BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB
March 28, 2003

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, 2002

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 0-28931

BioDelivery Sciences International, Inc.
(Name of small business issuer in its charter)

Delaware	35-2089858
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
UMDNJ Medical School 185 South Orange Avenue, Bldg. #4 Newark, New Jersey	07103
(Address of principal executive offices)	(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 2002 were $827,972.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 20, 2003 was approximately $8,221,298 based on the closing sale price of the company's common stock on such date of U.S. $2.40 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" AND OTHER SIMILAR EXPRESSIONS. IN ADDITION, ANY STATEMENTS THAT REFER TO EXPECTATIONS, PROJECTIONS OR OTHER CHARACTERIZATIONS OF FUTURE EVENTS OR CIRCUMSTANCES ARE FORWARD-LOOKING STATEMENTS. FORWARD-LOOKING STATEMENTS 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 BIORALTM TECHNOLOGY PLATFORM AND ANY PROPOSED PRODUCTS, THE DOMESTIC AND INTERNATIONAL REGULATORY PROCESS INCLUDING THE US 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;

- THE COMPETITION THAT MAY ARISE IN THE FUTURE;

- OUR ABILITY TO ENTER INTO SUBLICENSES;

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

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

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 which 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 BioralTM, licensing our encochleation technology to other pharmaceutical companies and entering into various types of agreements with other bio-technology or pharmaceutical companies.

In addition to developing and commercializing our drug delivery technology and initial BioralTM 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.

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, our current President and CEO, 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. Prior to Dr. O'Donnell's investment group purchasing a majority interest, MAS XXIII was controlled by Mr. Aaron Tsai who was the President and CEO 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

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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.

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 directors, officers or

persons owning 10 percent of the securities of the Company.
The net offering proceeds we received, after deducting the offering expenses described above, was $8,176,690. From June 25, 2002 until June 30, 2002, $1,050,000 of such proceeds was used to repay the 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 the securities of the Company. 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 the Company 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, referred to herein as PPDI, pursuant to which PPDI was granted a license to apply our BioralTM 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 a new Delaware subsidiary, Bioral Nutrient Delivery, LLC, or BND, to exploit our delivery technology for non-pharmaceutical use in the processed food and beverage industries for both human and animal consumption. We intend to grant BND an exclusive world-wide perpetual sub-license to our proprietary, licensed Bioral(TM) technology for use in such segments. We will at all times act as the managing member of BND and, through a board of directors and officers appointed directly or indirectly by us, will at all times make all management decisions relating to BND. As a limited liability company, BND may, at the discretion of its board of directors, distribute available net cash to its member shareholders.

We have previously entered into an evaluation agreement and begun testing of the encochleation technology for use in the pet food industries, which technology will be licensed to BND. BND will continue to monitor and develop the progress under the evaluation agreement. Although neither BND nor we have 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.

On February 13, 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, 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 intend to enter into a management services and administrative agreement with BND, pursuant to which certain of our officers and employees will provide services and space to BND, since we believe that BND's short-term objectives can be met without hiring full-time employees or renting space.

We are intending to distribute to our stockholders, as a dividend, rights to purchase directly from us Class B membership shares of BND, which Class B membership shares we currently own. Our plan is to initially distribute rights to purchase approximately 50% of the currently outstanding economic interests in BND and then, on a quarterly basis for a three (3) year period, distribute additional rights to purchase additional Class B membership shares from us. Such

interests will be subject to significant dilution. In February, 2003, BND filed a registration statement with the SEC to register such rights and such Class B membership, and we will not declare any such dividend of rights until such registration statement is declared effective, for which no assurances can be given.

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.

BioralTM cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our BioralTM 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:

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 BioralTM 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 BioralTM 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 BioralTM products for development.

Product Status

Indication	Products	Category	Pre-Clinical Development	
Systemic fungal infection	Antifungal	Antimicrobial	Formulation	Submis

	Bioral Amphotericin B		development almost completed. In vitro and in vivo efficacy data in progress	being manufa
Tuberculosis and bacterial infections	Antibacterial Bioral	Antimicrobial	Formulation development in process.	Pre-cl
Inflammatory disease	Bioral Anti-Inflammatory	OTC Medicine	Formulation and in vitro studies in process	Pre-cl

Bioral Amphotericin B. We are currently developing a BioralTM 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 first 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 BioralTM products may minimize.

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 three-year grant totaling approximately $2.7 million (the first two years of which total $1.7 million, with an additional $1.0 million for the third year) from the NIH 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 BioralTM 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 BioralTM drug and that we obtain FDA approval, we believe that it may provide an effective, orally administered version of a tuberculosis agent. This BioralTM 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. We estimate that the preparation of an IND will be completed in the third quarter of 2004, assuming the data in pre-clinical trials are favorable and the funding is available.

Bioral Anti-Inflammatory. We have targeted inflammation disorders, such as arthritis, for development of BioralTM 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 BioralTM 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.

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 and Albany Medical College

We have had and continue to have critical relationships with the University of Medicine and Dentistry of New Jersey 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 the University of Medicine and Dentistry of New Jersey, 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, 2002, the University of Medicine and Dentistry of New Jersey 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, which options are subject to stockholder approval. As of December 31, 2002, 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, which options are subject to stockholder approval. 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.

The Universities have reserved the right to use and permit the use of our licensed technology and licensed patents by non-profit organizations for educational and research purposes on a non-commercial basis. In April 2001, we entered into a research agreement with the University of Medicine and Dentistry of New Jersey 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 BioralTM 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. 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.

- 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 International, Inc. We are entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into the product. The planned RetinaPharma product is in its early stage of development and no sales of such product 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

We have 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, which technology will be licensed to our subsidiary, BND. 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 BioralTM 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	
US06,340,591	1/22/2002	1/14/18	Integrative protein DNA cochleate formulations and methods for transforming	The Univ and Dent and the

			cells	Maryland
EUR0722338	7/25/2001	9/30/2014	Protein- and peptide cochleate vaccines methods of immunizing using the same	The Univ and Dent and Alba
US06,165,502	12/26/2000	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The Univ and Dent and Alba

US06,153,217	11/28/2000	1/22/2019	Nanocochleate formulations, process of preparation and method delivery of pharmaceutical agents	BioDeliv Internat Universi Dentistr Albany M
AUS722647	11/23/2000	9/02/2017	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The Univ and Dent and Alba
US05,994,318	11/30/1999	11/24/2015	Cochleate delivery vehicles	The Univ and Dent and Alba
US05,840,707	11/24/1998	11/24/2015	Stabilizing and delivery means of biological molecules	The Univ and Dent and Alba
US05,834,015	11/10/1998	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The Univ and Dent and Alba
AUS689505	2/2/1998	9/30/2014	Protein- or peptide-cochleate immunotherapeutics and methods of immunizing using the same	The Univ and Dent and Alba
US05,643,574	07/01/1997	7/01/2014	Protein- or peptide-cochleate immunotherapeutics methods of immunizing using the same	The Univ and Dent and Alba
US04,871,488	10/03/1989	10/03/2006	Reconstituting viral glycoproteins into largephospholipid vesicles	Albany M
US04,663,161	05/05/1987	4/22/2005	Liposome methods and compositions	Albany M

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.

History of Our Technology

Below is a table summarizing technology development milestones:

April	1995	BDS obtained the worldwide exclusive rights to the Bioral Cochleate Technology owned by the Universities.
September	1995	BDS was awarded a vaccine research grant from Wyeth Lederle Vaccines
September	1995	BDS established a Research Agreement with the University of Medicine and Dentistry of New Jersey
June	1996	BDS established research and development, and License Agreement for Vaccines with Wyeth Lederle Vaccines which expired in December 1999.

August	1996	BDS signed a Material Transfer Agreement ("MTA") and started collaboration with the University of Maryland, Gene Therapy.
July	1997	U.S Patent No. 5,643,574 issued to the Universities. PROTEIN - OR PEPTIDE-COCHLEATE VACCINES
September	1997	BDS expanded its scientific and administrative staff and moved to new laboratories
November	1997	Initiated on-going collaboration with Public Health Research Institute of New York ("PHRI")
February	1998	Initiated on-going National Institute of Health funded amphotericin cochleate studies with University of Texas
February	1998	AUS Patent No 689505 issued to the Universities. VACCINE & METHODS OF IMMUNIZING
November	1998	U.S Patent No. 5,834,015, issued to the Universities. AUTOGENOUS VACCINE (HIV)
November	1998	U.S Patent No. 5,840,707 issued to the Universities. STABILIZING AND DELIVERY MEANS OF BIOLOGICAL MOLECULES
March	1999	Moved into current 8,000 square foot facility on the campus of the University of Medicine and Dentistry of New Jersey.
July	1999	Awarded Phase I SBIR for Amphotericin Cochleates
September	1999	Awarded Phase I SBIR for Cochleate Gene Therapy
November	1999	U.S Patent No. 5,994,318 issued to the Universities. COCHLEATE DELIVERY VEHICLES
December	1999	Signed a MTA and started an on-going collaboration in drug delivery with a major pharmaceutical company under a non-disclosure agreement

April	2000	Signed a MTA and started an on-going collaboration in drug delivery with a major pharmaceutical company under a non-disclosure agreement.
June	2000	Initiate an on-going collaboration with the National Cancer Institute Drug Delivery.
October	2000	Initiated an on-going collaboration with the Institute for Tuberculos Research, University of Illinois of Chicago, drug delivery.
November	2000	AUS Patent No 722,647 to the Universities. AUTOGENOUS VACCINE (HIV)
November	2000	U.S Patent No. 6,153,217 issued to BDS and the University of Medicine and Dentistry of New Jersey. NANOCOCHLEATE FORMULATIONS. Initiate process for preparation of IND for amphotericin B cochleates
December	2000	U.S Patent No. 6,165,502, issued to the Universities. AUTOGENOUS VACCINE (cancer etc.)
January	2001	Signed a MTA and started an on-going collaboration with a major pharmaceutical company under a non-disclosure agreement in drug deliv
April	2001	Establish a MTA and started an on-going collaboration with Utrecht Institute for Pharmaceutical Sciences, and University Medical Center Nijmegen, The Netherlands, to study mechanism of cochleates in drug d

May	2001	Signed a MTA with PHRI, NY to develop the cochleates for the treatmen Staphylococcus, drug delivery
June	2001	Signed a MTA with EUR Erasmus University of Rotterdam, The Netherland to develop the cochleates for the treatment of Staphylococcus, drug d
June	2001	Joint-Venture agreement with Retina Pharma and Tatton Technology, LLC affiliates of a shareholder, director and officer of BDSI, to develop cochleates as nutraceuticals for neurodegenerative diseases.
June		2001 Based upon the rating of our application, we believe we will receive an award of $3,000,000 SBIR Phase II for Preclinical and Clin development of Amphotericin B cochleates
July	2001	European Patent No. 722338, issued to the Universities and the Univer Maryland.
September	2001	Award of $0.9 million, with an additional $1.8 million expected to be awarded NIH(SBIR) Grant for Pre-clinical and Clinical development of Amphotericin B cochleates.
January		2002 US Patent N 06,340,591 issued on gene therapy "Integrative prote DNA cochleate formulations and methods for transforming cells" to UMD and to the University of Maryland
June	2002	Initial Public Offering
August	2002	NIH Grant awarded in collaboration with M.D. Anderson Cancer Center t an innovative HIV vaccine strategy

September	2002	Evaluation agreement with a leading manufacturer of processed foods f companion animals. The agreement grants the manufacturer a temporary exclusive license in the veterinary field to evaluate the nanocochle delivery technology for applications to pet food.
October	2002	Signed an evaluation agreement with a major pharmaceutical company to design a cochleate formulation of one of their injectable compound
December	2002	Signed a license agreement with PPDI which granted PPDI the right to apply BDSI's BioralTM nano-delivery technology to two therapeutic products. The BDSI technology can be used by PPDI to encapsulate the therapeutic products to enable oral delivery without the need for fur chemical modification.

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 (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, 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 BioralTM 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 BioralTM 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.

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. We have entered into an agreement with Pharma Research, Inc., Wilmington, Delaware, 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. Under the agreement, Pharma-Research, Inc. would provide scientific and other professional personnel to assist us in drafting and submitting the IND. We have been given an estimate of the total cost of the project which is subject to variables such as actual time spent on the project. However, at this time, we believe the total project

will approximate $100,000. Furthermore, this agreement may be terminated at any time by either party. We have not established similar relationships regarding anticipated clinical trials for any other intended BioralTM product.

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 20, 2003, 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 4 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 the University of Medicine and Dentistry of New Jersey. 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 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 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

Quarter Ended:	Common Stock		Warrants	
	High	Low	High	Low
September 30, 2002	$3.80	$1.25	$1.20	$0.40
December 30, 2002	$2.95	$1.25	$0.70	$0.15

As of March 20, 2003, we had approximately 233 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain any earnings for further business development.

We are intending to distribute to our stockholders, as a dividend, rights to purchase directly from us Class B membership shares of our subsidiary, Bioral Nutrient Delivery, LLC, which Class B membership shares we currently own. Our plan is to initially distribute rights to purchase approximately 50% of the economic interests in BND and then, on a quarterly basis for a three (3) year period, distribute additional rights to purchase additional Class B membership shares from us. In February, 2003, BND filed a registration statement with the SEC to register such rights and such Class B membership, and we will not declare any such dividend of rights until such registration statement is declared effective, for no which assurances can be given.

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 secur remaining avai for future iss
	(a)	(b)	(c)
Equity compensation plans approved by security holders	572,082	$7.69	-0-
Equity compensation plans not approved by security holders (*)	717,301	$4.22	---
Total	1,289,383	$5.76	-0-

(*) The options detailed in this row were authorized for issuance by our board

of directors and pursuant to increases in the number of shares available for issuance under our 2001 Stock Option Plan, which increase is subject to stockholder approval. Such options are intended to be issued under our 2001 Stock Option Plan, as the same may be amended and approved by our stockholders.

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.

In addition, during 2002 we issued options to purchase our common stock to members of our board of directors (372,536 shares in the aggregate), to members of our Scientific Advisory Board (33,484 shares in the aggregate), our outside legal counsel (25,000 shares), consultants (12,563 in the aggregate) and, in connection with a revision to our agreements with The University of Medicine and Dentistry of New Jersey and Albany Medical College (75,000 shares each), for a total of 593,583 options. There were no underwriters or placement agents employed in connection with any of 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 $8,176,690. 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 the Company of $394,707. During the quarterly period ended December 31, 2002, 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 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 the current year, we were a development stage company. In late December, 2002, we signed our first license agreement, which was funded in January 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) within the next 12 months. The funding will come primarily from the sale of securities, exercise of warrants, collaborative research agreements, including pharmaceutical companies, 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 $883,972, and a 2002 grant of $814,398, of which we have received $370,000 through December 31, 2002 and expect to receive the remainder through June 2003. The final year grant of approximately $989,000 is anticipated to be fully funded, subject to availability and satisfactory progress of the project. 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 January 2003 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 drugs and to fund expected operations in the next several years.

For the Year Ended December 31, 2002 Compared to the Year Ended December 31, 2001

Sponsored Research Revenue. During the years ended December 31, 2002 and 2001, we recognized sponsored research revenue of $828,000 and $478,000, respectively. From the 2002 NIH Grant award of $814,000, $370,000 was received in calendar 2002, and the balance is expected through June 2003. The 2001 revenue amount was

derived from the NIH Grant awarded to us in 2001. The total grant amount was $884,000, of which approximately $479,000 was received through December 31, 2001 and the balance was received in calendar 2002. 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.

Research and Development Expenses. During the years ended December 31, 2002 and 2001, research and development expenses totaled $1.5 million and $1.7 million, respectively. The scientific staff continued to work toward increased development and application of Bioral(TM) 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. Given the multiple uses of personnel and resources for different projects, separate tracking of expenses on a line item basis was historically not done for accounting purposes until the latter part of 2002 when a new accounting system was implemented.

General and Administrative Expenses. During the years ended December 31, 2002 and 2001, general and administrative expenses totaled $1.7 million and $.7 million, respectively. The increase is primarily due to increased staffing and administrative costs (such as travel costs to generate license agreements and legal and accounting costs following the initial public offering). Stock compensation expense of $0.7 million and $2.2 million in calendar 2002 and 2001 respectively, related to the elimination of the restrictions on the permanent discount redeemable common stock, and contractual obligations to former shareholders of BioDelivery Sciences, Inc., as well as compensation to employees and consultants who were granted stock options. 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.

Interest Income (Expense), Net. During the years ended December 31, 2002 and 2001, interest income (expense), net totaled $17,000 and $(22,000), respectively. The increase in net interest income is primarily due to the public offering, and investment of liquid funds, as well as payoff of all bank debt following the offering in June 2002.

Income Tax Benefit. We recognized an income tax benefit of $55,000 and $18,000 in 2002 and 2001, respectively. 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 $5.4 million at December 31, 2002. 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, 2002, we had cash and cash equivalents totaling approximately $5.2 million. At December 31, 2001 we had cash and cash equivalents totaling approximately $76,000.

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 a 2001 grant of $884,000, and a 2002 grant of $814,398, of which we have received approximately $370,000 through December 31, 2002 and expect to receive the remainder through June 2003. Additionally, this award refers to funding levels of $989,000 that we expect to be awarded in 2003 (and paid through June 2004), subject to availability and satisfactory progress of the project in NIH's opinion. 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 2002 compared to $1.6 million of cash used for operations in 2001. 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 lab. The collateral will be all equipment owned by us. As of December 31, 2002, we had expended approximately $325,000 toward equipment purchases, including deposits on equipment expected to be delivered by March 31, 2003. We expect to have approximately $600,000 to $700,000 in total equipment purchases and facility improvements by mid-summer 2003. We may not fully utilize this line in 2003.

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, 2002, we had stockholders' equity of $5.8 million, versus a deficit of $209,000 at December 31, 2001.

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(TM) 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(TM) cochleate technology itself and its use in a limited number of applications, and not on the marketing, production or sale of FDA approved products.

We formed a wholly-owned Delaware limited liability company subsidiary in January 2003, Bioral Nutrient Delivery, LLC, and we will sign 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. As part of the business plan for BND, our shareholders will have the right to purchase interests in BND directly from us at fair-market value, based on independent third-party appraisal. Over time (approximately three years) we will reduce our ownership in BND to approximately 10%, with the

balance owned by our stockholders, who we expect to purchase membership interests in BND. We will be the managing member of BND, and will exercise complete management activity and control of BND. Funds from the exercise of those rights, at fair market value, will inure to us, as will 8% royalties that will be paid 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, 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 intend to enter into a management services and administrative agreement with BND, pursuant to which certain of our officers and employees will provide services and space to BND. This agreement will provide that for a period of one year, we will not require repayment for allocated officer and employee salaries or certain other general and administrative costs.

We believe that our existing cash and cash equivalents, together with available equipment financing and the net proceeds of this offering will be sufficient to finance our planned operations and capital expenditures through at least the next 24 months. While we plan to manage our expenditures for development in accordance with the prior statement, we are currently unable to estimate the costs to complete or the completion dates of our current projects. Accordingly, we may be required to raise additional capital through a variety of sources, including:

- the public equity market, including the sale of membership interests in BND, as described above ;
- private equity financing;
- collaborative arrangements;
- grants;
- 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 July, 2001, the Financial Accounting Standards Board (FASB) issued SFAS 141, Business Combinations, and SFAS 142, Goodwill and Intangible Assets. SFAS 141 is effective for all business combinations completed after June 30, 2001. SFAS 142 is effective for the year beginning January 1, 2002; however certain provisions of this Statement apply to goodwill and other intangible assets acquired between July 1, 2001, and the effective date of SFAS 142. The adoption of these standards did not have a material impact on our financial statements.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This statement address financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes FASB Statement No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. The provisions of the statement are effective for financial statements issued for fiscal years beginning after December 15, 2001. We adopted this standard effective January 1, 2002, which did not have any material effect on our financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure, which (i) amends SFAS 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation (ii) amends the disclosure provisions of SFAS 123 to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation and (iii) requires disclosure about those effects in interim financial information. Items (ii) and (iii) of the new requirements in SFAS 148 are effective for financial statements for fiscal years ending after December 15, 2002. We have adopted the reporting requirements of item (ii) and will include the reporting requirements of item (iii) beginning in our first interim period after December 15, 2002.

In November 2002, the FASB issued FASB Interpretation No. 45, Guarantors Accounting and Disclosure Requirement for Guarantors, including Indirect Guarantors of Indebtedness to Others ("FIN 45"). FIN 45 creates new disclosure and liability recognition requirements for certain guarantees, including obligations to stand ready to perform. The initial recognition and measurement requirements of FIN 45 are effective prospectively for guarantees issued or modified after December 31, 2002, and the disclosure requirements are effective for financial statement periods ending after December 15, 2002. In accordance with FIN 45, we have disclosed guarantee information.

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 $2.2 million was required for our deferred tax assets as of December 31, 2002. If these estimates prove 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.

Item 7. Financial Statements.

Our Consolidated Financial Statements and Notes thereto and the report of Grant Thornton LLP, our independent certified public accountant, are set forth on pages F-1 through F-19 of this Report.

BIODELIVERY SCIENCES INTERNATIONAL, INC.
Consolidated Financial Statements

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

None.

PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance With Section 16(a) of the Exchange Act.

Our directors and executive officers and their ages as of March 21, 2003 are as follows:

Name	Age	Position(s) Held
Francis E. O'Donnell, Jr., M.D.	53	President, Chief Executive Officer, Chairm
Raphael J. Mannino, Ph.D.	56	Executive Vice President, Chief Scientific Director
James A. McNulty	52	Secretary, Treasurer and Chief Financial O

Donald L. Ferguson	54	Senior Executive Vice President
Christopher Chapman, M.D	50	Executive Vice President of Medical and Re Affairs and Director of New Business Devel
Susan Gould-Fogerite, Ph.D.	50	Vice President and Director of Innovation
L.M. Stephenson, Ph.D.	60	Director
William B. Stone	59	Director
James R. Butler	62	Director
John J. Shea	76	Director
Robert G.L. Shorr	49	Director
Alan Pearce	54	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 53, 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 five years, Dr. O'Donnell has served as managing director of The Hopkins Capital Group, an affiliation of limited liability companies which engage in business development and venture activities. He has been Chairman of Laser Sight Inc. (LASE), a publicly traded manufacturer of advanced refractive laser systems since 1993. 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 pharmacy and biotechnology companies. Dr. O'Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute. Dr. O'Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. Dr. O'Donnell holds 25 U.S. Patents. Dr. O'Donnell is the 2000 Recipient of the Jules Stein Vision Award sponsored by Retinitis Pigmentosa International. Dr. O'Donnell's address is 709 The Hamptons Lane, Chesterfield, MO 63017.

James A. McNulty, age 52, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis (estimated to constitute approximately 80% 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 54, 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 56, 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 1977 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.

Christopher Chapman, M.D., age 50, has been the Executive Vice President of Medical and Regulatory Affairs and Director of New Business Development (pharmaceuticals) on a part time basis since October 2000. Dr. Chapman received his M.D. degree from Georgetown University in Washington, D.C. in 1987 where he completed his internship in Internal Medicine. He completed a residency in Anesthesiology and a fellowship in Cardiovascular and Obstetric Anesthesiology at Georgetown University. Since 1995, Dr. Chapman has been a critical care physician on the staff at Doctor's Community Hospital, Lanham, Maryland. He was most recently President of Chapman Pharmaceutical Consulting. From 1995 to April 2000, Dr. Chapman was Executive Director, Medical Affairs, Quintiles Consulting and a founding Co-Director of Quintiles BRI (QBRI) Medical Affairs, Drug Safety

and Medical Writing Departments. Susan Gould-Fogerite, Ph.D., age 50, 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 60, is a member of our board of directors. Dr. Stephenson has been associated with the University of Medicine and Dentistry of New Jersey since 1995 where he is currently 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 serves as the Acting Associate Dean for Research of the New Jersey Medical School where he is temporarily responsible for managing and reorganizing the Sponsored Projects Office. Dr. Stephenson also currently serves as the Director of Patents and Licensing of the University of Medicine and Dentistry of New Jersey where he is responsible for management of the Intellectual Property Assets, including marketing of patents and establishment of new ventures. 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 59, 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 62, 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 a principal in a start up pharmaceutical company called Apothogen Pharmaceuticals. Mr. Butler earned a B.S. in marketing at the University of Florida.

John J. Shea, age 76, 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 and was enrolled in the Ph.D. Program at Kensington University in California.

Robert G.L. Shorr, Ph.D., age 49, is a member of our board of directors. He is currently President and CEO of Cornerstone Pharmaceuticals, a company focused on novel tumor targeting drug delivery and novel anticancer agent technologies. He is also on the faculty of State University of New York (SUNY) Stony Brook Department of Biomedical Engineering where he serves as the Director of Business Development for the Center for Advanced Technology State University of New York at Stony Brook. He has served in that position since October 1998. As Director of Business Development for the State University of New York at Stony Brook Center for Biotechnology, Dr. Shorr has been responsible for working with faculty and the university technology transfer office to establish grant funded entrepreneurial programs for promising commercializable technology. From 1991 to 1998, Dr. Shorr served as Vice President Science and Technology and as Vice President for Research and Development at Enzon Inc., a public company. Among his many accomplishments, Dr. Shorr was responsible for management of the co-development with Schering Plough of the product PEG INTRON A, which is now approved in the US and Europe. Dr. Shorr also served as chief scientist for another public company, United Therapeutics, Inc. since 1998 and continues to be a consultant. 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 54, is a member of our board of directors. He is currently Senior Vice President, Financial Services of McKesson Corporation. McKesson Corporation, a Fortune 50 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 BS in Industrial Management and University of Texas, where he earned his MBA 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 which 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:

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 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 Francois-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 the Scientific Director of The Public Health Research Institute, an internationally recognized 60 year-old biomedical research institute in New York City that emphasizes molecular approaches to infectious diseases research. Dr. Perlin is widely published, and his research activities focus on investigating the molecular properties of fungal membrane proteins, novel approaches to fungal diagnostics, and the molecular basis for clinical resistance to antifungal agents.

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, recipient of the Charnley award for excellence for research involving hip replacement surgery, and 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 various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by Securities and Exchange Commission 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 2002, all Forms 3, 4 and 5 were timely filed with the Securities and Exchange Commission by such reporting persons, except for John J. Shea, a director, who was granted 25,000 options to purchase our common stock in March 2002 upon his appointment to our board of directors.

Code of Ethics

On March 24, 2003 our board of directors adopted a code of ethics, a copy of which is filed as an exhibit to this Report, 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.

Directors do not receive compensation for their duties as directors.

SUMMARY COMPENSATION TABLE*

						Lo
		Annual Compensation(1)			Awards	
(a)	(b)	(c)	(d)	(e)	(f)	
Name and Principal Position	Year	Salary	Bonus	Other Annual Compensation	Restricted Stock Award(s)	Secu Unde Opti
		($)	($)	($)	($)	
Francis E. O'Donnell, Jr., M.D.	2002	$ 112,500	--	--	--	
CEO, President and Chairman	2001	--	--	--	--	
709 The Hampton Lane	2000	--	--	--	--	
Chesterfield, MO 63017						
James A. McNulty, CFO, Secretary and .	2002	$ 170,922	$35,000	--	--	
Treasurer	2001	40,000	--	--	--	
4419 W. Sevilla Street	2000	--	--	--	--	
Tampa, Florida 33629						
Donald L. Ferguson,.....	2002	--	--	--	--	
Senior Executive Vice President	2001	--	--	--	--	2
Land Dynamics, Inc.	2000	--	--	--	--	
11719 Old Ballas Road, Suite 110						
St. Louis, MO 63141						

Raphael J. Mannino, Ph.D.,(3).....	2002	$ 91,500	--	--	--
Executive Vice President,	2001	83,650	--	--	--
Chief Scientific Officer	2000	64,800	--	--	--
UMDNJ New Jersey Medical School					
185 South Orange Avenue, Building 4					
Newark, NJ 07103					
Christopher Chapman,.....	2002	$ 80,000	--	--	--
Executive Vice President of Medical	2001	80,000	--	--	--
and Regulatory Affairs and Director	2000	--	--	--	--
of New Business Development					
(pharmaceuticals)					
800 Falls Lake Drive					
Mitchelsville, MD 20720					
Susan Gould-Fogerite, Ph.D.,(4).....	2002	$ 46,660	--	--	--
Vice President and Director of	2001	$ 40,800	--	--	--
Innovation and Discovery	2000	$ 40,800	--	--	--
UMDNJ New Jersey Medical School					
185 South Orange Avenue, Building 4					
Newark, NJ 07103					

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* 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 $30,930, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2002 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

(4) Excludes $31,797, which funds were reimbursed by us during 2002 to the University of Medicine and Dentistry of New Jersey during 2002 (pursuant to a contractual arrangement) for services rendered by Dr. Gould-Fogerite to such university.

Option Grants During Year Ended December 31, 2002

	Individual Grants			Potential Realizable Value of Stock Price Appreci
(a)	(b)	(c)	(d)	(e)
	Number of Securities Underlying Options/SARs	Percent of Total Options/SARs Granted to Employees in	Exercise or Base Price	

Name	Granted(#)	Fiscal Year	($/Sh)	Expiration Date
Francis E. O'Donnell, Jr. M.D.....	26,991	27.71%	$ 5.50	March 5, 2007
	35,000	35.93%	$ 1.70	September 25, 2007
Raphael J. Mannino, Ph.D.....	15,423	15.83%	$ 5.50	March 5, 2007
	20,000	20.53%	$ 1.70	September 25, 2007
James A. McNulty.....	----	----	----	----
Donald L. Ferguson.....	----	----	----	----
Christopher Chapman, M.D.....	----	----	----	----
Susan Gould-Fogerite, Ph.D.....	----	----	----	----

Aggregated Option Exercises in Last Fiscal year and Fiscal Year-End Option Values

No options were exercised during the fiscal year-end December 31, 2002.

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 Securit Underly Unexerc Options/S Fiscal Year Exercis Unexerci
(a)	(b)	(c)	(d)
Francis E. O'Donnell, Jr., M.D..... CEO, President and Chairman 709 The Hampton Lane Chesterfield, MO 63017	--	--	--
James A. McNulty, CFO..... Secretary and Treasurer 4419 W. Sevilla Street Tampa, Florida 33629	--	--	--
Donald L. Ferguson..... Senior Executive Vice President Land Dynamics, Inc. 11719 Old Ballas Road, Suite 110 St. Louis, MO 63141	--	--	--
Raphael J. Mannino, Ph.D..... Executive Vice President, Chief Scientific Officer	--	--	--

UMDNJ New Jersey Medical School 185 South Orange Avenue, Building 4 Newark, NJ 07103			
Christopher Chapman..... Executive Vice President of Medical and Regulatory Affairs and Director of New Business Development (pharmaceuticals) 800 Falls Lake Drive Mitchelsville, MD 20720	--	--	--
Susan Gould-Fogerite, Ph.D..... Vice President and Director of Innovation and Discovery UMDNJ New Jersey Medical School 185 South Orange Avenue, Building 4 Newark, NJ 07103	--	--	--

Employment Agreements

Except for Dr. Frank O'Donnell, Mr. James McNulty, Dr. Christopher Chapman, Dr. Susan Gould-Fogerite and Dr. Rafael 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. O'Donnell, President, CEO 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, CFO, 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, 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).

(vi) Christopher Chapman, M.D., Executive Vice President of Medical and Regulatory Affairs and Director of New Business Development (pharmaceuticals) -- Receives $6,667 per month pursuant to a consulting contract and receives no other benefits from us. This consulting contract was entered into prior to Dr. Chapman becoming an officer, however, he continues to receive remuneration under the consulting agreement. Prior to the effective date, such consulting agreement will be reconstituted into an employment agreement on similar terms and conditions.

Drs. Raphael Maninno and Susan Gould-Fogerite had outstanding debt payable to us which 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 which will be submitted to our stockholders for approval at the next annual meeting. Options to purchase 909,383 shares of common stock are outstanding as of December 31, 2002 under the 2001 stock option plan, a portion of which is subject to shareholder approval. An additional 380,000 options have been issued by our board of directors subject to stockholder approval. All options are intended to be 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 909,383 shares of our common stock at prices ranging from $2.87 to $17.48 are outstanding at December 31, 2002, a portion of which are subject to stockholder approval. An additional 380,000 options have been issued by our board of directors, subject to stockholder approval, at prices ranging from $1.70 to $5.50. 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 options 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. None of our outstanding options have terms in excess of five (5) years from the date of grant.

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

The following table sets forth, as of March 20, 2003, certain information as to the stock ownership of each person known by us to own beneficially 5% or more of our outstanding common stock, by each of our named officers and directors who owns any shares and by all officers and directors as a group. In computing the outstanding shares of common stock, we have excluded all shares of common stock subject to options or warrants since they are not currently exercisable or exercisable within 60 days and are therefore not deemed to be outstanding and beneficially owned by the person holding the options or warrants for the purpose of computing the number of shares beneficially owned and the percentage ownership of that person. 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 March 20, 2003
Hopkins Capital Group II, LLC (2)	3,111,579	43.97%
Francis E. O'Donnell, Jr., M.D. (3)	3,161,922	44.62%
Pharmaceutical Product Development, Inc. (4)	690,000	9.74%
Jonnie R. Williams, Sr. (5)	3,203,112	45.20%
Dennis Ryll, M.D. (6)	3,157,346	44.56%
Raphael J. Mannino, Ph.D. (7)	182,609	2.58%
James A. McNulty (8)	76,659	1.08%

Donald L. Ferguson (9)	91,533	1.30%
Christopher Chapman, M.D. (10)	---	---
Susan Gould-Fogerite, Ph.D. (11)	152,174	2.15%
L.M. Stephenson, Ph.D (12)	---	*
William B. Stone (13)	---	*
James R. Butler (14)	---	*
John J. Shea (15)	---	*
Robert G.L. Shorr (16)	---	*
Alan Pearce (17)	---	*
All Directors and Officers as a group (12 persons)	3,664,897	51.72%

* Less than 1%

(1) Based on 7,085,863 shares of common stock outstanding.

(2) Hopkins Capital Group II, LLC is owned one third by each of (i) various trusts of the Dr. 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) Per Form 4 filed with the SEC on October 7, 2002. 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. Does not include options to purchase 8,009 shares

of common stock at an exercise price of $3.06 per share, options to purchase 26,991 shares of common stock at an exercise price of $5.50 per share, in each case exercisable in July, 2003 and options to purchase 35,000 shares of common stock at $1.70 per share which are exercisable on September 26, 2004. The remaining 4,576 shares of common stock are owned by Dr. O'Donnell's sister. 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) and 45,767 shares of common stock owned by his wife, as to which he disclaims beneficial interest of. The remaining 45,766 shares of common stock are personally owned by Mr. Williams. Mr. William'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 1029 Speckledwood, Manor Court, Chesterfield, MO 63017.

(7) Per Form 4 filed with the SEC on October 7, 2002. Dr. Mannino is our Executive Vice President, Chief Scientific Officer and a Director. Does not include options to purchase 45,767 shares of common stock at an exercise price of $3.06 per share vesting in July, 2003, options to purchase 22,883 shares of common stock at an exercise price of $11.80 per share vesting in July, 2003, options to purchase 22,883 shares of common stock at an exercise price of $17.48 per share vesting in July, 2003, options to purchase 20,000 shares of common stock at $1.70 per share which are exercisable on September 26, 2004 or options to purchase 60,000 shares of common stock at $1.63 per share which were granted in January 2003.

(8) Mr. McNulty is out Secretary, Treasurer and Chief Financial Officer. 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. Does not include options to purchase 137,300 shares of common stock at an exercise price of $3.06 per share vesting in July, 2003, options to purchase 68,650 shares of common stock at an exercise price of $11.80 per share vesting in July, 2003 and options to purchase 68,650 shares of common stock at an exercise price of $17.48 per share vesting in July, 2003. Mr. Ferguson's address is 11719 Old Ballas Road, Suite 110, St. Louis, MO 63141.

(10) Dr. Chapman is our Executive Vice President of Medical and Regulatory Affairs. Does not include options to purchase 45,767 shares of common stock at an exercise price of $3.06 per share vesting in July, 2003, options to purchase 22,883 shares of common stock at an exercise price of $11.80 per share vesting in July, 2003 or options to purchase 22,883 shares of common stock at an exercise price of $17.48 per share vesting in July, 2003.

(11) Dr. Gould-Fogerite is our Vice President and Director of Innovation and Discovery. Does not include options to purchase 17,162 shares of common stock at an exercise price of $3.06 per share vesting in July, 2003, options to purchase 8,581 shares of common stock at an exercise price of $11.80 per share vesting in June 2003, and options to purchase 8,581 shares of common stock at an exercise price of $17.48 per share vesting in July, 2003.

(12) Per Form 4 filed with the SEC on October 11, 2002. Does not include options to purchase 6,865 shares of common stock at an exercise price of $3.06 per share and 23,135 shares of common stock at an exercise price of $5.50 per

share exercisable in July, 2003 or options to purchase 20,000 shares of common stock at $1.70 per share which are exercisable on September 26, 2004. Dr. Stephenson's address is c/o University of Medicine and Dentistry New Jersey Medical School, 65 Bergen Street, MB 1414, Newark, NJ 07103.

(13) Per Form 4 filed with the SEC on October 11, 2002. Does not includes options to purchase 8,009 shares of common stock at an exercise price of $3.06 per share and 26,991 shares of common stock at an exercise price of $5.50 per share exercisable in July, 2003 or options to purchase 35,000

shares of common stock at $1.70 per share which are exercisable on September 26, 2004. Mr. Stone's address is 11120 Geyers Down Lane, Frontenac MO 63131.

(14) Per Form 4 filed with the SEC on October 7, 2002. Does not include options to purchase 30,000 shares of common stock at an exercise price of $5.50 per share exercisable in July, 2003 or options to purchase 25,000 shares of common stock at $1.70 per share which are exercisable on September 26, 2004. Mr. Butler's address is 109 Cutter Court, Ponte Vedra Beach, FL 32082.

(15) Does not include options to purchase 25,000 shares of common stock at an exercise price of $5.50 per share exercisable in July, 2003. Mr. Shea's address is 90 Poteskeet Trail, Kitty Hawk, NC 27949.

(16) Per Form 4 filed with the SEC on October 11, 2002. Does not includes options to purchase 30,000 shares of common stock at an exercise price of $5.50 per share exercisable in July, 2003 or options to purchase 25,000 shares of common stock at $1.70 per share which are exercisable on September 26, 2004. Mr. Shore's address is 28 Brookfall Road, Edison, NJ 08817.

(17) Per Form 3 filed with the SEC on October 11, 2002. Does not include options to purchase 25,000 shares of common stock at $1.70 per share which are exercisable on September 26, 2004. Mr. Pearce's address is c/o McKesson Corporation, One Post Street, San Francisco CA 94104.

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 BioralTM cochleate technology, we will support drug development and will share in ten percent (10%) of all net revenue from such sales of BioralTM encapsulated drugs. The Hopkins Capital Group II, LLC, one of our significant stockholders and Dr. Francis E. O'Donnell, Jr., our CEO, President and a director 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.

Dr. Francis O'Donnell and Donald Ferguson had personally guaranteed a line of credit up to $1,050,000 with a bank and other liabilities for our benefit at a rate of prime plus 2% of which $850,000 matured in May 2002 but was deferred pending the completion of our public offering. The line of credit was paid off with proceeds from the offering.

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 BioralTM 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 BioralTM 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 and CEO.

On July 19, 2002, we issued Ellenoff Grossman Schole & Cyruli, LLP, our outside legal counsel, 25,000 options to purchase shares of our common stock at $7.00 per share. Ellenoff Grossman Schole & Cyruli, LLP is also counsel to our subsidiary, 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.

In 2001, we settled litigation commenced against BioDelivery Sciences, Inc. by Irving A. Berstein and certain of his family members and affiliates. Mr. Berstein was a stockholders, and former officer and director of BioDelivery Sciences, Inc. The settlement required that we pay $150,000 in cash and $125,000 by promissory note, which was satisfied in full out of the proceeds of our public offering. At the same time, we purchased the shares of BioDelivery Sciences, Inc. owned by these stockholders for $500,000 which was paid $200,000 in cash and $300,000 by promissory note which was satisfied in full out of the proceeds of our public offering.

In December 2001, we exchanged 447,391 shares of our stock for 1,470,000 shares of BioDelivery Sciences, Inc. redeemable common stock. Drs. Raphael J. Mannino and Susan Gould-Fogerite, officers of the company, and Leila Zarif, a former officer of the company, principally owned those BioDelivery Sciences Inc. shares. In connection with this exchange, we removed certain restrictions, put rights with respect to those shares and expect to forgive loans of approximately $320,000 that are secured by the BioDelivery Sciences Inc. shares upon the successful completion of the offering. In connection with forgiveness of the notes, we will provide them with approximately $200,000 for compensation for their tax liability. Due to the variable nature of the underlying stock award, we recognized compensation expense totaling $2,140,000 in 2001. This compensation expense does not include any amount with respect to the expected forgiveness of loans.

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.

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 four independent directors. These independent directors are William Stone, James Butler, John Shea, Robert 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
3.3	Bylaws of the Company as an Indiana corporation (6)
3.4	Articles of Incorporation of the Company after reincorporation merger into Dela
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

10.2	Licensing Agreement with the University of Medicine and Dentistry of New Jersey
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.
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
10.23	Amendment to Purchase Agreement dated March 29, 2002 (10)
10.24	Agreement between Mr. Aaron Tsai and BioDelivery Sciences International, Inc. (
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 an Sciences International, Inc. and Pharmaceutical Product Development, Inc. (conf requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 2 240.24b-2) (14)

10.29	Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, 2003, by BioDelivery Sciences International, Inc., as Managing Member and the o signatory thereto, as Class B Members. (15)
10.30	Promissory Note, dated February 13, 2003, by Bioral Nutrient Delivery, LLC in f Sciences International, Inc. (15)
20.1	Code of Ethical Conduct of the Registrant (*)
21.1	Subsidiaries of the Registrant (*)
99.1	Certification of the Company's Chief Executive Officer pursuant to 18 U.S.C. Se adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)
99.2	Certification of the Company's Chief Financial Officer pursuant to 18 U.S.C. Se adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)

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*	Filed herewith
**	A signed original of this written statement required by Section 906 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

(b) Reports on Form 8-K. We filed no Current Reports on Form 8-K during the fourth quarter of 2002.

Item 14. 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors
BioDelivery Sciences International, Inc.

We have audited the accompanying consolidated balance sheets of BioDelivery Sciences International, Inc. and subsidiary as of December 31, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioDelivery Sciences International, Inc. and subsidiary as of December 31, 2002 and 2001, and the consolidated results of their operations and cash flows for the years then ended 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.

CONSOLIDATED BALANCE SHEETS

	200
ASSETS	
CURRENT ASSETS:	
Cash and cash equivalents	$ 5,207
Accounts Receivable	2,000
Prepaid expenses and other assets	201
Total current assets	7,408
EQUIPMENT, net	435
LICENSES	517
OTHER ASSETS, net	28
TOTAL ASSETS	$ 8,390
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	
CURRENT LIABILITIES:	
Accounts payable and accrued liabilities	$ 538
Due to related parties	51
Line of credit	
Deferred revenue	2,000
Current portion of capital lease payable	12
Current portion of notes payable	
Total current liabilities	2,602
CAPITAL LEASE PAYABLE, less current portion	4
NOTES PAYABLE, less current portion	

COMMITMENTS AND CONTINGENCIES	
STOCKHOLDERS' EQUITY (DEFICIT):	
Preferred stock, $.001 par value, 20,000,000 shares authorized, no shares issued in 2002 and 2001	
Common stock, $.001 par value, 80,000,000 shares authorized, 7,085,863 and 5,000,863 shares issued and outstanding in 2002 and 2001, respectively	7
Additional paid-in capital	13,956
Accumulated deficit	(8,180
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	5,782
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 8,390

The accompanying notes are an integral part of these financial stat

BIODELIVERY SCIENCES INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2002	Year Ended December 31, 2001
Sponsored research revenues	$ 827,972	$ 478,385
Expenses:		
Research and development	1,532,104	1,663,932
General and administrative:		
General and administrative	1,667,031	679,883
Stock compensation	688,911	2,192,084
Legal settlement	75,000	383,625
Total expenses	3,963,046	4,919,524
Interest income (expense), net	16,994	(21,957)
Loss before income taxes	(3,118,080)	(4,463,096)
Income tax benefit	54,964	18,535
Net loss	$ (3,063,116)	$ (4,444,561)
Net loss per common share:		
Basic and diluted	$ (0.51)	$ (1.15)
Weighted average common stock shares outstanding-- basic and diluted	6,057,890	3,851,587

The accompanying notes are an integral part of these financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Preferred Shares		Common Shares		Additional Paid-In
	Shares	Amount	Shares	Amount	Capital
BALANCE, DECEMBER 31, 2000	462,243	$ 462	3,512,586	$ 3,513	$1,006,136
Shares issued for cash	--	--	368,421	369	804,631
Shares issued for satisfaction of debt	--	--	137,300	137	499,447
Shares issued in replacement of preferred stock	(462,243)	(462)	462,243	462	--
Shares issued in merger with subsidiary	--	--	520,313	520	2,540,148
Issuance of stock options	--	--	--	--	53,006
Net loss	--	--	--	--	--
BALANCE, DECEMBER 31, 2001	--	--	5,000,863	5,001	4,903,368
Shares issued for cash, net of offering costs of $2,374,853	--	--	2,085,000	2,085	8,569,312
Stock compensation	--	--	--	--	483,647
Net loss	--	--	--	--	--
BALANCE, December 31, 2002	--	$ --	7,085,863	$ 7,086	$13,956,327

The accompanying notes are an integral part of this financial statement.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	Year E Decembe

	2002	200
OPERATING ACTIVITIES:		
Net loss	$ (3,063,116)	$ (4,444
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization	126,737	104
Deferred revenue	1,963,000	37
Litigation settlement	--	425
Stock compensation expense	688,911	2,190
Changes in assets and liabilities:		
Accounts receivable	(2,000,000)	
Prepaid expenses and other assets	273,876	(417
Accounts payable and accrued liabilities	(481,533)	420
Due to/from related parties	(22,606)	52
Net cash used by operating activities	(2,514,731)	(1,631
INVESTING ACTIVITIES:		
Purchase of equipment	(325,436)	(84
Purchase of minority interest	--	(116
Net cash used by investing activities	(325,436)	(201
FINANCING ACTIVITIES:		
Issuance of Common Stock	8,571,397	805
Net change in line of credit	(282,527)	282
Payment on capital lease payable	(15,656)	(6
Payment on notes payable	(301,257)	(123
Net cash provided by financing activities	7,971,957	957
NET CHANGE IN CASH	5,131,790	(875
CASH AT BEGINNING OF PERIOD	75,513	950
CASH AT END OF PERIOD	$ 5,207,303	$ 75

The Company paid interest of $40,790 and $28,178 during 2002 and 2001, respectively.

In 2001, in addition to paying cash of $350,000, the Company issued notes payable totaling $425,000 in connection with a litigation settlement and re-acquisition of the BioDelivery Sciences, Inc. common shares previously held by certain minority stockholders. This transaction resulted in the recognition of licenses of $116,375. In 2001, the Company issued 137,300 shares of its common stock in full payment of a related-party payable of approximately $500,000.

In 2001, the Company exchanged 72,922 shares of its common stock for common shares of BioDelivery Sciences, Inc. previously held by minority stockholders. This exchange resulted in the recognition of licenses of $401,070. In addition, the Company exchanged 447,391 shares of its common stock for outstanding redeemable permanent discount common shares of BioDelivery Sciences, Inc. The variable nature of this underlying stock award, as modified by the removal of discount and redemption provisions, resulted in the recognition of compensation expense of approximately $2,140,000.

During 2002 and 2001, the Company granted stock options to non-employees resulting in the recognition of compensation expense of approximately $162,000

and $53,000 in 2002 and 2001, respectively. 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.

The accompanying notes are an integral part of these financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1--Organization

BioDelivery Sciences International, Inc. ("BDSI" or the "Company") (formerly known as MAS Acquisition XXIII Corp.) was incorporated in the State of Indiana on January 6, 1997. BDSI and its former subsidiary (prior to the merger discussed below), BioDelivery Sciences, Inc. ("BDS"), are collectively referred to as the Company. In October 2000, BDSI acquired 84.8% of the voting rights of BioDelivery Sciences Inc. through the purchase of BioDelivery Sciences Inc. Series A Preferred Stock.

As of December 2001, BDSI and BDS had entered into a merger agreement. The merger was subsequently consummated on January 7, 2002 (the "Merger"). The Company considers December 31, 2001 to be the acquisition date for accounting purposes as the rights of ownership of BDS had been essentially transferred to BDSI, without restrictions, by that date. The agreement required an exchange of 1.33 shares of identical BDSI common stock for each share of BDS common stock outstanding, including redeemable common stock. The Company also exchanged 72,922 shares of common stock for 239,600 shares of BDS common stock and 447,391 shares of common stock for 1,470,000 shares of BDS redeemable common stock. The acquisition of the 239,600 shares of common stock represents the acquisition of minority interest, which resulted in recorded licenses of approximately $400,000. Prior to the acquisition of the 1,470,000 shares of redeemable common stock the Company agreed to remove the permanent discount and redemption provisions and agreed to the forgiveness of the stockholder debt associated with these shares upon, or soon after, the 2002 public offering of securities. The redeemable stock was originally characterized as a variable stock award for accounting purposes and therefore, the acquisition of the redeemable stock and the removal of the restrictions in December 2001 involved the recognition of compensation costs totaling approximately $2,137,000. As of December 2001, the redemption provisions with respect to such shares have been terminated.

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 a licensing agreement, reflected in the balance sheet as a receivable and deferred revenue. As a result of the licensing agreement, the Company determined that it no longer meets the criteria for a development stage company. The Company intends to obtain additional funds for research and development through collaborative arrangements with corporate partners, license agreements, additional financings, and from other sources. The Company operates in one segment focused on the development of its drug delivery platform technology.

In March 2002, the Company approved a one for 4.37 reverse stock split. The financial statements have been retroactively restated to reflect this reverse stock split.

Note 2--Summary of Significant Accounting Policies

Principles of Consolidation

The financial statements include the accounts of BDSI and its subsidiary (until the Merger), BioDelivery Sciences Inc. All significant inter-company balances have been eliminated. At January 1, 2001 other stockholders owned 100% of the common stock of BioDelivery Sciences Inc. while BDSI owned preferred stock with voting rights, representing 84.8% of the total voting rights. At January 1, 2001, the equity attributable to the minority interest holders was at a deficit balance and accordingly was reduced to zero. In connection with a litigation settlement and in connection with the Merger of BDSI and BDS the remaining minority interest was acquired by the Company.

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, 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. 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. Patent costs are expensed as incurred as research and development expenses. During the fourth quarter of 2002, the Company evaluated the classification of certain overhead costs previously reported as research and development costs and determined that such costs are more representative of general and administrative expenses. Accordingly, the Company reclassified approximately $318,000 of such costs recognized through September 30, 2002 to general and administrative costs in the fourth quarter.

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

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, which was received in January 2003. The Company has deferred the revenue and will recognize it over the period of the related research and development commitment. The agreement also provides for milestone payments.

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.

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 value recognized for these licenses principally arose on December 31, 2001 in connection with the purchase of minority interest shares resulting from a merger agreement between BDSI and BDS and was allocated to licenses during December 2002. The licenses are amortized over their estimated useful life of 15 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.

Concentration of Credit Risk

The Company derived substantially all of its working capital from the sale of its Common Stock and from research and development arrangements. During December 2002, the Company entered into a licensing agreement with a company, which is also a shareholder. As a result, all of the accounts receivable at December 31, 2002 are due from this entity. Management has considered the third party's financial condition and expects the amount to be collected in full.

Stock Based Compensation

The Company follows Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation (SFAS 123), which establishes a fair value based method of accounting for stock-based employee compensation plans; however, 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 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 11):

	Year Ended December 31, 2002	Year Ended December 31, 2001
Net loss, as reported	$ (3,063,116)	$ (4,444,561)
Less: stock-based employee compensation cost under the fair value based method, net of related tax effects	(689,410)	(143,559)
Pro forma net loss	$ (3,752,526)	$ (4,588,120)
Net loss per common share-basic and diluted:		
as reported	$ (.51)	$ (1.15)
pro forma	$ (.62)	$ (1.19)

Stock Compensation

Under the terms of a 1999 redeemable common stock purchase agreement, the Company was required to re-purchase 1,470,000 shares of BDS redeemable permanent discount common stock at the option of the holder. The Company accounted for its ten-year re-purchase obligation (through 2009) using variable plan accounting; however, through the date of the Merger (see Note 1) the value of the stock (less the permanent discount) was lower than the initial redemption value. Under the terms of the redemption agreement, holders could require the Company to repurchase, at the then fair value (less the permanent discount), the permanent discount common stock beginning in 2004 or upon an employee's termination, whichever was earlier. In December 2001, the Company agreed to remove the permanent discount and put rights, resulting in the recognition of approximately $2,140,000 of compensation expense. During 2002, the Company also recognized $526,318 of compensation expense associated with the forgiveness of employee stock subscription notes receivable and related income tax payable on behalf of the employees. No future costs are expected with regard to this stock based compensation award.

Fair Value of Financial Instruments

At December 31, 2002, the carrying amount of cash, accounts receivable, accounts payable, accrued expenses, and capital lease obligations approximate fair value based either on the short term nature of the instruments or on the related interest rate approximating the current market rate.

New Accounting Pronouncements

In July, 2001, the Financial Accounting Standards Board (FASB) issued SFAS 141, Business Combinations, and SFAS 142, Goodwill and Intangible Assets. SFAS 141 is effective for all business combinations completed after June 30, 2001. SFAS 142 is effective for the year beginning January 1, 2002; however certain provisions of this Statement apply to goodwill and other intangible assets acquired between July 1, 2001, and the effective date of SFAS 142. The adoption of these standards did not have a material impact on the Company's financial statements.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes FASB Statement No. 121, Accounting for the Impairment of Long-Lived Assets and

for Long-Lived Assets to Be Disposed Of. The provisions of this statement are effective for the year beginning January 1, 2002. The adoption of this standard did not have a material impact on the Company's financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure, which (i) amends SFAS 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation (ii) amends the disclosure provisions of SFAS 123 to require prominent disclosure about the effects on reported net

income of an entity's accounting policy decisions with respect to stock-based employee compensation and (iii) requires disclosure about those effects in interim financial information. Items (ii) and (iii) of the new requirements in SFAS 148 are effective for financial statements for fiscal years ending after December 15, 2002. The Company has adopted the reporting requirements of item (ii) and will include the reporting requirements of item (iii) beginning in its first interim period after December 15, 2002.

In November 2002, the FASB issued FASB Interpretation No. 45, Guarantors Accounting and Disclosure Requirement for Guarantors, including Indirect Guarantors of Indebtedness to Others (FIN 45). FIN 45 creates new disclosure and liability recognition requirements for certain guarantees, including obligations to stand ready to perform. The initial recognition and measurement requirements of FIN 45 are effective prospectively for guarantees issued or modified after December 31, 2002, and the disclosure requirements are effective for financial statement periods ending after December 15, 2002. In accordance with FIN 45, the Company has disclosed guarantee information.

Note 3--Business Combination

On October 10, 2000, BDSI acquired 210,006 shares of newly issued BDS Series A Convertible Preferred Stock representing 84.8% of the voting rights of BDS in exchange for cash and notes payable to BDS of $1,000,000 and $14,000,000, respectively. Since its inception in 1995, BDS has been principally engaged in developing a cochleate based drug delivery platform and had no pre-existing relationship with BDSI prior to the acquisition. The business combination was accounted for as a purchase. The shares of Series A Preferred were convertible into BDS Common Stock on a 50-for-1 basis, subject to customary anti-dilution adjustments. Dividends accrued on the Series A Preferred at the rate of 8% per annum. In the event of liquidation, dissolution, or winding up of BDS, the Series A Preferred Stockholders would have been entitled to receive, in preference to Common Stockholders of BDS, an amount per share equal to the original purchase price plus any accrued dividends per share. The Series A Preferred Stock was convertible at the option of the preferred stockholders, but would automatically convert at the earlier of the initial public offering of BDS's common stock, or September 2005. The BDS Series A Preferred Stock and note are eliminated in consolidation. BDSI and BDS had amended the payment terms of the $14.0 million notes to defer the commencement of payments to August 1, 2001. The first scheduled payment under the notes was otherwise required on January 1, 2001.

All the BDS common stock was subsequently acquired with the settlement of certain litigation (see Note 7) and the merger of BDS with BDSI (see Note 1). The Series A Convertible Preferred Stock of BDS was retired as part of the merger.

Note 4--Research and Development Arrangements

Upon its formation, BDS originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, BDS 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 BDS proceeds); or (c) BDS 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.

BDS had entered into a research agreement with UMDNJ. BDS incurred costs of $306,477 and $159,025, for 2002 and 2001, respectively, to UMDNJ under the terms of the research agreement. The research agreement provides for the procurement of supplies, rent (until April 2001), certain payroll costs, and other expenses associated with research performed under the research agreement. On April 1, 2001, the Company agreed to issue approximately 137,300 shares of common stock in consideration for payment in full of its approximate $500,000 payable at March 31, 2001, to UMDNJ. At December 31, 2002 and 2001, the Company owed $51,725 and $74,331, respectively, under this 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 a deminimus amount of costs relating to these agreements in 2002 and 2001.

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 a deminimus amount of costs relating to this agreement in 2002 and 2001.

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 a deminimus amount of costs relating to this agreement in 2002 and 2001.

Note 5--Other Assets

Other assets consist of the following.

	Year ended December 31, 2002	
Deferred offering costs related to the 2002 public offering.....	--	
Other.....	45,505	
	45,505	
Less: Accumulated amortization.....	(16,650)	
Total other assets, net.....	$ 28,855	$

Note 6--Equipment

Equipment consists of the following:

	December 31 2002	
Office and laboratory equipment.....	$ 646,774	$
Leased equipment.....	39,679	
	686,453	
Less accumulated depreciation and amortization.....	(251,392)	(
Net equipment.....	$ 435,061	$

Depreciation and amortization expense related to equipment for the years ended December 31, 2002 and 2001 was approximately $124,000 and $104,000, respectively.

Note 7--Commitments and Contingencies

Litigation

During May 2001, the Company entered into a settlement agreement with a former consultant and certain stockholders related to the consultant (together, the "Plaintiffs"). Under the terms of the settlement agreement, the Company agreed to pay $150,000 in cash and $125,000 in a note payable to the Plaintiffs. The Company also agreed to re-purchase all of the BioDelivery Sciences Inc. common stock owned by the Plaintiffs valued at $116,375 for cash of $200,000 and a note payable of $300,000. Relating to this litigation, the Company accrued approximately $300,000 at December 31, 2000 and recorded an additional $380,000 of legal expense for the year ended December 31, 2001. As of December 31, 2002, all obligations under the settlement agreement have been satisfied.

Operating Lease

Beginning in April 2001, the Company leases a facility from UMDNJ under an operating lease that runs through December 31, 2005. Lease expense for the years ended December 31, 2002 and 2001 was approximately $45,000 and $30,000,

respectively. The future minimum commitments on this operating lease at December 31, 2002 are as follows:

2003	$ 50,580
2004	56,580
2005	62,580
	$ 169,740

Capital Lease

The Company leases certain equipment under a capital lease. Future minimum lease payments at December 31, 2002 remaining on this capital lease are as follows.

2003	$ 14,713
2004	4,905
Less amount representing interest	(2,101)
	$ 17,517

Indemnifications

The Company indemnified its officers and directors against costs and expenses related to shareholder 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, 2002, the Company has not recorded a liability for any obligations arising as a result of these indemnifications.

Note 8--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.

Note 9--Preferred Stock

During 2000, BDS issued 462,243 shares of preferred stock for $1,010,000. The preferred stock was convertible to common stock on a one-for-one basis, was non-redeemable, and did not pay dividends. In December 2001, the Company issued 462,243 shares of common stock as replacement for the preferred stock. The 462,243 shares of preferred stock were simultaneously rescinded.

Note 10--Line of Credit

In September 2001, the Company entered into a line of credit facility with a bank. Originally the available line of credit was $250,000 and was increased to $350,000 at December 31, 2001. Interest on the line of credit accrues at a rate of prime plus 2.0%. As of June 30, 2002, the line of credit terminated and was paid in full.

Note 11--Stock Options

In October 2001, the board of directors of the Company approved a stock option plan, which covers a total of 1,100,000 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 the pro forma presentation in Note 2, 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 2002 and 2001: No dividend yield, expected volatility of 73%; risk-free interest rates of 4.50% and 5.56% and expected lives of 5 and 3 years, respectively.

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 December 31, 2000.....	--	$ --
Granted in 2001:		
Officers and Directors.....	610,983	$ 8.59
Others.....	222,112	$ 5.01
Forfeitures.....	--	$ --
Outstanding at December 31, 2001.....	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	

Outstanding Options at December 31, 2002

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price

$1.70	220,000	9.7	1.70
$2.37	150,000	10	2.37
$2.88--$3.06	390,054	3.8	3.03
$5.50	186,024	4.2	5.50
$6.60	42,563	3.9	6.60
7.00	25,000	9.5	7.00
$11.80	137,871	3.8	11.80
$17.48	137,871	3.8	17.48

Exercisable Options at December 31, 2002

Range of Exercise Prices	Number Exercisable	Weighted Average Exercise Price
$2.88	27,649	$2.88
$5.50	7,000	$5.50

The options outstanding at December 31, 2002 expire on various dates throughout 2007.

The weighted average grant date fair value of options granted during 2002 and 2001 whose exercise price is equal to the market price of the stock at the grant date was $1.19 and $1.58, 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 $1.63 in 2001. The weighted average grant date fair value of options granted during 2002 and 2001 whose exercise price is greater than the estimated market price of the stock at the grant date is $2.46 and $1.37, respectively.

Compensation expense in connection with the issuance of stock options totaled approximately $163,000 and $53,000 for 2002 and 2001, respectively.

Note 12--Income Taxes

Other than a $54,964 income tax benefit recognized in 2002 due to the carryback of net operating losses allowed as a result of the enacted tax law changes, and a $18,535 income tax benefit recognized in 2001 due to the prior year understatement of income taxes receivables, the Company has no income tax expense or benefit for 2002 and 2001 as the Company has incurred net operating losses since inception and has recognized valuation allowances for all deferred tax assets.

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

Year Ended December 31,	
2002	2001

Federal statutory income tax rate.....	34.00%	34.00%
State taxes, net of federal benefit.....	5.50	4.95
Permanent differences - compensation expense.....	(2.30)	(21.23)
Net operating loss carryback.....	1.80	--
Valuation allowance.....	(37.20)	(17.30)
	1.80%	0.42%

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, 2002	December 31, 2001
Deferred tax assets (liabilities)		
Depreciation.....	$ (61,000)	$ (21,000)
Accrued liabilities and other.....	86,000	21,000
Net operating loss carryforward.....	2,115,000	1,077,000
	2,140,000	1,077,000
Less valuation allowance.....	(2,140,000)	(1,077,000)
Net deferred tax.....	$ --	$ --

At December 31, 2002, the Company has a federal and state net operating loss carryforward of approximately $5.4 million, which principally expires beginning in 2020 and 2007 for federal and state purposes, respectively.

Note 13--Net Loss Per Common Share

The following table reconciles the numerators and denominators of the basic and diluted income per share computations. The weighted average shares outstanding at December 31, 2001 include the 520,313 shares of common stock exchanged in the Merger, which was consummated on January 7, 2002. The Company considers December 31, 2001 to be the acquisition date as the rights of ownership of BDS had been essentially transferred to BDSI, without restrictions, by that date.

	Year Ended December 31, 2002	Year Ended December 31, 2001
Net loss--(numerator).....	$(3,063,116)	$ (4,444,56

Basic:		
Weighted average Shares outstanding (denominator).....	6,057,890	3,851,58
Net loss per common share--basic.....	$ (0.51)	$ (1.1
Diluted:		
Weighted average shares outstanding.....	6,057,890	3,851,58
Effect of dilutive options.....	--	-
Adjusted weighted average shares (denominator).....	6,057,890	3,851,58
Net loss per common share--diluted.....	$ (0.51)	$ (1.1

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

Note 14--Related Party Transactions

As more fully discussed in Note 4, the company is a party to research, development and distribution agreements with related entities. During 2002, the company repaid $35,000 to BioKeys Pharmaceutical, Inc. according to terms. As

more fully discussed in Note 2, BDSI entered into a licensing agreement with a shareholder.

Note 15--National Institutes of Health Grant

In 2001, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (SBIR), which will be utilized in research and development efforts. NIH has formally awarded the Company a 2002 grant of $814,398 and a 2001 grant of $883,972. Additionally, this award refers to funding levels of $989,352 that the Company expects to be awarded in 2003, subject to availability and satisfactory progress of the project. Therefore, the Company expects to receive a total of approximately $2.7 million related to its initial application for the grant through June 2004. The initial application was for approximately $3.0 million. However, due to the expected purchase of certain materials from sources outside the United States, the expected funding was accordingly reduced. 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, the 2003 amount noted above may be reduced or eliminated. The Company incurred approximately $881,273 and $477,000 of costs related to this agreement in 2002 and 2001, respectively.

During the year ended December 31, 2002, the Company received $774,972 and recognized revenue of $811,972 related to the grant. During the year ended December 31, 2001, the Company received $479,000 (inclusive of $37,000 of

deferred revenue) and recognized revenue of $442,000 from this grant. As awarded on September 19, 2001, the grant provided for reimbursement of, or advances for, future research and development efforts. During October 2001, the Company negotiated a lump sum payment of $220,000. The terms that were negotiated in October 2001 allowed the Company to recover $220,000 of costs principally incurred in the third quarter of 2001, which were recognized as revenue upon agreement of those negotiated terms in October 2001. 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 second grant is expected to begin funding in the second quarter of 2003.

Note 16--Subsequent Events - Unaudited

On January 8, 2003, the Company formed Bioral Nutrient Delivery, LLC, a Delaware limited liability company (BND). The Company intends to grant to 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 8,600,00 Class B Shares) and certain other individuals and entities (as the holders of an aggregate of 412,500 Class B Shares).

Upon the granting of the license, 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.

On February 13, 2003, the Company 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, 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.

In March 2003, BND filed a registration statement with the SEC to distribute as a dividend to the Company's shareholders an aggregate of 3,545,431 rights to purchase a corresponding number of Class B Membership Shares, which rights are exercisable for $0.01.

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 28, 2003

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

Name: Francis E. O'Donnell Jr.
Title: Chairman, CEO and President

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 28, 2
/s/ James A. McNulty James A. McNulty	Secretary, Treasurer and Chief Financial Officer	March 28, 2
/s/ Raphael J. Mannino Raphael J. Mannino	Executive Vice President and Chief Scientific Officer and Director	March 28, 2
/s/ William B. Stone William B. Stone	Director	March 28, 2
/s/ James R. Butler James R. Butler	Director	March 28, 2
/s/ John J. Shea John J. Shea	Director	March 28, 2
/s/ L.M. Stephenson L.M. Stephenson	Director	March 28, 2

/s/ Robert G.L. Shorr ----------	Director	March 28, 2
Robert G.L. Shorr		
/s/ Alan Pearce ----------		
Alan Pearce	Director	March 28, 2

CERTIFICATION

I, James A. McNulty, hereby certify that:

1. I have reviewed the Annual Report on Form 10-KSB of BioDelivery Sciences International, Inc. (the "Registrant");

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this annual report;

4. The Registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the Registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The Registrant's other certifying officers and I have disclosed, based

on our most recent evaluation, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the Registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal controls; and

6. The Registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/James A. McNulty

James A. McNulty
Chief Financial Officer

CERTIFICATION

I, Francis E. O'Donnell, Jr., hereby certify that:

1. I have reviewed the Annual Report on Form 10-KSB of BioDelivery Sciences International, Inc. (the "Registrant");

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this annual report;

4. The Registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the Registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effe