or FBW, to be our exclusive financial advisor for a period of one year in connection with the exploration of a number of potential strategic transactions. FBW advised us in connection with our recent financing with Laurus. In consideration for services provided by FBW, we paid to FBW in November 2004 a non-refundable initial cash fee of $25,000 and issued to FBW warrants to purchase 225,000 shares of our common stock at an exercise price equal to $5.25. The warrants are not exercisable until August 22, 2005. The warrants expire on November 29, 2010. The warrants do not contain any cashless exercise or non-standard anti-dilution provisions, but do contain customary provisions for stock splits and stock dividends. We also agreed to pay FBW certain transaction-based fees at the closing of transactions introduced to us by FBW. We paid such fees to FBW in connection with the Laurus financing.

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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 21, 2005 are as follows:

Name	Age	Position(s) Held
Francis E. O Donnell, Jr., M.D.	55	Chief Executive Officer, Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	51	President and Chief Operating Officer
Raphael J. Mannino, Ph.D.	58	Executive Vice President, Chief Scientific Officer and Director
Andrew L. Finn, Pharm.D.	55	Executive Vice President of Clinical Development and Regulatory Affairs
James A. McNulty	54	Chief Financial Officer, Secretary and Treasurer
Donald L. Ferguson	55	Senior Executive Vice President
Susan Gould-Fogerite, Ph.D.	55	Vice President and Director of Innovation and Discovery
L.M. Stephenson, Ph.D.	61	Director
William B. Stone	61	Director
John J. Shea	78	Director
Robert G.L. Shorr	51	Director
Alan Pearce	55	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 55, has been our Chief Executive Officer, Chairman and Director on a full time basis since March 29, 2002 when Dr. O Donnell executed an employment agreement to become our full-time interim President and Chief Executive Officer. In January 2005, he relinquished the title of President. 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 51, has been our President and Chief Operating Officer since January 2005. 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 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 and 7 years in marketing,

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sales, and business development. Prior to his involvement with Arius 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 among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc., 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 58, 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 Science, Inc. 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 55, 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 2 migraine products. From 1996 to 1999, Dr. Finn was Co-Founder and Chief Executive Officer of enVision Sciences, a regulatory and clinical service company. From 1991 to 1996, he was Vice President of U.S. Clinical Research for Solvay Pharmaceuticals, where he oversaw NDA submissions in the areas of inflammatory bowel disease, osteoporosis prevention and treatment of obsessive-compulsive disorder. Prior to this he spent 10 years in positions of increasing responsibility at Glaxo Inc., where he oversaw a number of NDA submissions, including Zofran for chemotherapy induced nausea and vomiting. Dr. Finn received his BS in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

James A. McNulty, age 54, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis (estimated to constitute approximately 50% of his time) since October 2000. Mr. McNulty has, since May 2000, also served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture activities. Hopkins Capital Group is owned and controlled by Dr. Francis E. O Donnell, Jr. Mr. McNulty also serves as the Treasurer and Corporate Secretary of Accentia Biopharmaceuticals, Inc., a holding company with commercialization assets representing a vertically-integrated platform for specialty pharmaceuticals and biologics. 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 principal in Pinnacle Group Holdings, a Tampa real estate development company. 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.

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Donald L. Ferguson, age 55, has been Senior Executive Vice President on a part time basis since October 2000. Mr. Ferguson has been Chief Executive Officer and principal owner of Land Dynamics, Inc., a developer of real estate projects since its founding in 1979 and currently owns in excess of 20 real estate properties. Mr. Ferguson is an investor in early stage technology and biotechnology companies including Nanovision Technologies, Inc., Star Scientific, Inc., BioKeys Pharmaceuticals, Inc. (now Adventrx) and PhotoVision Pharmaceuticals, Inc. Mr. Ferguson holds an M.B.A. Degree from the University of Kansas and a B.S. Degree in industrial engineering from Oklahoma State University.

Susan Gould-Fogerite, Ph.D., age 51, has been Vice President and Director of Innovation and Discovery since July 2002. She was previously Executive Vice President of Business Development Vaccines and Gene Therapy from October 2000. Dr. Gould-Fogerite served as Vice President and Secretary, and has been a member of the Board of Directors of BioDelivery Sciences, Inc. since its incorporation in 1995. Dr. Gould-Fogerite s previous experience includes her positions as Assistant Professor, at University Of Medicine And Dentistry Of New Jersey, New Jersey Medical School (1991 to present), and Research Instructor (1985 to 1988), then Research Assistant Professor (1988-1990), at Albany Medical College. Dr. Gould-Fogerite received her Ph.D. in Microbiology and Immunology from the Albany Medical College in 1985.

L.M. Stephenson, Ph.D., age 61, 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 new responsibilities at Drexel are closely similar to UMDNJ. Dr. Stephenson is a graduate of the University of North Carolina where he earned a BS in chemistry and was awarded the Venable Medal for outstanding senior in chemistry. Dr. Stephenson earned his Ph.D. in chemistry from the California Institute of Technology where he earned the Kodak Prize for outstanding chemistry graduate student and was an NSF Predoctoral Fellow. Additionally, Dr. Stephenson was a Research Fellow at Harvard University. Dr. Stephenson also serves on the board of directors of the following institutions: University City Science Center (Non-Profit), and Crescent Genomics.

William B. Stone, age 61, 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 78, 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

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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.

Robert G.L. Shorr, Ph.D., age 51, is a member of our board of directors. He is currently President and Chief Executive Officer of Cornerstone Pharmaceuticals, a company focused on novel tumor targeting drug delivery and novel anticancer agent technologies. He is also on the faculty of State University of New York (SUNY) Stony Brook Department of Biomedical Engineering where he serves as the Director of Business Development for the Center for Advanced Technology State University of New York at Stony Brook. He has served in that position since October 1998. As Director of Business Development for the State University of New York at Stony Brook Center for Biotechnology, Dr. Shorr has been responsible for working with faculty and the university technology transfer office to establish grant funded entrepreneurial programs for promising commercializable technology. From 1991 to 1998, Dr. Shorr served as Vice President Science and Technology and as Vice President for Research and Development at Enzon Inc., a public company. Among his many accomplishments, Dr. Shorr was responsible for management of the co-development with Schering Plough of the product PEG INTRON A, which is now approved in the US and Europe. Dr. Shorr also served as chief scientist and consultant for another public company, United Therapeutics, Inc. from 1998 until April 2003. Dr. Shorr was also Associate Director for Molecular Pharmacology at SmithKline and French Upper Marion, PA; working under the direction of Stanley T. Crooke, M.D., Ph.D. and President of World Wide Research and Development. Dr. Shorr received his B.S. in Biology from the State University of New York (Buffalo) in 1975, his D.I.C. from Imperial College of Science & Technology in London, England in 1982, and his Ph.D., in Biochemistry from the University of London in 1981.

Alan Pearce, age 55, is a member of our board of directors. Since August 2004, he has served as the Chief Financial Officer of Accentia Biopharmaceuticals, Inc. Prior to this, Mr. Pearce served as Senior Vice President, Financial Services for McKesson Corporation, a large publicly traded healthcare company, from April 1999 to March 2004. Mr. Pearce also currently serves on the advisory boards of The Georgia Institute of Technology, or Georgia Tech, the Emory University BioEngineering Foundation, and The Hopkins Capital Group. He also previously served as a director and a member of the finance committee of XL Insurance. Mr. Pearce is a graduate of Georgia Tech, where he earned a B.S. degree in Industrial Management, and the University of Texas, where he earned an MBA degree in finance.

Scientific Advisory Board

We have established our Scientific Advisory Board as an additional scientific and technical resource for our management team. Members of our historical 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.

When we merged with Arius, we added their Scientific Advisory Board members to our Scientific Advisory Board. Simultaneously with such merger, the options held by the Arius Scientific Advisory Board members to purchase shares of Arius common stock were accelerated and converted into shares of Arius common stock. As a result, in the merger, each Scientific Advisory Board member received a small amount of Series A Preferred shares. Such Arius Scientific Advisory Board members have not been granted options to purchase shares of our common stock.

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The following is a short discussion of the backgrounds of our Scientific Advisory Board members:

Stephane E. Allard, M.D. is the Vice President of Pharmaceutical Development at BDSI and Chief Executive Officer, President, and a Director of Biovest International. He was formerly Vice President of Medical Affairs with Sanofi-Synthelabo, a six billion dollar global pharmaceutical company manufacturing and marketing of products such as Plavix, Ambien, Avapro, Hyalgan and Primacor and was responsible for a staff of 120 people. Dr. Allard has served as President of Synthelabo, Inc. and Director of Research and Development at Lorex Pharmaceuticals. At Synthelabo, Dr. Allard was responsible for the start up of Synthelabo, Inc. (USA). He was also key in establishing Phase I through IV clinical activities for products such as Ambien, Kerlone and Alfuzosin, and managed and led the liaison with the FDA and other government agencies. Dr. Allard staffed and led the group s 11 person New Jersey operation and the 40 person (Clinical, Biostatistics, and Data Management) Chicago office. Dr. Allard served as European Clinical Director of Clinical Research from 1990 to 1993 for six divisions in Synthelabo (Paris), France, Director of Clinical Development from 1987 to 1990, and as Associate Director of Clinical Development from 1985 to 1987. From 1978 to 1985, Dr. Allard was Associate Medical Director and Medical Advisor at Wyeth, a division of American Home Products. Dr. Allard received his medical doctorate from Rouen Medical College and has been awarded a Diplomate of CESAM (Certificate of Statistical Studies Applied to Medicine) Ph.D, as well as a Diplomate of Clinical Pharmacology and Pharmacokinetics (Pitie-Salpetriere Hosp.); Paris, France.

Ralph Arlinghaus, Ph.D. is Professor and Chairman of the Department of Molecular Pathology at M. D. Anderson Cancer Center since 1986. Dr. Arlinghaus has an extensive research background and experience in several fields, including small RNA viruses (picornaviruses), retroviruses, including HIV, molecular mechanisms involved in signal transduction, and molecular aspects of leukemia research both at the level of diagnostics and developing novel strategies to treat leukemia. From 1983-1986 Dr. Arlinghaus was Director of Vaccine Development at the Johnson & Johnson Biotechnology Center in La Jolla, CA.

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.

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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 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.

Gerald Lee Mandell, M.D., MACP is the Owen R. Cheatham Professor of the Sciences and Professor of Medicine at the University of Virginia. He is the founding editor of the world s leading reference source, *Principles and Practices of Infectious Diseases* and the journal *Current Infectious Diseases*. He is a past-President of the Infectious Diseases Society of America and was holder of an NIH MERIT Award for his research focused on neutrophils and infection and neutrophil interactions with antibiotics. He is a member of the Institute of Medicine.

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.

James M. Oleske, M.D., MPH is François-Xavier Bagnoud Professor of Pediatrics and Director, Division of Pulmonary, Allergy, Immunology and Infectious Diseases Department of Pediatrics UMD-New Jersey Medical School. Dr. Oleske is an internationally recognized expert in the management of children with HIV/AIDS. His earlier interest in immune based therapy for infants and children with primary immunodeficiency has been extended to children with HIV infection. His multiple medical Board certifications (Allergy/Immunology, Infectious Disease, Laboratory Immunology and Palliative/Hospice Care and Pain) reflect his lifelong commitment of advocacy for children.

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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.

Arius Commercial Advisory Board

Arius has also established a Commercial Advisory Board as an additional sales and marketing resource for our management team. When we merged with Arius, we kept their Commercial Advisory Board in place. At the merger, the options of the Arius Commercial Advisory Board in the predecessor Arius were accelerated. As a result, each such member received shares of our Series A Preferred upon the consummation of the merger. Such Arius Commercial Advisory Board members have not been granted options to purchase shares of our common stock. The following is a short discussion of our advisory board members background:

William Poole has had extensive experience within the Bio-Pharmaceutical and Medical Device Industry for over thirty years. He began his career as a pharmaceutical sales representative for Lederle Laboratories, a Division of American Cyanamid Company. During his 24-year career at Cyanamid, Mr. Poole held positions of increasing responsibility and was World-Wide Division President of the Medical Device Division when Wyeth acquired American Cyanamid in 1995. Subsequently, Mr. Poole has served as President of North America for Novo Nordisk Pharmaceuticals and most recently for Biovail Pharmaceuticals. In both companies, Mr. Poole was instrumental in aggressively growing revenue, building a solid management team and dramatically improving profitability. As President, Mr. Poole had total P&L responsibility s and had directly reporting to him, Vice President of the following service functions: Manufacturing, Research & Development, Sales, Legal, Marketing, Finance, Regulatory and Human Resources. A graduate of Boston University, Mr. Poole is currently a Consultant to the Medical Industry and resides in Raleigh, North Carolina.

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 Commercial Development for Andrx Pharmaceutcials. Prior to holding this position Bill Baicy held several senior commercial management positions at Glaxo, Glaxo Wellcome and GlaxoSmithKline

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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.

Board Committees

The 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.

Audit Committee

The Board of Directors has an Audit Committee, comprised of William B. Stone, L.M. Stephenson and John J. Shea, all of whom are independent directors as defined by the rules of the National Association of Securities Dealers, or 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.

The Audit Committee met eight times during 2004. 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

The Board of Directors has a Nominating and Corporate Governance Committee, comprised of William B. Stone, L.M. Stephenson and John J. Shea. Mr. Stone serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing the Company s 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 formally meet during 2004. 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

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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 the Board of Directors of the Company have previously served in such capacity. During 2004, we did not pay any fees to any third parties to assist in the identification of nominees. During 2004, we did not receive any director nominee suggestions from stockholders.

Compensation and Investment Committees

The Board of Directors also has a compensation committee, which, either alone or in conjunction with the full board, as the case may be, reviews and recommends the compensation arrangements for our management. The members of the compensation committee are Dr. Francis E. O Donnell, Jr., L.M. Stephenson and William B. Stone. The compensation committee as such did not meet during 2004.

The 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 the Company. The members of the investment committee are Dr. Francis E. O Donnell, William Stone, L.M. Stephenson and Alan Pearce. The investment committee as such did not meet during 2004.

There are no other Board of Directors committees at this time.

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 2004, all Forms 3, 4 and 5 were not timely filed with the SEC by such reporting persons. We believe there are some delinquent filings in 2005.

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 10,000 options to purchase

common stock per year for serving as a chairman of a committee of the board of directors and 5,000 options to purchase common stock per year for serving on a committee of the board of directors.

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SUMMARY COMPENSATION TABLE*

		Annual Compensation[1]			Long Term Compensation: Awards		Long Term Compensation: 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.	2004	$ 117,692				35,000		
	2003	145,962				35,000		
Chief Executive Officer and Chairman	2002	112,500				61,991		
709 The Hampton Lane								
Chesterfield, MO 63017								
Mark A. Sirgo, Pharm.D. [2],	2004	$ 62,596	$ 31,177.90			5,147		
	2003							
President and Chief Operating Officer	2002							
3100 Stone Gap Court								
Raleigh, North Carolina 27612								
Andrew L. Finn, Pharm.D. [3],	2004	$ 62,596	$ 28,092.04			5,147		
	2003							
Executive Vice President of Clinical Development	2002							
and Regulatory Affairs								
737 West Hargett Street								
Raleigh, NC 27603								
James A. McNulty,	2004	$ 105,866				3,235		
	2003	141,769	$			18,616		
Chief Financial Officer, Secretary and Treasurer	2002	170,922	35,000					
4419 W. Sevilla Street								
Tampa, FL 33629								
Raphael J. Mannino, Ph.D [4],	2004	$ 88,788		11,423		26,176		$ 5,015
	2003	90,000	52,500			111,449		5,015
Executive Vice President and Chief Scientific Officer	2002	91,500				35,423		5,015

UMDNJ New Jersey Medical School 185 South Orange Avenue, Building 4 Newark, NJ 07103					
Susan Gould-Fogerite, Ph.D [5],	2004	$ 49,408		4,295	
	2003	63,494		19,438	
Vice President and Director of Innovation and Discovery	2002	46,660			$
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) Dr. Sirgo joined our company on August 24, 2004. Under his employment agreement with us, he is entitled to an annual base salary of $175,000. The amounts reflected under column (c) reflect the amount of base salary paid to him from August 24 through December 31, 2004.

(3) Dr. Finn joined our company on August 24, 2004. Under his employment agreement with us, he is entitled to an annual base salary of $175,000. The amounts reflected under column (c) reflect the amount of base salary paid to him from August 24 through December 31, 2004.

(4) Includes: (a) a car allowance of $6,750 and 401(k) matching of $4,673 paid in 2004 as reflected in column (e) and (b) premiums paid on key-man life insurance has set forth in column (i). Excludes $126,286, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2004 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

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(5) Excludes $83,524, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2004 (pursuant to a contractual arrangement) for services rendered by Dr. Gould-Fogerite to such university.

Option Grants During Year Ended December 31, 2004

	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.	35,000	12.04%	$ 2.29	August 29, 2014	$ 4,007.50	$ 8,015.00
Mark A. Sirgo	5,147	1.77%	$ 3.40	October 21, 2014	$ 874.99	$ 1,749.98
Andrew L. Finn	5,147	1.77%	$ 3.40	October 21, 2014	$ 874.99	$ 1,749.98
Raphael J. Mannino	6,176	2.12%	$ 3.40	October 21, 2014	$ 1,049.92	$ 2,099.84
	20,000	6.887%	$ 2.29	August 29, 2014	$ 2,290.00	$ 4,580.00
James A. McNulty	3,235	1.11%	$ 3.40	October 21, 2014	$ 549.95	$ 1,099.90
Susan Gould-Fogerite	4,295	1.48%	$ 3.40	October 21, 2014	$ 730.15	$ 1,460.30

In July and August 2004, certain of our directors exercised an aggregate of 160,000 options to acquire shares of our common stock. We raised $272,000 from such exercises.

AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR

AND FY-END OPTION/SAR VALUES

Name and Principal Position	Shares Acquired On Exercise(#)	Value Realized($)	Number of Securities Underlying Unexercised Options/SARs At Fiscal Year-End(#) Exercisable / Unexercisable	Value of Unexercised In-The-Money Options/SARs At Fiscal Year-End($) Exercisable / Unexercisable
(a)	(b)	(c)	(d)	(e)
Francis E. O Donnell, Jr., M.D.	35,000		105,000/0	$ 46,734/0
Mark A. Sirgo, Pharm.D.			0/5,147	$ 0/617
Andrew L. Finn, Pharm.D.			0/5,147	$ 0/617

Raphael J. Mannino, Ph.D.	242,016/27,142	$	197,558/741
James A. McNulty	6,206/15,645	$	0/388
Susan Gould-Fogerite, Ph.D.	40,804/17,253	$	7,895/515

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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, Chief Executive Officer and 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 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.

(b) Mark A. Sirgo, Pharm.D., President and Chief Operating 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 Operating Officer of our company. Dr. Sirgo also received a signing bonus in the amount of $31,177.90 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. Dr. Finn also received a signing bonus in the amount of $28,092.04 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).

(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 agreement terminates on September 1, 2005. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(f) Dr. Susan Gould-Fogerite, Vice President and Director of Innovation and Discovery On August 31, 2002, Dr. Gould-Fogerite executed an employment agreement with us at an annual salary of $146,030. Such agreement terminates on August 31, 2005. Under the terms of this agreement, she is also entitled to the following benefits: medical, dental and disability and 401(k).

Drs. Mannino and Gould-Fogerite had outstanding debt payable to us that was incurred with their purchase of stock in our predecessor, BioDelivery Sciences, Inc., in 1999. Simultaneously with the closing of our public offering in June 2002, we forgave those notes and provided these same individuals with a total of approximately $200,000 as compensation for their tax liability.

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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 1,861,480 shares of common stock are outstanding as of December 31, 2004 under the Amended and Restated 2001 Stock Option Plan. All options were issued under our stock option plan, as the same may be amended. Options may be awarded during the ten-year term of the stock option plan to our employees (including employees who are directors), consultants who are not employees and our other affiliates. Our stock option plan provides for the grant of options intended to have been approved by our board of directors and qualify as incentive stock options, or Incentive Stock Options, under Section 422A of the Internal Revenue Code of 1986, as amended, and options which are not Incentive Stock Options, or Non-Statutory Stock Options.

Only our employees or employees of our subsidiaries may be granted Incentive Stock Options. Our affiliates or consultants or others as may be permitted by our board of directors, may be granted Non-Statutory Stock Options.

Directors are eligible to participate in our stock option plan. The Amended and Restated 2001 Stock Option Plan provides for an initial grant of an option to purchase up to 20,000 shares of common stock to each director upon first joining our board of directors and subsequent grants of options to purchase 20,000 shares upon each anniversary of such director s appointment. Additionally, directors will be granted 10,000 options for each committee chairmanship and 5,000 options for each committee membership. Such options are granted at an exercise price equal to the fair market value of the common stock on the grant date and immediately vest.

Options and warrants to purchase 2,086,480 shares of our common stock at prices ranging from $1.63 to $17.48 are outstanding at December 31, 2004. None of our options have been granted at less than 85% of the fair market value at the time of grant. Options issued during 2004 to employees and directors totaled 290,591 shares, at exercise prices ranging from $2.29 and $3.40. In addition, in November 2004, we issued warrants to purchase 225,000 shares of common stock at exercise an exercise price of $5.25 to Ferris, Baker, Watts.

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

The following table sets forth, as of March 17, 2005, 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 17, 2005
Hopkins Capital Group II, LLC [2]	3,111,580	42.6%
Francis E. O Donnell, Jr., M.D.[3]	3,492,113	47.8%
The Francis E. O Donnell, Jr. Irrevocable Trust #1[4]	3,279,080	44.9%
Pharmaceutical Product Development, Inc. [5]	690,000	9.4%
Jonnie R. Williams, Sr. [6]	3,203,114	43.9%
MOAB Investments, LP [7]	3,157,347	43.2%
Mark A. Sirgo, Pharm.D. [8]	6,000	*
Andrew L. Finn, Pharm.D. [9]		*
Raphael J. Mannino, Ph.D. [10]	397,025	5.4%
James A. McNulty [11]	82,865	1.1%
Donald L. Ferguson [12]	274,600	3.8%
Susan Gould-Fogerite, Ph.D. [13]	192,978	2.6%
L.M. Stephenson, Ph.D [14]	85,000	1.2%
William B. Stone [15]	140,000	1.9%
John J. Shea [16]	70,000	1.0%
Robert G.L. Shorr [17]	65,000	*
Alan Pearce [18]	85,000	1.2%
All Directors and Officers as a group (12 persons)	4,965,581	68.0%

* Less than 1%

(1) Based on 7,304,686 shares of common stock outstanding as of March 17, 2005.

(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 none are presently convertible into shares of our common stock.

(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 105,000 shares of our common stock, all of which is currently exercisable. Dr. O Donnell s address is 709 The Hampton Lane, Chesterfield MO 63017.

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(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 s wife. Mr. Williams s 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) Includes 6,000 shares owned by Dr. Sirgo, our President and Chief Operating 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. Dr. Sirgo s address is 3100 Stone Gap Court Raleigh, North Carolina 27612.

(9) Dr. Finn is our Executive Vice President and Chief Operating Officer. Dr. Finn owns 797,414 shares of our Series A Convertible Preferred Stock, of which none are presently convertible into shares of our common stock. Dr. Finn s address is 737 West Hargett Street, Raleigh, NC 27603.

(10) Dr. Mannino is our Executive Vice President, Chief Scientific Officer and a Director. Includes options to purchase 242,016 shares of our common stock, all of which are currently exercisable.

(11) Mr. McNulty is our Chief Financial Officer, Secretary and Treasurer. Includes 2,288 shares owned by his wife, as to which he disclaims beneficial interest of. His address is 4419 W. Sevilla Street, Tampa, FL 33629.

(12) Mr. Ferguson is our Senior Executive Vice President. Includes options to purchase 274,600 shares of our common stock, all of which are currently exercisable. Mr. Ferguson s address is 11477 Olde Cabin Road, Suite 110, St. Louis, MO 63141.

(13) Dr. Gould-Fogerite is our Vice President and Director of Innovation and Discovery. Includes options to purchase 40,804 shares of our common stock, all of which are currently exercisable.

(14) Includes options to purchase 55,000 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 105,000 shares of our common stock, all of which are currently exercisable. Mr. Stone s address is 11120 Geyers Down Lane, Frontenac MO 63131.

(16) Includes options to purchase 60,000 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 65,000 shares of our common stock, all of which are currently exercisable. Dr. Shorr s address is 28 Brookfall Road, Edison, NJ 08817.

(18) Includes options to purchase 60,000 shares of our common stock, all of which are currently exercisable. Mr. Pearce s address is 35 Watergate Drive, #706, Sarasota, FL 34236.

Item 12. Certain Relationships and Related Transactions.

We have several business relationships with Accentia Biopharmaceuticals, Inc. and its affiliates. HCG, which is controlled by Dr. Frank O Donnell, our Chairman and CEO 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, Alan Pearce, a member of our board of directors, is the CFO of Accentia and James A. McNulty, our Secretary, Treasurer and CFO, is the Treasurer and Corporate Secretary 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 Mayo Foundation for Medical Education and Research for the treatment of CRS and asthma on a worldwide basis. The license agreement was amended effective June 1, 2004, then modified in September 2004 by our asset purchase agreement with Accentia, and was twice amended again in 2005 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 the 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., 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.

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 Chief Executive Officer and Chairman.

During 2001, we entered into agreements with RetinaPharma, Inc. (now call 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 Chief Executive Officer and Chairman, are affiliated as stockholders and a director of RetinaPharma Technologies, Inc. Dr. O Donnell is the managing director of Hopkins Capital Group, LLC and 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. HCG, which is affiliated with Dr. Francis E. O Donnell, Jr., our Chairman and CEO, 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 37,843 shares of our common stock as compensation for services rendered.

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Ellenoff Grossman & Schole LLP is also counsel to our subsidiary, Bioral Nutrient Delivery, LLC. We also issued options for an additional 19,607 shares of common stock an exercise price of $2.55 to such law firm for partial compensation in connection with our registration of 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. These independent directors are currently William B. Stone, L.M. Stephenson, John J. Shea and Robert G.L. Shorr.

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. (11)
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)

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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)
4.1	Form of Class A Warrant Agreement with Forms of Class A Warrant Certificate (9)
4.2	Form of Representative s Unit Purchase Option (11)
4.3	Form of Specimen of Unit Certificate (12)
4.4	Form of Specimen of Common Stock Certificate (12)
4.5	Form of Specimen of Warrant Certificate (12)
4.6	Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 20, 2004 (21)
4.7	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 25, 2004. (22)
4.8	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated September 2, 2004 (23)
4.9	Certificate of Designations of the Series B Convertible Preferred Stock of the Company, dated September 3, 2004 (23)
4.10	Secured Convertible Term Note, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.11	Common Stock Purchase Warrant, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
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)

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10.13	Employment Agreement with Christopher Chapman (2)
10.14	Employment Agreement with James A. McNulty (2)
10.15	Employment Agreement with Dr. Frank E. O Donnell (10)
10.16	Confidentiality Agreement for Dr. Frank E. O Donnell (10)
10.17	Covenant Not to Compete with Dr. Frank E. O Donnell (10)
10.18	2001 Incentive Stock Option Plan (8)
10.19	Promissory Note for BioKeys Pharmaceuticals, Inc. dated August 22, 2001 (11)
10.20	Research Agreement with PharmaResearch Corporation (9)
10.21	Credit Facility Loan Agreement (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)

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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)
10.35	First Amendment to Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (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	Evaluation Agreement and Option to License, dated September 5, 2002 by and between the Company and ***** (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (18)
10.38	License Agreement, dated effective April 12, 2004, between the Company and Accentia, Inc. (19)
10.39	Amendment to License Agreement, dated effective June 1, 2004, between the Company and Accentia, Inc. (19)
10.40	Facility Loan Agreement, dated effective August 2, 2004, between the Company and Hopkins Capital Group II, LLC (20)
10.41	Binding Letter of Intent and Termination Agreement, dated August 23, 2004, between Hopkins Capital Group II, LLC and the Company (22)
10.42	Registration Rights Agreement, dated August 24, 2004, by and among the Company and the former stockholders of Arius (22)
10.43	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.44	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.45	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.46	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.47	Voting Agreement, dated August 24, 2004, by Mark A. Sirgo and Andrew L. Finn in favor of the Company (22)
10.48	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)
10.49	Loan Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)

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10.50	Security Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)
10.51	Limited Waiver and Forbearance Agreement, dated effective May 14, 2004, by and between the Company and Gold Bank (22)
10.52	Equity Line of Credit Agreement, dated September 3, 2004, by and between the Company and Hopkins Capital Group II, LLC (23)
10.53	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)
10.54	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)
10.55	First Amendment to Employment Agreement, dated January 31, 2005, by and between the Company and Francis E. O Donnell, Jr. (26)
10.56	Securities Purchase Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.57	Registration Rights Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.58	Subsidiary Guaranty, dated February 22, 2005, by Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.59	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)
10.60	Stock Pledge Agreement, dated February 22, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.61	Grant of Security Interest in Patents and Trademarks, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
10.62	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)
10.63	Letter Amendment to License Agreement, dated March 28, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (*)
10.64	Letter Amendment to License Agreement, dated April 25, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (*)
20.1	Code of Ethical Conduct of the Registrant (29)
21.1	Subsidiaries of the Registrant (+)

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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
\+ Previously filed
** A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
(2) Previously filed with Form 10QSB, for the quarter ended March 31, 2001.
(3) Previously filed with Form 10KSB, for the fiscal year ended December 31, 2000 filed on August 15, 2001.
(5) Previously filed with Form 8K filed October 26, 2000 under our prior name of MAS Acquisition XXIII Corp.
(6) Previously filed with Form 10SB filed January 18, 2000 under our prior name of MAS Acquisition XXIII Corp.
(8) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(9) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.
(10) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.
(11) Previously filed with Form SB-2, Amendment No. 5, May 23, 2002.
(12) Previously filed with Form SB-2, Amendment No. 6, June 24, 2002.
(13) Previously filed with Form 10-QSB, November 15, 2002.
(14) Previously filed with Form 8-K, January 7, 2003.
(15) Previously filed with Form 8-K, February 26, 2003.
(16) Previously filed with Form 8-K, April 25, 2003.
(17) Previously filed with Form 10-QSB/A, September 2, 2003.
(18) Previously filed with Form 8-K, November 19, 2003.
(19) Previously filed with Form 8-K, June 4, 2004.
(20) Previously filed with Form 8-K, August 6, 2004.
(21) Previously filed with Form 8-K, August 12, 2004.
(22) Previously filed with Form 8-K, August 26, 2004.
(23) Previously filed with Form 8-K, September 8, 2004.
(24) Previously filed with Form 8-K, September 8, 2004.
(25) Previously filed with Form 8-K, January 24, 2005.
(26) Previously filed with Form 8-K, February 3, 2005.
(27) Previously filed with Form 8-K, February 25, 2005.
(28) Previously field with Form 10-KSB, March 28, 2003.

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, 2004 and 2004, the review of the financial statements included in our Forms 10-QSB and consents issued in

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connection with BND s registration statement filings for 2003 totaled, respectively, $85,000 and $37,426. Note, new rule includes interim procedures as audit fees. Audit committee meetings are also included here.

Audit-Related Fees. The aggregate fees billed by Aidman, Piser & Company, P.A. for audit-related fees for the years ended December 31, 2004 and 2003 were $34,025 and $26,700, respectively. Audit-related fees in 2003 were related to the BND registration statements and amendments thereto filed with the SEC.

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, 2004 and 2003 were $17,600 and $10,000, 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, 2004 and 2003 totaled none 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 2004. 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, 2004, 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. 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, 2004, 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

February 8, 2005

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

DECEMBER 31, 2004

ASSETS	
Current assets:	
Cash and cash equivalents	$ 749,932
Accounts receivable	27,145
Due from related party	9,290
Prepaid expenses and other current assets	242,849
Total current assets	1,029,216
Equipment, net	895,294
Goodwill	2,715,000
Other intangible assets:	
Licenses	2,417,445
Non-compete agreements	500,000
Accumulated amortization	(211,658)
Total other intangible assets	2,705,787
Other assets	24,726
Total assets	$ 7,370,023
LIABILITIES AND STOCKHOLDERS EQUITY	
Current liabilities:	
Current maturities of note payable, bank	$ 333,333
Accounts payable and accrued expenses	758,220
Due to related party	171,327
Deferred revenue	123,311
Total current liabilities	1,386,191
Commitments and contingencies (Note 10)	
Stockholders equity:	
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 1,647,059 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, 7,245,863 shares issued; 7,145,863 shares outstanding	7,246
Additional paid-in capital	14,619,701
Treasury stock, at cost, 100,000 shares	(303,894)
Accumulated deficit	(13,495,104)
Total stockholders equity	5,983,832

Total liabilities and stockholders equity	$ 7,370,023

See notes to consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2004 AND 2003

	2004	2003
Sponsored research revenues	$ 778,898	$ 913,231
License fees, related parties	1,000,000	2,000,000
	1,778,898	2,913,231
Expenses:		
Research and development:		
Related party	807,524	298,251
Other	3,180,513	2,335,694
General and administrative:		
Stock-based compensation	263,798	200,039
Related party	263,804	220,266
Other	2,747,087	2,416,341
	7,262,776	5,470,591
Loss from operations	(5,483,828)	(2,557,360)
Other income (expense):		
Sale of royalty rights, related party	2,500,000	
Sale of tax loss carryforwards	216,674	
Interest income (expense), net	(59,361)	69,254
	2,657,313	69,254
Loss before income taxes	(2,826,515)	(2,488,106)
Income tax benefit		
Net loss	(2,826,515)	(2,488,106)
Preferred stock dividends	(22,303)	
Loss attributable to common stockholders	$ (2,848,818)	$ (2,488,106)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (0.40)	$ (0.35)
Weighted average common stock shares outstanding:		
Basic and diluted	7,054,616	7,016,679

See notes to consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2004 AND 2003

	Series A Preferred Stock		Series B Preferred stock						Total Stockholders
	Shares	Amount	Shares	Amount	Common Stock		Additional Paid-In	Treasury Equity	Accumulated Deficit	Equity
Balances, January 1, 2003		$		$	7,085,863	$ 7,086	$ 13,956,327	$	$ (8,180,483)	$ 5,782,930
Stock-based compensation							200,039			200,039
Stock offering costs							(50,000)			(50,000)
Purchase of treasury stock								(303,894)		(303,894)
Net loss									(2,488,106)	(2,488,106)
Balances, December 31, 2003					7,085,863	7,086	14,106,366	(303,894)	(10,668,589)	3,140,969
Stock-based compensation							263,798			263,798
Exercise of stock options					160,000	160	271,840			272,000
Series A Preferred Stock issuance in connection with business acquisition	1,647,059	3,705,883								3,705,883
Issuance of Series B Preferred Stock for cash			341,176	1,450,000						1,450,000
Series B Preferred Dividends							(22,303)			(22,303)
Net loss									(2,826,515)	(2,826,515)
Balances, December 31, 2004	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,245,863	$ 7,246	$ 14,619,701	$ (303,894)	$ (13,495,104)	$ 5,983,832

See notes to consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2004 AND 2003

	2004	2003
Operating activities:		
Net loss	$ (2,826,515)	$ (2,488,106)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation	284,251	200,048
Amortization	174,081	41,706
Loss on sale of marketable securities	9,899	
Stock-based compensation expense	263,798	200,039
Expense in-process research and development from acquisition	200,000	
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(27,145)	2,000,000
Prepaid expenses and other assets	(20,359)	(20,972)
Accounts payable and accrued expenses	(1,089,023)	(413,617)
Deferred revenue	99,337	(1,942,271)
Net cash flows from operating activities	(2,931,676)	(2,423,173)
Investing activities:		
Purchase of equipment	(111,949)	(832,583)
Cash acquired in business acquisition	57,675	
Proceeds from disposal (purchase) of investments	2,017,753	(2,027,652)
Net cash flows from investing activities	1,963,479	(2,860,235)
Financing activities:		
Proceeds from exercise of stock options	272,000	
Expense associated with stock offering		(50,000)
Proceeds from issuance of Series B Preferred stock	1,450,000	
Proceeds from notes payable		1,000,000
Repurchase of treasury stock		(303,894)
Proceeds from related party borrowings	100,201	10,111
Payment on capital lease obligations	(4,742)	(12,775)
Payment on notes payable	(625,000)	(41,667)
Net cash flows from financing activities	1,192,459	601,775
Net change in cash	224,262	(4,681,633)
Cash at beginning of year	525,670	5,207,303
Cash at end of year	$ 749,932	$ 525,670

The Company paid interest of $0.06 million and $0.04 million during 2004 and 2003, respectively.

In August 2004, the Company issued 1,647,059 shares of Series A Preferred stock at a value of $3.7 million for the acquisition of Arius Pharmaceuticals, Inc.

The Company accrued $0.02 million in annual cumulative dividends in connection with its Series B Preferred stock during 2004.

See notes to consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

Organization:

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

BDSI is a specialty biopharmaceutical company that is exploiting its licensed and proprietary patented drug delivery technologies to develop and commercialize clinically-significant new formulations of proven therapeutics and micronutrients. The Company s drug delivery technologies include: (i) the licensed and patented Bioral® nanocochleate technology, designed for a potentially broad base of applications, and (ii) the licensed and patented BEMA (transmucosal, or applied to the inner cheek membrane) drug delivery technology being developed by the Company s Arius Pharmaceuticals, Inc. subsidiary (Arius), which was acquired in August 2004. Arius is developing products for acute treatment opportunities such as pain, anxiety, nausea and vomiting.

Principles of consolidation:

The financial statements include the accounts of BDSI and its majority-owned subsidiaries, Arius (from the date of acquisition of August 24, 2004) and Bioral Nutrient Delivery, LLC (BND), which is currently an inactive subsidiary. All significant inter-company balances have been eliminated.

Revenue recognition:

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

License fees are payments for the initial license of and access to the Company s technology. For nonrefundable license fees received at the initiation of license agreements for which the Company has an ongoing research and development commitment, the Company defers these fees and recognizes them ratably over the period of the related research and development. For nonrefundable license fees received under license agreements where the continued performance of future research and development services is not required, the Company recognizes revenues upon delivery of the technology. In addition to license fees, the Company may also generate revenue from time to time in the form of milestone payments. Milestone payments are only received and recognized as revenues if the specified milestone is achieved and accepted by the customer

and continued performance of future research and development services related to that milestone are not required. The Company, for arrangements where non-refundable upfront fees exist and there are further payments due upon achieving certain milestones, recognizes such revenue pursuant to Emerging Issues Task Force 00-21, Revenue Arrangements with Multiple Deliverables, whereby multiple deliverables are evaluated to determine whether such deliverables should be considered a single unit of accounting.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

In April 2004, the Company entered into a sublicensing agreement (the Accentia License Agreement) with Accentia Biopharmaceuticals, Inc., f/k/a Accentia, Inc. (Accentia), a related company, pursuant to which the Company was entitled to a 12% to 14% royalty stream from an oral compound for the treatment of chronic rhinosinusitus. Under the terms of the Accentia License Agreement, all development costs are paid by Accentia. The Company is entitled to that royalty stream based on its application of encochleated technology to licensed drugs. In September 2004, in part to address the Company s liquidity, the Company entered into an asset purchase agreement with Accentia whereby the Company sold to Accentia an asset consisting of 50% of a portion of the future revenue stream under the Accentia License Agreement (and a resulting reduction of future royalty payments) for a one-time non-refundable payment of $2.5 million. The Company has no ongoing material monetary obligations under the agreement or its asset purchase agreement with Accentia, and the Company has subsequently clarified with Accentia the actual original agreement between the parties regarding Accentia s payment obligations. As such, the $2.5 million, which was paid in September, is recognized as other income in the 2004 financial statements.

Research and development:

Research and development expenses are charged to operations as incurred. Research and development expenses principally include consulting fees and cost reimbursements to The University of Medicine and Dentistry of New Jersey (UMDNJ), testing of compounds under investigation, and salaries and benefits of employees engaged in research and development activities.

Cash and cash equivalents:

The Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. The Company maintains its financial instruments in a variety of high-credit quality financial institutions. At December 31, 2004, approximately $0.5 million exceeded those amounts insured by the FDIC.

Fair value of financial instruments:

At December 31, 2004, the carrying amount of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and note payable approximate fair value based either on the short term nature of the instruments or on the related interest rate approximating the current market rate.

Equipment:

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

Goodwill and other intangible assets:

Other intangible assets include licenses and noncompete agreements, which are accounted for based on Financial Accounting Standard Statement No. 142 *Goodwill and Other Intangible Assets* (FAS 142). In that regard, goodwill and intangible assets that have indefinite useful lives are not amortized but are tested at least annually for impairment, or more frequently if events or changes in circumstances indicate that the asset might be impaired.

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

	Estimated Useful Lives
Noncompete agreements	2 years
Licenses	13 years

Estimated aggregate future amortization expense for other intangible assets with finite lives for each of the next five years and thereafter is as follows:

Year ending December 31,	
2005	$ 289,800
2006	206,475
2007	39,804
2008	39,804
2009	39,804
Thereafter	238,818
	$ 854,505

Income taxes:

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

Use of estimates in financial statements:

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

Impairment of assets:

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

Net loss per common share:

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

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

	2004	2003
Numerator:		
Net loss attributable to common stockholders	$ (2,848,818)	$ (2,488,106)
Denominator:		
For basic loss per share weighted average shares	7,054,616	7,016,679
Effect of dilutive securities		
Weighted average shares for dilutive loss per share	7,054,616	7,016,679
Net loss per share attributable to common Stockholders, basic and dilutive	$ (0.40)	$ (0.35)

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

	2004	2003
Options and warrants to purchase common stock	2,086,480	1,744,043
Preferred stock convertible to common stock	1,988,235	

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

Stock-based compensation:

The Company has elected to account for its employee stock compensation plans using the intrinsic value method under Accounting Principles Board Opinion No. 25 with pro forma disclosures of net earnings and earnings per share, as if the fair value based method of accounting defined in Statement of Financial Accounting Standards (SFAS) 123 had been applied.

Had compensation cost for the Company s stock option plan been determined based on the fair value at the grant dates for stock-based employee compensation arrangements consistent with the method required by SFAS 123, the Company s net loss and net loss per common share would have been the pro forma amounts indicated below (see Note 12):

	Years ended December 31,	
	2004	**2003**
Loss attributable to common stockholders, as reported	$ (2,848,818)	$ (2,488,106)
Stock-based employee compensation, as reported		19,200
Stock-based employee compensation cost under the fair value based method	(620,467)	(640,091)
Pro forma loss attributable to common stockholders under fair value method	$ (3,469,285)	$ (3,108,997)
Loss per share attributable to common stockholders - basic and diluted:		
As reported	$ (0.40)	$ (0.35)
Pro forma under fair value method	$ (0.49)	$ (0.44)

Accounting and reporting developments:

In June 2003, the Securities and Exchange Commission (SEC) adopted final rules under Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404). Commencing with the Company s 2006 Annual Report, the Company is required to include a report of management on the Company s internal control over financial reporting. The internal control report must include a statement of management s responsibility for establishing and maintaining adequate internal control over financial reporting for the Company; of management s assessment of the effectiveness of the

Company s internal control over financial reporting as of year end; of the framework used by management to evaluate the effectiveness of the Company s internal control over financial reporting; and that the Company s independent accounting firm has issued an attestation report on management s assessment of the Company s internal control over financial reporting, which report is also required to be filed as part of the Annual Report on Form 10-K.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

Accounting and reporting developments (continued):

In November 2004, the FASB issued SFAS No. 151, Inventory Costs. The statement amends Accounting Research Bulletin (ARB) No. 43, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material. ARB No. 43 previously stated that these costs must be so abnormal as to require treatment as current-period charges. SFAS No. 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, this statement requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005, with earlier application permitted for fiscal years beginning after the issue date of the statement. The adoption of SFAS No. 151 is not expected to have any significant impact on the Company s current financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets An Amendment of APB Opinion No. 29. APB Opinion No. 29, Accounting For Nonmonetary Transactions, is based on the opinion that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. SFAS No. 153 amends Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets whose results are not expected to significantly change the future cash flows of the entity. The adoption of SFAS No. 153 is not expected to have any impact on the Company s current financial condition or results of operations.

In December 2004, the FASB revised its SFAS No. 123 (SFAS No. 123R), Accounting for Stock Based Compensation. The revision establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, particularly transactions in which an entity obtains employees services in share-based payment transactions. The revised statement requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is to be recognized over the period during which the employee is required to provide service in exchange for the award. The provisions of the revised statement are effective for financial statements issued for the first interim or annual reporting period beginning after December 15, 2005 for small business issuers, with early adoption encouraged. The Company plans to adopt this standard on January 1, 2005.

This Statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

Accounting and reporting developments (continued):

As of the required effective date, the Company will apply this Statement using a modified version of prospective application. Under that transition method, compensation cost is recognized on or after the required effective date for the portion of outstanding awards for which the requisite service has not yet been rendered, based on the grant-date fair value of those awards calculated under Statement 123 for pro forma disclosure purposes.

2. Bioral Nutrient Delivery, LLC corporate structure:

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

During 2003, BND filed a registration statement on Form SB-1 on behalf of BDSI. In connection therewith, the Company made plans to distribute to BDSI stockholders 3,545,431 of BND s Class B Shares, or approximately 43% of BND s outstanding equity interests, including the Class A Shares. After having reevaluated this strategic opportunity, the Company decided in early 2005 to forego the planned distribution of Class B Shares and presently have no intention of effecting any such distribution. Offering costs aggregating approximately $0.3 million have been expensed in the accompanying 2003 statement of operations. BND is substantially inactive at December 31, 2004.

3. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, through short-term borrowings, which were subsequently repaid, and from funded research arrangements. The Company has not generated revenue from the sale of any product but has generated revenues from licensing arrangements in 2004 and 2003 and the sale of royalty rights in 2004. The Company intends to finance its research and development efforts and its working capital needs from existing cash, new sources of financing and licensing agreements.

In July and August 2004, certain directors of the Company exercised certain of their options to acquire shares of Company common stock (the Common Stock) and, as a result, $0.3 million in equity proceeds was generated.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

3. Liquidity and management s plans (continued):

On September 3, 2004, the Company entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC (HCG), a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman and CEO. Pursuant to the Equity Line Agreement, HCG will, at the Company s request, invest up to $4.0 million in the 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. As of December 31, 2004, $1.45 million had been drawn under the Equity Line Agreement.

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

The Laurus investment takes the form of a convertible note secured by certain 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 Common Stock at a price equal to $3.10 per share. In connection with the financing, Laurus was issued a common stock purchase warrant to purchase up to 350,000 shares of Common Stock at a price equal to $3.88 per share. The Company agreed, pursuant to a registration rights agreement, to register the shares of Common Stock underlying the Laurus note and the warrant.

The Company s existing cash and cash equivalents, together with available financing, including the remaining balances of the Company s existing equity line of credit and grant, and potential new license revenue is considered by management to be sufficient to finance the planned operations and capital expenditures through at least December 31, 2005. Based on product development timelines and agreements with the Company s development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, the Company anticipates it may be required to raise additional capital through a variety of sources, including:

the 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

3. Liquidity and management s plans (continued):

There can be no assurance that additional capital will be available on favorable terms, if at all. If adequate funds are not available, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company, financial condition and 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.

4. Business acquisition:

On August 24, 2004, the Company completed the acquisition of Arius through a stock transaction. The transaction was structured as a reorganization of Arius by way of merger with and into a newly formed, wholly-owned subsidiary of the Company. As part of the transaction, the Company issued to the former stockholders of Arius 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of convertible preferred stock, designated as Series A Non-Voting Convertible Preferred Stock (the Series A Preferred). The Series A Preferred will be convertible (upon the satisfaction of certain conditions) into shares of Common Stock on a one for one basis. The Series A Preferred is eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date.

The Company engaged an independent valuation firm to prepare a valuation of the Series A Preferred issued, and the intangibles acquired, in connection with the Arius transaction. The Series A Preferred was valued at $2.25 per share, which included a 30% discount from the public trading price. The stock contains an enforced holding period of up to six years and as such the value was measured by calculating the cost of a put option resulting in the $2.25 per share value.

Arius is a specialty pharmaceutical company created to develop and commercialize products for acute conditions associated with surgery and cancer. The Company believes its acquisition of Arius will assist the Company in the furtherance of its strategy of shifting its corporate focus from being solely a drug delivery concern to a company focusing on the area of specialty pharmaceuticals , namely, applying the Company s licensed drug delivery technologies to existing therapeutics to create the Company s own proprietary formulations, for which the Company will then seek to obtain FDA approval and subsequently commercialize. This strategy seeks to avoid the high risk and cost of developing new chemical entities by focusing on the development and commercialization of new formulations of existing, FDA-approved therapeutic pharmaceuticals to which the Company s delivery technologies are applied.

The Arius acquisition was treated as a business acquisition as opposed to an asset acquisition, pursuant to guidance provided by Statement of Financial Accounting Standard 141, *Business Combinations* (SFAS 141) and Emerging Issues Task Force Release 98-3 *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business* (EITF 98-3).

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

4. Business acquisition (continued):

While Arius was a development stage enterprise, it was considered to be such based on an absence of a significant amount of revenue. Arius had entered into licensing arrangements which resulted in revenue recognized of $176,000 at the time of the acquisition, with deferred revenue recognizable in the future of $123,500. Pursuant to EITF 98-3, if the business involves a self-sustaining integrated set of activities and assets conducted and managed for the purpose of providing a return to investors, absence of significant revenues does not preclude treatment as a business acquisition as opposed to an asset acquisition. Further, Arius possessed all elements necessary to continue to conduct normal operations and met other criteria specified in EITF 98-3 to qualify as a business acquisition.

Intangible assets acquired consisted of $1.9 million in licenses which have estimated lives of 13 years, $0.5 million in non-compete agreements which have estimated lives of 2 years and $2.7 million of purchased goodwill.

As noted above, Arius business focus is to develop and commercialize products for pain associated with surgery and cancer, incorporating a novel delivery system that improves the speed of onset and provides convenience to the patient and healthcare provider.

The BEMA technology was licensed from a third party and is associated with several products that have INDs (investigational new drug applications). As an example, one of these products is BEMA Fentanyl, a mucosal analgesic targeted for use in breakthrough treatment for cancer pain. The Company will sell its products containing the BEMA technology to wholesalers, and management s business plan estimates significant revenues to be generated from this agreement.

The license acquired for the BEMA technology did not qualify as in-process research and development since the technology was licensed from a third party, Atrix, which granted the BEMA technology to Arius, and which grants Arius an exclusive worldwide license to utilize the technology in its developed products or license the technology to others. This license is a contract-based intangible asset and recognizable as an asset apart from goodwill in accordance with SFAS 141.

Emezine® is a special delivery anti-emetic, which is used to treat nausea and vomiting that may result from chemotherapy and other surgical procedures. The Company, through Arius, has finalized a product distribution agreement for Emezine®, which will generate royalties once product development is complete.

Emezine® is a product that has substance and is a project that is measurable; however, because Emezine® is a new drug not yet approved by the FDA, it is incomplete, and as such, was determined to be in-process research and development based on accepted valuation methodology, specifically the AICPA Practice Aid Assets Acquired in a Business Combination to be Used in Research and Development Activities: a Focus on Software, Electronic Devices and Pharmaceutical Industries.

Goodwill was calculated using the residual method, and after deduction of the above values, including amounts allocable to cash and covenants not to compete, was determined to be $2.7 million, pursuant to SFAS 141.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

4. Business acquisition (continued):

Pro forma results of operations as if the acquisition of Arius Pharmaceuticals, Inc. had taken place on January 1, 2004 are as follows:

	As presented for the year ended December 31, 2004	Arius January 1, 2004 through August 23, 2004	Pro forma year ended December 31, 2004
Revenues	$ 1,778,898	$ 176,500	$ 1,955,398
Loss attributable to common Stockholders	$ (2,848,818)	$ (136,597)	$ (2,985,415)
Loss per common share attributable to common Stockholders	$ (0.40)		$ (0.42)

Pro forma results of operations as if the acquisition of Arius Pharmaceuticals, Inc. had taken place on January 1, 2003 are as follows:

	As presented for the year ended December 31, 2003	Arius for year ended December 31, 2003	Pro forma year ended December 31, 2003
Revenues	$ 2,913,231	$	$ 2,913,231
Net loss	$ (2,488,106)	$ (145,814)	$ (2,633,920)
Net loss per common share	$ (0.35)		$ (0.38)

Purchased in-process research and development:

As discussed above, in connection with its acquisition of Arius, the Company determined that $0.2 million of the acquisition price qualifies as purchased in-process research and development (for Emezine®), and as such, this amount was expensed as research and development expense on

the acquisition date.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

5. Research and development arrangements and related party transactions:

Upon its formation, BDSI originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, BDSI issued shares of Common Stock with anti-dilution provisions and agreed to make future royalty payments to the universities upon (a) the licensing of rights to sub-licensees (up to 5% of fees as amended on December 16, 2002); (b) sales by sub-licensees (25% of BDSI proceeds); or (c) BDSI sales (3% of revenue). The amendment to the agreement on December 16, 2002 also provided for the granting of options to purchase 75,000 shares of the Common Stock to each of the two universities.

During 2004, the Company entered into a license agreement with TEAMM Pharmaceuticals, Inc., a subsidiary of a company in which BDSI s Chairman and CEO is a significant stockholder. The license agreement granted exclusive rights to Emezine®, revenues of which aggregated $1.0 million and which were earned upon satisfaction of milestones specified in the agreement. BDSI will earn future royalties commencing with FDA approval of the product.

During 2003, the Company entered into a licensing agreement with a company that is also a stockholder. The agreement included a non-refundable payment of $2.0 million in license fee revenue, which the Company deferred and recognized monthly from January through October 2003 (the period of the related research and development commitment). The agreement also provides for milestone payments for each licensed product upon the filing, acceptance and approval of a new drug application by the Food and Drug Administration. During the year ended December 31, 2003, the Company recognized $2.0 million in license fee revenue from this related party. No milestone payments were earned during 2004 or 2003.

The Company has a collaborative research agreement with UMDNJ, an entity that is also a Company stockholder, under which BDSI pays salaries for UMDNJ employees of approximately $0.2 million per year, laboratory supplies and employee parking costs of approximately $0.04 million annually. In addition, the Company paid to UMDNJ approximately $0.05 million for leasehold improvements in 2003. The Company has approximately $0.1 million recorded as due to related party for each year presented. The agreement expires at the end of 2005. As further discussed in Note 10, the Company also leases its Newark, New Jersey facility from UMDNJ under a non-cancelable operating lease agreement.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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

The Company has also entered into various agreements with other biotechnology/pharmaceutical companies in which the Company s Chairman and CEO is affiliated. These agreements provide for future royalties to the Company. The Company received a total of $1.0 million in development cost reimbursements from Accentia in connection with the Company s Emezine® license.

The Company has an agreement with Pharmaceutical Product Development, Inc., a Company stockholder, for research work in connection with a product under development. The Company had expense of $0.5 million under this agreement in 2004.

The Company paid research-related costs for a product under development to a subsidiary of Accentia in the amount of $0.04 million in 2004.

The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia, and shares three employees, with costs paid based on the approximate time spent on Company activities.

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

6. Equipment:

Equipment consists of the following at December 31, 2004:

Office and laboratory equipment	1,862,977
Less accumulated depreciation and amortization	(967,683)
	$ 895,294

Depreciation and amortization expense related to equipment for the years ended December 31, 2004 and 2003 was approximately $0.3 million and $0.2 million, respectively.

7. Note payable, bank:

Note payable, bank consists of borrowings under a $1.0 million four-year term loan to Gold Bank. Principal and interest at 7.5% per annum is payable in monthly installments of $0.02 million through maturity in October 2007. The note is secured by all equipment of the Company.

The loan agreement contains various restrictive covenants, including a minimum cash-to-liability ratio. The Company was not in compliance with this covenant as of December 31, 2004, and as such, the entire note subject to being called by the lender and has been classified as a current liability in the accompanying financial statements. Further, the balance was repaid subsequent to December 31, 2004.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

8. Income taxes:

The Company has no income tax expense or benefit for 2004 or 2003 as the Company has incurred net operating losses and has recognized valuation allowances for all deferred tax assets.

The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	Year Ended December 31,	
	2004	**2003**
Federal statutory income tax rate	34.00 %	34.00 %
State taxes, net of federal benefit	3.45	3.00
Permanent differences - compensation expense	(8.77)	(9.00)
Acquisition	24.09	
Valuation allowance	(52.77)	(28.00)
	%	%

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

	December 31,	
	2004	**2003**
Deferred tax assets (liabilities)		
Basis difference in equipment	$ (200,000)	$ (324,000)
Basis difference in intangibles	(1,623,000)	
Accrued liabilities and other	70,000	22,000
Net operating loss carry-forward	3,931,000	3,156,000
	2,178,000	2,854,000
Less: valuation allowance	(2,178,000)	(2,854,000)
Net deferred tax	$	$

In 2004, the Company sold New Jersey net operating losses for aggregate proceeds of $0.2 million. As a result of this sale $3.2 million in state tax operating loss carryforwards are no longer available. At December 31, 2004, the Company has a federal and state net operating loss carryforwards of approximately $10.5 million which principally expire beginning in 2020 and 2007 for federal and state purposes, respectively.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

9. Stockholders equity:

Preferred stock:

The Company has authorized five million shares of $.001 par value preferred stock. At December 31, 2004, 2,588,236 shares were designated as follows:

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

The holders of outstanding shares of Series A Preferred stock have the right to convert one (1) share of Series A Preferred stock into one (1) share of fully paid and non-assessable Common Stock. The Series A Preferred is eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date. The Series A Preferred enjoys certain other rights and privileges.

The Series B Preferred is convertible into shares of Common Stock at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to shares of the Company s Common Stock and the Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges.

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

Additionally, the Company has the right, in its discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. Furthermore, the Certificate of Designations for the Series B Preferred provides for certain limitations on the conversion of the Series B Preferred into shares of Common Stock without the prior

approval of the Company s stockholders. Finally, HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

9. Stockholders equity (continued):

Treasury stock:

During the second quarter of 2003, the Company purchased 100,000 shares of Common Stock with a per share price between $2.80 and $3.20 for a total cost of $303,894.

Stock options:

The Company has a stock option plan, which covers a total of 2,100,000 shares of Common Stock (as amended). Options may be awarded during the ten-year term of the 2001 stock option plan to Company employees, directors, consultants and other affiliates.

For the purpose of determining non-employee stock-based compensation and the pro forma presentation in Note 1, the fair value of each option grant is estimated on the date of grant using the Black Scholes options-pricing model with the following weighted-average assumptions used for grants in 2004 and 2003: no dividend yield, expected volatility of 73%; risk-free interest rates between 2.62% and 4.50% and expected lives of 5 years.

Activity related to options is as follows and excludes 2,085,000 warrants issued in connection with the 2002 public offering of securities.

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding at January 1, 2003	1,289,383	$ 5.76
Granted in 2003:		
Officers and Directors	205,000	3.82
Others	409,149	3.46
Forfeitures	(159,489)	6.89
Outstanding at December 31, 2003	1,744,043	4.81
Granted in 2004:		

Officers and Directors	225,000	2.29
Others	132,591	3.63
Exercised	(160,000)	1.70
Forfeitures	(80.154)	2.85
Outstanding at December 31, 2004	1,861,480	$ 5.03

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

9. Stockholders equity (continued):

Stock options (continued):

Options outstanding at December 31, 2004 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
$ 1.00 5.00	1,430,480	5.5	$ 3.06
$ 5.01 10.00	201,024	2.5	$ 5.81
$10.01 15.00	114,988	1.8	$ 11.80
$15.01 20.00	114,988	1.8	$ 17.48
	1,861,480		

Options exercisable at December 31, 2004 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
$ 1.00 5.00	1,256,601	5.7	$ 2.98
$ 5.01 10.00	180,192	2.5	$ 5.84
$10.01 15.00	114,988	1.8	$ 11.80
$15.01 20.00	114,988	1.8	$ 17.48
	1,666,769		

The weighted average grant date fair value of options granted during 2004 and 2003 whose exercise price is equal to the market price of the stock at the grant date was $2.54 and $1.96, respectively. The weighted average grant date fair value of options granted whose exercise price is less than the estimated market price of the stock at the grant date is $1.83 in 2003. The weighted average grant date fair value of options granted during 2004 and 2003 whose exercise price is greater than the estimated market price of the stock at the grant date is $2.15 and $4.54,

respectively.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

10. Commitments and contingencies:

Employment agreements:

The Company has employment agreements with certain employees, which extend for 36 months. These agreements provide for base levels of compensation and separation benefits. Future minimum payments under these employment agreements as of December 31, 2004 are $0.7 million, $0.4 million and $0.2 million for the years ended December 31, 2005, 2006 and 2007, respectively.

Operating lease:

Since April 2001, the Company has leased a facility from UMDNJ (a stockholder), under an operating lease that runs through December 31, 2005. Lease expense for the years ended December 31, 2004 and 2003 was approximately $0.06 million and $0.05 million, respectively. During 2004, the Company entered into two additional operating lease agreements for office space and equipment. Related party rent expense was $0.01 million for each year presented..

The future minimum commitments on all operating leases at December 31, 2004 are as follows:

Years ending December 31,	
2005	$ 101,585
2006	41,237
2007	33,295
2008	7,188
2009	5,092
	$ 188,397

Indemnifications:

The Company indemnified its officers and directors against costs and expenses related to stockholder and other claims (i.e., only actions taken in their capacity as officers and directors) that are not covered by the Company s directors and officers insurance policy. This indemnification is ongoing and does not include a limit on the maximum potential future payments, nor are there any recourse provisions or collateral that may

offset the cost. As of December 31, 2004, the Company has not recorded a liability for any obligations arising as a result of these indemnifications as the cause thereof is deemed nominal.

Litigation:

During 2004, the Company was named as the defendant in an action commenced by MAS Capital Inc. (MAS Capital). In the lawsuit, plaintiff seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital, at the Company s request, procured an underwriter to raise capital for us through an initial public offering. The Company has answered the complaint, denying the material allegations asserted by plaintiff. The case is presently in the pre-trial discovery stage. Management believes that plaintiff s claims are without merit and intends to vigorously defend the lawsuit.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

10. Commitments and contingencies (continued):

Litigation (continued):

The Company may, from time to time, be involved in other actual or potential legal proceedings that are considered to be in the normal course of our business. Management does not believe that any of these proceedings will have a material adverse effect on the Company s business.

11. Retirement Plan:

During 2003, the Company became the sponsor of a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation requirements. Participants may contribute up to 90% of their eligible earnings, as limited by law. The Company makes a matching contribution equal to 100% on the first 5% that a participant contributes to the plan. The Company made contributions of approximately $0.06 million and $0.05 million in 2004 and 2003, respectively.

12. National Institutes of Health Grant:

In 2001, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (the SBIR), which has been utilized in research and development efforts. The grant consisted of a 2003 grant of $1.0 million (which was fully-funded through August 2004), a 2002 grant of $0.8 million and a 2001 grant of $0.9 million, a total of approximately $2.7 million related to its initial application for the grant through August 2004.

The grant is subject to provisions for monitoring set forth in NIH Guide for Grants and Contracts dated February 24, 2000, (specifically, the NIAID Policy on Monitoring Grants Supporting Clinical Trials and Studies). The Company incurred approximately $0.9 million and $0.8 million of costs related to this agreement for the year ended December 31, 2004 and 2003, respectively.

During the years ended December 31, 2004 and 2003, the Company received $0.7 million and $0.6 million, respectively, and recognized revenue of $0.7 million and $0.6 million, respectively, from this grant. These amounts are included in sponsored research revenues in the accompanying statements of operations. The grant provides for reimbursement of or advances for future research and development efforts. Upon receiving funding under the grant and utilizing the funds as specified, no amounts are refundable.

In August 2002, the NIH awarded the Company a second grant for $0.6 million over two years. The Company incurred approximately $0.2 million of costs related to this agreement and received and recognized revenue of $0.1 million from this grant for the year ended December 31,

2004.

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SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: April 29, 2005

By: /s/ Francis E. O Donnell, Jr.

Name: Francis E. O Donnell Jr.
Title: Chief Executive Officer and Chairman
(Principal Executive Officer)

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

Person	Capacity	Date
/s/ Francis E. O Donnell, Jr. Francis E. O Donnell, Jr.	Chief Executive Officer, Chairman of the Board and Director	April 29, 2005
/s/ James A. McNulty James A. McNulty	Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)	April 29, 2005
/s/ Raphael J. Mannino Raphael J. Mannino	Executive Vice President, Chief Scientific Officer and Director	April 29, 2005
/s/ William B. Stone William B. Stone	Director	April 29, 2005
/s/ John J. Shea John J. Shea	Director	April 29, 2005
/s/ L.M. Stephenson L.M. Stephenson	Director	April 29, 2005
/s/ Alan Pearce Alan Pearce	Director	April 29, 2005

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