BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB
March 30, 2004

United States Securities and Exchange Commission

Washington, D.C. 20549

Form 10-KSB

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

For the fiscal year ended December 31, 2003

¨ 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 **(State or other jurisdiction of incorporation or organization)**	**35-2089858** **(I.R.S. Employer Identification No.)**
UMDNJ Medical School **185 South Orange Avenue, Bldg. #4** **Newark, New Jersey** **(Address of principal executive offices)**	**07103** **(Zip Code)**

Issuer s telephone number 973-972-0015

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

(Title of class)

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 2003 were $2,913,231.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 25, 2004 was approximately $9,749,753 based on the closing sale price of the company s common stock on such date of U.S. $2.83 per share, as reported by the Nasdaq SmallCap Market.

Transitional Small Business Disclosure Format: Yes ¨ No x

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, ANTICIPATE, EXPECT, INTEND, PLAN, WILL, MAY A 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 IN THESE DOCUMENTS 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 TECHNOLOGY PLATFORM AND ANY PROPOSED PRODUCTS, THE DOMESTIC AND INTERNATIONAL REGULATORY PROCESS INCLUDING THE U.S. FOOD AND DRUG ADMINISTRATION;

- OUR ABILITY TO GENERATE COMMERCIAL ACCEPTANCE OF OUR COCHLEATE DRUG DELIVERY TECHNOLOGY PLATFORM;

- THE PROTECTION AND CONTROL AFFORDED BY OUR INTEREST IN LICENSED PATENTS, OR OUR ABILITY TO ENFORCE OUR RIGHTS UNDER SUCH LICENSES;

- OUR ABILITY TO ENTER INTO SUBLICENSES;

- THE ABILITY OF OUR SUBLICENSE PARTNERS TO COMMERCIALLY EXPLOIT OUR DRUG DELIVERY PLATFORM;

- OUR ABILITY TO RETAIN MEMBERS OF MANAGEMENT AND EMPLOYEES OF THE COMPANY;

- OUR ABILITY TO RECEIVE FEDERAL, STATE, GOVERNMENT OR PRIVATE GRANTS AND/OR ATTRACT CAPITAL; AND

- THE COMPETITION THAT MAY ARISE IN THE FUTURE;

FACTORS THAT COULD CAUSE ACTUAL RESULTS OR CONDITIONS TO DIFFER FROM THOSE ANTICIPATED BY THESE AND OTHER FORWARD-LOOKING STATEMENTS INCLUDE THOSE MORE FULLY DESCRIBED IN THE RISK FACTORS SECTION AND ELSEWHERE IN THIS REPORT. WE ARE NOT OBLIGATED TO UPDATE OR REVISE THESE FORWARD-LOOKING STATEMENTS TO REFLECT NEW EVENTS OR CIRCUMSTANCES.

PART I

Item 1. Description of Business.

Overview

We are a biotechnology company that is developing and seeking to commercialize a drug delivery technology designed for a potentially broad base of prescription drugs, vaccines, and over-the-counter drugs. Our proposed drug delivery technology encapsulates the selected drug in a nanocrystalline structure termed a cochleate cylinder. All of the components of the cochleate cylinder are naturally occurring substances. We believe that the cochleate cylinder provides an effective delivery mechanism without forming a chemical bond, or otherwise chemically altering, the drug. Our drug delivery technology was developed in collaboration with the University of Medicine and Dentistry of New Jersey and the Albany Medical College that have each granted us the exclusive worldwide licenses under applicable patents.

We believe that our drug delivery technology is potentially applicable with a broad base of existing and new drugs, vaccines, and over-the-counter drugs. Once we have established our licensed drug delivery technology, we intend to seek commercialization through a combination of marketing approaches which, we anticipate, may include marketing drugs no longer under patent protection under our brand name Bioral, licensing our encochleation technology to other pharmaceutical companies and entering into various types of agreements with other bio-technology or pharmaceutical companies.

Programs under development include Bioral Amphotericin B which in animal models has exhibited effective antifungal activity and low toxicity following oral delivery. A commercially viable, scaled up manufacturing protocol has been developed and preclinical studies leading to the filling of an IND for this product are in progress. In addition, Bioral formulations of NSAIDS which exhibit higher efficacy and lower toxicity than free drug are in development. Proof of concept programs with other drug candidates are in progress with several pharmaceutical companies.

In addition to developing and commercializing our drug delivery technology and initial Bioral products, we are also preparing an application seeking to begin Phase I clinical trials with the FDA with regard to our HIV therapy. This technology is being developed as a patient specific (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.

Cochleate formulations of important nutrients have been prepared in kilogram quantities using standard manufacturing processes. These preparations stabilize the encochleated micronutrients during food processing and enhance the shelf life of the endproduct.

Our offices and scientific facilities are located at the University of Medicine and Dentistry of New Jersey, 185 South Orange Avenue, Administrative Building 4, Newark, New Jersey 07103 and our telephone number is 973-972-0015. In this Report, the terms Company, we, us, our and similar terms refer to BioDelivery Sciences International, Inc., a Delaware corporation.

Historical and Recent Events

Formation Activities

MAS Acquisition XXIII Corp., our original corporate name (referred to herein as MAS XXIII), was formed in Indiana on January 6, 1997. In January 2000, an investment group, led by Dr. Francis E. O Donnell, Jr., our current President, Chief Executive Officer and Chairman, acquired a controlling interest in MAS XXIII for the purpose of facilitating an investment by us in BioDelivery Sciences, Inc., a Delaware corporation. At the time of the investment, MAS XXIII did not conduct any business, nor did it have any meaningful operations.

Our business opportunity is primarily the drug delivery technology developed by BioDelivery Sciences, Inc. BioDelivery Sciences, Inc., the Delaware entity, was formed in 1995 by Drs. Raphael Mannino and Susan Gould-Fogerite, who are currently members of our management, and others, in order to conduct research and development on various vaccines. On October 10, 2000, with the proceeds of the investment from the investment group led by Dr. O Donnell, we purchased shares of the Series A convertible preferred stock of BioDelivery Sciences, Inc. which resulted in our owning securities representing 84.8% of its voting stock. In September 2000, immediately prior to completing the investment and gaining control of BioDelivery Sciences, Inc., we changed our name from MAS Acquisition XXIII Corp. to BioDelivery Sciences International, Inc. In May 2001, we acquired common stock of BioDelivery Sciences, Inc. from a group of its stockholders, which resulted in our owning 9% (representing 1.4% of the total voting rights of BioDelivery Sciences, Inc.) of the outstanding common stock.

In January 2002, we completed our merger with BioDelivery Sciences, Inc. bringing our aggregate voting right in BioDelivery Sciences, Inc. to 100% and resulted in our owning all of its assets, including but not limited to the control over the intellectual property involving the drug delivery technology, subject to all the liabilities as well. As a result of the merger, we were the surviving company and BioDelivery Sciences, Inc. ceased operations as a separate entity. Consequently, except where specifically noted to the contrary, all discussions in this Report reflect our completion of the merger of BioDelivery Sciences, Inc. and thus refers to such business operations as those of ours. We ceased being an Indiana corporation and became a Delaware corporation through a re-incorporation merger effected on June 3, 2002.

Stock Split

In May 2002, we also effected a reverse stock split of our capital stock on a one for 4.37 shares basis. All references in this Report to our outstanding common stock and other securities reflect such reverse split.

Public Offering and Financing

On June 24, 2002, the Securities and Exchange Commission 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 2,000,000 units, or 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 for a period of four years commencing on June 24, 2003.

The offering price for each Unit was $5.25 and the aggregate offering price was $10,500,000. The managing underwriter of the offering was Kashner Davidson Securities Corporation. The aggregate underwriting discount was $897,750 and the non-accountable expense allowance paid

to the underwriter was $315,000. Additional offering expenses paid between the offering date and June 30, 2002 was $230,000 for printing, $410,000 for legal fees, $200,000 for accounting fees and $270,560 for other expenses of the offering. The expenses of the offering equaled $2,323,310. None of these expenses were paid to our directors, officers or persons owning 10 percent of our securities.

The net offering proceeds we received, after deducting the offering expenses described above, was $8,226,758. From June 25, 2002 until June 30, 2002, $1,050,000 of such proceeds was used to repay a line of credit, which terminated June 30, 2002. The remaining proceeds were invested in short-term certificates of deposit. There were no payments made to officers, directors, and persons owning more than 10 percent of our securities. During the three month period ended September 30, 2002, the underwriters exercised an over-allotment option for 85,000 Units, resulting in net proceeds to us of $394,707.

We intend to finance our research and development efforts and our working capital needs with the proceeds from the offering and through licensing and joint venture arrangements with pharmaceutical companies, whose own proprietary pharmaceutical products may benefit from our nanocochleate technology. On December 31, 2002, we entered into an agreement with Pharmaceutical Product Development, Inc, a North Carolina corporation and stockholder of ours, referred to herein as PPDI, pursuant to which PPDI was granted a license to apply our Bioral nano-delivery technology to two therapeutic products. There is also the possibility of licensing income from applications of our technology to over-the-counter drugs, generics, nutraceuticals and, through our subsidiary, Bioral Nutrient Delivery, LLC, processed foods and beverages. To the extent that additional capital needs are required, we may 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.

Bioral Nutrient Delivery, LLC

On January 8, 2003, we formed Bioral Nutrient Delivery, LLC, a Delaware limited liability company, referred to herein as BND. BND presently has two classes of equity interests: Class A Shares and Class B Shares. As of the date of this annual report, we own approximately 94.5% of BND s Class B Shares and all 708,586 of BND s Class A Shares. Upon the effectiveness of a registration statement on Form SB-1 filed by BND with the Securities and Exchange Commission, we will make a distribution to our stockholders of 3,545,431 Class B Shares, or approximately 43% of BND s currently outstanding equity interests, including the Class A Shares. We will be the only holder of Class A Shares, which entitles us, directly or indirectly, to make all of BND s management decisions. We also hold a five (5) year option from BND to purchase, from time to time, up to an aggregate of 4,185,000 additional Class B Shares at a price per Class B Share of $0.01. We have been granted this option in order that we may, at a later date, provide our option and warrant holders with the ability to obtain interests in BND following the exercise by such persons of their options or warrants. Assuming that all 3,545,431 Class B Shares being distributed, BND will have approximately 700 holders of membership shares.

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 sublicensed 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 we receive 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, since BND believes its short-term objectives can be met without hiring full-time employees or renting its own space. This agreement will provide BND with such resources. The management services agreement with BND will terminate on December 31, 2004 unless renewed by the parties on terms to be mutually agreed upon.

Overview of the Drug Delivery Industry

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

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.

We believe that focusing our drug delivery technology for use with existing FDA approved drugs to be less risky than attempting to discover new drugs. When management believes that the market opportunity exists and given the right circumstances however, we may consider devoting resources to discovering new drugs.

We intend to primarily target drugs that have large established markets for which there is an established medical need and therefore doctors are familiar with the drug compounds and are accustomed to prescribing them. We anticipate that many of the drug candidates we target will have been through the regulatory process and therefore the safety and efficacy of the drug has been previously established. Consequently, we believe that our clinical trials would primarily need to show that our encapsulation technology delivers 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.

Description of Our Drug Delivery Technology

Overview

Our drug delivery technology is based upon encapsulating 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.

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 (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 University of Medicine and Dentistry of New Jersey and Albany Medical College, referred to herein as 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. See Description of Business Relationship with the University of Medicine and Dentistry of New Jersey and Albany Medical College.

Potential Advantages

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

All-natural ingredients: Our 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.

Oral Availability. Our 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.

Encapsulation. Our drug delivery encapsulates, rather than chemically bonds, with the drug.

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

Stability. Our drug delivery technology employs cochleate cylinders which consist of unique multi-layered structures of large, continuous, solid, lipid bilayer sheets rolled up in a spiral, with no internal aqueous space. We believe that our cochleate preparations can be stored in cation-containing buffer, or lyophilized to a powder, 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 lyophilized powder at room temperature.

Cellular Delivery. Our drug delivery technology is being developed as membrane fusion intermediates. We believe that, when drugs encapsulated in our 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 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.

Resistance to Environmental Attack. Our 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 cylinder 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 drug delivery technology to a potentially broad array of established and promising pharmaceuticals. Each intended Bioral product (i.e. drug and neutraceutical 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. As summarized below, we have initially targeted three potential Bioral products for development.

Product Status

Indication	Products	Category	Pre-Clinical Development	FDA Status
Systemic fungal infection	Antifungal Bioral Amphotericin B	Antimicrobial	Formulation development almost completed. In vitro and in vivo efficacy data in progress	Submission for Phase I IND being prepared, GMP manufacturing initiated.
Tuberculosis and bacterial infections	Antibacterial Bioral	Antimicrobial	Formulation development in process.	Pre-clinical development
Inflammatory disease	Bioral Anti-Inflammatory	OTC Medicine	Formulation and in vitro studies in process	Pre-clinical development
Gauchers Disease	Biorazyme	Enzyme replacement therapy	Formulation Development	Pre-clinical development
Atherosclerosis	Bioral Apo-A1	Protein Delivery	Formulation Development	Pre-clinical development
Infectious diseases/ Cancer	Bioral siRNA	Oligonucleotide Delivery	Formulation Development	Pre-clinical development

Bioral Amphotericin B. We are currently developing a Bioral product for treatment of fungal infection which we plan to submit to the FDA for a Phase I Investigational New Drug Application (IND). 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 been investigating the ratio of PS to cargo molecules in order to optimize clinical

performance while moderating costs simultaneously. Accordingly we estimate the filing of our IND will be made in the fourth quarter of 2004. 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.

The major types of systemic fungal infections are normally controlled and disposed of by the body s immune system. However, patients whose immune systems have been suppressed by therapies for cancer, bone marrow transplants or diseases such as AIDS can lose the ability to combat these infections. Systemic Candidiasis, the most common type of invasive fungal infection, represents the majority of all such infections, with fatality rates between 30 and 40 percent. Aspergillosis, while occurring less frequently, is a significant threat as fatality rates for this infection range as high as 90 percent. Cryptococcal meningitis is a disease that frequently strikes patients with AIDS. The use of conventional 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.

Amphotericin B is an established drug which is delivered intravenously. The primary advantage which we are seeking for our proposed Bioral Amphotericin B product is an oral form 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 and that we obtain FDA approval, we believe that Bioral Amphotericin B (a Bioral encapsulation of Amphotericin B) may provide an effective orally administered version of Amphotericin B which may be more effective and less toxic.

In the development of this drug, we are collaborating with the National Institutes of Health, or NIH, the Public Health Research Institute of New York and the University of Kentucky. Further, we have been awarded a grant totaling approximately $2.7 million from the National Institutes of Health to support the further development of this drug if it believes in its judgment that progress continues to be made.

Tuberculosis Development. We are currently developing a Bioral product to target tuberculosis. The bacillus is suspected to reside latently in a large population of people, and remains viable for infection in those people for many years past the initial infection stage.

We are targeting an off-patent drug, and may target other drugs which treat tuberculosis, for potential encapsulation in our drug delivery technology. The primary advantages which we are seeking for our proposed Bioral product include increased oral bio-availability, reduce required dosage and decrease side effects. Assuming that we complete development of this Bioral drug and that we obtain FDA approval, we believe that it may provide an effective, orally administered version of a tuberculosis agent. This Bioral product in development may be administered orally, be more effective and have fewer side effects. Before finalizing our selection of an anti-tuberculosis therapeutic for commercialization, we will be consulting with experts from our Scientific Advisory Board, the Public Health Research Institute of New York and the NIH.

Bioral Anti-Inflammatory. We have targeted inflammation disorders, such as arthritis, for development of Bioral products, based upon accepted, unpatented, over-the-counter, 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 significantly decrease inflammation at higher dosages.

We believe that our drug delivery technology 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. As part of our pre-clinical development, initial formulations have been tested in vitro. We are in the process of preparing formulations as part of our preparation to commence pre-clinical development.

Biorazyme. We are establishing a majority-owned Israeli subsidiary to pursue the application of our technology to the field of hereditary lysosomal storage diseases, and in particular to Gaucher Disease. The worldwide market for intravenously administered chronic enzyme replacement therapy for Gaucher Disease is estimated to be approx. $600M/year. The Company believes that an oral replacement therapy would have obvious advantages in terms of patient acceptance. Accordingly, the Company believes that the market size for an oral formulation could be significantly greater than the current market which is restricted to particularly severe cases of the disease. Because of the ability of our delivery technology to target macrophages for cell-delivery, the Company believes that its Bioral formulation of the lysosomal enzyme may be particularly effective.

Apo-A1. We are pursuing collaborative studies for the purpose of determining the ability of our delivery technology to orally deliver Apo-A1, a component of HDL. Other investigators have reported evidence suggesting that intravenous delivery of Apo-A1 can reverse atherosclerosis by stimulating reverse cholesterol transport from macrophages laden with cholesterol within arteries (atheroma).

siRNA. Short inhibitory RNA 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. The Company is exploring the use of its delivery technology for intravenous and/or oral delivery of siRNA.

Our 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 preparing a submission to the FDA seeking to begin Phase I clinical trials as a follow-up to our initial clinical trials which were conducted pursuant to an Institutional Review Board process. Our development for this proposed Autologous HIV Therapy has not been completed. We estimate that the preparation of an IND will begin in the second quarter of 2003, assuming that funding is available. We believe that the time, expense and risk to market 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 drug delivery technology. Accordingly, we intend to primarily rely upon the availability of grants and corporate partners to largely finance the further research and development of this technology.

Relationship With The University of Medicine and Dentistry Of New Jersey (UMDNJ) and Historical Relationship With Albany Medical College

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

In September 1995, we entered into a license agreement with the Universities to be the exclusive worldwide developer and sub-licensor of the cochleate technology. Under the license agreement, we and the Universities have also jointly patented certain aspects of the cochleate technology and co-own such patents with them.

Pursuant to the license agreement, we agreed that each university would be issued an equity interest in our capital stock, originally equal to 2% of our outstanding capital stock. These arrangements were subsequently revised in December, 2002. On December 16, 2002, we amended our license agreement with the Universities to provide for a decrease in the royalty payments to be paid to the Universities on sublicenses in consideration of an increase in the royalty on product sales and the issuance to the Universities of options to purchase shares of our common stock. As of December 31, 2003, 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, 2003, 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 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 our net sales; and

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

Our royalty payments to the Universities will be divided equally among them pursuant to the license. In 2003, we paid royalties to the Universities of $100,000 (5% of the $2 million license fee we received as a result of our agreement with Pharmaceutical Product Development, Inc.).

In April 2001, we entered into a research agreement with UMDNJ whereby we and the university agree to share the rights to new research and development that jointly takes place at the university s facilities until December 31, 2005. We also agreed to provide the university 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 2003 and $5,340 for 2005.

In addition to our rent payments, we have also agreed to pay for certain other services provided by the university. These include employing three graduate students from the university for a total of $51,840, a budget to purchase chemicals totaling approximately $40,000 (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 graduate students and chemicals. Research assistants and personnel provided to us are university employees and they belong to various unions on campus. Beginning in the fourth quarter of 2002, the university employees and graduate students transferred to our payroll, including one graduate student who subsequently completed her Ph.D., and the monthly payments directly to UMDNJ were reduced accordingly. The payments for rent and supplies are expected to be approximately $75,000 annually.

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:

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. The terms of the license require one upfront royalty payment to us, additional royalty payments based on regulatory milestones and a running royalty rate based on worldwide sales.

National Institutes of Health. To investigate the properties of new antifungal cochleate formulations. Grants totaling approximately $2.7 million have been awarded to us by NIH for the development of our proposed Amphotericin B product. Additionally, we are conducting anti-fungal studies using our 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 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.

University of Texas, MD Anderson Cancer Center. On August 9, 2002, a NIH grant was awarded to develop an innovative HIV vaccine strategy. The grant will test the utility of novel adjuvants using our cochleate delivery vehicle for formulating the peptide cocktail vaccine and testing it in mice before contemplating primate studies and clinical trials.

University of Kentucky. Contracts have been signed with the University of Kentucky to scale up our Amphotericin B formulation. The University of Kentucky will also perform a radio labeled study in rabbits to assess the biodistribution of our Amphotericin B formulation.

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. As of December 31, 2003, no new related party contracts have been entered into since our initial public offering in June 2002. The following are the related-party agreements entered into prior to such offering:

RetinaPharma International, Inc. We have entered into a license agreement with this development-stage biotechnology company to use our delivery technology in connection with their proposed neutraceutical product with potential application for macular degeneration and retinitus pigmentosa, a disease affecting the retina. This exclusive worldwide right to use our drug delivery technology in conjunction with their effort to develop, commercialize and manufacture their proposed product, or to sublicense to a third party, is only for the purpose of treating antiapoptotic pharmaceutical and nutriceutical treatment of retinal disease and glaucoma. This license shall remain in effect as long as RetinaPharma International, Inc. remains in compliance with the terms of the agreement.

Tatton Technologies, LLC. We have entered into a license agreement with this development-stage biotechnology company to use our delivery technology in connection with their proposed neutraceutical products with potential application to various neuro-degenerative diseases. Tatton Technologies, LLC is developing and plans to commercialize technology regarding certain apoptotic drugs and apoptotic naturally occurring substances to treat certain neuro-degenerative diseases. We have entered into exclusive worldwide licenses allowing Tatton Technologies, LLC to incorporate our drug delivery technology into their effort to develop and potentially commercialize their drug. Tatton Technologies, LLC may sublicense our drug delivery technology to third parties to incorporate into their proposed product and this license shall remain in effect as long as both parties remain in compliance with the terms of the agreement. During 2003, Tatton Technologies merged with RetinaPharma International, Inc., and the entity changed its name to RetinaPharma Technologies, Inc.

BioKeys Pharmaceuticals, Inc. We have entered into a letter of intent to seek a license agreement with this development-stage biotechnology company to use our delivery technology in connection with the development of its proposed vaccine technology. BioKeys Pharmaceuticals, Inc., in conjunction with a third party, will conduct research to develop their EradicAids Vaccine Project. This proposed license shall remain in effect as long as BioKeys remains in compliance with the terms of the agreement.

Biotech Specialty Partners, LLC. We have entered into a non-exclusive distribution agreement with this development-stage distribution company to market and distribute our proposed products once we have completed the commercialization of our products. Our financial arrangement with Biotech Specialty Partners, LLC, or 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

(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 drug delivery technology, we are not required to share in the costs of the development of the pharmaceutical product or technologies of these companies.

We are entitled to receive the following royalty payments:

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.

Tatton Technologies, LLC. We are entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into their proposed product with potential application to various neuro-degenerative diseases. The planned Tatton Technologies product is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future.

BioKeys Pharmaceuticals, Inc. We are in the process of negotiating a royalty on net revenue from the license of our drug delivery technology. We previously received a $35,000 loan from BioKeys Pharmaceuticals, Inc. to begin research on BioKeys Pharmaceuticals, Inc. products incorporating our technology, which loan was paid in full in July 2002. The planned BioKeys Pharmaceuticals, Inc. product is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future.

In pursuing potential commercial opportunities, we intend to seek and rely upon additional collaborative relationships with corporate partners. Such relationships may include initial funding, milestone payments, licensing payments, royalties, access to proprietary drugs or potential nano-encapsulation with our drug delivery technology or other relationships. While we have not, to date, entered into any such arrangements, we are currently in discussion with a number of pharmaceutical companies.

Collaborative Agreements in Negotiation

BND has entered into an evaluation agreement with a major manufacturer of pet food with global sales and have begun related testing of our encochleation technology for use in the pet food industries. We have and will continue to monitor and develop the progress of our licensed technology under such evaluation agreement. Although we have not entered into any formal licensing agreements or come to terms with any potential licensees, we are encouraged by our preliminary results and findings and believe that a viable business opportunity exists.

We have signed an evaluation agreement with a major pharmaceutical company to design a cochleate formulation of one of their injectable products.

Licenses, Patents and Proprietary Information

We are the exclusive licensee of nine issued United States patents and three foreign issued patents owned by the parties listed in the chart below.[1] 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
US06,340,591	1/22/2002	1/14/2018	Integrative protein DNA cochleate formulations and methods for transforming cells	The University of Medicine and Dentistry of New Jersey and the University of Maryland
EUR0722338	7/25/2001	9/30/2014	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	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
US06,153,217	11/28/2000	1/22/2019	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	9/02/2017	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,994,318	11/30/1999	11/24/2015	Cochleate delivery vehicles	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	2/2/1998	9/30/2014	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	7/01/2014	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 largephospholipid vesicles	Albany Medical College
US04,663,161	05/05/1987	4/22/2005	Liposome methods and compositions	Albany Medical College

[1] We also co-own U.S. Patent 06,340,591 with the University of Maryland and University of Medicine and Dentistry of New Jersey, dealing with gene therapy which has no relation with either drug delivery or vaccines as described herein.

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 technology and our HIV therapy, 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. 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. 04,978,654, 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 appears to be the basis for the existing patent. The second of these patents, United States Patent No. 05,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we require a license under this patent. If a court were to determine that we infringe either of these patents, we might be required to seek a license to commercialize Amphotericin B products. There can be no assurance that we would be able to obtain a license from either patent holder. 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 patents were made with the United States government support. Therefore, the United States government might have certain rights in the technology, 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 technology due to their funding, we have to either obtain a waiver from the United States government relating to the United States government s rights in the technology, or have agreements with the United States government which would grant us exclusive rights.

We also 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.

Competition

The biopharmaceutical industry in general is competitive and subject to rapid and substantial technological change. Developments by others may render our proposed technology, proposed drugs and HIV therapy 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.

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 (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 amongst companies which we believe are developing potentially competitive technologies are Emisphere Technologies, Inc. (NASDAQ: EMIS), CIMA LABS INC. (NASDAQ: CIMA) and Novavax, Inc. (NASDAQ: NVAX), each a publicly traded company, and NOBEX Corporation, 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 of lipid soluble) compounds with limited customization for each specific drug.

We believe that our technology may have cell-targeted delivery attributes as well. Additional companies which are developing potentially competitive technologies in this area may include Valentis Inc. (NASDAQ: VLTS) and Enzon Pharmaceuticals Inc. (NASDAQ: ENZN), both publicly traded companies, which we believe may be seeking to develop technologies for cell-targeted delivery of drugs. While we have limited information regarding these potential competitors and their development status and strategy, we believe that our technology may be differentiated because unlike these potential competitors, we seek to use our cochleate to encapsulate the therapeutic to achieve drug delivery into the interior of the cells such as inflammatory cells.

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

Our drug delivery technology, specific drugs encapsulated with our drug delivery technology and HIV autologous immunotherapeutics must compete with other existing technologies and/or technologies in development. 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.

Manufacturing

During drug development and the regulatory approval process, we plan to rely on third-party manufacturers to produce our compounds for research purposes and for pre-clinical and clinical trials. We are now using a US-based pre-clinical, Phase I and Phase II manufacturing partner for scale-up of our formulation (University of Kentucky). To date, we have not entered into manufacturing arrangements for any other intended Bioral product. 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 technology and product development and regulatory approval, is to market each of our approved orally delivered products under the Bioral brand name. Marketing may be conducted through 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 a non-exclusive distribution arrangement with Biotech Specialty Partners, LLC. BSP is an early-stage alliance of specialty pharmaceutical and biotechnology companies.

Government Regulation

The manufacturing and marketing of any drug encapsulated in our drug delivery technology, our autologous HIV therapeutic and 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 to be encapsulated by us in our drug delivery technology. 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.

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

1. Pre-clinical laboratory tests, in vivo pre-clinical studies and formulation studies;

2. The submission to the FDA of an Investigational New Drug Application (IND) for human clinical testing which must become effective before human clinical trials can commence;

3. Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;

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

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

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

Pre-clinical Trials

Pre-clinical testing includes laboratory evaluation of chemistry and formulation, as well as tissue culture and animal studies to assess the potential safety and 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 human clinical trials. Unless the FDA objects to an IND, the IND will become effective 30 days following its receipt by the FDA.

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

Clinical Trials

Clinical trials involve the administration of the new product to healthy volunteers or to patients under the supervision of a qualified principal 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 as part of the IND. 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. Compounds must be formulated 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:

Determine the efficacy of the product for specific, targeted indications;

Determine dosage tolerance and optimal dosage; 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 further evaluate clinical efficacy and to test for safety within an expanded patient population at geographically dispersed multi-center clinical study sites. Phase III frequently involves randomized controlled trials and, whenever possible, double blind studies. 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 our clinical trials and to assist in the preparation and filing of our IND with regard to Phase I clinical trials and upon acceptance to potentially oversee clinical trials of our nano-encapsulated Amphotericin B.

New Drug Application and FDA Approval Process

The results of the pharmaceutical development, pre-clinical studies and clinical studies are submitted to the FDA in the form of a New Drug Application for approval of the marketing and commercial shipment 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 and manufacturing and controls that will determine how the product will be 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 products if it does not believe the New Drug Application contains adequate evidence of the safety and efficacy of the drug. Notwithstanding the submission of such data, the FDA may ultimately decide that a New Drug Application does not satisfy its regulatory criteria for approval. 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 New Drug Application approval is the requirement that any prospective manufacturer s quality control and manufacturing procedures conform to Good Manufacturing Practices and the requirement specifications of the approved 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 Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Our research and development may involve the controlled use of hazardous materials, chemicals, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of any accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Employees

As of March 25, 2004, we had nineteen full-time employees, of which twelve are scientists and seven are administrative/accounting and IT. Six of our scientists have Ph.D. degrees and four 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.

Item 2. Description of Property.

We conduct our operations in laboratory and administrative facilities on a single site located on the campus of UMDNJ. Pursuant to a five year lease agreement with the university ending 2005, we occupy a total of approximately 8,000 square feet. The monthly rent is $3,340 in 2001, $3,840 in 2002, $4,340 in 2003, $4,840 in 2004 and $5,340 in 2005 plus agreed payments for graduate student assistants, two BDSI executives and supplies used by us. During the fourth quarter of 2002, the graduate students transferred to our payroll, including one who completed her Ph.D., and the monthly payments directly to UMDNJ were reduced accordingly. The payments to UMDNJ for BDSI executive salaries totaled $211,747 for 2003. The payments for rent and supplies are expected to be 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.

Item 3. Legal Proceedings.

We may, from time to time, be involved in 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.

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 since our initial public offering in June 2002, 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, 2003	$ 3.04	$ 1.45	$ 0.79	$ 0.21
June 30, 2003	$ 4.50	$ 2.35	$ 0.77	$ 0.30
September 30, 2003	$ 5.00	$ 3.33	$ 1.35	$ 0.60
December 31, 2003	$ 4.04	$ 1.80	$ 0.80	$ 0.50

As of March 25, 2004, we had approximately 229 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.

Upon the declaration of effectiveness of a registration statement on Form SB-1 filed by our subsidiary, BND, with the Securities and Exchange Commission, we are intending to distribute to our stockholders an aggregate of 3,545,431 of BND s Class B Shares. Neither we nor BND will receive any proceeds upon the distribution of the Class B Shares. No assurances can be given that such registration statement will be declared effective or that such distribution will be made.

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	1,744,043	$ 4.81	355,957
Equity compensation plans not approved by security holders			
Total	1,744,043	$ 4.81	355,957

Recent Sales of Unregistered Securities

As part of the merger with BioDelivery Sciences, Inc. consummated in January 2002, we issued 520,313 shares of common stock to the BioDelivery Sciences, Inc. stockholders. There were no underwriters or placement agents employed in connection with the transactions set forth above.

The issuances described above were deemed exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act as transactions by an issuer not involving a public offering. Certain issuances described above were deemed exempt from registration under the Securities Act in reliance on Rule 701 promulgated thereunder as transactions pursuant to compensatory benefit plans and contracts relating to compensation. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and other instruments issued in such transactions. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Use of Proceeds From Registered Securities

On June 24, 2002, the Securities and Exchange Commission 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 2,000,000 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 for a period of four years commencing on June 24, 2003. 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.

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

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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. In late December 2002, we signed our first license agreement, which was funded in 2003. We expect to continue research and development of our drug delivery technology, and while we are seeking additional license agreements, which may include up-front payments, we do not anticipate any revenues from the sale or commercialization of our products under development (other than license fees) during 2004. The funding will come primarily from the sale of securities, exercise of warrants, collaborative research agreements, including pharmaceutical companies, and grants from public service entities and government entities.

In 2001, the National Institutes of Health awarded us a three-year Small Business Innovation Research Grant, which is being utilized in our research and development efforts. NIH awarded to us and fully funded a 2001 grant of $884,000, a 2002 grant of $814,000, and a 2003 grant of $989,000, of which we have received $330,000 through December 31, 2003 and expect to receive the remainder through June 2004. The final year grant of approximately $989,000 is anticipated to be fully funded. This grant is more fully discussed below under Liquidity and Capital Resources. Although there can be no assurance that the full grant will be realized, we expect to receive a total of approximately $2.7 million related to our initial application for the grant through June 2004, assuming that we continue to achieve positive results from the research. 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. If NIH believes that satisfactory progress is not achieved by us in its subjective opinion, the total future expected funding amounts noted above may be reduced or eliminated.

We have a limited history of operations, and while we received in December 2002 an initial payment for licensing our technology, we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future. Prior to our October 2000 acquisition of a majority interest in BioDelivery Sciences, Inc., we had no operations. 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, 2003 Compared to the Year Ended December 31, 2002

Sponsored Research Revenue. During the year ended December 31, 2003, we recognized sponsored research revenue of $913,000. Of this amount, $790,000 was from a grant from the National Institutes of Health, and $89,000 was from collaborative research agreements. In 2002, all revenue aggregating $828,000 was derived from the grant. While no assurances can be made, assuming positive results are achieved through our sponsored research activities, we expect to receive a total of approximately $2.7 million through 2004 related to our initial application for the grant.

License Fee Revenues. During December 2002, the Company entered into a licensing agreement with a company (which is a shareholder), which included an up-front non-refundable payment of $2 million. The Company recognized it over the period of the related research and development commitment, with the entire $2,000,000 having been recognized by December 31, 2003.

Research and Development Expenses. During the years ended December 31, 2003 and 2002, research and development expenses totaled $2.6 million and $1.5 million, respectively. The scientific staff continued to work toward increased development and application of Bioral cochleate technology and other drug-related areas. Funding of this research was obtained through sponsored research revenue, common stock issuance, initial public offering funding in June 2002 and line of credit borrowings through the offering period. 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 Bioral cochleate drug delivery technology.

General and Administrative Expenses. During the years ended December 31, 2003 and 2002, general and administrative expenses totaled $2.6 million and $1.7 million, respectively. The increase in 2003 is primarily due to increased staffing following receipt of our initial licensing revenues (received in late 2002, and recognized in 2003), and administrative costs associated with additional projects. Also included in general and administrative costs are legal settlement costs, legal and professional fees, and other costs including office supplies, conferences, travel costs, executive personnel costs, consulting fees, website update and development and business development costs. Furthermore, 2003 expenses include approximately $440,000 related to BND operating activities that commenced in 2003, approximately $215,000 of which related to offering costs associated with a registration statement.

Stock-Based Compensation Expense. Stock- based compensation expenses of $200,000 and $689,000 were incurred during the year ended December 31, 2003 and 2002, respectively. The charge in 2002 results principally from non-recurring items in 2002 associated with the Company s forgiveness of employee stock subscription notes receivable and related income taxes paid on behalf of such employees. In 2003, the amounts are for stock options granted for services rendered by our underwriter and legal counsel.

Interest Income (Expense), Net. During the years ended December 31, 2003 and 2002, interest income (expense), net totaled $69,000 and $17,000, respectively. The increase in net interest income is primarily due to the public offering, and investment of liquid funds. In addition, the company borrowed funds to purchase laboratory equipment and to make leasehold improvements in 2003. The bank note terms called for interest-only through October 2003, and amortization of principal over 48 months beginning in November 2003.

Income Tax Benefit. We recognized an income tax benefit of $55,000 in 2002 due to the carryback of net operating losses allowed as a result of the enacted tax law changes. While net operating losses were generated during both years presented, we did not recognize any benefit associated with these losses. We had federal and state net operating loss carryforwards of $8.4 million at December 31, 2003. The federal net operating loss carryforwards will expire beginning in 2020, if not utilized. The state operating loss carryforwards will expire beginning in 2007, 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.

Liquidity and Capital Resources

Since inception, we financed our operations primarily from the sale of our convertible preferred stock and common stock, until the initial public offering in June 2002. 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 underwriter s over-allotment (the green shoe), raised approximately $8.6 million. At December 31, 2003, we had cash and cash equivalents, including investments (certificates of deposit, and corporate bonds) totaling approximately $2.6 million. At December 31, 2002 we had cash and cash equivalents totaling approximately $5.2 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.

In 2001, the National Institutes of Health awarded us a three-year Small Business Innovation Research Grant, which is being utilized in our research and development efforts. NIH awarded us and fully funded 2001 and 2002 grants of $884,000 and $814,000, and a 2003 grant of $989,000, of which we have received approximately $330,000 through December 31, 2003 and expect to receive the remainder through June 2004. Therefore, we expect to receive a total of approximately $2.7 million related to our initial application for the grant through June 2004, assuming that we continue to achieve positive results from the research. The grant is subject to provisions for monitoring set forth in NIH Guide for Grants and Contracts dated February 24, 2000. If NIH believes that satisfactory progress is not achieved in its opinion, the future funding noted above may be reduced or eliminated in its sole discretion.

We used $2.5 million of cash for operations in each of years 2003 and 2002. Until the offering in June 2002, we paid limited compensation to certain executive employees, including the CEO and chairman of the board. While members of the board of directors and other executive officers have received compensation in the form of stock options, we expect that increases in their compensation will occur in future periods commensurate with the level of services rendered.

In the first quarter of 2003, we received a commitment for a $1 million bank line of credit, to be 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. We drew 100% of these funds during 2003, all of which was utilized for our Newark laboratory needs.

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, 2003, we had stockholders equity of $3.1 million, versus $5.8 million at December 31, 2002.

During the second quarter of 2003, we, as authorized by the 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.

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 drugs. While we believe further application of our Bioral cochleate technology 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 Bioral cochleate technology itself and its 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 a majority-owned Delaware limited liability company subsidiary in January 2003, Bioral Nutrient Delivery, LLC, and signed an exclusive sub-license to BND for the purpose of exploiting our cochleate technology in the processed food and beverage industry, as opposed to the pharmaceutical industry that is our focus. The minority members are Class B founder shareholders with no cost basis and no obligation to fund deficits. As part of the business plan for BND, our shareholders will receive a dividend of approximately 50% interest in BND directly from us at nominal fair-market value, based on independent third-party appraisal. This dividend will be distributed upon SEC approval of our pending registration statement for BND. Over time we may further reduce our ownership in BND to approximately 10%, with the balance owned by our stockholders, who may receive additional dividends of interests in BND. We will be the managing member of BND, and will exercise complete management activity and control of BND. We will receive no funds as a result of the distribution of the interests to our shareholders, but we will receive reimbursement of funds expended in the organization of BND. 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 $500,000 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 $500,000. We 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. (Note that all of the transactions between BDSI and BND eliminate in consolidation.)

We believe that our existing cash and cash equivalents, together with available financing, grants and new license revenue will be sufficient to finance our planned operations and capital expenditures through at least the next 18 to 24 months. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we may be required to raise additional capital through a variety of sources, including:

the public equity market,

private equity financing;

collaborative arrangements;

grants and new license revenues;

bank loans;

public or private debt; and

redemption and exercise of 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 of our technologies, drugs or potential markets, either of which could have a material adverse effect on our business, 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 our existing stockholders.

New Accounting Pronouncements

In December 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Valuable Interest Entities. This interpretation clarifies rules relating to consolidation where entities are controlled by means other than a majority voting interest and instances in which equity investors do not bear the residual economic risks. This interpretation was originally effective immediately for variable interest entities created after January 31, 2003 and for interim periods beginning after June 15, 2003 for interests acquired prior to February 1, 2003. However, the FASB is reviewing certain provisions of the standard and has deferred the effective date for public companies to periods ending after December 15, 2003. The Company currently has no ownership in variable interest entities and therefore adoption of this standard currently has no financial reporting implications.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. The statement amends and clarifies accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and hedging activities. This statement is designed to improve financial reporting such that contracts with comparable characteristics are accounted for similarly. The statement, which is generally effective for contracts entered into or modified after June 30, 2003, did not have impact on The Company s financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the first interim period beginning after June 15, 2003. At December 31, 2003, The Company had no such financial instruments outstanding and therefore adoption of this standard had no financial reporting implications.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure 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. We believe that the following are some of the more critical judgment areas in the application of our accounting policies that affect our financial condition and results of operations. We have discussed the application of these critical accounting policies with our Board of Directors and its Audit Committee.

Revenue Recognition and Research and Development Expenses

Sponsored research amounts are recognized as revenue, when the research underlying such payments has been performed or when the funds have otherwise been utilized, such as for the purchase of operating assets. Revenue is recognized to the extent provided for under the related grant or collaborative research agreement. Research and development expenses are charged to operations as incurred.

Revenues may also include nonrefundable technology license fees and milestone payments. The non-refundable license fees are generally up-front payments for the initial license of and access to our technology. For nonrefundable license fees received at the initiation of license agreements for which the

Company has an ongoing research and development commitment, we defer these fees and recognize 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, we recognize revenue upon delivery of the technology. In addition to license fees, we 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.

Stock Compensation

We have historically compensated certain employees, directors and consultants with common stock, common stock options or warrants as a portion of their total compensation. The valuation of the underlying award or the related service generally requires estimates and judgment with regard to assumptions applicable to the award. Those assumptions include management s estimates of the fair value of the services received and assumptions underlying the valuation of equity securities, such as stock volatility and estimated lives of the stock based award.

Income Taxes

Based on estimates of future taxable losses, management determined that a valuation allowance of $2.8 million was required for our deferred tax assets as of December 31, 2003. If this estimate proves inaccurate, a change in the valuation allowance could be required in the future. This valuation allowance was determined based on the uncertainty regarding our ability to generate adequate future taxable income during the loss carryforward period.

Asset Impairment

We review long-lived assets and licenses for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. If indicators of impairment were present, we would evaluate the carrying value of property and equipment and licenses in relation to estimates of future undiscounted cash flows. These undiscounted cash flows and fair values are based on judgment and assumptions.

Contractual obligations

At December 31, 2003, the Company s contractual cash obligations, with initial or remaining terms in excess of one year, were as follows:

	Amount of Commitment ($) Expired by Year Ended December 31,		
	Long-term Debt	**Operating Leases**	**Annual Total**
Less than 1 year	$ 225,979	$ 56,590	$ 282,559

2	3 years	505,951	62,580	568,531
3	5 years	226,403		226,403
Total		$ 958,333	$ 119,160	$ 1,077,493

Item 7. Financial Statements.

Our Consolidated Financial Statements and Notes thereto and the report of Aidman, Piser & Company, P.A., our current independent certified public accountants, and the report of Grant Thornton LLP, our predecessor independent certified public accountants, are set forth on pages F-1 through F-[__] of this Report.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Consolidated Financial Statements

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

On April 18, 2003, the Company, with the approval of the Audit Committee of the Board of Directors of the Company (the Audit Committee) and the full Board of Directors of the Company, dismissed its independent accountants, Grant Thornton LLP (GT). During the years ended December 31, 2002 and 2001, and the subsequent interim period through April 18, 2003 (the date of GT s dismissal as the Company s independent accountants), GT acted as the independent accountants for the Company and its subsidiary, Bioral Nutrient Delivery, LLC, and, during such period there were no disagreements with GT on any matters of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of GT, would have caused GT to make a reference to the subject matter of the disagreements in connection with its reports in the financial statements for such years.

The independent accountant s report of GT on the Company s consolidated financial statements for the years ended December 31, 2002 and 2001 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

GT has advised the Audit Committee and management that it noted a lack of segregation of accounting and financial reporting duties as a result of the Company s small size, which condition GT considered to be reportable under standards established by the American Institute of Certified Public Accountants. The Company believes this matter is not reportable under Regulation S-B since, among other factors, the noted issue did not preclude the Company from developing reliable financial statements as contemplated by Item 304(a)(1)(iv)(B)(1) of Regulation S-B. The Company is voluntarily making the disclosure contained in this paragraph, however, as an accommodation to its former independent accountants. The Company has taken GT s notation under advisement but believes its internal accounting controls are in

compliance with applicable accounting standards, rules and regulations. The Company will continue to monitor and assess the costs and benefits of additional staffing in the accounting area in conjunction with its newly appointed independent accountants. The Company recently added to its staff a CPA who is working on implementation of the Sarbanes-Oxley Act on a full-time basis. This task is projected to be implemented by December 31, 2004, and will address as a matter of course the internal control processes throughout the company, in accordance with the mandates of the Sarbanes-Oxley Act.

The Company has provided a copy of this disclosure to its former accountants, and the Company requested that the former accountants furnish the Company with a letter addressed to the Securities and Exchange Commission stating whether they agree with the statements made by the Company. A copy of that letter was attached on a Current Report on Form 8-K, filed with the SEC on April 25, 2003.

On April 18, 2003, with the approval of the Audit Committee and the full Board of Directors of the Company, the firm of Aidman, Piser & Company, P.A. was appointed as the Company s independent accountants.

Item 8A. Controls and Procedures.

Our Chief Executive Officer and Chief Financial Officer (collectively, the Certifying Officers) are responsible for establishing and maintaining disclosure controls and procedures for the Company. 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 the Company s disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in this report is accumulated and communicated to the Company s management, including its 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 the Company s 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.

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 25, 2004 are as follows:

Name	Age	Position(s) Held
Francis E. O Donnell, Jr., M.D.	54	President, Chief Executive Officer, Chairman and Director
Raphael J. Mannino, Ph.D.	57	Executive Vice President, Chief Scientific Officer and Director
James A. McNulty	53	Chief Financial Officer, Secretary and Treasurer

Donald L. Ferguson	55	Senior Executive Vice President
Susan Gould-Fogerite, Ph.D.	51	Vice President and Director of Innovation and Discovery
L.M. Stephenson, Ph.D.	61	Director
William B. Stone	60	Director
James R. Butler	63	Director
John J. Shea	77	Director
Robert G.L. Shorr	50	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 54, has been our Chief Executive Officer, President, 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. 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. Dr. O Donnell s address is 709 The Hamptons Lane, Chesterfield, MO 63017.

James A. McNulty, age 53, 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 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 real estate development company developing a major downtown Tampa destination entertainment complex. 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. Mr. McNulty s address is 4419 W. Sevilla Street, Tampa, FL 33629.

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. 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.

Raphael J. Mannino, Ph.D., age 57, has been 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.

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 President for Research at Drexel University. He was associated with the University of Medicine and Dentistry of New Jersey (UMDNJ) 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: Kessler Medical Rehabilitation & Research Corporation (Non-Profit), University Heights Sciences Park (Non-Profit), New Jersey Entrepreneurs Network, Rutgers Help Desk & Business Incubator, Crescent Genomics and the New Jersey Research and Development Council.

William B. Stone, age 60, is a member of our board of directors. For thirty years, until his retirement in October 2000, Mr. Stone was continuously 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 CIO 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.

James R. Butler, age 63, is a member of our Board of Directors. He is currently a director of Durect Corporation and has served in this capacity since July 1999. Mr. Butler is retired from ALZA Corporation where the last position he held was President of Alza International and from which he retired in June 2001. Mr. Butler was employed at Alza from August 1993 to June 2001. Prior to that, Mr. Butler worked at Glaxo Inc. for 23 years where the last position he held was Vice President General Manager of Corporate Division. He is currently on the Board of Directors of Hematrope Pharmaceuticals and is the Chairman of the Board of Directors of Respirics, Inc. In addition, he is also a Senior Advisor/Principal to Apothogen, Inc., which is a start up company funded by J.P. Morgan Partners, as well as Pharmaceutical Products Development, Inc. Mr. Butler is on the Pharmacy School Board at the University of Florida and is on the Board of Advisors at Campbell University, North Carolina. Mr. Butler is also an advisor to the Chairman of Reliant Pharmaceuticals, a private pharmaceutical company. Mr. Butler earned a B.S. in marketing at the University of Florida.

John J. Shea, age 77, is a member of our board of directors. He is currently the head of his own firm of John J. Shea & Associates and 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 which is responsible for the implementation of quality assurance procedures in a number of public and private companies. From 1987-1989, he served as Director of Quality Assurance at NeoRx Corporation. Mr. Shea was also the Director of Corporate Quality Assurance at Hexcel Corporation from 1980-1987. Mr. Shea has also served as the quality assurance person for other companies including, Teledyne Relays, Ortho Diagnostics, Inc. and Bio Reagents & Diagnostics, Inc. Mr. Shea earned a B.S. in Chemistry at Bethany College.

Robert G.L. Shorr, Ph.D., age 50, 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 commecializable 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. He is currently Senior Vice President, Financial Services of McKesson Corporation. McKesson Corporation, a Fortune 12 company, is the leading provider of supply, information and care management products and services designed to reduce costs and improve quality across healthcare. Mr. Pearce has held his current position since April 1999. Prior to this date, he was treasurer of McKesson Corporation. Mr. Pearce is a graduate of Georgia Institute of Technology, where he earned a B.S. in Industrial Management and University of Texas, where he earned his M.B.A. 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 advisory board have entered into consulting agreements that provide for expense reimbursements, 10,000 non-qualified stock options and cash compensation of $1,500 for attendance at each formal board meeting. The following is a short discussion of our advisory board members background:

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.

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.

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.

David S. Perlin, Ph.D., is Scientific Director of the Public Health Research Institute (PHRI), 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.

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 Securities and Exchange Commission (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 2003, all Forms 3, 4 and 5 were not timely filed with the Securities and Exchange Commission by such reporting persons. We believe there are some delinquent filings in 2004.

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, 20,000 options to purchase common stock per year, 5,000 options to purchase common stock per year for serving on a committee of the board of directors, and 5,000 options to purchase common stock per year for serving as a chairman of a committee of the board of directors.

SUMMARY COMPENSATION TABLE*

					Long Term Compensation			
		Annual Compensation[1]			Awards		Payouts	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)
Name and Principal Position	Year	Salary	Bonus	Other Annual Compensation	Restricted Stock Award(s)	Securities Underlying Options/SARs	LTIP Payouts	All Other Compensation[2]
		($)	($)	($)	($)	(#)	($)	($)
Francis E. O Donnell, Jr., M.D.	2003	$ 145,962				35,000		
	2002	112,500				61,991		
President, Chief Executive Officer and Chairman	2001					8,009		
709 The Hampton Lane								
Chesterfield, MO 63017								
James McNulty,	2003	$ 141,769				18,616		
	2002	170,922	$ 35,000					

Chief Financial Officer, Secretary and Treasurer	2001	40,000			
4419 W. Sevilla Street					
Tampa, FL 33629					
Donald L. Ferguson,	2003	$			
	2002				
Senior Executive Vice President	2001			274,600	
Land Dynamics, Inc.					
11719 Old Ballas Road, Suite 110					
St. Louis, MO 63141					
Raphael J. Mannino, Ph.D [(3)].,	2003	$ 90,000	52,500	111,449	
	2002	91,500		35,423	
Executive Vice President	2001	83,650		96,110	$ 726,957
Chief Scientific Officer					
UMDNJ New Jersey Medical School					
185 South Orange Avenue, Building 4					
Newark, NJ 07103					
Susan Gould-Fogerite, Ph.D [(4)].,	2003	$ 63,494		19,438	
	2002	46,660			
Vice President and Director of Innovation	2001	40,800		34,324	$ 581,564
and Discovery					
UMDNJ New Jersey Medical School					
185 South Orange Avenue, Building 4					
Newark, NJ 07103					

* Salary reflects total compensation paid to these executives (pre-merger and post-merger with BioDelivery Sciences, Inc. during these periods).

(1) 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) Reflects the increase in value of the permanent discount stock (a variable award) and the compensation expense recorded by us as a result of the agreement to remove the permanent discount and put rights.

(3) Excludes $117,606, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2003 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

(4) Excludes $94,141, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2003 (pursuant to a contractual arrangement) for services rendered by Dr. Gould-Fogerite to such university.

Option Grants During Year Ended December 31, 2003

	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. M.D.	35,000	11.03%	$ 3.83	August 14, 2013	$ 6,702.50	$ 13,405.00
Raphael J. Mannino, Ph.D.	51,449	16.23%	$ 3.83	August 14, 2013	$ 9,852.48	$ 19,704.97
	60,000	18.92%	$ 1.63	January 31, 2008	$ 25,050.00	$ 30,900.00
James A. McNulty	18,616	5.87%	$ 3.83	August 14, 2013	$ 3,564.96	$ 7,129.93
Donald L. Ferguson						
Susan Gould-Fogerite, Ph.D.	19,438	6.13%	$ 3.83	August 14, 2013	$ 3,722.38	$ 7,444.75

No options were exercised during the fiscal year-end December 31, 2003.

AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR

AND FY-END OPTION/SAR VALUES

Name and Principal Position	Shares Acquired On Exercise(#)	Value Realized($)	Number of Securities Underlying Unexercised Options/SARs At Fiscal Year-End(#) Exercisable Unexercisable	Value of Unexercised Unexercisable In-The-Money Options/SARs At Fiscal Year-End($) Exercisable Unexercisable
(a)	(b)	(c)	(d)	(e)
Francis E. O Donnell, Jr., M.D.			105,000/0	$ 35,350/0
Raphael J. Mannino, Ph.D.			242,892/0	$ 85,000/0
James A. McNulty			18,616/0	
Donald L. Ferguson			274,600	
Susan Gould-Fogerite, Ph.D.			34,324/19,438	

Employment Agreements

Except for Dr. Frank E. O Donnell, Mr. James McNulty, Dr. Christopher Chapman, Dr. Susan Gould-Fogerite, Mr. James Wachholz and Dr. Raphael J. Mannino, we currently have no written employment agreements with any of our officers, directors, or key employees. We may elect to pursue obtaining employment agreements with certain of these individuals at some point in the future. All directors and officers have executed confidentiality and non-compete agreements with us.

Under our employment at will arrangement, our officers received the following annualized salaries and other benefits in 2001:

(i) Dr. Francis E. O Donnell, President, 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 shall be no longer than three years or until another CEO candidate is appointed.

(ii) James A. McNulty, Chief Financial Officer, Secretary and Treasurer Although he is a part-time CFO, he has an employment agreement with us (which was amended on August 31, 2002) for a base salary of $185,000, reduced to $110,000 in June 2003, which terminates on August 31, 2005. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(iii) Donald Ferguson, Senior Executive Vice President Receives no salary and no benefits.

(iv) 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).

(v) 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. Maninno and Gould-Fogerite had outstanding debt payable to us that was incurred with their purchase of stock of 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.

2001 Stock Option Plan

The purpose of the 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 will administer the 2001 stock option plan, select the persons to whom options are granted and fix the terms of such options.

Under our 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 increase the plan to 1,100,000 shares, and later to 2,100,000 shares, which was approved by our stockholders at the Annual Meeting in August 2003. Options to purchase 1,744,043 shares of common stock are outstanding as of December 31, 2003 under the 2001 Stock Option Plan. All options were issued under our 2001 Stock Option Plan, as the same may be amended. Options may be awarded during the ten-year term of the 2001 stock option plan to our employees (including employees who are directors), consultants who are not employees and our other affiliates. Our 2001 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 the 2001 Stock Option Plan. The 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 fully vest following one year of service after the date of grant.

Options and warrants to purchase 1,744,043 shares of our common stock at prices ranging from $1.70 to $17.48 are outstanding at December 31, 2003. None of our options have been granted at less than 85%

of the fair market value at the time of grant. Certain options granted under the 2001 Stock Option Plan do not vest or are not exercisable until the earlier of: (i) 13 months following the completion this offering registered with the SEC; or (ii) 24 months from the date of grant.

Options issued on August 14, 2003 to employees and directors totaled 467,149 shares, at exercise prices ranging from $1.63 and $3.83. Also during 2003, we issued options to outside parties totaling 86,607 shares, with exercise prices ranging from $2.55 to $2.75 per share. In addition, options issued during 2003 to consultants and SAB members totaled 65,000 shares, with exercise prices ranging from $2.10 to $5.50.

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

The following table sets forth, as of March 25, 2004, 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 the Company at UMDNJ Medical School 185 South Orange Avenue, Bldg. #4, Newark, New Jersey 07103.

Name of Beneficial Owner	Number of Shares of Common Stock Owned[1]	Percentage of Class as of March 25, 2004
Hopkins Capital Group II, LLC [2]	3,111,580	43.9%
Francis E. O Donnell, Jr., M.D.[3]	3,289,613	46.4%
Pharmaceutical Product Development, Inc. [4]	690,000	9.7%
Jonnie R. Williams, Sr. [5]	3,203,114	45.2%
Dennis Ryll, M.D. [6]	3,157,347	44.6%
Raphael J. Mannino, Ph.D. [7]	425,591	6.0%
James A. McNulty [8]	76,659	1.1%
Donald L. Ferguson [9]	274,600	3.9%
Susan Gould-Fogerite, Ph.D. [10]	186,498	2.6%
L.M. Stephenson, Ph.D [11]	85,000	1.2%
William B. Stone [12]	105,000	1.5%
James R. Butler [13]	50,000	*
John J. Shea [14]	45,000	*
Robert G.L. Shorr [15]	45,000	*
Alan Pearce [16]	50,000	*
All Directors and Officers as a group (11 persons)	4,632,961	65.4%

* Less than 1%

(1) Based on 7,085,863 shares of common stock outstanding as of March 25, 2004.

(2) Hopkins Capital Group II, LLC is owned one third by each of: (i) various trusts of the O Donnell family; (ii) John R. Williams, Sr. and his family trusts; and (iii) MOAB L.L.C., which is beneficially owned by Dennis Ryll and members of his family.

(3) Dr. O Donnell is our President, Chief Executive Officer, Chairman 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 he disclaims beneficial interest of. 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 the Company s common stock, all of which is currently exercisable. Dr. O Donnell s address is 709 The Hampton Lane, Chesterfield MO 63017.

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

(5) 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.

(6) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 1). The remaining 45,767 shares of common stock are personally owned by Mr. Ryll. Dr. Ryll s address is 2595 Red Springs Drive, Las Vegas, NV 89135.

(7) Dr. Mannino is our Executive Vice President, Chief Scientific Officer and a Director. Includes options to purchase 242,982 shares of the Company s common stock, all of which are currently exercisable.

(8) 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.

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

(10) Dr. Gould-Fogerite is our Vice President and Director of Innovation and Discovery. Includes options to purchase 34,324 shares of the Company s common stock, all of which are currently exercisable.

(11) Includes options to purchase 85,000 shares of the Company s common stock, all of which are currently exercisable. Dr. Stephenson s address is 2401 Pennsylvania Ave., Apt. 5B, Philadelphia, PA 19130.

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

(13) Includes options to purchase 50,000 shares of the Company s common stock, all of which are currently exercisable. Mr. Butler s address is 109 Cutter Court, Ponte Vedra Beach, FL 32082.

(14) Includes options to purchase 45,000 shares of the Company s common stock, all of which are currently exercisable. Mr. Shea s address is 90 Poteskeet Trail, Kitty Hawk, NC 27949.

(15) Includes options to purchase 45,000 shares of the Company s common stock, all of which are currently exercisable. . Mr. Shorr s address is 28 Brookfall Road, Edison, NJ 08817.

(16) Includes options to purchase 50,000 shares of the Company s common stock, all of which are currently exercisable. Mr. Pearce s address is 255 Eagle Ct. Alamo, CA 94507.

Item 12. Certain Relationships and Related Transactions.

During 2001, we entered into agreements with RetinaPharma, Inc. and Tatton Technology LLC. Both are biotechnology companies which are developing neutraceutical 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. The Hopkins Capital Group II, LLC, one of our significant stockholders, and Dr. Francis E. O Donnell, Jr., our President, Chief Executive Officer and Chairman, are affiliated as stockholders and a director of RetinaPharma, Inc. Additionally, Hopkins Capital, LLC, which is affiliated with Hopkins Capital Group II, LLC and Dr. O Donnell, is a significant stockholder of Tatton Technologies, LLC. Dr. O Donnell is the managing director of Hopkins Capital Group, LLC and Hopkins Capital Group II, LLC.

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, Biotech Specialty Partners, LLC 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 have determined to be commercially reasonable. The Hopkins Capital Group II, LLC, which is affiliated with Dr. Francis E. O Donnell, Jr., our CEO and director, are affiliated as stockholders, and a member of the management, of Biotech Specialty Partners, LLC.

We have also entered into a letter agreement with BioKeys Pharmaceutical, Inc, a biotechnology company, which is developing several potential products which are vaccine based. To the extent that BioKeys Pharmaceutical, Inc. utilizes our Bioral drug delivery technology, we will earn a flat royalty which we will negotiate and be approved by our independent audit committee. Regent Court Technologies LLC, which is affiliated with one of our stockholders, and Dr. Francis E. O Donnell, our CEO and a director, and Donald L. Ferguson, our senior executive vice president, are affiliated as stockholders, and Dr. O Donnell is a member of the board of directors, of BioKeys Pharmaceutical, Inc. We had also received a $35,000 loan from BioKeys Pharmaceutical, Inc. to begin research on their

products using our technology. The loan was in the form of a demand note with an interest rate of 1% plus prime. The loan has been repaid.

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 President, Chief Executive Officer and Chairman.

Prior to Dr. O Donnell s investment group purchasing a majority interest, MAS Acquisition XXIII Corp. (MAS XXIII) was controlled by Mr. Aaron Tsai, who was the President and Chief Executive Officer as well as a majority stockholder. Several companies which are not affiliated with us in any capacity, that Mr. Tsai and MAS Capital, Inc., a registered broker dealer, have been involved with previously, have been the subject of regulatory investigation. After Dr. O Donnell s investment group bought a majority interest in MAS XXIII, Mr. Tsai resigned from any position in management and has no direct or indirect role in our management. On March 29, 2002, Hopkins Capital Group II, LLC, controlled by Dr. O Donnell, entered into an agreement with MAS Capital, Inc. and Mr. Tsai to purchase and surrender all of their interest in our securities, consisting of 74,966 shares of common stock and to return to us 22,881 options, respectively for $150,696 in the form of a promissory note payable March 29, 2003.

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. 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 the law firm for partial compensation in connection with our registration of Bioral Nutrient Delivery, LLC.

Samuel S. Duffey, Esq., through Friday Harbour, LLC, a Florida limited liability company owned with his spouse, owns 74,371 shares of our common stock. An aggregate of 51,487 additional shares are owned by trusts for the benefit of Mr. Duffey s adult children. Mr. Duffey is a partner in Duffey & Dolan, P.A., which provides legal services to us and Friday Harbour, LLC, which provides consulting services to us and Hopkins Capital Group, LLC.

During 2002, we also issued an additional 75,000 options to purchase our common stock to each of the University of Medicine and Dentistry of New Jersey and Albany Medical College in connection with the amendment of our license agreement with such institutions.

During 2003, BND issued 37,500 Class B Shares of BND to Ellenoff Grossman & Schole LLP, our outside legal counsel and outside legal counsel to our subsidiary BND. These Class B Shares were issued at the inception of BND 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 the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present board of directors includes five independent directors. These independent directors are William B. Stone, James R. Butler, John J. Shea, Robert G.L. Shorr and Alan Pearce.

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. We intend to maintain at least two independent members on our Board of Directors.

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

(a) The following exhibits are filed with this Report.

Number	Description
1.1	Form of Underwriting Agreement. (11)
3.1	Articles of Incorporation of the Company as an Indiana corporation (6)
3.2	Articles of Amendment of the Article of Incorporation as an Indiana corporation (5)
3.3	Bylaws of the Company as an Indiana corporation (6)
3.4	Articles of Incorporation of the Company after reincorporation merger into Delaware (8)
3.5	Bylaws of the Company after reincorporation merger into Delaware (8)
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)
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. (*)
10.8	Addendum to License Agreement with RetinaPharma, Inc. (9)
10.9	License Agreement with Biotech Specialty Partners, LLC (8)
10.10	National Institutes of Health Grant Letter (8)
10.11	Merger Agreement with BioDelivery Sciences, Inc., dated July 20, 2001 (2)
10.12	Settlement Agreement and Stock Purchase Agreement with Irving Berstein, et al. (2)

10.13	Employment Agreement with Christopher Chapman (2)
10.14	Employment Agreement with James A. McNulty (2)
10.15	Employment Agreement with Dr. Frank E. O Donnell (10)
10.16	Confidentiality Agreement for Dr. Frank E. O Donnell (10)
10.17	Covenant Not to Compete with Dr. Frank E. O Donnell (10)
10.18	2001 Incentive Stock Option Plan (8)
10.19	Promissory Note for BioKeys Pharmaceuticals, Inc. dated August 22, 2001 (11)
10.20	Research Agreement with PharmaResearch Corporation (9)
10.21	Credit Facility Loan Agreement (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 BioDelivery Sciences International, Inc. (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 and BioDelivery Sciences International, Inc. 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 BioDelivery Sciences International, Inc., 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 BioDelivery Sciences International, Inc. (15)
10.31	First Amendment to Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, dated March 31, 2003. (16)
10.32	Sub-License Agreement, dated effective April 1, 2003, by and between BioDelivery Sciences International, Inc. and Bioral Nutrient Delivery, LLC. (16)
10.33	Management Services and Administrative Agreement, dated effective April 1, 2003, by and between BioDelivery Sciences International, Inc. and Bioral Nutrient Delivery, LLC. (16)
10.34	Amended and Restated Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated October 1, 2003, by the Company, as Managing Member (17)

10.35	First Amendment to Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (17)
10.36	First Amendment to Management Services and Administrative Agreement, dated effective April 1, 2003, by and between BioDelivery Sciences International, Inc. and Bioral Nutrient Delivery, LLC (17)
10.37	Evaluation Agreement and Option to License, dated September 5, 2002 by and between BioDelivery Sciences International, Inc. 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) (17)
16.1	Letter of Grant Thornton LLP, dated April 25, 2003. (18)
16.2	Letter of Grant Thornton LLP, dated July 3, 2003. (19)
20.1	Code of Ethical Conduct of the Registrant (*)
21.1	Subsidiaries of the Registrant (*)
31.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
31.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)

* Filed herewith

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

(2) Previously filed with Form 10QSB, for the quarter ended March 31, 2001.

(3) Previously filed with Form 10KSB, for the fiscal year ended December 31, 2000 filed on August 15, 2001.

(5) Previously filed with Form 8K filed October 26, 2000 under our prior name of MAS Acquisition XXIII Corp.

(6) Previously filed with Form 10SB filed January 18, 2000 under our prior name of MAS Acquisition XXIII Corp.

(8) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.

(9) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.

(10) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.

(11) Previously filed with Form SB-2, Amendment No. 5, May 23, 2002.

(12) Previously filed with Form SB-2, Amendment No. 6, June 24, 2002.

(13) Previously filed with Form 10-QSB, November 15, 2002.

(14) Previously filed with Form 8-K, January 7, 2003.

(15) Previously filed with Form 8-K, February 26, 2003.

(16) Previously filed with Form 10-QSB, August 14, 2003.

(17) Previously filed with Form 8-K, November 19, 2003.

(18) Previously filed with Form 8-K, April 25, 2003.

(19) Previously filed with Form 8-K/A, July 3, 2003.

(b) Reports on Form 8-K. We filed one Current Report on Form 8-K during the fourth quarter of 2003 on November 19, 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 the Company s annual financial statements for the year ended December 31, 2003, the review of the financial statements included in the Company s Forms 10-QSB and consents issued in connection with the Company s filings on Form SB-2 for 2003 totaled $37426. Grant Thornton s fees for the year ended December 31, 2002, and until their termination in April 2003 totaled $154,227. 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, 2003 and 2002 were $26,700 and and none, 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 year ended December 31, 2003 were $10,000. Grant Thornton s fees for the year ended December 31, 2002 and until their termination in April 2003 totaled $23,783.

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 year ended December 31, 2003 totaled $0. Grant Thornton s fees for the year ended December 31, 2002 and until their termination in April 2003 totaled $140,959.

The Audit Committee has established its pre-approval policies and procedures, pursuant to which the Audit Committee approved the foregoing audit, tax and non-auditservices provided by Aidman, Piser & Company, P.A. in 2003. Consistent with the Audit Committee s responsibility for engaging the Company s 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.

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors

BioDelivery Sciences International, Inc.

We have audited the accompanying consolidated balance sheet of BioDelivery Sciences International, Inc. and Subsidiary as of December 31, 2003, and the related consolidated statements of operations, stockholders equity (deficit), and cash flows for the year 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 audit.

We conducted our audit in accordance with auditing standards generally accepted in the 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 audit provides 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 Subsidiary as of December 31, 2003, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

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

Tampa, Florida

January 27, 2004

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors

BioDelivery Sciences International, Inc.

We have audited the accompanying consolidated statements of operations, stockholders equity (deficit), and cash flows of BioDelivery Sciences International, Inc. and Subsidiary for the year ended December 31, 2002. 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 audit.

We conducted our audit in accordance with auditing standards generally accepted in the 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of the operations and cash flows of BioDelivery Sciences International, Inc. and Subsidiary for the year ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

Tampa, Florida

February 13, 2003

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEET

DECEMBER 31, 2003

ASSETS	
Current assets:	
Cash and cash equivalents	$ 525,670
Investments	2,027,652
Prepaid expenses and other current assets	222,490
Total current assets	2,775,812
Equipment, net	1,067,596
Licenses, net	477,641
Other assets, net	26,953
Total assets	$ 4,348,002
LIABILITIES AND STOCKHOLDERS EQUITY	
Current liabilities:	
Current maturities of note payable, bank	$ 225,979
Accounts payable and accrued liabilities	158,148
Due to related party	61,836
Deferred revenue	23,974
Other	4,742
Total current liabilities	474,679
Note payable, bank, less current maturities	732,354
Commitments and contingencies (Note 10)	
Stockholders equity:	
Preferred stock, $.001 par value; 20,000,000 shares authorized, no shares issued	
Common stock, $.001 par value; 80,000,000 shares authorized, 7,085,863 shares issued; 6,985,863 shares outstanding	7,086
Additional paid-in capital	14,106,366
Treasury stock, at cost, 100,000 shares	(303,894)
Accumulated deficit	(10,668,589)
Total stockholders equity	3,140,969
Total liabilities and stockholders equity	$ 4,348,002

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2003 AND 2002

	2003	2002
Sponsored research revenues	$ 913,231	$ 827,972
License fees, related party	2,000,000	
	2,913,231	827,972
Expenses:		
Research and development	2,633,945	1,532,104
General and administrative:		
General and administrative	2,636,607	1,742,031
Stock-based compensation	200,039	688,911
	5,470,591	3,963,046
Loss from operations	(2,557,360)	(3,135,074)
Interest income, net	69,254	16,994
Loss before income taxes	(2,488,106)	(3,118,080)
Income tax benefit, current		54,964
Net loss	($2,488,106)	($3,063,116)
Net loss per common share:		
Basic and diluted	($0.35)	($0.51)
Weighted average common stock shares outstanding:		
Basic and diluted	7,016,679	6,057,890

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

YEARS ENDED DECEMBER 31, 2003 AND 2002

	Preferred stock		Common Stock		Additional Paid-in	Treasury	Accumulated	Total Shareholders Equity
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
BALANCES at December 31, 2001		$	5,000,863	$ 5,001	$ 4,903,368	$	($5,117,367)	($208,998)
Shares issued for cash, net of offering costs of $2,374,853			2,085,000	2,085	8,569,312			8,571,397
Stock compensation					483,647			483,647
Net loss for the year							(3,063,116)	(3,063,116)
BALANCES, at December 31, 2002			7,085,863	7,086	13,956,327		(8,180,483)	5,782,930
Issuance of stock options					200,039			200,039
Stock offering costs					(50,000)			(50,000)
Purchase of treasury stock						(303,894)		(303,894)
Net loss for the year							(2,488,106)	(2,488,106)
BALANCES at December 31, 2003		$	7,085,863	$ 7,086	$ 14,106,366	($303,894)	($10,668,589)	$ 3,140,969

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2003 AND 2002

	2003	2002
Operating activities:		
Net loss	($2,488,106)	($3,063,116)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	241,754	126,737
Stock-based compensation expense	200,039	688,911
Changes in assets and liabilities:		
Accounts receivable	2,000,000	(2,000,000)
Prepaid expenses and other assets	(20,972)	273,876
Accounts payable and accrued liabilities	(413,617)	(481,533)
Deferred revenue	(1,942,271)	1,963,000
Net cash flows from operating activities	(2,423,173)	(2,492,125)
Investing activities:		
Purchase of equipment	(832,583)	(325,436)
Purchase of investments	(2,027,652)	
Net cash flows from investing activities	(2,860,235)	(325,436)
Financing activities:		
Issuance of Common Stock, proceeds (expenses)	(50,000)	8,571,397
Net proceeds from (repayments of) short-term borrowings	958,333	(282,527)
Purchase of treasury stock	(303,894)	
Proceeds from (repayments of) related party borrowings	10,111	(22,606)
Payment on capital lease obligations	(12,775)	(15,656)
Payment on notes payable		(301,257)
Net cash flows from financing activities	601,775	7,949,351
Net change in cash	(4,681,633)	5,131,790
Cash at beginning of year	5,207,303	75,513
Cash at end of year	$ 525,670	$ 5,207,303

The Company paid interest of $39,202 and $40,790 during 2003 and 2002, respectively.

Tax refunds aggregating $54,964 were received in 2002.

During 2002, the Company forgave employee stock subscription notes receivable, which resulted in compensation expense of approximately $321,000. These notes were secured by common stock and were previously included as a reduction of stockholders equity.

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

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. BDSI and its majority-owned subsidiary effective January 2003, Bioral Nutrient Delivery, LLC (BND), are collectively referred to as the Company.

The Company has devoted substantially all of its efforts to research and product development involving drug delivery technology (e.g., cochleate technology) and in December 2002 secured its first licensing agreement, which was funded in January 2003. As a result of the licensing agreement, the Company determined that it no longer met the criteria for a development stage company at December 2002.

Principles of consolidation:

The financial statements include the accounts of BDSI and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC. All significant inter-company balances have been eliminated.

Revenue recognition:

Sponsored research amounts are recognized as revenue when the research underlying such payments has been performed or when the funds have otherwise been utilized, for their restricted purposes 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. The Company defers these fees and recognizes them ratably over the period of the related research and development. License fees received under license agreements where the continued performance of future research and development services is not required, is recognized upon delivery of the technology.

Research and development:

Research and development expenses are charged to operations as incurred. Research and development expenses principally include, among other things, 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.

Financial instruments:

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents and investments.

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, 2003, approximately $275,000 exceeded those amounts insured by the FDIC.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

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

Investments:

Investments consist of certificates of deposit with an original maturity in excess of 3 months and are recorded at cost. These certificates of deposits range from $95,000 to $300,000 and are placed with high quality credit institutions.

Fair value of financial instruments:

At December 31, 2003, the carrying amount of cash and cash equivalents, investments, accounts payable, accrued expenses, and notes 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.

Licenses:

Licenses are composed of license agreements with UMDNJ and Albany Medical College (AMC). The licenses are amortized over their estimated useful life of 13 years.

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.

Impairment of Assets:

The Company periodically reviews long-lived assets and licenses 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

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 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 10):

	Years ended December 31,	
	2003	**2002**
Net loss, as reported	($2,488,106)	($3,063,116)
Stock-based employee compensation, as reported	19,200	
Stock-based employee compensation cost under the fair value based method	(640,091)	(689,410)
Pro forma net loss under fair value method	($3,108,997)	($3,752,526)
Net loss per common share-basic and diluted:		
As reported	($0.35)	$ (0.51)
Pro forma under fair value method	($0.44)	$ (0.62)

Recent accounting pronouncements:

In December 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Valuable Interest Entities. This interpretation clarifies rules relating to consolidation where entities are controlled by means other than a majority voting interest and instances in which equity investors do not bear the residual economic risks. This interpretation was originally effective immediately for variable interest entities created after January 31, 2003 and for interim periods beginning after June 15, 2003 for interests acquired prior to February 1, 2003. However, the FASB is reviewing certain provisions of the standard and has deferred the effective date for public companies to periods ending after December 15, 2003. The Company currently has no ownership in variable interest entities and therefore adoption of this standard currently has no financial reporting implications.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. The statement amends and clarifies accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and hedging activities. This statement is designed to improve financial reporting such that contracts with comparable characteristics are accounted for similarly. The statement, which is generally effective for contracts entered into or modified after June 30, 2003, did not have impact on The Company s financial position or results of operations.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

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

Recent accounting pronouncements (continued):

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the first interim period beginning after June 15, 2003. At December 31, 2003, The Company had no such financial instruments outstanding and therefore adoption of this standard had no financial reporting implications.

2. Subsidiary corporate structure:

On January 8, 2003, the Company formed Bioral Nutrient Delivery, LLC, a Delaware limited liability company (BND) as a wholly-owned subsidiary and subsequent thereto issued Class B founder shares at a zero value. The Company granted BND an exclusive worldwide perpetual sub-license to the Company s proprietary encochleation drug delivery technology for non-pharmaceutical use in the processed food and beverage industries for both human and animal consumption. BND is governed by a limited liability company operating agreement, dated January 8, 2003. The agreement was executed by the Company (as the managing member and a holder of 708,586 of BND s Class A Membership Shares, or Class A Shares, and 8,600,000 Class B Shares) and certain other individuals and entities (as the holders of an aggregate of 412,500 Class B Shares). These individuals have no cost basis in this subsidiary and no obligation to fund deficits; therefore, no minority interest has been recorded.

BND intends to identify licensees who will apply the Company s encochleating technology to processed foods, including snacks such as chips, candies, breads, canned goods, packaged meals (such as microwaveable entrees), pet foods and pet treats, cheeses, cereals, soups, popcorn, pretzels and condiments. BND further believes the technology might be applied to beverages, including sports drinks, enhanced waters, carbonated beverages, infant formulas, milk, juices, beer and wine. BND will seek to commercialize the delivery technology through a combination of licensing programs to manufacturing, marketing and distribution companies within these industries.

BND has filed a registration statement on Form SB-1 on behalf of BDSI. BDSI, as selling security holder, intends initially to distribute as a dividend to its stockholders, upon the effectiveness of such registration statement, 3,545,431 of the Company s Class B Membership Shares currently held by BDSI.

The Class B Shares neither are or will be listed on any exchange and will not be publicly-traded securities. No such Class B Shares have been distributed by BDSI to its stockholders as of December 31, 2003.

Because the Company will receive no proceeds from the offering as these rights are distributed as dividends, offering costs aggregating $258,201 have been expensed in the accompanying statements of operations. Total offering costs are estimated to be $275,000.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

3. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, through short-term and long-term borrowings, some of 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 2003. The Company intends to finance its research and development efforts and its working capital needs from existing cash, investments, new sources of financing, and licensing agreements. For instance, the Company was granted approximately $2.7 million from the National Institutes of Health (NIH) to fund specific research efforts conducted by the Company through August 2004, of which $2.0 million has been received through December 31, 2003. The balance of approximately

$700,000 has been approved for funding through August 2004. The Company was also awarded a second NIH grant in August 2002, for $600,000 over 2 years. This grant is expected to commence funding in the first or second quarter of 2004.

In the second quarter of 2003, the Company obtained a $1 million, four-year term bank loan, which was used for the acquisition of laboratory and other equipment and facilities improvements in its Newark, New Jersey lab in the third quarter of 2003.

We believe that our existing cash and short-term investments, together with available financing, grants and new license revenue will be sufficient to finance our planned operations and capital expenditures through at least the next 18 to 24 months. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we may be required to raise additional capital through a variety of sources, including:

the public equity market;

private equity financing;

collaborative arrangements;

grants and new license revenues;

public or private debt; and

redemption and exercise of warrants

4. Research and development arrangements and related party transactions:

Upon its formation, BDSI originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, BDSI issued shares of common stock 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 Company s common stock to each of the two universities.

BDSI has entered into a research agreement with UMDNJ. BDSI incurred costs of $284,011 and $306,477, for 2003 and 2002, respectively, to UMDNJ under the terms of the research agreement. The research agreement provides for the procurement of supplies, certain payroll costs, and other expenses associated with research performed by UMDNJ under the research agreement. At December 31, 2003, the Company owed $61,836, under this agreement.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

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

During 2003, the Company entered into a licensing agreement with a company that is also a shareholder. The agreement included an non-refundable payment of $2,000,000 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 $2,000,000 in license fee revenue from this related party. No milestone payments were earned during 2003.

The Company has a collaborative research agreement with UMDNJ, a Company that is also a shareholder, under which BDSI pays salaries for UMDNJ employees of approximately $140,000 per year. The Company has approximately $62,000 and $52,000 recorded as due to related party for the year ended December 31, 2003 and 2002, respectively. The agreement expires at the end of 2005. As further discussed in Note 11, the Company also leases its Newark, New Jersey facility from UMDNJ under a non-cancelable operating lease agreement.

During 2001, the Company entered into agreements with RetinaPharma International Inc. and Tatton Technology LLC. Both are biotechnology companies, which are developing neutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson s disease. To the extent that such drugs utilize Bioral cochleate technology, the Company will support drug development and will be entitled to a royalty of ten percent (10%) of net revenues from such sales of Bioral encapsulated drugs. The CEO/director of the Company is a significant shareholder of these companies. The Company incurred deminimus costs relating to these agreements in 2003 and 2002.

The Company has 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, Biotech Specialty Partners, LLC will serve as a nonexclusive distributor of the Company s Bioral drugs in consideration of a ten percent (10%) discount to the wholesale price, which the board of directors has determined commercially reasonable. The CEO/director of the Company is affiliated with this company. The Company incurred deminimus costs relating to this agreement in 2003 and 2002.

The Company has also entered into an agreement with BioKeys Pharmaceutical, Inc., a biotechnology company, which is developing several potential products, which are vaccine based. To the extent that BioKeys Pharmaceutical, Inc. utilizes the Company s Bioral drug delivery technology, the Company will earn a royalty ranging between 15% to 30% of product sales incorporating its technology and between 10% and 20% of any royalty income earned by BioKeys Pharmaceutical, Inc. with regard to licenses involving its technology. BioKeys provided a $35,000 advance to the Company under their agreement in 2002, which was repaid during 2002. The CEO/director and the senior executive vice president of the Company are affiliated with this company. The Company incurred deminimus costs relating to this agreement in 2003 and 2002.

Other than the $2,000,000 royalty from shareholders as previously discussed in these footnotes, no royalties or other revenues have been generated from any of these agreements through 2003, and there can be no assurance that any royalties will be generated in the near terms, if at all.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

5. Equipment:

Equipment consists of the following at December 31, 2003:

Office and laboratory equipment	1,711,349
Leased equipment	39,679
	1,751,028
Less: Accumulated depreciation and amortization	(683,432)
Net equipment	$ 1,067,596

Depreciation and amortization expense related to equipment for the years ended December 31, 2003 and 2002 was approximately $200,000 and $124,000, respectively.

6. Licenses:

Licenses consist of the following at December 31, 2003:

Licensing costs	$ 517,445
Less accumulated amortization	(39,804)
	$ 477,641

Estimated aggregate future amortization expense for each of the next five years is as follows:

Year ending December 31,	
2004	$ 39,803
2005	39,803
2006	39,803
2007	39,803
2008	39,803
Thereafter	278,626

	$ 477,641

7. Note payable, bank:

Note payable, bank consists of borrowings under a $1,000,000 four-year term loan with interest only payable monthly at 7.5% through October 2003 and monthly interest and principal payments aggregating $24,179 thereafter, maturing 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 in compliance with these covenants as of December 31, 2003.

Future annual maturities of this note are as follows:

Year ending December 31,	
2004	$ 225,979
2005	243,523
2006	262,428
2007	226,403
	958,333
Less: current maturities	(225,979)
	$ 732,354

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

8. Income taxes:

The Company recognized a $54,964 current income tax benefit in 2002 due to the carry-back of net operating losses allowed as a result of the enacted tax law changes. The Company has no income tax expense or benefit for 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 35% to the effective rate is as follows:

	Year Ended December 31,	
	2003	**2002**
Federal statutory income tax rate	35.00%	35.00%
State taxes, net of federal benefit	3.00	5.50
Permanent differences - compensation expense	(9.00)	(2.30)
Net operating loss carry-back		1.80
Valuation allowance	(29.00)	(38.20)
	%	1.80%

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,	
	2003	**2002**
Deferred tax assets (liabilities)		
Depreciation	($324,000)	($61,000)
Accrued liabilities and other	22,000	86,000
Net operating loss carry-forward	3,156,000	2,115,000
	2,854,000	2,140,000
Less: valuation allowance	(2,854,000)	(2,140,000)
Net deferred tax	$	$

At December 31, 2003, the Company has a federal and state net operating loss carry-forward of approximately $8,400,000 , which principally expires beginning in 2020 and 2007 for federal and state purposes, respectively.

9. Stockholders equity:

Common stock and warrants:

During 2002 the Company completed a public offering of securities consisting of 2,085,000 units at a sales price of $5.25 per unit. Each unit is composed of one share of common stock and one Class A warrant to purchase a share of common stock at a price of $6.30 per share. All of the Class A warrants and common shares issued under this offering began to trade separately thirty days following the offering. Net proceeds from the offering amounted to $8,571,397.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

9. Stockholders equity (continued):

Treasury stock:

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

Stock options:

In October 2001, the board of directors of the Company approved 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 2003 and 2002: no dividend yield, expected volatility of 73%; risk-free interest rates between 2.62% and 4.50% and expected lives of 5 years.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

9. Stockholders equity (continued):

Stock options (continued):

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, 2002	833,095	$ 7.64
Granted in 2002:		
Officers and Directors	372,536	3.26
Others	221,047	2.67
Forfeitures	(137,295)	6.89
Outstanding at December 31, 2002	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

Options outstanding at December 31, 2003 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
$ 1.00 5.00	1,459,067	5.18	$ 3.19
$ 5.01 10.00	55,000	3.21	$ 6.62
$10.01 15.00	114,988	2.75	$ 11.80
$15.01 20.00	114,988	2.75	$ 17.48
	1,744,043		

Options exercisable at December 31, 2003 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
$ 1.00 5.00	1,156,614	5.18	$ 3.06
$ 5.01 10.00	55,000	3.21	$ 6.62
$10.01 15.00	114,988	2.75	$ 11.80
$15.01 20.00	114,988	2.75	$ 17.48
	1,441,590		

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARY

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2003 AND 2002

9. Stockholders equity (continued):

Stock options (continued):

The weighted average grant date fair value of options granted during 2003 and 2002 whose exercise price is equal to the market price of the stock at the grant date was $1.96 and $1.19, 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 2003 and 2002 whose exercise price is greater than the estimated market price of the stock at the grant date is $4.54 and $2.46, respectively.

Stock Compensation:

Compensation expense in connection with the issuance of stock options totaled approximately $200,000 and $162,000 for 2003 and 2002, respectively.

During 2002, the Company recognized approximately $527,000 of compensation expense associated with the forgiveness of employee stock subscription notes receivable and related income tax payable on behalf of the employees.

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, 2003 are $691,000 and $378,000, for the years ended December 31, 2004 and 2005, respectively. The Company incurred $691,000 related to these agreements during 2003.

Operating lease:

Since April 2001, the Company has leased a facility from UMDNJ (a shareholder), under an operating lease that runs through December 31, 2005. Lease expense for the years ended December 31, 2003 and 2002 was approximately $51,000 and $45,000, respectively. The future

minimum commitments on this operating lease at December 31, 2003 are as follows:

Years ending December 31,	
2004	$ 56,580
2005	62,580
	$ 119,160

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, 2003, the Company has not recorded a liability for any obligations arising as a result of these indemnifications.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. Net Loss Per Common Share:

The following table reconciles the numerators and denominators of the basic and diluted net loss per share computations.

	Year Ended December 31,	
	2003	**2002**
Net loss (numerator)	($2,488,106)	($3,063,116)
Basic:		
Weighted average Shares outstanding (denominator)	7,016,679	6,057,890
Net loss per common share basic	($0.35)	($0.51)
Diluted:		
Weighted average shares outstanding	7,016,679	6,057,890
Effect of dilutive options		
Adjusted weighted average shares (denominator)	7,016,679	6,057,890
Net loss per common share diluted	($0.35)	($0.51)

The effects of all stock options and warrants have been excluded from Common Stock equivalents because their effect would be anti-dilutive.

12. 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 to $12,000 for 2003. 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 $46,000 in 2003.

13. 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 will be utilized in research and development efforts. NIH formally awarded the Company a 2003 grant of $989,000, a 2002 grant of $814,000 and a

2001 grant of $884,000. Therefore, the Company expects to receive 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 $824,000 and $881,000 of costs related to this agreement for the year ended December 31, 2003 and 2002, respectively.

During the year ended December 31, 2003, the Company received $848,000 and recognized revenue of $824,000 related to this grant. During the year ended December 31, 2002, the Company received $775,000 and recognized revenue of $812,000 related to 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 addition, in August of 2002, the NIH awarded a second grant for $600,000 over two years. The grant is expected to begin funding in the second quarter of 2004.

SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: March 29, 2004

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

Name: **Francis E. O Donnell Jr.**
Title: **President, Chief Executive Officer and Chairman**

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.**	President, Chief Executive Officer, Chairman and Director	March 29, 2004
/s/ James A. McNulty **James A. McNulty**	Chief Financial Officer, Secretary and Treasurer	March 29, 2004
/s/ Raphael J. Mannino **Raphael J. Mannino**	Executive Vice President, Chief Scientific Officer and Director	March 29, 2004
/s/ William B. Stone **William B. Stone**	Director	March 29, 2004
/s/ James R. Butler **James R. Butler**	Director	March 29, 2004
/s/ John J. Shea **John J. Shea**	Director	March 29, 2004
/s/ L.M. Stephenson **L.M. Stephenson**	Director	March 29, 2004
/s/ Robert G.L. Shorr	Director	March 29, 2004

Robert G.L. Shorr			
/s/ ALAN PEARCE		Director	March 29, 2004
Alan Pearce			