UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-KSB

Annual Report Pursuant to Section 13 or 15 (d)
of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2001 Commission file number 0-28931

BIODELIVERY SCIENCES INTERNATIONAL, INC.

(Name of small business issuer as specified in its charter)

INDIANA	35-2089858
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer I.D. No.)

185 SOUTH ORANGE AVENUE, ADMINISTRATIVE BUILDING 4
NEWARK, NEW JERSEY 07103

(Address of Principal Executive Offices) (Zip Code)

(813) 902-8980
(Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

TITLE OF EACH CLASS

COMMON STOCK. $.001 PAR VALUE

Indicate by check mark 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 [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained herein, 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.

Yes [X] No [ ]

Issuer's revenues from continuing operations for its most recent fiscal year were $478,385.

There is no market value for the voting stock as of the date of this document.

The Issuer had 5,000,863 shares of common stock issued and outstanding as of December 31, 2001.

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 IN, 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 BIORAL TECHNOLOGY PLATFORM AND ANY PROPOSED PRODUCTS, THE DOMESTIC AND INTERNATIONAL REGULATORY PROCESS INCLUDING THE US FOOD AND DRUG ADMINISTRATION

- - 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 GENERATE COMMERCIAL ACCEPTANCE OF OUR COCHLEATE TECHNOLOGY PLATFORM AND ANY PROPOSED DRUGS PRODUCTS DERIVED THEREFROM;

- - OUR ABILITY TO CREATE DISTRIBUTION CHANNELS WHICH WILL RESULT IN SALES;

- - 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. - BUSINESS

OVERVIEW

Biodelivery Sciences International, Inc. is a development-stage 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 jellyroll-like 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 is being developed in collaboration with the University of Medicine and Dentistry of New Jersey and the Albany Medical College which have granted us the exclusive worldwide licenses under applicable patents. When wrapped in our cochleate cylinders, we anticipate that these drugs may be marketed under our brand name, "Bioral".

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

In addition to completing development of our drug delivery technology and initial Bioral products, we are also preparing an application seeking to begin Phase I clinical trials with the FDA with regard to our HIV therapy. This technology is being developed as a patient specific (autologous) therapy for treatment following HIV infection. Our autologous HIV therapy is based upon a patented proteoliposome technology which we believe facilitates uptake by cells responsible for stimulating immune responses. We believe that the ongoing research and development of this technology will require significant time and resources and we intend to primarily rely upon the availability of grants and corporate support to largely finance further development of this technology.

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 jellyroll-like structures, termed "cochleate" cylinders, after the Greek name for a snail with a spiral shell.

Bioral cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our Bioral cochleate technology are phosphatidylserine (PS) and calcium. Phosphatidylserine is a natural component of essentially all biological membranes, and is most concentrated in the brain. Clinical studies by other investigators (more than 30 have been published that we are aware of), to evaluate the potential of phosphatidylserine as a nutrient supplement indicate that PS is safe and may play a role in the support of mental functions in the aging brain. As an indication of its nontoxic nature, today phosphatidylserine isolated from soybeans is sold in health food stores as a nutritional supplement.

Research and development of cochleates has been conducted at the University of Medicine and Dentistry of New Jersey and Albany Medical College ("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 bond, 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 consists 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 at 4(LOGO) C in a cation-containing buffer, and at least one year as a lyophilized powder at room temperature.

- Cellular Delivery. Our drug delivery technology is being developed as membrane fusion intermediates. We believe that, when drugs encapsulated in our drug delivery technology come into close approximation to a target membrane, a fusion event between the outer layer of the cochleate cylinder and the cell membrane may occur. This fusion may result in the delivery of a small amount of the encochleated material into the cytoplasm of the target cell. Further, we believe that drugs encapsulated in our drug delivery

technology may slowly fuse or break free of the cell and be available for another fusion event, either with this or another cell.

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

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

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

Initial Bioral Products in Development

We plan a diverse pipeline of products to be developed by applying our drug delivery technology to a potentially broad array of established and promising pharmaceuticals. Each intended Bioral product (i.e. drug and neutraceutical encapsulated with our drug delivery technology) will, upon completion of development, require separate FDA regulatory approval, and accordingly, will be subject to the uncertainty, time and expense generally associated with the FDA regulatory process. Even though we are targeting FDA approved, market-accepted drugs for encapsulation, each of the products currently in development face, development hurdles, regulatory requirements and uncertainty before market introduction. As summarized below, we have initially targeted three potential Bioral products for development.

PRE-CLINICAL INDICATION	DRUGS	CATEGORY	DEVELOPMENT STATUS -
Systemic fungal infection	Amphotericin B	Antifungal Bioral Antimicrobial Formulation	development for Phase I Submission completed. In vitro and in vitro efficacy data initiated.
Tuberculosis and Antibacterial	Clofazimine	Bioral Antimicrobial Formulation	IND being prepared, GMP manufacturing completed Pre-clinical development in process.

In vitro and animal studies in process		
Inflammatory disease		
Bioral Anti-OTC Anti-Formulation		
Pre-clinical		
Inflammatory (such as inflammatory and in vitro development generic aspirin or studies in ibuprofen) process		

Bioral Amphotericin B. We are currently developing a Bioral product for treatment of fungal infection which we plan to submit to the FDA for a Phase I Investigational New Drug Application (IND). Our IND has not been completed and assuming that the funding is available, we estimate the filing will be made in the fourth quarter of 2002. 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 U.S.

The major types of systemic fungal infections are normally controlled and disposed of by the body's immune system. However, patients whose immune systems have been suppressed by therapies for cancer, bone marrow transplants or diseases such as AIDS can lose the ability to combat these infections. Systemic

Candidiasis, the most common type of invasive fungal infection, represents the majority of all such infections, with fatality rates between 30 and 40 percent. Aspergillosis, while occurring less frequently, is a significant threat as fatality rates for this infection range as high as 90 percent. Cryptococcal meningitis is a disease that frequently strikes patients with AIDS. The use of conventional Amphotericin B to treat these infections is often limited by its propensity to cause kidney damage which we believe our Bioral products may minimize.

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, the Public Health Research Institute of New York and the University of Texas. Further, we have been awarded a grant totaling approximately $0.9 million, with an additional $1.8 million expected to be awarded from the National Institutes of Health to support the further development of this drug.

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

We are targeting clofazimine, an off-patent oral drug, and may target other drugs no longer under patent protection which treat tuberculosis, for potential encapsulation in our drug delivery technology. The primary advantages which we are seeking for our proposed Bioral Clofazimine product include increased oral bio-availability, reduce required dosage and decrease side effects. Assuming that we complete development of this Bioral drug and that we obtain FDA approval, we believe that it may provide an effective, orally administered version of a tuberculosis agent such as clofazimine. This Bioral product in development may be administered orally, be more effective and have fewer side effects. We are currently in pre-clinical development of a Bioral encapsulated clofazimine in collaboration with the University of Chicago. Our development for the proposed Bioral Clofazamine has not been completed. We estimate that the preparation of an IND will be completed in the first quarter of 2003 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 Bioral products, based upon accepted, unpatented, over-the-counter, anti-inflammatory drugs such as generic aspirin or ibuprofen. Various types of over-the-counter ("OTC") anti-inflammatory compounds are currently available. Nonsteroidal anti-inflammatory drugs ("NSAIDs") significantly decrease inflammation at higher dosages.

We believe that our drug delivery technology can be used to effectively deliver anti-inflammatory drugs with reduced side effects. The primary advantages which we are seeking for our proposed Bioral anti-inflammatory products include reduced gastrointestinal side effects, reduce required dosage and improve 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 IND for our proposed Bioral Anti-Inflammatories has not been completed and we believe that the earliest that we may begin the preparation of an IND would be the first quarter of 2003 assuming the data in pre-clinical trials are favorable and funding is available.

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 (proteoliposone) 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 fourth quarter of 2002 assuming the data in pre-clinical trials are favorable and 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, 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 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. There are no further requirements to provide either university any additional equity interest.

The license agreement 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 3% of our net sales;

(b) For commercial sales made by any of our sublicensee, we shall pay to the universities royalties up to 25% of our revenues received from the sublicensee from the sale of the product;

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 located on their campus pursuant a lease agreement ending December 31, 2005. We occupy a total of approximately 8,000 square feet. The monthly rent is $3,340 for the first year; $3,840 for the second year; $4,340 for the third year; $4,840 for the fourth year and $5,340 for the fifth year. Additionally, we owe payments for graduate student assistants, personnel provided by the university and supplies used by us on an ongoing basis. Research assistants and personnel provided to us are university employees and they belong to various unions on campus.

In addition to our rent payments, we have also agreed to pay for certain other services provided by the university totaling approximately $100,000 annually. 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 totaling $7,347.

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:

- National Institutes of Health. To investigate the properties of new antifungal and anti-staphylococcal cochleate formulations. Grants totaling approximately $2.7 million have been or are expected to be awarded, to us by NIH for the development of our proposed Amphotericin B product of which we have been awarded $0.9 million. 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 and anti-staphylococcal applications of our drug delivery technology. This relationship may involve shared expense reimbursement and shared intellectual property with regard to joint inventions.

- Institute for Tuberculosis Research, University of Illinois at Chicago. To support our development of Bioral Clafozimine product and other anti-tuberculosis cochleate formulations. This relationship may involve shared intellectual property with regard to joint inventions.

- University of Utrecht. To study and quantify pursuant to a Material Transfer Agreement, the various aspects of drug delivery using our technology. This relationship may involve expense reimbursement and shared intellectual property with regard to joint inventions.

- Erasmus University of Rotterdam. To develop the cochleate as a delivery system for glycopeptides

- Avanti Polar Lipids, Inc. To supply lipids which is a required material for the manufacture of our drug delivery technology.

- Octo Plus Pharmaceutical Development, B.V. To supply Amphoterican cochleates under Good Manufacturing Practice for our anticipated Phase I clinical trials

We also have agreements with entities that are affiliated with and partially-owned by key members of our management to conduct research and develop certain technologies. See "Certain Relationships and Related Transactions" for affiliations with our management. As of March 6, 2002, 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 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. The following are the related-party agreements:

- 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 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 neutraceuticals product 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 technology. Tatton Technologies, LLC may sublicense our drug delivery technology to third parties to incorporate into their 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 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 license shall remain in effect as long as BioKey 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 products once we have completed the commercialization of our products. Our financial arrangement with Biotech Specialty Partners, LLC requires us to sell to Biotech Specialty Partners, LLC all of our products, as and when purchased by with Biotech Specialty Partners, LLC 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. Biotech Specialty Partners, LLC 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 the greater of the "base royalty" (as defined in the agreement) or 30% of all pre-tax profits plus 30% of all net proceeds, if any, from the sale, assignment or sub-license 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 30% of all net profits from the sale, assignment or sub-license for the authorized use of our technology incorporated into their proposed neutraceuticals 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 entitled to a 10% royalty on its net adjusted royalty received from BioKeys Pharmaceuticals, Inc.'s marketing partner, if any, for the injectable form of the vaccine and 20% royalty for the oral form of the vaccine. If BioKeys Pharmaceuticals, Inc. directly markets the product incorporating our technology, we will share a profit of 15% for the injectable form, 20% for a "non-proprietary (liposomal) oral form", and 30% for a cochleate oral form of the product. The agreement provides for license payments in the amount of $341,000. We have also received a $35,000 loan from BioKeys Pharmaceuticals, Inc. to begin research on BioKeys Pharmaceuticals, Inc.

products incorporating our technology. The loan is in the form of a demand note with an interest rate of 1% plus prime. 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.

LICENSES, PATENTS AND PROPRIETARY INFORMATION

We are the exclusive licensee of eight issued United States patents and two foreign issued patents owned by the parties listed in the chart below. We believe that our licenses to this intellectual property will enable us to develop this new drug delivery technology based upon cochleate and cochleate related technology. Our intellectual property strategy is intended to maximize our potential patent portfolio, license agreements, proprietary rights and any future licensing opportunities we might pursue. With regard to our Bioral cochleate technology, we intend to seek patent protection for not only our delivery technology, but also potentially for the combination of our delivery technology with various drugs no longer under patent protection. Below is a table summarizing patents we believe are currently important to our business and technology position.

PATENT NUMBER ISSUED EXPIRES	TITLE	PATENT OWNER
US06,165,502 12/26/2000 9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,153,217 11/28/2000 1/22/2019	Nanocochleate formulations, process of preparation and method of pharmaceutical agents	BioDelivery Sciences International, Inc., The University of Medicine delivery of and Dentistry of New Jersey
AUS722647 11/23/2000 9/02/2017	Protein-lipid vesicles and autogenous immunotherapeutic	The University of Medicine and Dentistry of New Jersey and

Albany comprising the same	Medical College	US05,994,318	11/30/1999	11/24/2015
Cochleate delivery vehicles and	The University of Medicine and Dentistry of New Jersey and Albany Medical College	US05,840,707	11/24/1998	11/24/2015
Stabilizing and delivery means of molecules	The University of biological Medicine and Dentistry of New Jersey and Albany Medical College	US05,834,015	11/10/1998	9/11/2016
Protein-lipid vesicles and immunotherapeutic comprising the same	The University of autogenous Medicine and Dentistry of New Jersey and Albany Medical College	AUS689505	7/16/1998	9/30/2014
Protein- or peptide- cochleate delivery vehicles and immunotherapeutics	The University of Medicine and Dentistry of New Jersey and Albany Medical College	US05,994,318	11/30/1999	11/24/2015
Cochleate delivery vehicles and methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College	US05,840,707	11/24/1998	11/24/2015

PATENT NUMBER ISSUED EXPIRES TITLE PATENT OWNER
US05,643,574 07/01/1997 7/01/2014 Protein- or peptide- The University of cochleate Medicine and Dentistry of immunotherapeutics and New Jersey and Albany methods of immunizing Medical College using the same
US04,871,488 10/03/1989 10/03/2006 Reconstituting viral Albany Medical College glycoproteins into large phospholipid vesicles
US04,663,161 05/05/1987 4/22/2005 Liposome methods and Albany Medical College compositions

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 assure 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. Litigation to establish the validity of patents, to defend against infringement claims or to assert infringement claims against others can be lengthy and expensive, even if a favorable result is obtained. Moreover, much of our expertise and technology cannot be patented.

We also rely on trade secrets and confidentiality agreements with collaborators, advisors, employees, consultants, vendors and other service providers.

We filed a trademark registration for our proposed brand name, Bioral, which we plan to establish as our brand to use in conjunction with all of our potential oral delivery drugs. There can be no assurance it will be issued.

HISTORY OF OUR TECHNOLOGY

Below is a table summarizing technology development milestones:

April	1995	BioDelivery Sciences, Inc. obtained the worldwide exclusive rights to the Bioral cochleate technology owned by the Universities.
September	1995	BioDelivery Sciences, Inc. was awarded a vaccine research

		grant from Wyeth Lederle Vaccines, an affiliate of American Home Products and American Cyanamid Company.
September	1995	BioDelivery Sciences, Inc. established a Research Agreement with the University of Medicine and Dentistry of New Jersey.
June	1996	BioDelivery Sciences, Inc. established research and development, and License Agreement for Vaccines with Wyeth Lederle Vaccines which expired in December 1999.
August	1996	BioDelivery Sciences, Inc. 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	BioDelivery Sciences, Inc. 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.
July	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 Tuberculosis Research, University of Illinois of Chicago, drug delivery.
November	2000	A U.S. Patent No 722,647 to the Universities. AUTOGENOUS VACCINE (HIV)
November	2000	U.S. Patent No. 6,153,217 issued to BioDelivery Sciences, Inc. and the University of Medicine and Dentistry of New Jersey. NANOCOCHLEATE FORMULATIONS. Initiate process for preparation of Investigational New Drug Application 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 delivery.
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 delivery.
May	2001	Signed a MTA with PHRI, NY to develop the cochleates for the treatment of Staphylococcus, drug delivery.
June	2001	Signed a MTA with EUR Erasmus University of Rotterdam, The Netherlands, to develop the cochleates for the treatment of Staphylococcus, drug delivery.
June	2001	License Agreement with Retina Pharma International, Inc. and Tatton Technology, LLC, affiliates of Dr. O'Donnell a stockholder, director and officer, for such entities to potentially use our technology to encapsulate their proprietary therapies for potential of certain neurodegenerative diseases.
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.

COMPETITION

The biopharmaceutical industry in general is competitive and subject to rapid and substantial technological change. Developments by others may render our proposed technology and 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 develope potentially competitive technologies. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more research capabilities, marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing development-stage pharmaceutical or biotechnology companies by large corporations could increase such competitors' research, financial, marketing, manufacturing and other resources.

While many development activities are private, 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), a publicly-traded company and Nobex, a privately-held company. We believe that these potential competitors are seeking to develop and commercialize technologies for the oral delivery of drug 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 lipid soluble) compounds with limited customization for each specific drug.

We believe that our technology may have cell-targeted delivery attributes. Additional companies which are developing potentially competitive technologies in this area may include Valentis (NASDAQ: VLTS) and Enzon (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 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.

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. With regard to our intended Amphotericin B product, we have entered into a manufacturing agreement with Octo Plus, Inc. Under our agreement, Octo Plus, Inc. will manufacture our encochleated Amphotericin B for use in clinical and preclinic trials. Manufacturing by Octo Plus, Inc. is required to comply with Good Manufacturing Practices with demonstrated scale-up capability for submission to the FDA. To date, we have not entered into

manufacturing arrangements for any other intended Bioral product. As our intended products near market introduction, we intend to outsource manufacturing to third party manufacturers, which comply with the FDA's applicable Good Manufacturing Practices. While we believe that such commercial manufacturing arrangements may be available, no such relationships have been establish to date.

We intend to purchase component raw materials from various suppliers. With regard to our lipids, we have a supply relationship with Avanti Polar Lipids, Inc. which we believe is capable of meeting our anticipated requirements during clinical trials. Avanti Polar Lipids, Inc. is located in Alabaster, Alabama. As our intended products near market introduction, we intend to seek multiple suppliers of all required components.

In the event that Avanti Polar Lipids, Inc. fails to provide us with the necessary supply of required lipids, we would have difficulty replacing such supply in a timely manner which could negatively affect our research and production capabilities.

SALES AND MARKETING

Our marketing strategy, assuming completion of our drug delivery technology and product development and regulatory approval, is to market each of our approved orally delivered products under the Bioral brand name. Marketing may be conducted through a wide range of potential arrangements such as licensing, direct sales, co-marketing, joint venture and other arrangements. Such arrangements may be with large or small pharmaceutical companies, general or specialty distributors, biotechnology companies, physicians or clinics, or otherwise. We have a non-exclusive distribution arrangement with Biotech Specialty Partners, LLC ("BSP"). 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 Drug License Application to the FDA; and

5. FDA approval of the New Drug Application or Biologic Drug 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. With regard to Bioral Clofazimine, our pre-clinical trials are being coordinated by the Institute for Tuberculosis research, University of Illinois at Chicago. To date, we have not established any relationship with regard to pre-clinical testing of our intended Bioral anti-inflammatory products.

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 is found to 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 Bioral 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 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 as Phase IV 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 FDA. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of drugion 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.

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 December 31, 2001, we had eight full-time employees, of which six are scientists and two are administrative. Three of these scientists have Ph.D. degrees. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our engineering and support and administrative functions. We consider relations with our employees to be good. Each of our current scientific personnel has entered into confidentiality and non-competition agreements with us.

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 for the fiscal year ended December 31, 2001. These payments are expected to be approximately $100,000 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 are not subject to any pending legal actions. However, in May 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 founder, officer, director and more than 10% stockholder of Biodelivery Sciences, Inc. A dispute arose between Mr. Berstein and the remaining management team of Biodelivery Sciences, Inc. which was considered to be disruptive to the ongoing operation of Biodelivery Sciences, Inc. The litigation was based upon various legal theories arising out of Mr. Berstein's conduct as an officer and director of Biodelivery Sciences, Inc., the terms and enforceability of certain agreements between Mr. Berstein and Biodelivery Sciences, Inc., the termination of employment of Mr. Berstein as an employee and officer of Biodelivery Sciences, Inc. and the subsequent issuance of stock by Biodelivery Sciences, Inc. to stockholders other than Mr. Berstein. The litigation involved both direct claims by Mr. Berstein against Biodelivery Sciences, Inc. and certain members of management individually and counterclaims by Biodelivery Sciences, Inc. against Mr. Berstein. Claims for compensation for past and future services and under long term contracts were alleged. Further, Mr. Berstein alleged that an issuance of stock to other stockholders of Biodelivery Sciences, Inc. except him around the time of his termination was inappropriate and dilutive. Mr. Berstein alleged an entitlement to additional shares of stock to prevent dilution to him. In the settlement, all claims of Mr. Berstein and the counterclaims against Mr. Berstein were fully resolved and we purchased Mr. Berstein's entire stock position in Biodelivery Sciences, Inc.

The settlement required that we pay $150,000 in cash and $125,000 by promissory note. At the same time, we purchased the shares of BioDelivery Sciences, Inc. held by these plaintiffs for $500,000 which was paid $200,000 in cash and $300,000 by promissory note. As part of the settlement, there is a lien upon all of our assets until all of the outstanding promissory notes have been paid.

We have received notification of a potential claim for a finder's fee arising out of an introduction to BioDelivery Sciences, Inc. in 2000. While litigation has not been, and may not be, instituted against us, settlement discussions have been conducted. Informal telephonic settlement discussions, which have been inactive for the last several months, ranged between an approximately $120,000 cash demand upon us to our counter-offer of approximately $5,000 in cash and 5,000 shares of stock. We do not know if the matter will be settled, litigated or remain inactive. If litigation is instituted against us, or if settlement is reached, the damages sought or obtained may be different or greater than that previously discussed in settlement negotiations. We intend to vigorously defend any litigation. It is our belief that the potential claim is neither material nor meritorious.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We held our annual shareholders' meeting on October 1, 2001. The following matters were approved by our shareholders:

1) Election of directors.

Dr. Francis E. O'Donnell, Dr. Raphael J. Mannino, L.M. Stephenson, and William Stone were elected directors.

2) Adoption of the 2001 incentive stock option plan and reservation of 2,500,000 shares prior to the pending reverse split of common stock thereunder.

There were 14,932,600 votes prior to the pending reverse split for, zero votes against, and none abstained.

3) Adoption of an amendment to the Articles of Incorporation to reverse split the Company's common stock on a structured basis or on such other basis or such other amount as the board of directors may determine in its discretion.

There were 14,932,600 votes prior to the pending reverse split for, zero votes against, and none abstained.

PART II

ITEM 5. - MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is not publicly traded on any market and no trading symbol has been assigned to us. As of July 31, 2001, we had approximately 200 holders of record of our common stock. No dividends have been paid on the common stock to date. We currently intend to retain any earnings for further business development.

We have filed a registration statement on Form SB-2 with the Securities and Exchange Commission seeking to register 2,000,000 units, with each unit consisting of one share of our common stock and warrant ("Unit"). Each warrant entitles the holder to purchase one share of common stock subject to earlier redemption by us. The final exercise price and terms will be set in the registration statement once we go effective. At the date hereof, the registration statement is not effective. In connection with this offering, we have reserved the symbols BDSI, BDSIA and BDSIU.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS AND 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 Form 10-KSB. 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 set forth under "Risk Factors" and elsewhere in this Form 10-KSB.

LIMITED OPERATING HISTORY; BACKGROUND OF OUR COMPANY

We are a development-stage company and we expect to continue research and development of our drug delivery technology. As such, we do not anticipate any revenues from the sale or commercialization of our products under development within the next 12 months. The funding will come primarily from the sale of securities, collaborative research agreements, including pharmaceutical companies, grants from public service entities and government entities.

In 2001, the National Institutes of Health awarded us a Small Business Innovation Research Grant, which will be utilized in our research and development efforts. NIH has formally awarded us a 2001 grant of $883,972, of which we have received approximately $479,000 in 2001 and $222,000 in 2002. 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, the total expected funding amounts noted above may be reduced or eliminated.

Prior to our acquisition of a majority interest in BioDelivery Sciences, Inc., we had no operations. For the foreseeable future, we must, among other things, seek regulatory approval for and commercialize our drugs, which may not occur. We may not address these risks and difficulties. We may require additional funds to complete the development of our drugs and to fund operating losses to be incurred in the next several years.

Our operations include the results of operations of BioDelivery Sciences, Inc. which we refer to as BioDelivery Sciences Inc. BioDelivery Sciences Inc. was incorporated in Delaware in March 1995. Effective October 10, 2000, we acquired Series A Preferred Stock of BioDelivery Sciences Inc. for an aggregate purchase price of $15,000,000, consisting of $1,000,000 in cash and a note of $14,000,000. Through the purchase of the Series A Preferred Stock, we acquired 84.8% of the voting rights of BioDelivery Sciences Inc. Prior to our acquisition of our interest in BioDelivery Sciences Inc., we had no operations. All of the science related to our drug delivery technology has been developed through BioDelivery Sciences Inc. and its relationship with the University of Medicine and Dentistry of New Jersey and Albany Medical College.

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 voting rights of BioDelivery Sciences, Inc.) of the common stock of BioDelivery Sciences Inc. This purchase settled outstanding litigation with a former officer and stockholder group.

Further, in December 2001 we entered into a merger agreement with BioDelivery Sciences Inc. and the remaining stockholders of BioDelivery Sciences Inc. received 520,313 shares of our common stock. The merger was consummated on January 7, 2002. As a result of the merger, the Series A preferred stock of

BioDelivery Sciences Inc. which was owned by us was cancelled, as well as the outstanding $14,000,000 note issued in payment thereof.

On a combined basis (our company and BioDelivery Sciences, Inc.) since inception through December 31, 2001, we received approximately $7.9 million of sponsored research revenue. $6.7 million of the funding was from a single commercial entity, American Cyanamid Company. The contract with American Cyanamid Company was completed, as amended, in 2000. Of the remaining $1.2 million, approximately $0.5 million was received from the National Institutes of Health.

FOR THE YEAR ENDED DECEMBER 31, 2001 COMPARED TO THE YEAR ENDED DECEMBER 31, 2000 (WHICH INCLUDES OUR OPERATIONS AFTER THE ACQUISITION OF OUR CONTROLLING INTEREST IN BIODELIVERY SCIENCES, INC.)

Sponsored Research Revenue. During the years ended December 31, 2000 and 2001, we recognized sponsored research revenue of $56,000 and $478,000, respectively. The 2000 revenue was derived from a research agreement that has since been terminated. The 2001 revenue amount was derived from the National Institutes of Health Small Business Research Grant awarded to us in 2001. The total grant amount is $884,000, of which we expect to receive the remaining amount by June 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, 2000 and 2001, research and development expenses totaled $313,000 and $1,664,000, respectively. The increase was due to our increased development and application of Bioral cochleate technology and other drug-related areas. Funding of this research was obtained through sponsored research revenue, common stock issuance and line of credit borrowings. 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. We are unable to track costs on a project by project basis as our accounting system does not allow us to do so. 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.

General and Administrative Expenses. During the years ended December 31, 2000 and 2001, general and administrative expenses totaled $540,000 and $3,256,000, respectively. The increase is primarily due to compensation expense of $2,137,000 recognized related to the BioDelivery Sciences Inc. permanent discount redeemable common stock. This stock represents a variable stock award and will continue to require variable plan accounting until the related stockholder loans are forgiven or paid. To the extent that related stockholder loans are forgiven, which is anticipated in 2002 upon the completion of our proposed public offering of our securities or the fair market value of our common stock exceeds $5.50 per share (the value assigned to a share of our common stock at December 31, 2001) prior to the loan forgiveness date, additional compensation expense will be recognized. 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, 2000 and 2001, interest income (expense), net totaled $22,000 and $(22,000), respectively. The increase in interest income (expense), net is primarily due to an increase in the average outstanding borrowings in 2001 versus 2000.

Income Tax Benefit. We recognized an income tax benefit of $18,000 in 2001 for a previous year's income tax receivable understatement. While net operating losses were generated during the year ended December 31, 2001, we did not recognize any benefit associated with these losses. We had federal and state net operating loss carryforwards of $2.7 million at December 31, 2001. 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.

Minority Interest. Minority interest relates to the amount of loss that is attributable to the common stockholders of BioDelivery Sciences, Inc. and is limited to the minority interest in the equity of BioDelivery Sciences, Inc. In 2000, we recognized $103,000 of minority interest losses of subsidiary. In 2001, no minority interest in losses of subsidiary was recognized due to the minority interest in the equity of BioDelivery Sciences, Inc. being zero throughout 2001. In addition, as a result of a litigation settlement and the merger of the Company with BioDelivery Sciences, Inc., the minority interest in BioDelivery Sciences, Inc. no longer exists. The Company and BDS consummated a merger on January 7, 2002. However, the merger agreement was entered into and accounted for as of December 2001.

PRO FORMA ANALYSIS FOR THE YEAR ENDED DECEMBER 31, 2001 COMPARED TO THE YEAR ENDED DECEMBER 31, 2000

The following pro forma discussion was derived from our historical financial statements combined with those of BioDelivery Sciences, Inc. included elsewhere in this prospectus. With regard to the year ended December 31, 2000, the amounts include the historical results of operations of BioDelivery Sciences, Inc. for the nine month period ended September 30, 2000 and our results of operations for the year ended December 31, 2000. With regard to the year ended December 31, 2001, the amounts are the historical results of operations of our Company.

Sponsored Research Revenue. Revenue decreased from $670,000 for the year ending December 31, 2000 to $479,000 for the year ending December 31, 2001. Revenue during both periods was principally generated from a collaborative research agreement and certain grants, and was recognized as the related costs were incurred.

Research and Development Expenses. Research and development expenses increased from $1.1 million for the year ended December 31, 2000 to $1.7 million for the year ended December 31, 2001. The increase was due to our increased development and application of Bioral cochleate technology and other drug-related areas. Funding of this research was obtained through sponsored research revenue, common stock issuance and line of credit borrowings. 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. We are unable to track costs on a project by project basis as our accounting system does not allow us to do so.

General and Administrative Expenses. General and administrative expenses increased from $603,000 for the year ended December 31, 2000 to $3.3 million for the year ended December 31, 2001. The increase is primarily due to compensation expense of $2.1 million recognized in 2001 related to the BioDelivery Sciences Inc. permanent discount redeemable common stock. This stock represents a variable stock award and will continue to require variable plan accounting until the related shareholder loans are forgiven or paid. To the extent that related stockholder loans are forgiven or the fair market value of our common stock exceeds $5.50 per share prior to the loan forgiveness date, additional compensation expense will be recognized. 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. Interest Income (Expense), Net decreased from $47,000 for the year ended December 31, 2000 to $(22,000) for the year ended December 31, 2001. The decrease in interest income (expense), net is primarily due to an increase in the average outstanding borrowings and decrease in the average outstanding cash balances in 2001 versus 2000.

Income Tax Benefit. The Company recognized an income tax benefit of $18,000 in 2001 for the previous year's income tax receivable understatement. The Company recognized an income tax benefit of $38,000 in 2000 which was attributable to net operating losses that were carried back to periods in which taxes were paid.

Minority Interest. Minority interest relates to the amount of loss that is attributable to the common stockholders of BioDelivery Sciences, Inc. and is limited to the minority interest in the equity of BioDelivery Sciences, Inc. subsequent to the Company's October 2000 84.8% acquisition of BioDelivery Sciences, Inc. In 2000, the Company recognized $103,000 of minority interest losses of subsidiary. In 2001, no minority interest in losses of subsidiary was recognized due to the minority interest in the equity of BioDelivery Sciences, Inc. being zero throughout 2001. In addition, as a result of a litigation settlement and the merger of the Company with BioDelivery Sciences, Inc., the

minority interest in BioDelivery Sciences, Inc. no longer exists. The Company and BDS consummated a merger on January 7, 2002. However, the merger agreement was entered into and accounted for as of December 2001.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, we have financed our operations primarily from the sale of our convertible preferred stock and common stock. From inception through December 31, 2001, we raised approximately $1.8 million, net of issuance costs, through private placements or convertible preferred stock and common stock financings. At December 31, 2001, we had cash and cash equivalents totaling approximately $76,000. At February 28, 2002, we had cash and cash equivalents totalling approximately $30,000.

In 2001, the National Institutes of Health awarded us a Small Business Innovation Research Grant, which will be utilized in our research and development efforts. NIH has formally awarded us a 2001 grant of $883,972, of which we have received approximately $479,000 in 2001 and received $222,000. Additionally, this award refers to funding levels of $814,398 and $989,352 that we expect to be awarded in 2002 and 2003, respectively, 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. Our initial application was for approximately $3.0 million. However, due to our proposed purchase of certain materials from sources outside the United States, the funding was accordingly reduced because NIH grants require materials to be purchased from U.S. based entities. 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, the 2002 and 2003 amounts noted above may be reduced or eliminated in its sole discretion.

On a pro forma basis (our results combined with BDS) we used $253,000 of cash for operations in 2000 compared to $1.6 million of cash used for operations in 2001. On a pro forma basis (BioDelivery Sciences, Inc. combined with us) we have used $1.2 million of cash for operations since inception through December 31, 2001, net of sponsored research proceeds received since inception of $7.9 million. We have 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.

Since our inception through December 31, 2001, we have incurred approximately $2.0 million of research and development expenses. Additionally, during the period March 28, 1995 (date of BioDelivery Sciences, Inc.'s incorporation) through the acquisition of a controlling interest in BioDelivery Sciences, Inc. in October 2000, we incurred approximately $6.8 million of research and development expenses.

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 University of Medicine and Dentistry of New Jersey.

We have also obtained a $650,000 line of credit personally guaranteed by Dr. Francis O'Donnell, our President and CEO and Donald Ferguson, our Senior Executive Vice President, at a rate of prime plus 2% that matures in May 2002. At February 28, 2002, $478,000 was outstanding under the credit line.

We have incurred significant net losses and negative cash flows from operations since our inception. As of December 31, 2001, we had an accumulated deficit of approximately $5.1 million and our working capital deficit at December 31, 2001 was $1.2 million.

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 drugs. While we believe further application of our Bioral cochleate technology to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, our plan of operations in the next 18 months is focused

on our further development of the Bioral cochleate technology itself and its use in a limited number of applications, and not on the marketing, production or sale of FDA approved products.

We entered into a Letter of Intent with Roan/Meyers Associates, L.P., a registered broker dealer pursuant to which they have agreed to underwrite, on a firm committent basis 2,000,000 units, at an offering price between $5.00 and $6.00 per unit. Each unit consists of (i) one share of common stock and (ii) one redeemable common stock purchase warrant. We also granted the underwriter, an option to purchase an additional 300,000 units to cover overallotments. There can not be any assurances that the public offering will be consummated at all and if it is consummated, at what prices and in what amounts.

We believe that our existing cash and cash equivalents, together with available equipment financing and the net proceeds of a public offering will be sufficient to finance our planned operations and capital expenditures through at least the next 12 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;

- 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 drugs, technologies 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 Statement of Financial Accounting Standards (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 that Statement applied to goodwill and other intangible assets acquired between July 1, 2001 and the effective date of SFAS 142. We do not believe that these standards will have any material effect on our financial statements.

In July 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. This statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This Statement applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. This Statement is effective for financial statements issued for fiscal years beginning after June 15, 2002. The Company is evaluating the impact of the adoption of this standard and has not yet determined the effect of adoption on its financial position and results of operations.

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 do not believe that this statement will have any material effect on our financial statements.

RISK FACTORS

You should carefully consider the following risks, in addition to the other information presented in this Form 10-KSB. If any of the following risks actually materialize, our business and prospects could be seriously harmed in connection with an evaluation of our business. A more complete statement of risks can be found in our pending registration statement filing with the SEC filed under Form SB-2.

RISKS RELATED TO OUR TECHNOLOGIES

THE FAILURE TO COMPLETE DEVELOPMENT OF OUR DRUG DELIVERY TECHNOLOGY, OBTAIN GOVERNMENT APPROVALS, INCLUDING REQUIRED FDA APPROVALS, OR TO COMPLY WITH ONGOING GOVERNMENTAL REGULATIONS COULD DELAY OR LIMIT INTRODUCTION OF OUR PROPOSED PRODUCTS AND RESULT IN FAILURE TO ACHIEVE REVENUES OR MAINTAIN OUR ONGOING BUSINESS.

Our research and development activities, the manufacture and marketing of our intended products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA clearance to market our proposed products, we will have to demonstrate that our products are safe and effective on the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical trials and regulatory approval can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources.

In order to be commercially viable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our technologies. For each drug encapsulated with our drug delivery technology and for the HIV therapy, as the case may be, we must successfully meet a number of critical developmental milestones, including:

- demonstrate benefit from delivery of each specific drug through our drug delivery technology,

- demonstrate through pre-clinical and clinical trials that our drug delivery technology and our patient specific HIV therapy is safe and effective,

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

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

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

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

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

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

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

RISKS RELATING TO OUR BUSINESS

SINCE WE HAVE A LIMITED OPERATING HISTORY AND HAVE NOT GENERATED ANY REVENUES FROM THE SALE OF PRODUCTS TO DATE, YOU CANNOT RELY UPON OUR PAST PERFORMANCE TO MAKE AN INVESTMENT DECISION.

Since our inception in January 1997 and through December 31, 2001, we have recorded operating losses totaling approximately $5,117,367. As of December 31, 2001, we had a working capital deficit of ($1,185,268) and a stockholder's deficit of ($208,998). In addition, we expect to incur increasing operating losses over the next several years as we continue to incur increasing costs for research and development and clinical trials. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products.

We have not generated any revenue from the commercial sale of our proposed products or any encapsulated drugs and do not expect to receive such revenue in the near future. Our primary activity to date has been research and development. All revenues to date are from grants, both public and private and collaborative agreements. We cannot be certain as to when or whether to anticipate commercializing and marketing our proposed products in development, and do not expect to generate sufficient revenues from proposed product sales to cover our expenses or achieve profitability in the near future.

WE RELY SOLELY ON THE FACILITIES OF THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY FOR ALL OF OUR RESEARCH AND DEVELOPMENT, WHICH COULD BE MATERIALLY DELAYED SHOULD WE LOSE ACCESS TO THOSE FACILITIES.

We have no research and development facilities of our own. As of the date of this prospectus we are entirely dependent on third parties to use their facilities to conduct research and development. To date, we have relied on the University of Medicine and Dentistry of New Jersey and Albany Medical College for this purpose. Additionally, these universities own certain of the patents to our drug delivery technology. Our inability to conduct research and development may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technology and products.

We do not currently have plans nor are we planning in the near future, to relocate out of our offices and research facilities at the University of Medicine and Dentistry of New Jersey. We currently maintain a good working relationship with the University of Medicine and Dentistry. Should the situation change and we are required to relocate on short notice, we do not currently have an alternate facility where we could relocate. The cost and time to establish or locate an alternative research and development facility to develop our technology, other than through the universities, would be substantial and would delay gaining FDA approval and commercializing our products.

WE ARE DEPENDENT ON OUR COLLABORATIVE AGREEMENTS FOR THE DEVELOPMENT OF OUR DRUG DELIVERY TECHNOLOGY AND BUSINESS DEVELOPMENT WHICH EXPOSES US TO THE RISK OF RELIANCE ON THE VIABILITY OF THIRD PARTIES.

In conducting our research and development activities, we rely upon numerous collaborative agreements with universities, governmental agencies, manufacturers, contract research organizations and corporate partners. The loss of or failure to perform under any of these arrangements, by any of these entities, may substantially disrupt or delay our research and development activities including our anticipated clinical trials.

We have a license agreement with the University of Medicine and Dentistry of New Jersey and Albany Medical College in which they grant us exclusive license to conduct research and development of the drug delivery technology. Our research facilities are also located on the premises of the University of Medicine and Dentistry of New Jersey pursuant to a research agreement.

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

REQUIREMENTS IMPOSED BY OUR NATIONAL INSTITUTES OF HEALTH GRANT COULD DELAY OR HINDER OUR ABILITY TO DEVELOP OUR AMPHOTERICIN B PRODUCT OR RECEIVE ADDITIONAL FUNDING.

In 2001, the National Institutes of Health awarded us a Small Business Innovation Research Grant (SBIR), which will be utilized in our research and development efforts. NIH has formally awarded us a grant of $883,972 of which we have received approximately $479,000 in 2001 and expect to receive the remainder through June 2002. Additionally, this award refers to future funding levels of $814,398 and $989,352 that we expect to be awarded in 2002 and 2003, respectively, subject to availability and satisfactory progress of the project in NIH's opinion. 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 2002 and 2003 amounts noted above may be reduced or eliminated in their entirety at NIH's sole discretion.

KEY COMPONENTS OF OUR DRUG DELIVERY AND AUTOLOGOUS HIV THERAPY TECHNOLOGIES MAY BE PROVIDED BY SOLE OR LIMITED NUMBERS OF SUPPLIERS, AND SUPPLY SHORTAGES OR LOSS OF THESE SUPPLIERS COULD RESULT IN INTERRUPTIONS IN SUPPLY OR INCREASED COSTS.

Certain components used in our research and development activities such as lipids are currently purchased from a single or a limited number of outside sources. For example, we currently purchase our lipid supplies from Avanti Polar Lipids. The reliance on a sole or limited number of suppliers could result in:

- potential delays associated with research and development and clinical and pre-clinical trials due to an inability to timely obtain a single or limited source component;

- potential inability to timely obtain an adequate supply of required components; and

- potential of reduced control over pricing, quality and timely delivery.

We do not have long-term agreements with any of our suppliers, and therefore the supply of a particular component could be terminated without penalty to the supplier. Any interruption in the supply of components could cause us to seek alternative sources of supply or manufacture these components internally. If the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required timeframes, if at all, to meet our needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing; or cause us to lose sales, incur additional costs, delay new product introductions or harm our reputation.

Further, components from a new supplier may not be identical to those provided by the original supplier. Such differences if they exist could affect product formulations or the safety and effect of our products that are being developed.

As of the date of this prospectus and based upon our discussions with these suppliers, we do not foresee nor have any current reason to believe that there will be any meaningful interruption, delay, or termination of supplies.

WE MAY HAVE DIFFICULTY RAISING NEEDED CAPITAL IN THE FUTURE BECAUSE OF OUR LIMITED OPERATING HISTORY AND BUSINESS RISKS ASSOCIATED WITH OUR COMPANY.

Our business currently does not generate any sales from our proposed products and revenue from grants and collaborative agreements may not be sufficient to meet our future capital requirements. We do not know when this will change. We have expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of our drug delivery technology and autologous HIV immunotherapeutic. We will require additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials, commercial-scale manufacturing arrangements

and to provide for the marketing and distribution of our products. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from any available source, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs or product launches or marketing efforts which may materially harm our business, financial condition and results of operations.

RISKS RELATED TO OUR INDUSTRY

THE MARKET FOR OUR PRODUCTS IS RAPIDLY CHANGING AND COMPETITIVE, AND NEW DRUG DELIVERY MECHANISMS, DRUG DELIVERY TECHNOLOGIES, NEW HIV THERAPEUTICS, NEW DRUGS AND NEW TREATMENTS WHICH MAY BE DEVELOPED BY OTHERS COULD IMPAIR OUR ABILITY TO MAINTAIN AND GROW OUR BUSINESS AND REMAIN COMPETITIVE

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and intended products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

We are a development-stage enterprise and are engaged in the development of novel drug delivery and therapeutic technologies. As a result, our resources are limited and we may experience technical challenges inherent in such novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our technology. Our competitors may develop drug delivery technologies and drugs that are safer, more effective or less costly than our intended products and, therefore, present a serious competitive threat to us.

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

ITEM 7. FINANCIAL STATEMENTS

See pages F-1 through F-25.

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

Our directors and executive officers and their ages as of March 1, 2002 are as follows:

NAME	AGE	POSITION(S) HELD
- Francis E. O'Donnell, Jr., M.D.	52	President, Chief Executive Officer, Chairman, and Director
Raphael J. Mannino, Ph.D.	55	Executive Vice President, Chief Scientific Officer and Director
James A. McNulty	51	Secretary, Treasurer, and Chief Financial Officer
Donald L. Ferguson	53	Senior Executive Vice President
Leila Zarif, Ph.D., MBA	47	Executive Vice President of Research and Development
Christopher Chapman, M.D.	49	Executive Vice President of Medical and Regulatory Affairs and Director of New Business Development
Susan Gould-Fogerite, Ph.D.	49	Executive Vice President of Business Development-Vaccines and Gene Therapy
L.M. Stephenson, Ph.D.	59	Director
William B. Stone	58	Director
James R. Butler	61	Director
John J. Shea	75	Director
Robert G.L. Shorr	48	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., MD, age 52, has been CEO, President, Chairman and Director on a part time basis since inception in October 2000. We are intending to identify a replacement CEO and President for Dr. O'Donnell, who will assume full day-to-day responsibilities of our operations. 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 also the founder and a director of BioKeys Pharmaceuticals, Inc., a publicly traded biopharmaceutical company. He is a founder and chairman of PhotoVision Pharmaceuticals, Inc. and since early 2001, the chairman of RetinaPharma, Inc. He is a non-managing partner of Tatton Technologies, LLC, a biotechnology company and a managing partner 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.

James McNulty, age 51, has been 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. Mr. McNulty has performed accounting and consulting services as a certified public accountant for approximately 27 years. 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. (STSI) from October 1998 to May 2000. Since June 2000 he has 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 Through Golf, and is chairman of Business Links International, Inc., a business development training company, which uses golf as its focus. Mr. McNulty is a graduate of University South Florida, a licensed Certified Public Accountant, and is a member of the American and Florida Institutes of CPA's.

Donald L. Ferguson, age 53, 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 55, 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.

Leila Zarif, Ph.D., MBA., age 47, has been Executive Vice President of Research and Development since October 2000. Dr. Zarif joined BioDelivery Sciences, Inc. in 1997 as Director of European Operations, and then moved to the United States headquarters as Vice President from October 1997 until October 2000. Dr. Zarif served as a Director and Treasurer from March 1998 until March 2000. Dr. Zarif's prior experience includes eleven (11) years with ATTA, SA. (Application and Transfer of Advanced Technology, French subsidiary of Alliance Pharmaceutical Corp., San Diego) beginning as Head of New Technology Assessment and promoted to President in 1993. Previously, Dr. Zarif worked as a postdoctoral fellow with the French CNRS (National Center of Scientific Research). Dr. Zarif received her Ph.D. in Chemistry in 1988, her MBA in 1992, and her Habilitation to Direct Research in 1995 from the University of Nice, France.

Christopher Chapman, MD, age 49, 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 49, has been Executive Vice President of Business Development -- Vaccines and Gene Therapy since 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 59, is a member of the Board of Directors of the Company. 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 58, is a member of our Board of Directors. For the past 20 years, Mr. Stone has been continuously employed with Mallinckrodt Inc. in various capacities such as Vice-President, Corporate Controller and CIO. Mr. Stone retired in October 2000. Mr. Stone is a graduate of the University of Missouri-Columbia where he earned a BS and MA degree in accounting. Mr. Stone is also a Certified Public Accountant.

James R. Butler, age 61, 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 75, 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 is currently enrolled in the Ph.D. Program at Kensington University in California.

Robert G.L. Shorr, Ph.D., age 48, is currently President and CEO of Cornerstone Pharmaceuticals, a company focussed on novel tumor targeting drug delivery and novel anticancer agent technologies. He is also on the faculty of State University of New York (SUNY) Stony Brook Department of Biomedical Engineering where he serves as the Director of Business Development for the Center for Advanced Technology State University of New York at Stony Brook. He has served in that position since October 1998. As Director of Business Development for the State University of New York at Stony Brook Center for Biotechnology, Dr. Shorr has been responsible for working with faculty and the university technology transfer office to establish grant funded entrepreneurial programs for promising commecializable technology. From 1991 to 1998, Dr. Shorr served as Vice President Science and Technology and as Vice President for Research and Development at Enzon Inc., a public company. Among his many accomplishments, Dr. Shorr was responsible for management of the co-development with Schering Plough of the product PEG INTRON A, which is now approved in the US and Europe. Dr. Shorr also served as chief scientist 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.

BOARD COMPOSITION

Directors are elected annually at our annual meeting of stockholders, and serve for the term for which they are elected and until their successors are duly elected and qualified. There is only one class of directors.

BOARD COMPENSATION

The Company's policy is to pay $1,000 per diem compensation to members of the Board for attendance at formal Board meetings or committee meetings and no compensation for informal meetings such as telephonic meetings and written consent actions. All directors are reimbursed for travel and other related expenses incurred in attending meetings of the Board.

Directors are eligible to participate in our 2001 stock option plan. We grant each director upon agreeing to serve an option to purchase 20,000 shares of common stock. We award an additional 10,000 for each committee chairmanship and 5,000 shares for each committee membership. We grant subsequent grants of options to purchase 20,000 shares upon each anniversary of such director's appointment. Such options are granted at an exercise price equal to the fair market value of the common stock on the grant date and are exercisable 13 months following the completion of this offering or 24 months from the date of grant.

We have indemnified each member of the board of directors and our executive officers to the fullest extent authorized, permitted or allowed by law.

BOARD COMMITTEES

The board of directors has a compensation committee that reviews and recommends the compensation arrangements for our management. The members of the compensation committee are Dr. O'Donnell, L.M. Stephenson, and William Stone.

The board of directors designated an audit committee on March 6, 2002 that reviews our annual audit and meets with our independent auditors to review our internal controls and financial management practices. The board's audit committee currently consists of James R. Butler, John J. Shea, Robert G.L. Shorr, and William Stone. We believe that these individuals qualify as independent directors in accordance with the rules of the Nasdaq Stock Market. The functions of the audit committee are to make recommendations to the board of directors regarding the selection of independent auditors, review the results and scope of the audit and other services provided by our independent auditors and review and evaluate our audit and control functions. The audit committee is also charged with reviewing all related party transactions. The audit committee reviewed all related-party agreements and transactions which we had executed.

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, non-qualified stock options and in some instances cash compensation. 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.

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, MD, 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 orthopaedic 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 Orthopaedics and Related Research.

LIMITATION ON LIABILITY AND INDEMNIFICATION MATTERS

Our certificate of incorporation and bylaws limit or eliminate the personal liability of our directors for monetary damages for breach of the directors' fiduciary duty of care. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, our directors or officers will not be personally liable to us or our stockholders for monetary damages for breach of their fiduciary duty as a director, except for:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions; and
- any transaction from which the director derived an improper personal benefit.

These provisions are permitted under Delaware law which will be the controlling law upon the completion of the reincorporation.

Our certificate of incorporation also provides that we will indemnify, to the fullest extent permitted by law, any person made or threatened to be made a party to any action or proceeding by reason of the fact that

he or she is or was one of our directors or officers or serves or served at any other enterprise as a director, officer or employee at our request.

Our bylaws provide that we will, to the maximum extent and in the manner permitted by Delaware law, indemnify each of the following persons against expenses, including attorneys' fees, judgments, fines, settlements, and other amounts incurred in connection with any proceeding arising by reason of the fact that he or she is or was our agent:

- one of our current or past directors or officers;

- a current or past director or officer of another enterprise who served at our request; or

- a current or past director or officer of a corporation that was our predecessor corporation or of another enterprise at the request of a predecessor corporation.

We have entered into indemnification agreements with each of our directors and executive officers to give them additional contractual assurances regarding the scope of the indemnification described above and to provide additional procedural protections. These agreements, among other things, indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines, penalties and settlement amounts incurred by them in any action or proceeding arising out of their services to us, our subsidiaries or any other enterprise to which they provide services at our request. In addition, we will acquire directors' and officers' insurance providing indemnification for our directors, officers and certain employees for certain liabilities.

ITEM 10. EXECUTIVE COMPENSATION

The following table provides certain summary information concerning the compensation earned for services rendered to us during the fiscal year ended December 31, 2001 by our Chief Executive Officer and our four other most highly compensated executive officers who earned more than $100,000 in fiscal 2001 and were serving as executive officers at the end of fiscal 2001, whom we refer to collectively as the named executive officers.

The annual and long-term remuneration to or accrued for the executive officers, for services rendered during the years ended December 31, 1999, 2000 and 2001 was as follows:

SUMMARY COMPENSATION TABLE*

LONG TERM COMPENSATION -----

-- ANNUAL COMPENSATION(1)
AWARDS PAYOUTS ---

--- (a) (b) (c)
(d) (f) (g) (e) RESTRICTED
SECURITIES (h) (i) OTHER
ANNUAL STOCK UNDERLYING LTIP
ALL OTHER NAME AND PRINCIPAL
POSITION YEAR SALARY BONUS
COMPENSATION AWARD(S)
OPTIONS/SARS PAYOUTS
COMPENSATION(2) - ---

--- --- ---
--- --- ---
--- ---
--- ($) ($) ($)
($) (#) ($) ($) Francis E.
O'Donnell, Jr., 2001 -- -- -
- -- 8,009 -- --
M.D.,.....
CEO, President and Chairman
2000 -- -- -- -- -- -- --
709 The Hampton Lane 1999 --
-- -- -- -- -- --
Chesterfield, MO 63017 James
McNulty, CFO,.....
2001 $ 48,000 -- -- -- -- --
-- Secretary and Treasurer
2000 -- -- -- -- -- -- --
4419 W. Sevilla Street 1999

-- -- -- -- -- -- -- Tampa,
Florida 33629

LONG TERM COMPENSATION -------- ---------- ------ ANNUAL COMPENSATION(1) AWARDS PAYOUTS ------ ---------- ---- ---------- --------- ---------- ---------- (a) (b) (c) (d) (f) (g) (e) RESTRICTED SECURITIES (h) (i) OTHER ANNUAL STOCK UNDERLYING LTIP ALL OTHER NAME AND PRINCIPAL POSITION YEAR SALARY BONUS COMPENSATION AWARD(S) OPTIONS/SARS PAYOUTS COMPENSATION(2) - --- ---------- --- ---- -------- --- -- ---------- ----- ----- ---------- -- ----- ---------- ($) ($) ($) ($) (#) ($) ($) Donald L. Ferguson,..... 2001 -- -- -- -- 274,600 -- -- Senior Executive Vice 2000 - - -- -- -- -- -- -- -- President Land Dynamics, Inc. 1999 - - -- -- -- -- -- -- -- 11719 Old Ballas Road, Suite 110 St. Louis, MO 63141 Raphael J. Mannino, Ph.D., ... 2001 $ 83,650 -- -- -- 91,533 -- $726,957 Executive Vice President, 2000 $ 64,800 -- -- -- -- -- -- -- Chief Scientific Officer 1999 $ 64,800 -- -- -- -- -- -- -- UMDNJ New Jersey Medical School 185 South Orange Avenue Building 4 Newark, NJ 07103 Christopher Chapman, ... 2001 $ 80,000 -- -- - - 91,533 -- -- Director of Medical and 2000 -- -- -- -- -- -- -- Regulatory Affairs and 1999 -- - - -- -- -- -- -- Director of New Business Management 800 Falls Lake Drive Mitchelsville, MD 20720 Leila Zarif, Ph.D., ... 2001 $139,514 -- -- - - 91,533 -- $726,957 Executive Vice President 2000 $114,716 -- -- -- -- -- -- -- of Research and Development 1999 $109,622 -- -- -- -- -- -- UMDNJ New Jersey Medical School

185 South Orange Avenue Building 4 Newark, NJ 07103 Susan Gould-Fogerite, 2001 $ 40,800 -- -- - - 34,324 -- $581,564 Ph.D., ... Director of Business 2000 $ 40,800 -- -- - - -- -- -- Development -- Vaccines and 1999 $ 40,800 -- -- -- -- -- -- Gene Therapy UMDNJ New Jersey Medical School 185 South Orange Avenue Building 4 Newark, NJ 07103

- ---

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

(1)The annual amount of perquisites and other personal benefits, if any, did not exceed the lesser of $50,000 or 10% of the total annual salary reported for each named executive officer and has therefore been omitted.

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

OPTION GRANTS DURING YEAR ENDED DECEMBER 31, 2001

INDIVIDUAL GRANTS					POTENTIAL REALIZABLE VALUE AT ASSUMED ANNUAL RATES OF STOCK PRICE APPRECIATION FOR OPTION TERM	
(a) NAME	(b) NUMBER OF SECURITIES UNDERLYING OPTIONS/SARS GRANTED (#)	(c) PERCENT OF TOTAL OPTIONS/SARS GRANTED TO EMPLOYEES IN FISCAL YEAR	(d) EXERCISE OR BASE PRICE ($/SH)	(e) EXPIRATION DATE	(f) 5% ($)	(g) 10% ($)
Francis E. O'Donnell, Jr. M.D.	8,009	0.96%	$ 3.06	September 30, 2006	$ 6,808	$ 14,977
Donald L. Ferguson	137,300	16.48%	$ 3.06	September 30, 2006	$ 116,705	$ 256,751
	68,650	8.24%	$11.80	September 30, 2006	$ --	$ --
	68,650	8.24%	$17.48	September 30, 2006	$ --	$ --
Raphael J. Mannino, Ph.D.	45,767	5.49%	$ 3.06	September 30, 2006	$ 38,902	$ 85,584
	22,883	2.75%	$11.80	September 30, 2006	$ --	$ --
	22,883	2.75%	$17.48	September 30, 2006	$ --	$ --
Christopher Chapman, M.D.	45,767	5.49%	$ 3.06	September 30, 2006	$ 38,902	$ 85,584
	22,883	2.75%	$11.80	September 30, 2006	$ --	$ --
	22,883	2.75%	$17.48	September 30, 2006	$ --	$ --
Leila Zarif, Ph.D.	45,767	5.49%	$ 3.06	September 30, 2006	$ 38,902	$ 85,584
	22,883	2.75%	$11.80	September 30, 2006	$ --	$ --
	22,883	2.75%	$17.48	September 30, 2006	$ --	$ --
Susan						

Gould-Fogerite, Ph.D. ..... 17,162 2.06% $ 3.06 September 30, 2006 $ 14,588 $ 32,093 8,581 1.03% $11.80 September 30, 2006 $ -- $ -- 8,581 1.03% $17.48 September 30, 2006 $ -- $ --

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END OPTION VALUES

No options were exercised during the fiscal year-end December 31, 2001.

AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR AND FY-END OPTION/SAR VALUES

NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS/SARS AT FISCAL YEAR-END(#) EXERCISABLE/ UNEXERCISABLE	VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS/SARS AT FY-END($) EXERCISABLE/ UNEXERCISABLE	NAME AND PRINCIPAL POSITION	SHARES ACQUIRED ON EXERCISE(#)	VALUE REALIZED($)
(a)	(b)	(c)	(d)	(e)
Francis E. O'Donnell, Jr., M.D. ..... CEO, President and Chairman 709 The Hampton Lane Chesterfield, MO 63017			--	--
James 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			--	--

NUMBER OF SECURITIES UNEXERCISED UNDERLYING UNEXERCISABLE	VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS/SARS AT OPTIONS/SARS AT SHARES FISCAL YEAR-END(#) FISCAL YEAR-END($) ACQUIRED ON VALUE EXERCISABLE/ EXERCISABLE/ NAME AND PRINCIPAL POSITION EXERCISE(#) REALIZED($) UNEXERCISABLE UNEXERCISABLE - ----- ---------- - ---------- ---- ------- ---------- ----- ---------- --- (a) (b) (c) (d) (e) 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..... -- -- -- -- Director of Medical and Regulatory Affairs and Director of New Business Management 800 Falls Lake Drive Mitchelsville, MD 20720 Leila Zarif, Ph.D. ..... -- -- -- -- Executive Vice President of Research and Development UMDNJ New Jersey Medical School 185 South Orange Avenue Building 4 Newark, NJ 07103 Susan Gould-Fogerite, Ph.D. ..... -- -- -- -- Director of Business Development -- Vaccines and Gene Therapy UMDNJ New Jersey Medical School 185 South Orange Avenue Building 4 Newark, NJ 07103

EMPLOYMENT AGREEMENTS

Except for Mr. James McNulty and Dr. Christopher Chapman, we currently have no written employment agreements or confidentiality and non-compete agreements with any of our officers, directors, or key employees. We may elect to pursue obtaining employment agreement with certain of these individuals at some point in the future. Under our employment at will arrangement, our officers will receive the following annualized salaries and other benefits in 2001:

(i) Dr. O'Donnell, President, CEO and Chairman - Receives no salary and no benefits.

(ii) James McNulty, CFO, Secretary and Treasurer - Although he is a part-time CFO, he has an employment agreement with us for a base salary of

$48,000, which terminates on March 1, 2004. Under the terms of this agreement, he is also entitled to the following benefits: medical and dental.

(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-Receives a salary of $87,110 and receives no benefits.

(v) Dr. Leila Zarif, Executive Vice President of Research and Development - Receives a salary of $144,898. Under the terms of this agreement, she is also entitled to the following benefits: medical and dental.

(vi) Dr. Susan Gould-Fogerite, Director of Business Development - Receives a salary of $42,368 and is entitled to the following benefits: a 401k Plan.

(vii) Chistopher Chapman, MD, Director of Medical and Regulatory Affairs and Director of New Business Management -- 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, Leila Zarif, and Susan Gould-Fogerite have outstanding debt payable to us which was incurred with their purchase of stock of BioDelivery Sciences, Inc. in 1999. Simultaneously with the closing of the proposed public offering, we are forgiving those notes and will be providing 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 1,001,236 shares of common stock have been granted under the 2001 stock option plan (options to purchase 22,881 shares of common stock were granted outside the 2001 stock option plan). 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 and qualify as incentive stock options under Section 422A of the Internal Revenue Code of 1986, as amended, ("Incentive Stock Options"), and options which are not Incentive Stock Options ("Non-Statutory Stock Options").

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

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

Options and warrants to purchase 1,024,117 shares of our common stock at prices ranging from $2.87 to $17.48 have been granted as of March 6, 2002. 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 of the Company's proposed public offering; 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. SECURITIES OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table presents information concerning the beneficial ownership of the shares of our common stock.

- each person who is known by us to beneficially own more than 5% of our common stock;

- each of our directors;

- each of the named executive officers; and

- all of our directors and executive officers of as a group.

The number and percentage of shares beneficially owned are based on 5,000,863 shares of common stock outstanding. 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.

Except as indicated in the footnotes to this table, and subject to applicable community property laws, these persons have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

NAME OF BENEFICIAL OWNER	POSITION	NO. OF SHARES OF COMMON STOCK	PERCENTAGE OF COMMON STOCK
Hopkins Capital Group II, LLC(1)	Stockholder	3,036,613	60.72%
4419 W. Sevilla Street Tampa, FL 33629			
Francis E. O'Donnell, Jr., M.D.(2)	CEO, President and Chairman	3,086,957	61.73%
709 The Hampton Lane Chesterfield, MO 63017			
University of Medicine and Dentistry of New Jersey(6)	Chief Executive Officer, Chairman and Director	65	
65 Bergen			

Street MB 1414 University Heights Newark, NJ 07103 Stockholder 139,522 2.79% Albany Medical College(6) Director of Research Admin 47 New Scotland Avenue Albany, NY 12202 Stockholder 2,222 0.04% John R. Williams, Sr.(3) 1 Starwood Lane Manakin-Sabot, VA 23103 Stockholder 3,128,146 62.55% Dennis Ryll, M.D.(4) 1029 Speckledwood Manor Court Chesterfield, MO 63017 Stockholder 3,082,380 61.64% James A. McNulty 4419 W. Sevilla Street Tampa, FL 33629 Chief Financial Officer and Secretary 76,659 1.53%

NAME OF BENEFICIAL OWNER	POSITION	NO. OF SHARES OF COMMON STOCK	PERCENTAGE OF CLASS
Donald L. Ferguson(7) 11719 Old Ballas Road, Suite 110 St. Louis, MO 63141	Sr. Executive Vice President	91,533	1.83%
Raphael J. Mannino, Ph.D.(8) 185 South Orange Avenue Building 4 Newark, NJ 07103	Executive Vice President, Chief Scientific Officer and Director	182,609	3.65%
Susan Gould-Fogerite, Ph.D.(9) 185 South Orange Avenue Building 4 Newark, NJ 07103	Director of Business Development -- Vaccines and Gene Therapy	152,174	3.04%
Leila Zarif, Ph.D.(10) 185 South Orange Avenue Building 4 Newark, NJ 07103			

Executive Vice President of Research and Development	152,174	3.04%		
L.M. Stephenson, Ph.D.(11)	University of Medicine and Dentistry of New Jersey 65 Bergen Street MB 1414 University Heights Newark, NJ 07103	Director		
William Stone(12)	11120 Geyers Down Lane Frontenac, MO 63131	Director		
James R. Butler(13)	109 Cutler Court Ponte Bedra Beach, FL 32082	Director		
John J. Shea(13)	90 Poteskeet Trail Kitty Hawk, NC 27949	Director		
Robert G. L. Shorr(13)	28 Brookfall Road Edison, NJ 08817	Director		
All directors and officers as a group(5)	3,742,105	74.83%		

- ---

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

(2) Includes the shares owned by Hopkins Capital Group II, LLC and 45,767 shares of common stock, owned by his wife, as to which he disclaims beneficial interest of. Does not include option 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 13 months from the date of the Company's proposed public stock offering.

(3) Includes the shares owned by Hopkins Capital Group II, LLC and 45,767 shares of common stock, converted from preferred stock prior to the Company's proposed public stock offering, owned by his wife, as to which he disclaims beneficial interest of.

(4) Includes the shares owned by Hopkins Capital Group II, LLC.

(5) Includes the shares described in footnote (2) above.

(6) Both of the universities each own warrants to purchase 9,951 additional shares of common stock at an exercise price of $3.05 per share vesting 13 months from the date of the Company's proposed public stock offering. These warrants were granted in October 2001.

(7) Does not include options to purchase 137,300 shares of common stock at an exercise price of $3.06 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; options to purchase 68,650 shares of common stock at an exercise price of $11.80 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; and options to purchase 68,650 shares of common stock at an exercise price of $17.48 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003.

(8) Does not include options to purchase 45,767 shares of common stock at an exercise price of $3.06 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; options to purchase 22,883 shares of common stock at an exercise price of $11.80 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; and options to purchase 22,883 shares of common stock at an exercise price of $17.48 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003.

(9) Does not include options to purchase 17,162 shares of common stock at an exercise price of $3.06 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; options to purchase 8,581 shares of common stock at an exercise price of $11.80 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; and options to purchase 8,581 shares of common stock at an exercise price of $17.48 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003.

(10) Does not include options to purchase 45,767 shares of common stock at an exercise price of $3.06 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; options to purchase 22,883 shares of common stock at an exercise price of $11.80 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003; and options to purchase 22,883 shares of common stock at an exercise price of $17.48 per share vesting the earlier of 13 months from the date of the Company's proposed public stock offering or October 2003.

(11) 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 13 months from the date of the Company's proposed public stock offering.

(12) 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 13 months from the date of the Company's proposed public stock offering.

(13) Does not include options to purchase 25,000 shares of common stock at an exercise price of $5.50 per share exercisable 13 months from the date of the Company's proposed public stock offering.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

During 2001, we entered into agreements with RetinaPharma, Inc. and Tatton Technology LLC. Both are biotechnology companies which are developing neutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson's disease. To the extent that such drugs utilize Bioral cochleate technology, we will support drug development and will share in thirty percent (30%) of any profits from such sales of Bioral encapsulated drugs. The Hopkins Capital Group II, LLC, one of our significant stockholders and Dr. Francis E. O'Donnell, Jr., our CEO, President and a director are affiliated as stockholders and a director of RetinaPharma, Inc. Additionally, Hopkins Capital 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 have personally guaranteed a line of credit up to $650,000 with a bank and other liabilities for our benefit at a rate of prime plus 2% that matures in May 2002. As of February 28, 2002, we used $282,527 for expenses related to this 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 Bioral drugs in consideration of a ten (10%) discount to the wholesale price, which our board of directors have determined to be commercially reasonable. The Hopkins Capital Group, 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 in 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 our Bioral drug delivery technology, we will earn a royalty ranging between 15% to 30% of product sales incorporating our technology and between 10% and 20% of any royalty income earned by BioKeys Pharmaceutical, Inc. with regard to licenses involving our technology. Regent Court Technologies LLC, which is affiliated with one of our stockholders, and Dr. Francis E. O'Donnell, Jr., our CEO and director, and Donald L. Ferguson, our senior executive vice-president, are affiliated as stockholders and Dr. O'Donnell is a member of the management of BioKeys Pharmaceutical, Inc. We have also received a $35,000 loan from BioKeys Pharmaceutical, Inc. to begin research on their products using our technology. The loan is in the form of a demand note with an interest rate of 1% plus prime.

Mr. James McNulty, our current 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.

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 one of the founders, 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. 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.

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, Leila Zarif and Susan Gould-Fogerite, officers of the company, principally owned those BioDelivery Sciences Inc. shares. In connection with this exchange, we removed certain restrictions and put rights with respect to those shares and expect to forgive loans of 38

approximately $320,000 that are secured by the BioDelivery Sciences Inc. shares upon the successful completion of the Company's proposed public stock offering. In connection with forgiveness of the notes, we will provide them with approximately $200,000 or compensation for their tax liability. Due to the variable nature of the underlying stock award, we recognized compensation expense totaling $2,035,478 in 2001. This compensation expense does not include any amount with respect to the expected forgiveness of loans.

We also issued an additional 137,300 shares during 2001 to the University of Medicine and Dentistry of New Jersey to settle outstanding payments owed to them under our research agreement.

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, and Robert Shorr.

ITEM 13. EXHIBITS, LIST AND REPORT ON FORM 8-K

(a) Exhibits

NUMBER - ------ DESCRIPTION 3.1 Articles of Incorporation of the Company as an Indiana corporation****** 3.2 Articles of Amendment of the Article of Incorporation as an Indiana corporation***** 3.3 Bylaws of the Company as an Indiana corporation****** 3.4 Articles of Incorporation of the Company after reincorporation merger into Delaware******** 3.5 Bylaws of the Company after reincorporation merger into Delaware******** 4.2 Form of Representative's Unit Purchase Option********* 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*** 10.4 License Agreement with BioKeys Pharmaceuticals, Inc.******** 10.5 License Agreement with Tatton Technologies, LLC******** 10.6 License Agreement with RetinaPharma, Inc.******* 10.7 License Agreement with Biotech Specialty Partners, LLC******** 10.8 National Institutes of Health Grant Letter******** 10.9 Merger Agreement with BioDelivery Sciences, Inc., dated July 20, 2001** 10.10 Settlement Agreement and Stock Purchase Agreement with Irving Berstein, et al.** 10.11 Employment Agreement with Christopher

Chapman** 10.12 Employment Agreement with James A. McNulty** 10.13 2001 Incentive Stock Option Plan******** 10.14 Promissory Note for BioKeys Pharmaceuticals, Inc. dated August 22, 2001******* 10.15 Research Agreement with PharmaResearch Corporation********* 10.16 Credit Facility Loan Agreement*******

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* Previously filed with Form SB-2 November 7, 2001.

** Previously filed with Form 10QSB, for the quarter ended March 31, 2001

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

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

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

******** Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.

********* Previously filed with Form SB-2, Amendment No. 3, March 25, 2002

******* To be filed with the Company's Form SB-2, Amendment No. 4.

All other documents are filed herewith.

Reports on Form 8-K

The Company filed a Form 8-K with the Securities and Exchange Commission on October 26, 2001, reporting the results of the annual meeting of Stockholders.

SIGNATURES

Pursuant to the requirements of Section 13 Or 15(D) of the Securities Act of 1933, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 28, 2002.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ FRANCIS E. O'DONNELL

Francis E. O'Donnell
President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

NAME AND SIGNATURE	TITLE	DATE
/s/ FRANCIS E. O'DONNELL	Director, President, Chief Executive Officer, and Chairman of the Board	March 28, 2002
/s/ JAMES A. MCNULTY	Secretary, Treasurer, and Chief Financial Officer	March 28, 2002
/s/ RAPHAEL J. MANNINO	Director, Executive Vice President and Chief Scientific Officer	March 28, 2002
/s/ L.M.		

STEPHENSON	Director	March 28, 2002
/s/ WILLIAM STONE	Director	March 28, 2002
/s/ JAMES R. BUTLER	Director	March 28, 2002
/s/ JOHN J. SHEA	Director	March 28, 2002
/s/ ROBERT G.L. SHORR	Director	March 28, 2002

INDEX TO FINANCIAL STATEMENTS

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. (a development stage company) and subsidiary as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity, 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, 2001 and 2000, 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.

We also audited the combination of the accompanying consolidated statements of operations and cash flows for the period January 6, 1997 (date of incorporation) to December 31, 2001, which includes the statements of operations and cash flows for the period January 6, 1997 (date of incorporation) to December 31, 1999 that were audited and reported on separately by another auditor; in our opinion, such consolidated statements have been properly combined.

/s/ GRANT THORNTON LLP

Tampa, Florida
March 1, 2002

BIODELIVERY SCIENCES INTERNATIONAL, INC.
(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

DECEMBER 31,	2000	2001
ASSETS CURRENT ASSETS: Cash and cash equivalents	$ 950,939	$ 75,513
Prepaid expenses and other assets	54,481	111,684
Total current assets	1,005,420	187,197
EQUIPMENT, net	253,390	233,562
OTHER ASSETS, net	30,124	912,810
TOTAL ASSETS	$1,288,934	$ 1,333,569
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) CURRENT LIABILITIES: Accounts payable and accrued liabilities	$ 394,020	$ 814,279
Due to related parties	515,584	74,331
Line of credit	--	282,527
Deferred revenue	-	- 37,000
Current portion of capital lease payable	11,307	14,804
Current portion of notes payable	--	149,524
Total current liabilities	920,911	1,372,465
CAPITAL LEASE PAYABLE	28,372	18,369
NOTES PAYABLE, less current portion	--	151,733
COMMITMENTS AND CONTINGENCIES	--	--
REDEEMABLE COMMON STOCK, net of notes receivable of approximately $321,000	2,346	--
STOCKHOLDERS' EQUITY (DEFICIT): Preferred stock, $.001 par value, 20,000,000 shares authorized, 462,243 and 0 shares issued and outstanding in 2000 and 2001, respectively	462	--
Common stock, $.001 par value, 80,000,000 shares authorized, 3,512,586 and 5,000,863 shares issued and outstanding in 2000 and 2001, respectively	3,513	5,001
Additional paid-in capital	1,006,136	4,903,368
Deficit accumulated during development stage	(672,806)	(5,117,367)
Total stockholders' equity (deficit)	337,305	(208,998)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$1,288,934	$ 1,333,569

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.
(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

	PERIOD FROM JANUARY 6, 1997 (DATE OF INCORPORATION) TO DECEMBER 31, 2000	YEAR ENDED DECEMBER 31, 2001	YEAR ENDED DECEMBER 31, 2001
Sponsored research revenues	$ 56,000	$ 478,385	$ 534,385
Expenses: Research and development	312,736	1,663,932	1,976,668
General and administrative: General and administrative	265,239	679,883	945,197
Stock compensation	--	2,192,084	2,192,084
Legal settlement	275,000	383,625	658,625
Total expenses	852,975	4,919,524	5,772,574
Interest income (expense), net	21,772	(21,957)	(185)
Loss before income taxes and minority interest	(775,203)	(4,463,096)	(5,238,374)
Income tax benefit	--	18,535	18,535
Loss before minority interest	(775,203)	(4,444,561)	(5,219,839)
Minority interest in net loss of subsidiary	102,472	--	102,472
Net loss	$ (672,731)	$(4,444,561)	$(5,117,367)
Net loss per common share: Basic and diluted	$ (0.19)	$ (1.15)	
Weighted average common stock shares outstanding -- basic and diluted	3,512,586	3,851,587	

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.
(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT	SHARES	AMOUNT			
BALANCE, JANUARY 6, 1997 (date of incorporation)	--	$ --	--	$ --	$ --	$ --	$ --
Shares issued to founders	--	--	80,091	80	31	--	111
Shares issued for services	--	--	1	--	--	--	--
Net loss	--	--	--	--	--	(75)	(75)
BALANCE, DECEMBER 31, 1999	--	--	80,092	80	31	(75)	36
Shares issued to founders	--	--	3,432,494	3,433	(3,433)	--	--
Preferred stock issued for cash	462,243	462	--	--	1,009,538	--	1,010,000
Net loss	--	--	--	--	--	(672,731)	(672,731)
BALANCE, DECEMBER 31, 2000	462,243	462	3,512,586	3,513	1,006,136	(672,806)	337,305
Shares issued for cash	--	--	368,421	369	804,631	--	805,000
Shares issued for satisfaction of debt	--	--	137,300	137	499,447	--	499,584
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	--	2,540,668
Issuance of stock options	--	--	--	--	53,006	--	53,006
Net loss	--	--	--	--	--	(4,444,561)	(4,444,561)
BALANCE, DECEMBER 31, 2001	--	$ --	5,000,863	$5,001	$4,903,368	$(5,117,367)	$ (208,998)

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.
(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	PERIOD FROM JANUARY 6, 1997 (DATE OF INCORPORATION) TO DECEMBER 31, 2000	YEAR ENDED DECEMBER 31, 2001	YEAR ENDED DECEMBER 31, 2001
OPERATING ACTIVITIES: Net loss	$ (672,731)	$(4,444,561)	$(5,117,367)
Adjustments to reconcile net loss to net cash used in operating activities: Depreciation and amortization	23,455	104,789	128,298
Loss applicable to minority interest	(102,472)	--	(102,472)
Deferred revenue	(56,000)	37,000	(19,000)
Litigation settlement	--	425,000	425,000
Compensation expense	--	2,190,395	2,190,395
Changes in assets and liabilities: Prepaid expenses and other assets	33,077	(417,103)	(384,005)
Accounts payable and accrued liabilities	307,064	420,259	727,323
Due to/from related parties	178,081	52,754	230,835
Net cash used by operating activities	(289,526)	(1,631,467)	(1,920,993)
INVESTING ACTIVITIES: Net cash received with business combination	380,465	--	380,465
Purchase of equipment	--	(84,862)	(84,862)
Purchase of minority interest	--	(116,375)	(116,375)
Net cash provided (used) by investing activities	380,465	(201,237)	179,228
FINANCING ACTIVITIES: Issuance of Preferred Stock	1,010,000	--	1,010,000
Issuance of Common Stock	--	805,000	805,000
Net change in line of credit	--	282,527	282,527
Payment on capital lease payable	--	(6,506)	(6,506)
Payment on notes payable	(150,000)	(123,743)	(273,743)
Net cash provided by financing activities	860,000	957,278	1,817,278
NET CHANGE IN CASH	950,939	(875,426)	75,513
CASH AT BEGINNING OF PERIOD	--	950,939	--
CASH AT END OF PERIOD	$ 950,939	$ 75,513	$ 75,513

The Company paid interest of $0, and $28,178 during 2000 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 goodwill 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 goodwill 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 resulted in the recognition of compensation expense of approximately $2,140,000.

During 2001, the Company granted stock options to non-employees resulting in the recognition of compensation expense of approximately $53,000.

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 -- ORGANIZATION

BioDelivery Sciences International, Inc. ("BDSI" or "Company") (formerly known as MAS Acquisition XXIII Corp.) was incorporated in the State of Indiana on January 6, 1997. BDSI and its subsidiary, 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 then subsequently consummated on January 7, 2002 (the "Merger"). 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 would also exchange 520,313 shares of common stock for 239,600 shares of BDS common stock and 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 goodwill of approximately $401,000. The acquisition of the 1,470,000 shares of redeemable common stock also involves the removal of the permanent discount and redemption provisions in December 2001 and the forgiveness of the stockholder debt associated with these shares upon, or soon after, the proposed IPO (see Note 16). 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 is a development stage company that has devoted substantially all of its efforts to research and product development involving drug delivery technology (e.g., cochleate technology) and has not yet generated any revenues from the sale of products or licensing of technology. The Company intends to obtain additional funds for research and development through collaborative arrangements with corporate partners, additional financings, and from other sources. The Company operates in one segment focused on the development of its drug delivery platform technology.

The accompanying consolidated statements of operations and cash flows for the period January 6, 1997 (date of incorporation) to December 31, 2001 include the statements of operations and cash flows for the period January 6, 1997 (date of incorporation) to December 31, 1999 that were audited and reported on separately by an auditor previously engaged by the Company.

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. Minority interest in net loss of subsidiary reflects the losses attributable to the common stockholders of BioDelivery Sciences Inc. to the extent that net assets were attributed to those stockholders on the business combination date. At December 31, 2000 those stockholders owned 100% of the common stock of BioDelivery Sciences Inc. while BDSI owns preferred stock with voting rights, representing 84.8% of the total voting rights. At December 31, 2000, 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 (see Note 7) and in connection with the Merger of BDSI and BDS (see Note 1) the remaining minority interest was acquired by the Company.

NOTE 2 -- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES -- (CONTINUED)

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.

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.

GOODWILL

Goodwill represents amounts paid for the Company's acquisitions of the BDS minority interest common shares in excess of fair market value. Those amounts paid prior to July 1, 2001 are amortized over 10 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 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 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.

NOTE 2 -- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES -- (CONTINUED)

CONCENTRATION OF CREDIT RISK

The Company derived substantially all of its working capital from the sale of its Common and Preferred Stock. BioDelivery Sciences Inc. historically derived its working capital from research and development arrangements.

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 continue to account for its employee stock compensation plans 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.

REDEEMABLE COMMON STOCK

Redeemable Common Stock represents the Company's obligation to re-purchase the 1,470,000 shares of BioDelivery Sciences Inc. 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. Accordingly, no compensation expense has been recognized related to the redeemable permanent discount common stock. Under the terms of the redemption agreement, holders required 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 redemption features, resulting in the recognition of approximately $2,140,000 of compensation expenses.

FAIR VALUE OF FINANCIAL INSTRUMENTS

At December 31, 2001, the carrying amount of cash, accounts payable, accrued expenses, capital lease obligations and notes payable approximate fair value based either on the short term nature of the instruments or on the related interest rate approximating the current market rate.

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 Company does not believe the adoption of these standards will have a material impact on the Company's financial statements.

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 143, Accounting for Asset Retirement Obligations. This statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This Statement applies to all entities. It applies to legal

NOTE 2 -- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES -- (CONTINUED)

obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. This Statement is effective for financial statements issued for fiscal years beginning after June 15, 2002. The Company is evaluating the impact of the adoption of this standard and has not yet determined the effect of adoption on its financial position and results of operations.

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 financial statements issued for fiscal years beginning after December 15, 2001. The Company does not believe the adoption of this standard will have a material impact on the Company's financial statements.

NOTE 3 -- BUSINESS COMBINATION

On October 10, 2000, BDSI acquired 210,006 shares of newly issued BioDelivery Sciences Inc. Series A Convertible Preferred Stock representing 84.8% of the voting rights of BioDelivery Sciences Inc. in exchange for cash and notes payable to BioDelivery Sciences Inc. of $1,000,000 and $14,000,000, respectively. Since its inception in 1995, BioDelivery Sciences Inc. 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 and the operations of BioDelivery Sciences Inc. are included in the consolidated financial statements since September 30, 2000 as the operations during the period October 1, 2000 through October 10, 2000 were not significant. The shares of Series A Preferred were convertible into BioDelivery Sciences Inc. 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 BioDelivery Sciences Inc., the Series A Preferred Stockholders would have been entitled to receive, in preference to Common Stockholders of BioDelivery Sciences Inc., 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 BioDelivery Sciences Inc. Series A Preferred Stock and note are eliminated in consolidation. BDSI and BioDelivery Sciences Inc. 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.

In conjunction with the business combination, the following was acquired:

Cash acquired	$ 380,465
Fair value of non-cash assets acquired	394,491
Liabilities assumed, including minority interests of $102,472	$(774,956)

The following unaudited pro forma summary combines the historical results of operations of BDSI with the historical operations of BioDelivery Sciences Inc. (exclusive of the impact of minority interest) as if the acquisition had occurred at January 1, 2000. This pro forma summary does not necessarily reflect the results of

NOTE 3 -- BUSINESS COMBINATION -- (CONTINUED)

operations as they would have been if BDSI and BioDelivery Sciences Inc. operated as a single entity during such period.

YEAR ENDED DECEMBER 31, 2000 -	
------ --------- Sponsored research revenues.....	$ 670,001
Net income (loss).....	$(981,207)
Net income (loss) per share -- basic.....	$ (0.28)
Net income (loss) per share -- diluted.....	$ (0.28)

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

NOTE 4 -- RESEARCH AND DEVELOPMENT ARRANGEMENTS

Upon its formation, BioDelivery Sciences Inc. originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, BioDelivery Sciences Inc. 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 25% of fees); b) sales by sub-licensees (25% of BioDelivery Sciences Inc. proceeds); or c) BioDelivery Sciences Inc. sales (3% of revenue). BioDelivery Sciences Inc. has also entered into various collaborative research arrangements with third parties, whereby the third parties ultimately obtain licensing rights for new inventions/patents arising from the associated research. These agreements generally provide for joint ownership of the patent rights developed from collaborative efforts. The parties also agree to later negotiate a reasonable royalty arrangement upon commercialization of any such product developed under the collaborative efforts.

BioDelivery Sciences Inc. has entered into a research agreement with UMDNJ. For the period from the acquisition of voting rights of BioDelivery Sciences Inc. by BDSI through December 31, 2000 and for the year ended December 31, 2001, BioDelivery Sciences Inc. incurred costs of $78,081 and $159,025, respectively, to UMDNJ under the terms of the research agreement. At December 31, 2000, BioDelivery Sciences Inc. owed UMDNJ $415,584 under this agreement, which is included in due to related parties. The research agreement provides for the procurement of supplies, rent (until April 2001 -- See Note 7), 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, 2001, the Company owes an additional $74,331 under this agreement.

On July 1, 1996, BioDelivery Sciences Inc. entered into a license agreement with a commercial pharmaceutical company ("Funding Company"). This agreement allowed for the Funding Company to obtain an exclusive license in and to all inventions, developments, improvements, or know-how relating to cochleates, liposomes and proteoliposomes, owned, controlled or licensed to BioDelivery Sciences Inc. The Funding Company would also have the rights to all BioDelivery Sciences Inc. developed vaccines designed to induce an antigen specific immune response in humans; including vaccines to prevent or treat allergies. In exchange for the exclusive license, the Funding Company agreed to pay research and royalty payments which ultimately totaled $6.7 million. The agreement commenced upon execution and was to expire five years following the first commercial sale of a licensed product or the date of expiration of the last licensed patent having a valid claim covering any licensed product, whichever is later. However, the Funding Company chose to terminate the agreement effective in 2000. The Company incurred $56,000 of costs under this arrangement in 2000.

NOTE 4 -- RESEARCH AND DEVELOPMENT ARRANGEMENTS -- (CONTINUED)

During 2001, the Company entered into agreements with RetinaPharma, Inc. and Tatton Technology LLC. Both are biotechnology companies which are developing neutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson's disease. To the extent that such drugs utilize Bioral cochleate technology, the Company will support drug development and will share in thirty percent (30%) of any profits from such sales of Bioral encapsulated drugs. The CEO/director is affiliated with these companies. The Company incurred a deminimus amount of costs relating to these agreements in 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 is affiliated with this company. The Company incurred a deminimus amount of costs relating to this agreement in 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 has provided a $35,000 advance to the Company under their agreement, which is included with accounts payable and accrued expenses. The CEO/director and the senior executive vice president are affiliated with this company. The Company incurred a deminimus amount of costs relating to this agreement in 2001.

NOTE 5 -- OTHER ASSETS

Other assets consist of the following.

YEAR ENDED DECEMBER 31,	2000	2001
Goodwill	$ --	$517,445
Deferred offering costs	365,340	
Other	42,520	43,821
	42,520	926,606
Less: Accumulated amortization	(12,396)	(13,796)
Total other assets, net	$ 30,124	$912,810

The Company has incurred and capitalized offering costs of approximately $366,000 at December 31, 2001 related to the anticipated proposed public offering (see Note 16).

NOTE 6 -- EQUIPMENT

Equipment consists of the following:

DECEMBER 31, ---------- 2000 2001 -------- -- ------- Office and laboratory equipment..... $236,466 $ 321,338 Leased equipment..... 39,679 39,679 -------- --------- 276,145 361,017 Less accumulated depreciation and amortization..... (22,755) (127,455) -------- --------- Net equipment..... $253,390 $ 233,562 ======== =========

Depreciation and amortization expense related to equipment for the years ended December 31, 2000 and 2001 was approximately $23,000 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 $125,000 note is payable in monthly installments through June 2002 and bears interest at 9%. 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. The $300,000 note is payable monthly through June 2004 and bears interest at 9%. The notes are secured by all of BDS's tangible and intangible assets, including license agreements. 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.

At December 31, 2001 maturities of these notes payable are as follows:

YEAR ENDING DECEMBER 31, ----------
2002..... $149,524
2003..... 105,089
2004..... 46,644 -------- $301,257 ========

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 year ended December 31, 2001 was approximately $30,000. The future minimum commitments on this operating lease at December 31, 2001 are as follows:

2002.....	$44,580
2003.....	50,580
2004.....	56,580
2005.....	62,580

NOTE 7 -- COMMITMENTS AND CONTINGENCIES -- (CONTINUED)

CAPITAL LEASE

The Company leases certain equipment under a capital lease. Future minimum lease payments at December 31, 2001 remaining on this capital lease are as follows.

2002	$22,070
2003	14,713
2004	4,905
Less amount representing interest	(8,515)
	$33,173

NOTE 8 -- PREFERRED STOCK

During 2000, the Company 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, is non-redeemable, and does not pay dividends. In December 2001, the Company rescinded the 462,243 shares of preferred stock as replacement for issuance of 462,243 shares of common stock.

NOTE 9 -- 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 and has been subsequently increased to $550,000. Interest on the line of credit accrues at a rate of prime plus 2.0% (6.75% at December 31, 2001) and matures in April 2002. Borrowings under the line of credit are collateralized by all business assets of the Company and personal guarantees by certain stockholders. There are no restrictive covenants associated with the line of credit.

NOTE 10 -- STOCK OPTIONS

In October 2001, the Company approved a stock option plan, which covers a total of 572,082 shares of common stock. The Board has approved, subject to stock holder approval at the next meeting, to increase the shares available under the 2001 stock option plan to 1,100,000. Options may be awarded during the ten-year term of the 2001 stock option plan to Company employees, directors, consultants and other affiliates.

The Company has adopted only the disclosure provisions of Financial Accounting Standard No. 123, "Accounting for Stock-Based Compensation," as it relates to employment awards. It applies APB Opinion 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its plans and does not recognize compensation expense based upon the fair value at the grant date for awards under these plans

NOTE 10 -- STOCK OPTIONS -- (CONTINUED)

consistent with the methodology prescribed by SFAS 123, the Company's net loss and loss per share would be reduced to the proforma amounts indicated below:

2000	2001
Net Loss	
As Reported	$(672,731) $(4,444,561)
ProForma	$(672,731) $(4,588,120)
Net Loss Per Common Stock	
Basic As Reported	$ (0.19) $ (1.15)
Basic ProForma	$ (0.19) $ (1.19)
Net Loss Per Common Share	
Diluted As Reported	$ (0.19) $ (1.15)
Diluted ProForma	$ (0.19) $ (1.19)

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 2001: No dividend yield, expected volatility of 73%; risk-free interest rates of 5.5%, and expected lives of 3 years.

Activity related to options is as follows:

WEIGHTED AVERAGE EXERCISE PRICE PER SHARE	NUMBER OF SHARES
Outstanding at inception (January 6, 1997) through December 31, 2000	-- $ --
Granted in 2001: Officers and Directors	610,983 $8.59
Others	222,112 $5.01
Options Expired	-- $ --
Outstanding at December 31, 2001	833,095 $7.64

OUTSTANDING SHARES

RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	WEIGHTED AVERAGE EXERCISE PRICE
$2.87 -- $3.06	481,587	4.8	$ 3.03
$6.60	30,000	4.8	$ 6.60
$11.80	160,754		

4.8	$11.80				
	$17.48				
	160,754				
4.8	$17.48				

EXERCISABLE SHARES

RANGE OF EXERCISE PRICES	NUMBER OUTSTANDING	WEIGHTED AVERAGE EXERCISE PRICE
$2.87 -- $3.06	36,443	3.01

The options outstanding at December 31, 2001 expire on various dates throughout 2006.

The weighted average grant date fair value of options granted during 2001 whose exercise price is equal to the market price of the stock at the grant date was $1.58. The weighted average grant date fair value of options

NOTE 10 -- STOCK OPTIONS -- (CONTINUED)

granted whose exercise price is less than the estimated market price of the stock at the grant date is $1.63. The weighted average grant date fair value of options granted whose exercise price is greater than the estimated market price of the stock at the grant date is $1.37.

Compensation expense in connection with the issuance of stock options totaled approximately $53,000 for the year ended December 31, 2001.

NOTE 11 -- INCOME TAXES

Other than a $18,000 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 2001 and 2000 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,	2000	2001
Federal statutory income tax rate	34.00%	34.00%
State taxes, net of federal benefit	4.95	4.95
Permanent differences -- compensation expense	--	(21.23)
Valuation allowance	(38.95)	(17.30)
	--%	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,	2000	2001
Deferred tax assets (liabilities)		
Depreciation	$ (37,000)	$ (21,000)
Accrued liabilities and other	128,000	21,000
Net operating loss carryforward	214,000	1,077,000
	305,000	1,077,000
Less valuation allowance	(305,000)	(1,077,000)
Net deferred tax	$ --	$ --

At December 31, 2001, the Company has a federal and state net operating loss carryforward of approximately $2.7 million, which expires beginning in 2007.

NOTE 12 -- NET LOSS PER COMMON SHARE

The following table reconciles the numerators and denominators of the basic and diluted income per share computations. The 3,512,586 shares of common stock outstanding in 2000 reflects the recapitalization of

NOTE 12 -- NET LOSS PER COMMON SHARE -- (CONTINUED)

the Company in 2000. The recapitalization included the cancellation of all but 80,092 shares and the issuance of 3,432,494 shares for nominal consideration to founding members of management during 2000.

YEAR ENDED DECEMBER 31,		
-	2000	2001
Net loss -- (numerator)	$ (672,731)	$(4,444,561)
Basic: Weighted average Shares outstanding (denominator)	3,512,586	3,851,587
Net loss per common share -- basic	$ (0.19)	$ (1.15)
Diluted: Weighted average shares outstanding	3,512,586	3,851,587
Effect of dilutive options	--	--
Adjusted weighted average shares (denominator)	3,512,586	3,851,587
Net loss per common share -- diluted	$ (0.19)	$ (1.15)

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

NOTE 13 -- RELATED PARTY TRANSACTIONS

During the year ended December 31, 2000, the Company sold 45,767 shares of Preferred Stock to a relative of a principal stockholder for $100,000. The terms of the Preferred Stock sold to this related party were identical to those for Preferred Stock sold to unrelated parties.

NOTE 14 -- 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 2001 grant of $883,972. Additionally, this award refers to funding levels of $814,398 and $989,352 that the Company expects to be awarded in 2002 and 2003, respectively, 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 2002 and 2003 amounts noted above may be reduced or eliminated. The company incurred approximately $477,000 of costs related to this agreement in 2001.

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

NOTE 14 -- NATIONAL INSTITUTES OF HEALTH GRANT -- (CONTINUED)

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.

NOTE 15 -- PLAN OF OPERATIONS

Since inception, the Company has financed its operations principally from the sale of equity securities. Historically, the Company's subsidiary financed its operations principally from funded research arrangements. The Company has not generated revenue from the sale of any product or from any licensing arrangement since inception. The Company intends on financing its research and development efforts and its working capital needs from existing and new sources of financing. For instance, the Company was granted up to approximately $2.7 million from the National Institutes of Health to fund specific research efforts conducted by the Company (see Note 14). The Company has also recently filed Form SB-2 and expects to offer for sale up to 2,000,000 units, each consisting of one share of common stock and one warrant to purchase an additional share of common stock (see Note 16). The expected offering price for each unit is between $5.00 and $6.00 per unit. There can be no assurance that the offering will result in the sale of any such securities. Should the offering not occur nor additional funding be obtained, the principal shareholder has committed to fund the operations of the Company through 2002. The Company expects to raise additional funding from traditional financing sources, including term notes from unrelated parties or advances from related parties. While there can be no assurance that such sources will provide adequate funding for the Company's operations, management believes such sources will be available to the Company.

NOTE 16 -- SUBSEQUENT EVENTS

In 2002, the Company filed amendments to Form SB-2 with the Securities and Exchange Commission. The proposed public offering consists of up to 2,000,000 Units, each comprised of one share of common stock and one redeemable Class A common stock purchase warrant.

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders of
BioDelivery Sciences, Inc.

We have audited the accompanying statement of operations of BioDelivery Sciences, Inc. (a development stage company) and the related statement of cash flows for the nine months ended September 30, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United Stated of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operations of BioDelivery Sciences, Inc. and cash flows for the nine months ended September 30, 2000, in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Tampa, Florida
December 15, 2000

BIODELIVERY SCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS

PERIOD FROM MARCH 28, 1995 (DATE OF INCORPORATION) TO SEPTEMBER 30, 2000	NINE MONTHS ENDED SEPTEMBER 30, 2000	
	(UNAUDITED)	
Sponsored research revenues		$ 614,001
EXPENSES:		
Research and development	$7,338,501	
General and administrative	820,551	6,816,444
Total expenses	62,480	423,233
	883,031	7,239,677
OTHER INCOME (EXPENSE)		
Interest income		
	21,570	169,318
Other income		
	3,720	17,856
Net income (loss) before income tax benefit (expense)		
	(243,740)	285,998
Income tax benefit (expense)		37,736
Net income (loss)	(183,925)	
	$(206,004)	$ 102,073

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

BIODELIVERY SCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CASH FLOWS

	PERIOD FROM MARCH 28, 1995 (DATE OF INCORPORATION) TO SEPTEMBER 30, 2000	NINE MONTHS ENDED SEPTEMBER 30, 2000	NINE MONTHS ENDED SEPTEMBER 30, 1999
		(UNAUDITED)	(UNAUDITED)
Net income (loss)	$(206,004)	$ 102,073	
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	70,422	243,688	
Changes in assets and liabilities:			
Prepaid expenses and other assets	(31,124)	(87,558)	
Accounts payable and accrued liabilities	14,734	86,955	
Deferred revenue		(46,000)	56,000
Due to related party	234,471	337,503	
Net cash provided by operating activities	36,499	738,661	
INVESTING ACTIVITIES: Purchases of equipment		(18,391)	(468,458)
Purchase of other assets	--	(42,484)	
Net cash used in investing activities	(18,391)	(510,942)	
FINANCING ACTIVITIES: Issuance of common stock	-	-	2,746
Proceeds from notes payable	350,000	350,000	
Net cash provided by financing activities	350,000	352,746	
NET CHANGE IN CASH		368,108	580,465
CASH AT BEGINNING OF PERIOD		212,357	--
CASH AT END OF PERIOD	$ 580,465	$ 580,465	
SUPPLEMENTAL INFORMATION Cash paid for taxes	$ -	$ -	$ 221,661

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

BIODELIVERY SCIENCES, INC.
(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS

NOTE 1 -- ORGANIZATION

BioDelivery Sciences, Inc. ("BDS" or the "Company") was incorporated in the State of Delaware on March 28, 1995. The Company was formed to develop and commercialize the delivery of certain pharmaceutical drugs and vaccines orally.

The Company is a development stage company, which has devoted substantially all of its efforts to research and product development and has not yet generated any revenues from the sale of products. At this time, there can be no assurance of future revenues. In addition, the Company expects to continue to incur losses for the foreseeable future, and there can be no assurance that the Company will successfully complete the transition from a development stage company to successful operations.

In order to continue its research and product development activities as planned, the Company has raised capital through sponsored research agreements with commercial entities and other third parties. The Company has also raised capital from investors subsequent to September 30, 2000, as more fully discussed in Note 7, which management believes will provide adequate funding through September 30, 2001. The Company intends to obtain additional funds for research and development through collaborative arrangements with corporate partners, additional financings, and from other sources; however, there can be no assurance that the Company will be able to obtain necessary financing when required or what the terms of any such financing, if obtained, might be. Accordingly, there can be no assurance of the Company's future success.

NOTE 2 -- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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. 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.

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. Depreciation and amortization expense related to equipment for the nine months ended September 30, 2000 was $68,265.

INCOME TAXES

Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on 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.

NOTE 2 -- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES -- (CONTINUED)

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 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.

ACCOUNTING FOR THE IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews long-lived assets to be held and used or disposed of, 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 in measuring whether the assets to be held and used will be realizable.

CONCENTRATION OF CREDIT RISK

As described in Note 3, the Company derived substantially all of its working capital from a research and development arrangement that was terminated during 1999.

STOCK OPTIONS, WARRANTS, AND SARS

The Company follows 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 continue to account for its employee stock compensation plans 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 has been applied. Through September 30, 2000 no options or warrants have been granted by the Company.

NOTE 3 -- RESEARCH AND DEVELOPMENT ARRANGEMENTS

As part of the Company's grant of an exclusive technology license to a third party, the Company agreed to conduct research in certain areas in exchange for funding. Research funding received under this agreement was $325,000 in 2000, respectively. This agreement was terminated by the third party during 1999 and the Company was relieved of its obligations to provide exclusive technology licensing. Additionally, the Company has entered into various other collaborative research arrangements with third parties, whereby the third parties ultimately obtain licensing rights for new inventions/patents arising from the associated research.

In 1996, the Company issued 7,300 shares of common stock each to UMDNJ and Albany Medical College ("AMC") for exclusive, worldwide license agreement rights. Under the terms of the license agreement, the Company is obligated to pay royalties of 3% for sales of product and 25% of its income arising from sales of product sold by sub-licensees that the Company may contract with in the future.

The Company has also entered into a research agreement with UMDNJ. For the nine month period ended September 30, 2000, the Company incurred costs of $243,805, to UMDNJ under the terms of the research agreement. At September 30, 2000, the Company owed UMDNJ $337,503, under this agreement. The research agreement provides for the procurement of supplies, rent, certain payroll costs, and other expenses associated with research performed under the research agreement.

NOTE 4 -- COMMITMENTS AND CONTINGENCIES

LITIGATION

During 1996, the Company entered into an agreement with a consultant/stockholder under which the Company is obligated to pay a monthly consulting fee of $15,000 for services through January 2001. The agreement also provides for additional costs payable to the consultant beginning in 2000 through 2004, upon the Company obtaining certain levels of financing. In August 1999, the Company unilaterally terminated the contract with this consultant and ceased making further payments. The consultant subsequently filed suit against the Company alleging that, among other things, the Company is required to pay the monthly consulting fees. The Company has filed a counter suit against the consultant and management believes that the Company is not liable for any alleged damages and that the Company is entitled to a refund of a portion of previously paid consulting fees. Accordingly, no reserve has been recognized associated with this dispute.

The Company is subject to claims arising in the ordinary course of business, but does not believe that any such claims presently identified will have a material adverse effect on its financial condition or results of operations.

OPERATING LEASES

The Company leases a facility from UMDNJ under an operating lease. Lease expense for the nine months ended September 30, 2000 was approximately $30,000. While the Company intends to continue leasing this facility, there are no future minimum commitments on operating leases at September 30, 2000.

CAPITAL LEASES

The Company leases certain equipment under a capital lease. Future minimum lease payments remaining on this capital lease are as follows.

2000 (3 months)	$ 3,678
2001	14,713
2002	14,713
2003	14,713
2004	4,904
Less amount representing interest	(13,042)
	$ 39,679

NOTE 5 -- STOCK OPTIONS, WARRANTS, AND OTHER INCENTIVE COMPENSATION

In 1999, the board of directors of the Company approved the 1999 Stock Option Plan (1999 Plan) and reserved 500,000 shares of common stock for issuance of stock options to employees and consultants. No options were granted under this plan.

During 1999, certain employees of the Company purchased 1,470,000 shares of redeemable common stock for $0.22 per share (the fair value of the stock less a permanent discount) in exchange for cash and notes payable. The Company is obligated to re-purchase the stock at fair value less the original discount at the option of the holder beginning in 2004, or earlier upon termination of the respective employee. The notes amount to approximately $321,000, bear interest of 6% annually, and mature in 2009. Upon the fair value of the common stock exceeding $2.22 per share, the Company will recognize compensation expense for the

NOTE 5 -- STOCK OPTIONS, WARRANTS, AND OTHER INCENTIVE COMPENSATION -- (CONTINUED)

amount in excess of $2.22 per share and adjust compensation in future periods based on variable accounting requirements. Through September 30, 2000, no compensation expense has been recognized.

NOTE 6 -- INCOME TAXES

The Company's provision (benefit) for income taxes for the nine months ended September 30, 2000 is as follows:

Current Tax:	
Federal	$(37,736)
State	--
Deferred Tax:	
Federal	--
State	--
	$(37,736)

The Company's Federal net operating loss carryforward of $93,312 expires in 2020. The Company's State net operating loss of $289,836 expires in 2007. The Company's effective tax rate of approximately 15% in 2000 varies from the statutory rate primarily due to the valuation allowance associated with net operating loss carryforwards and the effect of graduated tax rates.

NOTE 7 -- SUBSEQUENT EVENT

On October 10, 2000, the Company sold 210,006 shares of Series A Convertible Preferred Stock representing 84.8% of the voting rights of the Company to BioDelivery Sciences International, Inc. in exchange for cash and notes receivable of $1.0 million and $14.0 million, respectively. The shares of Series A Preferred are convertible to Common Stock on a 50-for-1 basis, subject to customary anti-dilution adjustments. Dividends shall accrue on the Series A Preferred at the rate of 8% per annum. In the event of liquidation, dissolution, or winding up of the Company, the Series A Preferred Stockholders will be entitled to receive, in preference to the Company's Common Stockholders, an amount per share equal to the original purchase price plus any accrued dividends per share. The Series A Preferred Stock is convertible at the earlier of voluntary conversion by the preferred stockholders, initial public offering of the Company's common stock, or 2005.