

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

BIODELIVERY SCIENCES INTERNATIONAL INC  
Form 424B1  
June 26, 2002

Filed Pursuant To Rule 424(B) (1)  
Registration File No. 333-72872

[BIODELIVERY LOGO]

PROSPECTUS

BIODELIVERY SCIENCES INTERNATIONAL, INC.  
2,000,000 UNITS

-----  
This is a public offering of our securities. Our securities are being offered in Units, with each Unit consisting of: (i) one share of our common stock and (ii) one redeemable Class A common stock purchase warrant. The common stock and warrants will not trade as separate securities until 30 days after this offering unless the representative of the underwriters determines that separate trading should occur earlier. After 30 days the securities contained in the Units will automatically trade separately and the Units will no longer trade as a security.

Each Class A warrant entitles the holder to purchase one share of our common stock at a price of \$6.30. The exercise price of the Class A warrant is subject to adjustment, including anti-dilution provisions for corporate events, such as stock splits and for issuance of securities at less than the then current exercise price.

There is presently no public market for our Units, common stock or warrants. We expect that the initial public offering price of the Units will be \$5.25 per Unit. The actual initial public offering price of the Units will be determined by negotiations between the Representative and us.

The Units, the common stock and the Class A warrants have been accepted for listing on the Nasdaq SmallCap Market and the Boston Stock Exchange under the symbols "BDSIU", "BDSI", and "BDSIW", respectively.

Pharmaceutical Product Development, Inc. (Nasdaq: PPDI), a global provider of drug discovery and development services and products for pharmaceutical and biotechnology companies, has expressed an interest to the Representative in purchasing up to 690,000 Units as part of this offering.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 6.

-----  
NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.  
-----

	PER UNIT	TOTAL
	-----	-----
Public offering price.....	\$5.25	\$10,500,000
Underwriting discount.....	\$.448	\$ 897,750
Proceeds, before expenses.....	\$4.80	\$ 9,602,250

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

-----  
We expect total cost expenses of this offering to be approximately \$2,038,850, which will include a non-accountable expense allowance of 3% of the gross proceeds of this offering payable to the Representative of the underwriters. We have granted the Representative a 45-day option to acquire up to an additional 15% of the Units (300,000) to cover over-allotments.

Kashner Davidson Securities Corporation, as representative, on behalf of the underwriters, expects to deliver our securities to purchasers on or about June 28, 2002.

-----  
KASHNER DAVIDSON SECURITIES CORPORATION

ROAN/MEYERS ASSOCIATES, L.P.

June 24, 2002

Appearing above is a picture of our cochleate structure as magnified under a microscope.

Appearing below is a diagram showing the process of "nano-encapsulation" of a drug in our cochleate structure.

Our drug delivery technology is based upon encapsulating drugs to potentially deliver the drug safely and effectively. 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.

## TABLE OF CONTENTS

	PAGE
	----
Prospectus Summary.....	1
The Offering.....	4
Risk Factors.....	6
Special Note Regarding Forward Looking Statements.....	19
Use of Proceeds.....	21
Dividend Policy.....	21
Capitalization.....	22
Dilution.....	23
Selected Financial and Operating Data.....	24
Management's Discussion and Analysis of Financial Condition and Plan of Operation.....	26
Description of Business.....	32
Management.....	48
Certain Relationships and Related Transactions.....	58
Principal Stockholders.....	61
Description of Capital Stock.....	64
Shares Eligible for Future Sale.....	66
Underwriting.....	68
Legal Matters.....	71
Experts.....	71
Where You Can Find More Information.....	71
Index to Financial Statements.....	F-1

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

### NOTICE TO ARIZONA INVESTORS

Each purchaser of Units in Arizona must satisfy either of the following conditions: (1) minimum of \$100,000, or \$150,000 when combined with spouse, in gross income during 2001 and a reasonable expectation that the purchaser will have such income in 2002, or (2) minimum net worth of \$250,000, or \$300,000 when combined with spouse, exclusive of home, home furnishings and automobiles, with the investment not exceeding 10% of the net worth of the purchaser, together with spouse, if applicable.

### NOTICE TO CALIFORNIA INVESTORS

This offering was approved in California on the basis of a limited offering qualification. Investors must meet a "super suitability" standard of not less than \$250,000 liquid net worth (exclusive of home, home furnishings and automobiles), plus \$65,000 gross annual income or \$500,000 liquid net worth or \$1,000,000 net worth (inclusive) or \$200,000 gross annual income. We did not have to demonstrate compliance with some or all of the merit regulations of the California Department of Corporations, as found in Title 10, California Code of Regulations, Rule 260.140 et seq.

Residents of the State of California will be unable to sell shares of common stock they purchase in this offering, and investors residing in all other states will be unable to sell shares of common stock they purchase in this offering to California residents, pursuant to exemptions for secondary trading available under California Corporations Code ss.25104(h), as such exemptions have been withheld. However, secondary sales may be made to purchasers who meet the "super suitability" standards or there may be other exemptions to cover private sales by the bona fide owners of our securities for such owners' own account without advertising and without being effected by or through a broker dealer in a public offering.

i

We have been and will continue to file reports such as our annual reports on Form 10KSB, quarterly reports on Form 10QSB and other information with the Securities and Exchange Commission, once our securities are publicly-traded. You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, Units, consisting of shares of common stock and Class A warrants. We are offering these securities only in jurisdictions where offers and sales are permitted. Neither the delivery of this prospectus nor the sale of our securities means that the information contained in this prospectus is correct after the date of this prospectus, except that we will update this prospectus when required by law.

Until July 19, 2002 (25 days after the date of this prospectus) all dealers that buy, sell or trade our securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their allotments or subscriptions.

For investors outside the United States, neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about such local rules and regulations and to observe any restrictions relating to this offering and the distribution of this prospectus.

ii

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

## PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in this offering. For a more complete understanding of this offering, you should read the entire Prospectus carefully, including, the Risk Factors and the Financial Statements.

We are a development-stage biotechnology company that is developing and seeking to commercialize a drug delivery technology designed for a potentially broad base of pharmaceuticals, vaccines and over-the-counter drugs. In general, a drug delivery technology refers to any process, substance, or combination thereof, that delivers drugs into the body. Our proposed drug delivery technology varies from competitors by encapsulating or wrapping 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."

Drug delivery technologies generally seek to achieve a broad range of objectives in improving the way drugs are delivered into and within the body, including oral availability, minimizing side-effects, stability, delivery of the drug into the cell, resistance to environmental attack, patient compliance and release characteristics. We believe that available drug delivery technologies generally enhance some combination of these objectives, but in most applications, not all. In developing our drug delivery technology, our goal is to seek to enhance some or all of these objectives to potentially provide an improved delivery mechanism for a broad base of drugs identified by us. We believe that our technology may potentially enable oral delivery of certain drugs otherwise requiring injection, such as Amphotericin B. Drugs most likely to benefit from this aspect of our technology will usually have certain characteristics which make their oral delivery form unfavorable, such as poor water solubility and drugs which consist of proteins. We believe our technology may also benefit drugs which are currently administered orally or which currently require delivery through injection. These benefits include potentially reduced toxicity and side effects which may be associated with certain drugs and potentially improved therapeutic drug performance. We believe that our drug delivery technology holds promise in addressing certain of the limitations confronted by other lipid based drug delivery technologies which in the past may not have achieved their desired results. We could however conceivably devote significant operational and financial resources to this research effort only to discover that our methodology and approach is no better or maybe not as good as previous or existing delivery technologies. Additionally, the development of our own drug delivery technology is ongoing and accordingly is subject to numerous scientific and procedural hurdles, such as receiving FDA approvals, raising capital to fund development and the possibility that pre-clinical and clinical trials may reveal presently unknown disadvantages or problems associated with our technology.

If we establish our technology, we intend to seek commercialization through a combination of marketing approaches which we anticipate may include marketing off-patent drugs 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 biotechnology or pharmaceutical companies. As we seek commercialization, we face numerous scientific and procedural hurdles which may adversely affect,

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

delay or even frustrate our selected marketing approaches. Such hurdles may include, difficulty in obtaining FDA approval of our proposed products or difficulty in identifying, establishing, or maintaining research and commercial relationships. To achieve our objectives, our strategy includes the following key elements:

- Identify drugs which we believe may benefit from our drug delivery technology;
- Reduce development risk, regulatory approval process time and uncertainty of commercial acceptance by utilizing our technology with drugs which currently have both regulatory approval and commercial acceptance, including those which are not currently patent protected;

1

- Obtain relationships with pharmaceutical and biotechnology companies that have the rights to drugs, which may include access to their proprietary drugs, and licensing arrangements which may result in sharing some or all of the risks, time and expense generally associated with development and commercialization;
- Obtain regulatory approval, including FDA approval, for each drug encapsulated with our drug delivery technology; and
- Prepare for commercialization of our intended Bioral products.

We are presently engaged in research and development activities with regard to the following drugs and/or category of drugs, which are not currently patent protected:

- Bioral Amphotericin B: Amphotericin B, an accepted intravenous drug, has been identified by us for oral treatment of systemic fungal infections and as an oral prophylactic agent for immunosuppressed patients. We are collaborating with the National Institutes of Health, the Public Health Research Institute of New York and the University of Texas to develop this intended product. We have been awarded a grant totaling approximately \$0.9 million from the National Institutes of Health which, along with additional awards of \$1.8 million expected under the same grant, will support our planned Investigational New Drug Application (IND) submission for Phase I clinical trials.
- Bioral Clofazimine: Clofazimine, an antibiotic, currently an accepted drug used to treat cells infected with the microbacteria causing tuberculosis has also been identified for "encapsulation". Clofazimine is currently administered orally and our goal is to improve oral availability, reduce side effects, and improve the therapeutic effect. We are also pursuing applications of our drug delivery technology with generic injectable antibiotics used to treat other infections. We are currently in pre-clinical development of clofazimine using our drug delivery technology in collaboration with the Institute for Tuberculosis Research, University of Illinois.
- Bioral Anti-Inflammatories: We have identified several, commercially accepted over-the-counter, non-steroidal, anti-inflammatories such as generic aspirin or ibuprofen to be potentially "encapsulated" in our delivery technology. Our objective is to increase the availability of currently accepted anti-inflammatories for arthritis and other inflammations with potentially reduced risk of side effects. We are in the process of preparing formulations in anticipation of potential pre-clinical trials.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

We are also preparing an application seeking to begin Phase I clinical trials with the FDA with regard to the research and development of our autologous HIV immunotherapeutic which we currently believe may be filed in the first quarter of 2003. This technology is being developed as a patient specific (autologous) therapeutic for treatment following HIV infection. 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 finance further development of this technology.

### POSSIBLE STRATEGIC SALE OF SHARES TO PPDI

PPDI has expressed its interest in purchasing up to 690,000 Units in this offering, constituting approximately 34.5% of the offering (assuming an offering of 2,000,000 Units), at the initial public offering price. Following the offering, and assuming PPDI purchases these Units, PPDI will beneficially own up to 9.9% of our outstanding common stock (9.5% if the Representative's over allotment option is exercised in full). PPDI will agree not to sell any Units, shares of common stock or warrants for a period of at least 180 days, subject to the Representative's approval following the date of the final prospectus. The underwriters will receive the stated commission and expense allowance on the sale of these Units. In addition to its intent to purchase Units, PPDI has indicated an interest in securing a license for the use of our drug delivery technology for certain purposes. We have initiated early-stage negotiations with PPDI regarding such license, but no terms have been agreed upon and no license has been entered into as of the date of this prospectus, and the parties may not be able to reach agreement on any such license.

As of the date of this prospectus, PPDI does not own any of our securities nor is there any pre-existing relationship between us and PPDI. See "Description of Business -- Collaborative and Supply Relationships,"

2

"Certain Transactions," and "Principal Stockholders" for further discussion of our proposed relationship with PPDI.

### HISTORICAL AND RECENT EVENTS

MAS Acquisition XXIII Corp., our original corporate name, was formed in Indiana on January 6, 1997. In January 2000, an investment group, led by Dr. Francis E. O'Donnell, our current President and CEO, acquired a controlling interest in MAS Acquisition XXIII Corp. ("MAS XXIII") for the purpose of facilitating an investment by us in BioDelivery Sciences, Inc., a Delaware corporation. At the time of the investment, MAS XXIII did not conduct any business or have any meaningful operations. Prior to Dr. O'Donnell's investment group purchasing a majority interest, MAS XXIII was controlled by Mr. Aaron Tsai who was the President and CEO as well as a majority stockholder. Several companies which are not affiliated with us in any capacity, that Mr. Tsai and MAS Capital, Inc., a registered broker dealer, have been involved with previously, have been the subject of regulatory investigation. After Dr. O'Donnell's investment group bought a majority interest in MAS XXIII, Mr. Tsai resigned from any position in management and has no direct or indirect role in our management. On March 29, 2002, Hopkins Capital Group II, LLC, controlled by Dr. O'Donnell, entered into an agreement with MAS Capital, Inc. and Mr. Tsai to purchase and surrender all of their interest in our securities, consisting of 74,966 shares of common stock and to return to us 22,881 options, respectively for \$150,696 in the form of a promissory note payable March 29, 2003.

The business opportunity described in this prospectus is primarily the drug delivery technology developed by BioDelivery Sciences, Inc. BioDelivery

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

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

In May 2002, we also effected a reverse stock split of one for 4.37 shares. All references to our outstanding common stock and other securities reflect the reverse split.

Our offices and scientific facilities are located at the University of Medicine and Dentistry of New Jersey, 185 South Orange Avenue, Administrative Building 4, Newark, New Jersey 07103 and our telephone number is (973) 972-0015.

3

### THE OFFERING

Securities offered.....	2,000,000 Units, each Unit consisting of:
	(i) one share of common stock; and
	(ii) one Class A warrant.
Common Stock:	
Number outstanding prior to the Offering.....	5,000,863 shares.(1,2)
Number outstanding after this Offering.....	7,000,863 shares.(2)
Class A Warrant:	
Number outstanding after this Offering.....	2,000,000 warrants
Securities underlying Class A warrants.....	Each Class A warrant is exercisable to purchase one share of common

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

stock.

Exercise price.....	The initial exercise price of each Class A warrant is 120% of the purchase price of the Units. The exercise price is subject to adjustment, including anti-dilution provisions for corporate events such as stock splits and for issuance of securities at less than the then current exercise price.
Exercise period.....	The Class A warrants are exercisable from June 24, 2003 until June 24, 2007.
Redemption.....	We may redeem the outstanding Class A warrants for \$.10 per warrant upon 30 days written notice to the warrant holder; provided: <ul style="list-style-type: none"><li>(i) that there is then an effective registration statement under the Securities Act allowing the issuance of the shares issuable upon exercise of the Class A warrants; and</li><li>(ii) the average closing sale price of the common stock equals or exceeds 150% of the offering price of the Units for the 10 trading days prior to the date of the notice of redemption; and</li><li>(iii) that 12 months has elapsed since the date of this prospectus.</li></ul>

- 
- (1) As of April 25, 2002, the number of shares of common stock includes the issuance of 462,243 shares of common stock which were issued as part of our December, 2001 rescission of all our issued and outstanding Series A preferred stock. In connection with our merger with BioDelivery Sciences, Inc. which was consummated in January, 2002, we issued 520,313 shares of common stock, which are also included in the number of shares outstanding.
  - (2) Excludes an aggregate of 3,978,355 shares of common stock issuable under (i) the 2001 incentive stock option plan, (ii) the Representative's unit purchase option, (iii) the over-allotment option and (iv) Class A warrants. For a full discussion of the terms of these securities, see the sections entitled "Description of Capital Stock" and "Capitalization".

Nasdaq and Boston Stock Exchange  
Symbols:

Units

BDSIU



# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Common Stock	BDSI
Class A Warrants	BDSIW
Type of offering.....	This is a firm commitment offering by the underwriters. If PPDI fails to purchase 690,000 Units, the Representative may terminate the Offering.

5

## RISK FACTORS

An investment in this offering is extremely risky. You should carefully consider the following risks, in addition to the other information presented in this prospectus, before deciding to buy our securities. If any of the following risks actually materialize, our business and prospects could be seriously harmed, the price and value of our securities could decline and you could lose all or part of your investment. The risks and uncertainties described below are intended to be the material risks that are specific to us, to our industry or to companies going public.

### 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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. See "Description of Business -- Government Regulation."

6

DATA OBTAINED FROM CLINICAL TRIALS ARE SUSCEPTIBLE TO VARYING INTERPRETATIONS, WHICH COULD DELAY, LIMIT OR PREVENT REGULATORY CLEARANCES.

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data is susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry including those involved in competing drug delivery technologies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance of the potential drug, resulting in delays to commercialization, and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

We have conducted research regarding whether other companies have subject to FDA review regarding nano-encapsulation drug delivery systems and based upon this research are unaware of any FDA proceedings limiting the use of this technology. There can be no assurance that the FDA will not undertake any such actions against our technology or similar technologies developed by others. See "Description of Business -- Government Regulation."

COMPETITORS IN THE DRUG DEVELOPMENT INDUSTRY MAY DEVELOP COMPETING TECHNOLOGY.

Drug companies and/or other technology companies may seek to develop and market nanoencapsulation technologies which may compete with our technology. While we believe that our technology for nanoencapsulating drugs is unique because we utilize cochleate nanocrystals to encapsulate drugs; we capture the

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

drugs at the time when large lipid sheets are rolling up to form the scroll-like cochleate structure; and no chemical reactions are involved in this process which would otherwise result in drugs being exposed to potentially damaging chemicals, other competitors may develop similar or different nanoencapsulation techniques which may become more accepted by the marketplace.

OUR PATIENT-SPECIFIC HIV THERAPY MAY NOT GAIN FDA APPROVAL IN CLINICAL TRIALS OR BE EFFECTIVE AS A THERAPEUTIC AGAINST THE HIV VIRUS WHICH COULD AFFECT OUR FUTURE PROFITABILITY.

In order to obtain regulatory approvals of our patient-specific HIV therapy, we must demonstrate that the procedure is safe and effective for use in humans and functions as a therapeutic against the HIV virus. To date, we have only conducted a pilot study pursuant to Institutional Review Board oversight in anticipation of our initial FDA submission for our patient-specific HIV therapy.

We may not be able to demonstrate that this potential HIV therapy, is safe or effective in advanced clinical trials that involve human patients. We are also not able to assure that the results of the clinical trials already conducted and which we intend to conduct will support our applications for regulatory approval. As a result, our HIV therapy may be curtailed, redirected or eliminated at any time. The HIV virus is very complex and may be prone to genetic mutations. These mutations have produced strains of HIV that are resistant to currently approved therapeutics.

Even if we gain regulatory approval for our patient-specific HIV therapy, the virus may develop similar resistance to our treatment. This could have a material adverse effect on our business, financial condition and results of operations. See "Description of Business -- Government Regulation."

### RISKS RELATING TO OUR BUSINESS

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

Since our inception in January 1997 and through March 31, 2002, we have recorded operating losses totaling \$5,412,581. As of March 31, 2002, we had a working capital deficit of \$1,697,470 and a stockholder's deficit of \$504,212. In addition, we expect to incur increasing operating losses over the next several years as we

7

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. Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel. We have not generated any revenue to date, other than research grants, and have no licensing or royalty revenue or products ready for use or licensing in the marketplace. This limited history may not be adequate to enable you to fully assess our ability to develop our technologies and proposed products, obtain FDA approval and achieve market acceptance of our proposed products and respond to competition. We cannot be certain as to when or whether to anticipate commercializing and marketing our

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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, assuming that we have not defaulted on the terms of our intellectual property licenses and can continue with our approval process. See "Description of Business -- Relationship with University of Medicine and Dentistry and Albany Medical College."

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. This loss may also increase our expenses and materially harm our business, financial condition and results of operation.

We have a license agreement with the University of Medicine and Dentistry of New Jersey and Albany Medical College in which they grant us exclusive license to conduct research and development of the 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. See "Description of Business -- Collaborative and Supply Relationships."

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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 \$627,000 through March 2002 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 in its opinion, the 2002 and 2003 amounts noted above may be reduced or eliminated in their entirety at NIH's sole discretion. See "Description of Business -- Collaborative and Supply Relationships."

WE ARE EXPOSED TO PRODUCT LIABILITY, CLINICAL AND PRECLINICAL LIABILITY RISKS WHICH COULD PLACE A SUBSTANTIAL FINANCIAL BURDEN UPON US, SHOULD WE BE SUED, BECAUSE WE DO NOT CURRENTLY HAVE PRODUCT LIABILITY INSURANCE ABOVE AND BEYOND OUR GENERAL INSURANCE COVERAGE.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. We cannot assure potential investors that such claims will not be asserted against us. In addition, the use in our clinical trials of pharmaceutical products that our potential collaborators may develop and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We do not currently have any product liability insurance or other liability insurance relating to clinical trials or any products or compounds. We cannot assure you that we will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements with or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us could have a material adverse effect on our business, financial condition and results of operations.

WE DO NOT CURRENTLY HAVE SPECIFIC PLANS FOR UNALLOCATED OFFERING PROCEEDS AND OUR MANAGEMENT WILL HAVE BROAD DISCRETION IN DETERMINING FUTURE ALLOCATION.

The principal purposes of the funding from this offering are to conduct research and development of our drug delivery technology, obtain regulatory approval for our technology and proposed products, and expand our research facilities. We currently do not have specific plans for all of the net proceeds from this offering. We expect to use a percentage of the proceeds for general corporate purposes, including working capital, development of our technology, obtain regulatory approvals for our products and capital expenditures. The amounts expended for each purpose and the timing of such expenditures may vary depending upon numerous factors. Consequently, we will have broad discretion in determining the amount and timing of expenditures and in using the unallocated proceeds of this offering, and there can be no assurance that we will use such discretion effectively or in a manner that will not result in a material adverse effect on our business, financial condition and results of operation. Proceeds received by us as a result of the exercise of any of the Class A warrants may be used in any manner generally consistent with the use of proceeds of this

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

offering. See "Use of Proceeds."

9

ACCEPTANCE OF OUR PRODUCTS IN THE MARKETPLACE IS UNCERTAIN AND FAILURE TO ACHIEVE MARKET ACCEPTANCE WILL PREVENT OR DELAY OUR ABILITY TO GENERATE REVENUES

Our future financial performance will depend, at least in part, upon the introduction and customer acceptance of our proposed products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration of the advantages, safety and efficacy of our technologies;
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our intended products; and
- our ability to market our products.

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

WE MAY BE SUED BY THIRD PARTIES WHICH CLAIM THAT OUR PRODUCTS INFRINGE ON THEIR INTELLECTUAL PROPERTY RIGHTS, PARTICULARLY BECAUSE THERE IS SUBSTANTIAL UNCERTAINTY ABOUT THE VALIDITY AND BREADTH OF MEDICAL PATENTS

We may be exposed to future litigation by third parties based on claims that our technologies, products or activities infringe the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. Most of our license agreements require that we pay the costs associated with defending this type of litigation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling, making, using, importing, incorporating or using any of our technologies and/or products that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our products, which would be costly and time-consuming.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

We are aware of two issued United States patents dealing with lipid formulations of Amphotericin B products. The first of these patents, United States Patent No. 4,978,654, claims an Amphotericin B liposome product. We do not believe that our patents or our technology are in conflict with this existing patent, although there can be no assurance that a court of law or the United States' patent authorities might determine otherwise. Our belief is based upon the fact that our cochleate product does not contain liposomes, which appears to be the basis for the existing patent. The second of these patents, United States Patent No. 5,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we are in conflict with this second patent. If a court were to determine that we infringe either of these patents, we might be required to seek a license from the holders of the patent to commercialize our Amphotericin B products. In such event, we do not know whether we would be able to obtain a license from either patent holder. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, there would likely be a material adverse effect upon our business plan to commercialize our Amphotericin B products.

10

As of the date of this prospectus, we have not engaged in discussions, received any communications, nor do we have any well-founded reason to believe that any third party is challenging or has the right proper legal authority to challenge our intellectual property rights or those of the actual patent holders. See "Description of Business -- Licenses, Patents and Proprietary Information."

IF WE ARE UNABLE TO ADEQUATELY PROTECT OR ENFORCE OUR RIGHTS TO INTELLECTUAL PROPERTY OR SECURE RIGHTS TO THIRD-PARTY PATENTS, WE MAY LOSE VALUABLE RIGHTS, EXPERIENCE REDUCED MARKET SHARE, ASSUMING ANY, OR INCUR COSTLY LITIGATION TO PROTECT SUCH RIGHTS

Our ability to obtain license to patents, maintain trade secret protection and operate without infringing the proprietary rights of others will be important to our commercializing any products under development. The current and future development of our drug delivery technology is contingent upon whether we are able to maintain a license to access the patents. Without this license, the technology would be protected from our use and we would not be able to even conduct research without prior permission from the patent holder. Therefore, any disruption in access to the technology could substantially delay the development of our technology.

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

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We generally require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

Although our trade secrets and technical know-how are important, our continued access to the patents is a significant factor in the development and commercialization of our drug delivery technology. Aside from the general body of scientific knowledge from other drug delivery processes and lipid technology, these patents, to the best of our knowledge and based upon our current scientific data, are the only intellectual property necessary to develop our current drug delivery system using our proposed drugs. We do not believe that any other company is developing a drug delivery technology similar to ours or that we violating any other patents in developing our technology.

We may have to resort to litigation to protect our rights for certain intellectual property, or to determine their scope, validity or enforceability. Enforcing or defending our rights is expensive, could cause diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products. See "Description of Business -- Licenses, Patents and Proprietary Information."

11

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



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 effectiveness 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 HAVE LIMITED MANUFACTURING EXPERIENCE AND ONCE OUR PRODUCTS ARE APPROVED WE MAY NOT BE ABLE TO MANUFACTURE SUFFICIENT QUANTITIES AT AN ACCEPTABLE COST

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, once our proposed products are approved for commercial sale we will need to establish the capability to commercially manufacture our product(s) in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our intended products.

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

DUE TO OUR LIMITED MARKETING, SALES AND DISTRIBUTION EXPERIENCE, WE MAY BE UNSUCCESSFUL IN OUR EFFORTS TO SELL OUR PRODUCTS, ENTER INTO RELATIONSHIPS WITH THIRD PARTIES OR DEVELOP A DIRECT SALES ORGANIZATION

Except for our non-exclusive distribution agreement with BioTech Specialty Partners, Inc., a development-stage company affiliated with Dr. Francis E. O'Donnell, a member of our management and significant beneficial owner of our securities, we have yet to establish marketing, sales or distribution capabilities for our proposed products. Until such time as our proposed products are further along in the regulatory process, we will not devote any meaningful time and resources in this regard. At the appropriate time, we intend to enter into agreements with third parties to sell our proposed products or we may develop our own sales and marketing force. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors.

12

If we do not enter into relationships with third parties for the sales and marketing of our proposed products, we will need to develop our own sales and marketing capabilities. We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force on a cost effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. See "Description of Business -- Manufacturing" and "Sales and Marketing."

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

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

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

IF WE ARE UNABLE TO CONVINCING PHYSICIANS AS TO THE BENEFITS OF OUR INTENDED PRODUCTS, WE MAY INCUR DELAYS OR ADDITIONAL EXPENSE IN OUR ATTEMPT TO ESTABLISH MARKET ACCEPTANCE.

Broad use of our drug delivery technology may require physicians to be informed regarding our intended products and the intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our proposed products. We may be unable to timely educate physicians regarding our intended products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our products is created if at all.

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.

Our long term capital requirements which will exceed the anticipated net proceeds of this offering, are expected to depend on many factors, including:

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for commercial quantities of our drugs;
- competing technological and market developments;

13

- market acceptance of our products;
- costs for recruiting and retaining employees and consultants; and
- costs for training physicians

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through the exercising of warrants, equity or debt financings, collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. See "Management's Discussion and Analysis of Financial Condition and Plan of Operation." If adequate funds are not available, we may be required to significantly reduce or refocus our development efforts with regards to our drug delivery technology and the proposed encapsulation of certain drugs.

### RISKS RELATED TO OUR INDUSTRY

THE MARKET FOR OUR PROPOSED 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 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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. See "Description of Business -- Competition."

IF USERS OF OUR PROPOSED PRODUCTS ARE UNABLE TO OBTAIN ADEQUATE REIMBURSEMENT FROM THIRD-PARTY PAYORS, OR IF NEW RESTRICTIVE LEGISLATION IS ADOPTED, MARKET ACCEPTANCE OF OUR PROPOSED PRODUCTS MAY BE LIMITED AND WE MAY NOT ACHIEVE REVENUES

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

14

regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

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

WE COULD BE EXPOSED TO SIGNIFICANT DRUG LIABILITY CLAIMS WHICH COULD BE TIME CONSUMING AND COSTLY TO DEFEND, DIVERT MANAGEMENT ATTENTION AND ADVERSELY IMPACT OUR ABILITY TO OBTAIN AND MAINTAIN INSURANCE COVERAGE.

The testing, manufacture, marketing and sale of our intended products involve an inherent risk that product liability claims will be asserted against us. We currently have a general liability policy with an annual aggregate limit of \$2 million with a \$1 million limit per occurrence which does not provide coverage for product liability. All of our pre-clinical trials have been and all of our proposed clinical and pre-clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently do not have insurance which relate to product liability or insurance related to clinical or

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

pre-clinical trials. We intend to seek insurance against such risks before our product sales are commenced, although there can be no assurance that such insurance can be obtained at such time, or even if it is available, that the cost will be affordable. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs. The cost and availability of such insurance are unknown. Product liability claims or other claims related to our intended products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our drug delivery technology. A product liability claim could also significantly harm our reputation and delay market acceptance of our intended products.

OUR BUSINESS INVOLVES ENVIRONMENTAL RISKS RELATED TO HANDLING REGULATED SUBSTANCES WHICH COULD SEVERELY AFFECT OUR ABILITY TO CONDUCT RESEARCH AND DEVELOPMENT OF OUR DRUG DELIVERY TECHNOLOGY

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

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

15

### RISKS RELATED TO THIS OFFERING

OUR STOCK PRICE AFTER THIS OFFERING WILL BE SUBJECT TO MARKET FACTORS, AND YOUR INVESTMENT IN OUR SECURITIES COULD DECLINE IN VALUE

After this offering, an active trading market in our securities might not develop or continue. If you purchase shares of our securities in the offering, you will pay a price that was not established in a competitive market. Rather, you will pay a price that we negotiated with the representatives of the underwriters based upon an assessment of the valuation of our business, market factors and associated securities. The public market may not agree with or accept this valuation, in which case you may not be able to sell your securities

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

at or above the initial offering price. The market price of our securities may fluctuate significantly in response to factors which are beyond our control.

In addition, the market prices of securities of biotechnology and pharmaceutical companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our securities, which could cause a decline in the value of your securities. See "Dilution."

### FUTURE SALES OF OUR SECURITIES MAY DEPRESS OUR STOCK PRICE AND CAUSE A SUBSTANTIAL LOSS TO PURCHASERS OF OUR SECURITIES

Within 45 days of the completion of this offering, as many as an additional 15% of the Units in this offering may be purchased and subsequently resold by the underwriters, the over-allotment option. If substantial amounts of our securities were to be sold in the public market by the underwriters following this offering, the market price of our securities could fall. In addition, these sales could create the perception to the public of difficulties or problems in our business. As a result, these sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. For a more detailed discussion of shares eligible for sale after this offering, see "Shares Eligible for Future Sale."

The Units offered by this prospectus include Class A warrants to purchase up to an additional 2,000,000 shares (2,300,000 shares if the over-allotment option is exercised in full) of our common stock at a per share exercise price of 120% of the purchase price of the Units.

Under Rule 144 as currently in effect, commencing on the date of this prospectus, a person who has beneficially owned restricted shares of common stock for at least one year, including the holding period of any prior owner who is not an affiliate, would be entitled to sell a number of the shares within any three-month period equal to the greater of 1% of the then outstanding shares of the common stock or the average weekly reported volume of trading of the common stock on the NASDAQ SmallCap Market during the four calendar weeks preceding such sale. Immediately after the offering, 1% of our outstanding shares of common stock (excluding shares of common stock underlying all options and warrants) would equal approximately 70,009 shares. There are approximately 4,254,002 shares which would be eligible for resale under Rule 144 (although 3,330,115 of such shares are held by officers, directors and affiliates or other stockholders and are subject to a lock-up between 12 and 36 months from the date of this prospectus). In addition to the 3,330,115 referenced above, there are 1,624,327 shares owned by certain other stockholders that are subject to a lock-up agreement with the Representative. Therefore, a significant number of shares may be sold immediately and may negatively effect our market price. Under Rule 144, restricted shares are subject to manner of sale and notice requirements and requirements as to the availability of current public information concerning us.

### THE SALE OF A SUBSTANTIAL NUMBER OF SHARES OF OUR COMMON STOCK BY PPDI AFTER THE LOCK-UP PERIOD EXPIRES MAY CAUSE THE PRICE OF OUR COMMON STOCK TO DECLINE.

PPDI has expressed an interest in purchasing approximately 690,000 Units or 34.5% of this offering. Assuming that PPDI purchases these Units, the underlying securities are subject to a 180 day lock-up arrangement between PPDI and the Representative after the effective date of this prospectus. Upon the expiration of lock-up, PPDI may sell a substantial number of shares in the public market which could saturate the market for our common stock and substantially harm the market price.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

THE REDEMPTION OF OUR WARRANTS IN THIS OFFERING MAY ADVERSELY AFFECT POTENTIAL INVESTORS.

The warrants in this offering are redeemable, in whole or in part, pursuant to the following terms:

Our Class A warrants will be redeemable for \$.10 per warrant upon 30 days written notice to the warrant holder; provided that: (i) there is then an effective registration statement under the Securities Act covering the shares issuable upon exercise of the warrants; (ii) the average closing sale price of our common stock equals or exceeds 150% of the offering price of the Units for the 10 trading days prior to the date of the notice of redemption; and (iii) that 12 months has elapsed since the date of this prospectus.

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

CURRENT PROSPECTUS AND STATE BLUE SKY REGISTRATION REQUIRED TO EXERCISE WARRANTS.

Holders of our warrants will be able to exercise their warrants only if a current registration statement relating to such shares is then in effect and only if the shares are qualified for sale under the securities laws of the applicable state or states. We have undertaken and intend to file and keep current a registration statement covering the shares of common stock issuable upon exercise of the warrants, but there can be no assurance that we will be able to do so. Although we intend to seek to qualify such shares of common stock for sale in those states where the Units are to be offered, there is no assurance that such qualification will occur. The warrants may be deprived of any value if the current registration statement covering the shares underlying the warrants is not effective and available or such underlying shares are not or cannot be registered in the applicable states. See "Description of Securities."

OUR CERTIFICATE OF INCORPORATION, OUR BYLAWS AND DELAWARE LAW CONTAIN PROVISIONS THAT PRESERVE OUR CURRENT MANAGEMENT.

Our certificate of incorporation and by-laws may discourage, delay or prevent a change in our management team that stockholders may consider favorable. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

these provisions could in turn affect any attempt to replace our current management team.

THE INVESTMENT RISK IN THIS OFFERING WILL BE SUBSTANTIALLY BORNE BY PUBLIC INVESTORS.

Our current stockholders paid a relatively small amount of consideration for their shares or paid nothing and received such shares as compensation, while public investors in this offering will pay a substantially higher price. This creates a situation in which a larger portion of the investment risk will shift to the public investors participating in this offering.

PURCHASERS IN THIS OFFERING WILL EXPERIENCE IMMEDIATE AND SUBSTANTIAL DILUTION OF THEIR INVESTMENT

We expect that the initial public offering price of the Units will significantly exceed the net tangible book value per share of the outstanding common stock after this offering. Based upon an offering price per Units of \$5.25, you will incur immediate dilution of approximately \$4.19 (80% dilution of value) in net tangible book value for each share of our common stock included in the Units you purchase. If currently outstanding options or warrants to purchase our common stock are exercised, your investment may be further diluted. Accordingly,

17

purchasers of our securities will suffer immediate and substantial dilution of their investment. Although the amount of dilution may vary, holders of the Class A warrants will also suffer immediate and substantial dilution upon exercise of such securities based upon an initial exercise price of \$6.30 per share. See "Dilution."

LIMITED EXPERIENCE OF THE UNDERWRITERS COULD AFFECT THIS OFFERING AS WELL AS THE PRICE OF OUR SHARES IN THE SECONDARY MARKET

We have been advised that solely as a result of business considerations, one of our underwriters, Roan/Meyers Associates, LP, has not acted as lead underwriter in any firm commitment public offering in the last 3 years while the Representative, Kashner Davidson Securities Corporation has acted as lead underwriter only once in the last year. No assurance can be given that Kashner Davidson Securities Corporation or Roan/Meyers Associates, L.P.'s limited public offering experience will not affect the subsequent development of a trading market of our shares of common stock. Investors should consider this lack of public offering experience in making an investment decision. See "Underwriting". To obtain detailed information regarding this underwriter (or any underwriter), you should contact your state regulator or visit the National Association of Securities Dealers website at [www.nasdr.com](http://www.nasdr.com).

RISKS RELATED TO OUR MANAGEMENT AND KEY EMPLOYEES

WE DEPEND UPON KEY PERSONNEL WHO MAY TERMINATE THEIR EMPLOYMENT WITH US AT ANY TIME, AND WE WILL NEED TO HIRE ADDITIONAL QUALIFIED PERSONNEL

Our success will depend to a significant degree upon the continued services of key management, technical, and scientific personnel, including Drs. Francis O'Donnell, Raphael Mannino and Susan Gould-Fogerite. With the exception of Dr. Gould-Fogerite, our key scientific personnel devote full time to the company. Dr. Gould-Fogerite has on-going obligations as a professor at the University of Medicine and Dentistry of New Jersey. At such time as our board of directors deems it is necessary, we anticipate that a number of our executives will become full-time or recruit/hire as necessary. Mr. McNulty, has been intentionally



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

employed on a "part-time as required" basis. Notwithstanding his part-time status, he has been paid \$67,461 in 2002 through June 7, because we have been using his services on a more regular basis. On March 29, 2002, Dr. O'Donnell executed an employment agreement with us to serve as our full-time interim CEO. We have identified and are in discussions with potential replacement candidates for Dr. O'Donnell, as Chief Executive Officer, although we do not believe that any such candidate will accept a position with us until we receive funding and are sufficiently capitalized. Dr. O'Donnell is prepared to resign as an officer after this offering is consummated and an acceptable replacement has been identified and accepts such a position on terms acceptable to us.

We have applied for "key man" life insurance policy for Dr. Raphael Mannino in the amount of \$2,000,000. Our president and CEO, Dr. Frank O'Donnell does not currently have this coverage. This insurance, if issued, may not adequately compensate us for the loss of their services. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. See "Certain Transactions."

EXECUTIVE OFFICERS, DIRECTORS AND ENTITIES AFFILIATED WITH THEM WILL CONTINUE TO HAVE SUBSTANTIAL CONTROL OVER US AFTER THE OFFERING, WHICH COULD DELAY OR PREVENT A CHANGE IN OUR CORPORATE CONTROL FAVORED BY OUR OTHER STOCKHOLDERS

Our directors, executive officers and principal stockholders, together with their affiliates, will beneficially own, in the aggregate, approximately 58.48% of our outstanding common stock following the completion of this offering and 56.07% if the over-allotment option is exercised in full. In particular, our directors and executive officers will control approximately 54.52% of our common stock after this offering, 52.28% if the over-allotment option is exercised in full. These figures do not reflect the exercise of the Class A warrants into

18

shares of common stock. Additionally, these figures do not reflect the increased percentages that the officers and directors may have in the event that they exercise any of the options granted to them in the 2001 Stock Option Plan or if they otherwise acquire additional shares of common stock. The interests of our current officer and director stockholders may differ from the interests of other stockholders, including purchasers of shares in this offering. As a result, these current officer and director stockholders would have the ability to exercise control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders including purchasers in this offering may vote, including the following actions:

- the election of directors;
- adoption of stock option plans;
- the amendment of charter documents;
- issue blank check preferred stock; or
- the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

CERTAIN OF OUR MANAGEMENT TEAM HAVE RELATIONSHIPS WHICH MAY POTENTIALLY RESULT IN CONFLICTS OF INTERESTS.

Dr. O'Donnell, who is an executive officer, on our board of directors and also is a substantial beneficial owner of our securities, has a financial interest in a number of other companies which have business relationships with us. These companies include RetinaPharma International, Inc., Tatton Technologies, LLC, BioKeys, Inc., Biotechnology Specialty Partners, Inc, and American Prescription Partners, Inc. We have entered into license agreements with RetinaPharma International, Inc. and Tatton Technologies, LLC with regard to our proposed Bioral neutraceutical product. We have entered into a non-exclusive distribution with Biotechnology Specialty Partners, Inc. We have entered into a license agreement with BioKeys, Inc. with regard to their vaccine in development. Each of these business arrangements was approved by the Board of Directors of BioDelivery Sciences, Inc., the Delaware entity and have been approved by our board of directors of which Dr. O'Donnell abstained. These agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and Dr. O'Donnell.

Dr. L.M. Stephenson is on our board of directors and is also associated with the University of Medicine and Dentistry of New Jersey for the last five years. He is currently Vice President for Research at the university. Dr. Stephenson's association with the university may currently or in the future involve conflicting interests. In future matters involving the university, Dr. Stephenson will refrain from voting and a majority of the disinterested directors has been and will be required to approve all such transactions. Dr. Stephenson currently owns stock options which have been issued to him as a result of his agreeing to serve on the board of directors. See "Certain Relationships and Related Transactions."

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements under "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Plan of Operation," "Description of Business," and elsewhere in this prospectus are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by forward-looking statements. Such factors include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "proposed," "intended," or "continue" or the negative of these terms or other comparable terminology. You should read statements that contain these words carefully, because they discuss our expectations about our future operating results or our future financial condition or state other "forward-looking" information. There may be events in the future that we are not able to accurately predict or control. Before you invest in our securities, you should be aware that the occurrence of any of the events described in these risk factors and elsewhere in

19

this prospectus could substantially harm our business, results of operations and financial condition, and that upon the occurrence of any of these events, the trading price of our securities could decline and you could lose all or part of your investment.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, growth rates, levels of activity, performance, or achievements. We are under no duty to update any of the forward-looking statements after the date of this prospectus to conform these statements to actual results.

20

### USE OF PROCEEDS

The net proceeds (excluding any proceeds from the exercise of any warrants or the exercise of the over-allotment option) from the sale of the 2,000,000 Units in this offering are estimated to be approximately \$8,461,150, based upon an assumed initial public offering price of \$5.25 per Unit and after deducting estimated underwriting discounts and commissions (\$897,750) and our estimated offering expenses (\$1,141,100) consisting primarily of non-accountable expenses, SEC registration fees, legal, accounting and transfer agent and registrar expenses. If the underwriters' over-allotment option is exercised in full, the additional net proceeds would be approximately \$1,393,088. We currently intend to use the net proceeds of this offering as follows:

CATEGORY -----	AMOUNT ALLOCATED -----	PERCENTAGE OF TOTAL PROCEEDS -----
Product Development(1).....	\$6,000,000	70.9%
Licensing and Other Marketing Activities.....	\$ 800,000	9.5
Payment of Debt(2).....	\$1,250,000	14.8
Payment of stockholder tax liability(3).....	\$ 200,000	2.4
General and Administrative Support and Working Capital(4).....	\$ 211,150	2.4
	-----	----
Total Net Proceeds.....	\$8,461,150 =====	100% =====

-----

(1) Approximately \$6,000,000 to the further research and development of our drug delivery technology as well as our proposed drugs and our patient-specific HIV therapy, including research and development expenses, clinical and pre-clinical trial expenses, expenses associated with seeking regulatory approvals and expenses associated with the product manufacturing and marketing upon approval.

(2) Approximately \$1,250,000 for repayment of debt. Approximately \$200,000 of the debt was primarily incurred in 2001 in connection with our purchase of approximately 9% of the outstanding capital stock of BioDelivery Sciences, Inc. and settlement of certain litigation matters with a prior officer and stockholders of BioDelivery Sciences, Inc. The approximately \$1,050,000 remaining of the debt was incurred under a line of credit which was guaranteed and collateralized by Dr. O'Donnell and Mr. Ferguson, members of our management. The line of credit permits us to borrow up to \$1,050,000. See "Legal Proceedings."

(3) Reflects estimated taxes to be paid by us to certain stockholders in conjunction with the merger consummated in January 2002 with BioDelivery Science, Inc. See "Certain Transactions."

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

- (4) Approximately \$211,150 for working capital and corporate purposes. These purposes include rent, operating expenses, professional fees, license negotiations, research and product development, and salaries for employees and officers.

The amount of cash that we actually expend for any of the described purposes and the timing of any such expenditures may vary based on a number of factors, including the progress of our research and development programs and clinical trials, the establishment of collaborative relationships, the cost and pace of establishing and expanding our manufacturing capabilities, the development of sales and marketing activities if undertaken by us and competing technological and market developments.

Proceeds received by us as a result of the exercise of the Class A warrants will be used for working capital purposes.

We expect the proceeds to last approximately 12 months. Pending the uses described above, we will invest the net proceeds in investment-grade, interest-bearing securities. We intend to invest the net proceeds of this offering so as to avoid being subject to the registration requirements of the Investment Company Act of 1940, as amended, unless an exemption from such registration is available, because such registration would subject us to substantial regulations that could have a material adverse effect on our business.

### DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock or other securities and we do not intend to pay any cash dividends with respect to our common stock in the foreseeable future. For the foreseeable future, we intend to retain any earnings for use in the operation of our business and to fund future growth.

21

### CAPITALIZATION

The following table sets forth our total capitalization as of March 31, 2002, on an actual basis, which reflects the December 2001 rescission of our outstanding preferred stock and issuance of common stock in replacement thereof and the completion of the January 2002 merger with BioDelivery Sciences, Inc., and on an as adjusted basis to reflect the sale of the 2,000,000 Units in this offering at an initial public offering price of \$5.25 per Unit after deducting estimated underwriting discounts and commissions and our estimated offering expenses. This calculation excludes the proceeds from the exercise of the Class A warrants or other outstanding options.

You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Plan of Operations" and the consolidated financial statements and related notes to the financial statements.

	ACTUAL	AS ADJUSTED
	-----	-----
Capital Lease Payable.....	\$ 33,173	\$ 33,173
Notes Payable.....	246,210 (1)	--
Line of credit.....	618,732 (2)	--
Stockholders' Equity (Deficit):		
Preferred Stock, \$.001 par value; 20,000,000 shares		

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

authorized; no shares of Preferred Stock issued and outstanding.....	--	--
Common Stock, \$.001 par value; 80,000,000 shares authorized; 5,000,863 and 7,000,863 shares of Common Stock issued and outstanding.....	5,001	7,001
Additional paid-in capital.....	4,903,368	13,362,518
Deficit accumulated during development stage.....	(5,412,581)	(5,412,581)
	-----	-----
Total stockholders' equity (deficit).....	(504,212)	7,956,938
	-----	-----
Total capitalization.....	\$ 393,903	\$ 7,990,111
	=====	=====

-----

- (1) The Notes Payable will be paid out of the proceeds of this offering. Represents debt incurred as part of a litigation settlement with a former officer and stockholder. See "Legal Matters."
  
- (2) The line of credit is personally guaranteed by the personal assets of Dr. O'Donnell and Mr. Ferguson, members of our management and collateralized by all the business assets of the Company.

22

### DILUTION

Our net tangible book value as of March 31, 2002 was a deficit of approximately \$(1,051,000) or \$(.21) per share of common stock. Net tangible book value per share represents our stockholders' equity less intangible assets divided by the number of shares of common stock outstanding. Dilution per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of common stock immediately after completion of this offering.

After giving effect to the sale of 2,000,000 Units offered by us, at an initial public offering price of \$5.25 per Unit and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us as part of the Units, and the application of the estimated net proceeds, our net tangible book value at March 31, 2002 would have been \$7.4 million, or \$1.06 per share. This represents an immediate dilution to new investors of \$4.19 per share, or 80% of the purchase price value (assuming the shares have a price equal to the offering price of the Units of \$5.25). These calculations exclude the shares of common stock underlying the 2001 Incentive Option Plan and any warrants or options, including the Class A warrants.

The following table illustrates the pro forma information with respect to dilution to new investors on a per share basis:

Public offering price per share.....	\$ 5.25
Net tangible book value per share before this offering.....	\$ (.21)
Increase per share attributable to new investors.....	\$ 1.27
Net tangible book value per share after this offering.....	\$ 1.06
Dilution to new investors(1).....	\$ 4.19

-----

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

- (1) If the over-allotment option were exercised in full, the net tangible book value after this offering would be approximately \$1.21 per share, resulting in dilution to new investors in this offering of \$4.04 per share or 77% of the purchase price value.

The following table sets forth on a pro forma basis as of March 31, 2002, the Units purchased from us, the total consideration paid to us (after offering expenses) and the average price per share (i) paid by the existing stockholders and (ii) paid by the purchasers of the Units in this offering, assuming the sale of 2,000,000 Units at an initial public offering price of \$5.25 per Unit, ascribing no portion of the value of a unit to the Class A warrants, and the receipt of the net proceeds therefrom. The calculation in this table with respect to shares of common stock to be purchased by new investors in this offering excludes shares of common stock issuable upon exercise of the Class A warrants.

	SHARES PURCHASE		TOTAL CONSIDERATION	
	NUMBER	PERCENT	AMOUNT	PERCENT
Existing stockholders.....	5,000,863	71.4%	\$ 2,317,041	18.1%
New Investors.....	2,000,000	28.6%	\$ 10,500,000	81.9%
	-----	-----	-----	-----
Total.....	7,000,863	100%	\$ 12,817,041	100%
	=====	=====	=====	=====

This table assumes no exercise of the underwriters' over-allotment option nor the representative's unit purchase option, nor any option under the 2001 Incentive Stock Option Plan, the Class A warrants or any other outstanding options or warrants of which there will be 3,978,355 outstanding.

### SELECTED FINANCIAL AND OPERATING DATA

The following selected financial and operating data should be read in conjunction with and are qualified by reference to "Management's Discussion and Analysis of Financial Condition and Plan of Operation" and our financial statements and related notes, which are included elsewhere in this prospectus. The selected financial data for the period from inception through December 31, 1998 (unaudited) and the year ended December 31, 1999, has been derived from our audited financial statements which are not included herein. The selected financial data for the years ended December 31, 2000 and 2001 has been derived from our audited financial statements included elsewhere in this prospectus. The Selected Financial data for the three months ended March 31, 2001 and 2002 have been derived from our unaudited financial statements, which include all adjustments, consisting of normal recurring accruals, which we consider necessary for a fair presentation of the financial position and the results of operations for those periods. The selected financial data for the year ended December 31, 1999 has been derived from the audited financial statements of BioDelivery Sciences, Inc. which are not included herein. The selected financial data for the nine-month period ended September 30, 2000 has been derived from the audited financial statements of BioDelivery Sciences, Inc. included elsewhere in this prospectus. The selected financial data for the period from inception through December 31, 1998 has been derived from the unaudited financial statements of BioDelivery Sciences, Inc. which include all adjustments, consisting of normal recurring accruals, which BioDelivery

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Sciences, Inc. considers necessary for a fair presentation of the results of operations for this period. Historical operating results are not necessarily indicative of results in the future, and the results for interim periods are not necessarily indicative of the results that may be expected for the entire year.

	BIODELIVERY SCIENCES, INC. (1)			BIODELIVERY SCIEN	
	PERIOD FROM INCEPTION THROUGH DECEMBER 31, 1998  (UNAUDITED)	YEAR ENDED DECEMBER 31, 1999  (AUDITED)	NINE MONTHS ENDED SEPTEMBER 30, 2000  (AUDITED)	PERIOD FROM INCEPTION THROUGH DECEMBER 31, 1998  (AUDITED)	YEAR END DECEMBER 1999  (AUDITED)
STATEMENT OF OPERATIONS					
DATA:					
Sponsored research revenues.....	\$5,159,500	\$1,565,000	\$ 614,001	\$ --	\$
Research and development expenses.....	4,662,606	1,333,287	820,551	--	
General and administrative expenses.....	201,700	159,053	62,480	57	
Income (loss) from operations.....	295,194	72,660	(269,030)	(57)	
Interest income, net...	127,454	34,430	25,290		
Income (loss) before income taxes and minority interest....	422,648	107,090	(243,740)	(57)	
Income tax expense (benefit).....	207,082	14,579	(37,736)	--	
Income (loss) before minority interest....	215,566	92,511	(206,004)	(57)	
Minority Interest.....	--	--	--	--	
Net income (loss).....	\$ 215,566	\$ 92,511	\$ (206,004)	\$ (57)	\$
Net loss per common share -- basic and diluted.....					\$
Weighted average common shares outstanding -- basic and diluted.....					3,512,5

THREE MONTHS ENDED	
MARCH 31, 2001  (UNAUDITED)	MARCH 31, 2002  (UNAUDITED)

STATEMENT OF OPERATIONS

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

DATA:		
Sponsored research revenues.....	\$ --	\$ 275,000
Research and development expenses.....	331,483	450,475
General and administrative expenses.....	74,394	205,768
	-----	-----
Income (loss) from operations.....	(405,877)	(381,243)
Interest income, net...	13,406	(9,814)
	-----	-----
Income (loss) before income taxes and minority interest....	(392,471)	(391,057)
Income tax expense (benefit).....	--	95,343
	-----	-----
Income (loss) before minority interest....	(392,471)	(295,214)
Minority Interest.....	--	--
	-----	-----
Net income (loss).....	\$ (392,471)	\$ (295,214)
	=====	=====
Net loss per common share -- basic and diluted.....	\$ (0.11)	\$ (0.06)
	=====	=====
Weighted average common shares outstanding -- basic and diluted.....	3,518,179	5,000,863
	=====	=====

24

	BIODELIVERY SCIENCES, INC. (1)			BIODELIVERY SCIEN	
	PERIOD FROM INCEPTION THROUGH DECEMBER 31, 1998	YEAR ENDED DECEMBER 31, 1999	NINE MONTHS ENDED SEPTEMBER 30, 2000	PERIOD FROM INCEPTION THROUGH DECEMBER 31, 1998	YEAR END DECEMBER 1999
	(UNAUDITED)	(AUDITED)	(AUDITED)	(AUDITED)	(AUDITED)
BALANCE SHEET DATA:					
Cash and cash equivalents.....		\$ 212,357	\$ 580,465		\$
Total assets.....		588,076	974,956		
Total indebtedness.....		2,346	392,025		
Stockholders' equity (deficit).....		308,477	102,473		

THREE MONTHS ENDED



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

	MARCH 31, 2001	MARCH 31, 2002
	----- (UNAUDITED)	----- (UNAUDITED)
BALANCE SHEET DATA:		
Cash and cash equivalents.....	\$ 591,115	\$ --
Total assets.....	909,368	1,586,249
Total indebtedness.....	35,430	898,115
Stockholders' equity (deficit).....	44,834	(504,212)

-----

(1) The table covers periods before and after the Company acquired its controlling interest (approximately 84.8% voting interest) from BioDelivery Sciences, Inc. on October 10, 2000. The operations of BioDelivery Sciences, Inc. for the period October 1, 2000 through October 10, 2000 were not material.

25

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION 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 prospectus. 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 prospectus.

#### 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, exercise of warrants, collaborative research agreements, including pharmaceutical companies, grants from public service entities and government entities.

In 2001, the National Institutes of Health awarded us a 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 \$627,000 through March 31, 2002 and expect to receive the remainder through June 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 in its subjective opinion, the total expected funding amounts noted above may be reduced or eliminated.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

We have a limited history of operations and anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future. Prior to our acquisition of a majority interest in BioDelivery Sciences, Inc., we had no operations. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies at an early stage of development, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery, and biotechnology. For the foreseeable future, we must, among other things, seek regulatory approval for and commercialize our proposed drugs, which may not occur. We may not address these risks and difficulties. We will 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. 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. 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 July 2001 we entered into a merger agreement with BioDelivery Sciences Inc. and the remaining stockholders of BioDelivery Sciences Inc. acquired 520,313 shares of our common stock. The

26

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 March 31, 2002, we received approximately \$8.1 million of sponsored research revenue. Approximately \$6.7 million of the funding was from a single commercial entity, American Cyanamid Company. The contract with American Cyanamid Company as amended, was completed, in 2000. Of the remaining \$1.4 million, approximately \$.7 million was received from the National Institutes of Health.

FOR THE THREE MONTHS ENDED MARCH 31, 2002 COMPARED TO THE THREE MONTHS ENDED MARCH 31, 2001

Sponsored Research Revenue. During the three-month period ended March 31, 2002, we reported approximately \$275,000 of sponsored research revenues. With the exception of grants by the National Institutes of Health and funding provided to us through various collaborative agreements, we have not derived any revenues from our operations, technologies or products.

Research and Development. Research and development expenses of approximately \$331,000 and \$450,000 were incurred during the three-month periods

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

ended March 31, 2001 and 2002, respectively. Research and development expenses generally include: salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation, a portion of overhead operating expenses and other costs directly related to the development and application of the Bioral cochleate drug delivery technology.

General and Administrative Expense. General and administrative expenses of approximately \$74,000 and \$206,000 were incurred in the three-month periods ended March 31, 2001 and 2002, respectively. These expenses are principally comprised of legal and professional fees and other costs including office supplies, conferences, travel costs, salaries, website update and development, and other business development costs.

Interest Income (Expense). Interest income (expense) for the periods ended March 31, 2001 and 2002 was principally comprised of earnings from invested cash and from notes receivable from employees offset by interest expense on the line of credit, notes payable and capital leases payable.

Income Taxes. While net operating losses were generated during the three month period ended March 31, 2002, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved for. However, in March 2002, a new tax law changed a carryback period from two to five years, which allowed us to carryback prior losses to 1996 and 1997, resulting in a tax benefit of \$95,843. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets 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.

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 have received approximately \$479,000 through December 31, 2001 and 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

27

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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 elimination of the restrictions on the 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 immediately following this offering, 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. 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 our merger with BioDelivery Sciences, Inc., the minority interest in BioDelivery Sciences, Inc. no longer exists. We consummated the merger on January 7, 2002. However, the merger agreement was substantially complete and accounted for as of December 2001, as effective control of BioDelivery Sciences, Inc. was transferred to us without restrictions.

### 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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Revenue during both periods was principally

28

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 enable 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 elimination of restrictions on 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 our October 2000 84.8% acquisition 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 our merger with BioDelivery Sciences, Inc., the minority interest in BioDelivery Sciences, Inc. no longer exists. The merger was consummated on January 7, 2002. However, the merger agreement was substantially completed and accounted for as of December 2001, as effective control of BioDelivery Sciences, Inc. was transferred to us without restrictions.

LIQUIDITY AND CAPITAL RESOURCES

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Since inception, we have financed our operations primarily from the sale of our convertible preferred stock and common stock. From inception through March 31, 2002, we raised approximately \$1.8 million, net of issuance costs, through private placements or convertible preferred stock and common stock financings. On April 1, 2001, we issued 137,300 shares of common stock in consideration for payment in full of the approximate \$500,000 payable to the University of Medicine and Dentistry of New Jersey due through March, 2001. At December 31, 2001, we had cash and cash equivalents totaling approximately \$76,000. At March 31, 2002, we had cash and cash equivalents totalling approximately \$0.

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 \$884,000, of which we have received approximately \$627,000 through March 31, 2002 and expect to receive

29

the remainder through June 2002. 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 in its opinion, 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 BioDelivery Sciences, Inc.) 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 \$1.6 million of cash for operations since inception through March 31, 2002, net of sponsored research proceeds received since inception of \$8.1 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 March 31, 2002, 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.

We have also obtained a \$1,050,000 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% of which \$850,000 matured in May 2002 but is currently deferred until the completion of this offering and \$200,000 will mature in June 2002. At March 31, 2002, \$619,000 was outstanding under the credit line.

We have incurred significant net losses and negative cash flows from

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

operations since our inception. As of March 31, 2002, we had an accumulated deficit of approximately \$5.4 million and our working capital deficit at March 31, 2002 was \$1.7 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 proposed drugs. While we believe further application of our Bioral cochleate technology to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, our plan of operations in the next 18 months is focused on our further development of the Bioral cochleate technology itself and its use in a limited number of applications, and not on the marketing, production or sale of FDA approved products.

We believe that our existing cash and cash equivalents, together with available equipment financing and the net proceeds of this offering will be sufficient to finance our planned operations and capital expenditures through at least the next 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
- 30
- redemption and exercise of warrants.

There can be no assurance that additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our technologies, drugs or potential markets, either of which could have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders including investors in this offering.

### 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 are in the process of evaluating the effect, if any, of adopting SFAS 142, but do not believe that this standard will have any material effect on our financial statements.

In July 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 adopted this standard effective January 1, 2002, which did not have any material effect on our financial statements.

31

### DESCRIPTION OF BUSINESS

#### OVERVIEW

We are 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.



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Investors should be aware that we do not develop any new drugs. Our business is to license drugs from third parties and to encapsulate them in our delivery system. This requires that we enter into numerous license or development agreements with third parties.

### 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

32

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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 included 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

33

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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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.

INDICATION -----	DRUGS -----	CATEGORY -----	PRE-CLINICAL DEVELOPMENT -----	FDA STATUS -----
Systemic fungal infection	Antifungal Bioral Amphotericin B	Antimicrobial	Formulation development completed. In vitro and in vitro efficacy data completed	Submission for Phase I IND being prepared, GMP manufacturing initiated.
Tuberculosis and bacterial infections	Antibacterial Bioral Clofazimine	Antimicrobial	Formulation development in process. In vitro and animal studies in process	Pre-clinical development
Inflammatory disease	Bioral Anti-Inflammatory (such as generic aspirin or ibuprofen)	OTC Anti-inflammatory	Formulation and in vitro studies in process	Pre-clinical development

**Bioral Amphotericin B.** We are currently developing a Bioral product for treatment of fungal infection which we plan to submit to the FDA for a Phase I Investigational New Drug Application (IND). Our IND has not been completed and assuming that the funding is available, we estimate the filing will be made in the first quarter of 2003. Systemic fungal infections continue to be a major domestic and international health care problem. In the mid-1990s, Amphotericin B was the most commonly used drug to treat these infections in the United States.

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

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 which could be awarded from the National Institutes of Health to support the further development of this drug if it believes in its judgment that progress continues to be made.

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 people 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 Clofazimine 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 anti-inflammatory compounds are currently available. Nonsteroidal anti-inflammatory drugs significantly decrease inflammation at higher dosages.

We believe that our drug delivery technology can be used to effectively

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 second quarter of 2003 assuming the data in pre-clinical trials are favorable and the funding is available.

35

### OUR AUTOLOGOUS HIV THERAPY

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

We are preparing a submission to the FDA seeking to begin Phase I clinical trials as a follow-up to our initial clinical trials which were conducted pursuant to an Institutional Review Board process. Our development for this proposed Autologous HIV Therapy has not been completed. We estimate that the preparation of an IND will begin in the first quarter of 2003 assuming the data in pre-clinical trials are favorable and the 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. As of the date of this prospectus, the University of Medicine and Dentistry of New Jersey owns 139,522 shares (including shares issued under a research agreement) and warrants to purchase 9,952 shares of our

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

common stock and the Albany Medical College owns 2,222 shares and warrants to purchase 9,952 shares of our common 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; and

(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.

Our royalty payments to the Universities will be divided equally among them.

The Universities have reserved the right to use and permit the use of our licensed technology and licensed patents by non-profit organizations for educational and research purposes on a non-commercial basis.

In April 2001, we entered into a research agreement with the University of Medicine and Dentistry of New Jersey whereby we and the university agree to share the rights to new research and development that jointly takes place at the university's facilities until December 31, 2005. We also agreed to provide the university with progress and data updates and allow its researchers to publish certain projects. We lease our research facilities totaling approximately 8,000 square feet located on their campus pursuant a lease agreement ending December 31, 2005. The monthly rent 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.

In addition to our rent payments, we have also agreed to pay for certain other services provided by the university totaling approximately \$99,187 annually. These include employing three graduate students from the

36

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. Research assistants and personnel provided to us are university employees and they belong to various unions on campus.

### 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 could 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 Amphotericin 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 board of directors and management to conduct research and license certain proposed drugs. See "Certain 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 party transactions. At the meeting the independent board members, with Dr. O'Donnell abstaining, and after seeking and reviewing advice from an independent valuation firm and inquiring about the details of the various transactions, ratified all prior related party transactions. Subsequent to this meeting, the audit committee independently ratified these agreements. 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 retinitis pigmentosa, a

37

disease affecting the retina. This exclusive worldwide right to use our drug delivery technology in conjunction with their effort to develop, commercialize and manufacture their proposed product, or to sublicense to a third party, is only for the purpose of treating antiapoptotic

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

pharmaceutical and nutraceutical 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 drug. Tatton Technologies, LLC may sublicense our drug delivery technology to third parties to incorporate into their proposed product and this license shall remain in effect as long as both parties remain in compliance with the terms of the agreement.
- BioKeys Pharmaceuticals, Inc. We have entered into a letter of intent to seek a license agreement with this development-stage biotechnology company to use our delivery technology in connection with the development of its proposed vaccine technology. BioKeys Pharmaceuticals, Inc. in conjunction with a third party will conduct research to develop their EradicAids Vaccine Project. This proposed license shall remain in effect as long as 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 proposed 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 proposed 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 10% of all net revenue from the sale for the authorized use of our technology incorporated into the product. The planned RetinaPharma product is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future.
- Tatton Technologies, LLC. We are entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into their proposed product with potential application to various neuro-degenerative diseases. The planned Tatton Technologies product is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future.
- BioKeys Pharmaceuticals, Inc. We are in the process of negotiating a



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

royalty on net revenue from the license of our drug delivery technology. The letter of intent 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,

38

Inc. product is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future.

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

### COLLABORATIVE AGREEMENTS IN NEGOTIATION

We are currently in the beginning stages of negotiations to potentially establish one or more license agreements with PPDI, regarding the use of our drug delivery technology. No letter of intent has been negotiated or executed and no formal or legally binding license agreement has been reached and we cannot predict whether we and PPDI will be able to reach any agreement with regard to any such licensing agreement. The proposed sale of Units to PPDI in connection with this offering is not conditioned upon the consummation of any licensing arrangement between the parties.

### LICENSES, PATENTS AND PROPRIETARY INFORMATION

We are the exclusive licensee of eight issued United States patents and three foreign issued patents owned by the parties listed in the chart below. (1) We believe that our licenses to this intellectual property will enable us to develop this new drug delivery technology based upon cochleate and cochleate related technology. Our intellectual property strategy is intended to maximize our potential patent portfolio, license agreements, proprietary rights and any future licensing opportunities we might pursue. With regard to our Bioral cochleate technology, we intend to seek patent protection for not only our delivery technology, but also potentially for the combination of our delivery technology with various drugs no longer under patent protection. Below is a table summarizing patents we believe are currently important to our business and technology position.

PATENT NUMBER	ISSUED	EXPIRES	TITLE	PATENT OWNER
-----	-----	-----	-----	-----
EUR0722338	7/25/2001	9/30/2014	Protein- and peptide-cochleate vaccines and methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,165,502	12/26/2000	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

US06,153,217	11/28/2000	1/22/2019	Nanocochleate formulations, process of preparation and method of delivery of pharmaceutical agents	BioDelivery Sciences International, Inc., The University of Medicine and Dentistry of New Jersey
AUS722647	11/23/2000	9/02/2017	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,994,318	11/30/1999	11/24/2015	Cochleate delivery vehicles	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,840,707	11/24/1998	11/24/2015	Stabilizing and delivery means of biological molecules	The University of Medicine and Dentistry of New Jersey and Albany Medical College

39

PATENT NUMBER	ISSUED	EXPIRES	TITLE	PATENT OWNER
-----	-----	-----	-----	-----
US05,834,015	11/10/1998	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
AUS689505	2/2/1998	9/30/2014	Protein- or peptide-cochleate immunotherapeutics and methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,643,574	07/01/1997	7/01/2014	Protein- or peptide-cochleate immunotherapeutics and methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US04,871,488	10/03/1989	10/03/2006	Reconstituting viral glycoproteins into large phospholipid vesicles	Albany Medical College
US04,663,161	05/05/1987	4/22/2005	Liposome methods and compositions	Albany Medical College

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

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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

can develop our new drug delivery technology and our HIV therapy, we cannot provide any assurances that our patent applications will be successful or that our current or future intellectual property will afford us the desired protection against competitors. It is possible that our intellectual property will be successfully challenged or that patents issued to others may preclude us from commercializing our drugs. We are aware of two issued United States patents dealing with lipid formulations of Amphotericin B products. The first of these patents, United States Patent No. 04,978,654, claims an Amphotericin B liposome product. We do not believe that our patent or technology are in conflict with this existing patent, although there can be no assurance that a court of law in the United States' patent authorities might determine otherwise. Our belief is based upon the fact that our cochleate product does not contain liposomes, which appears to be the basis for the existing patent. The second of these patents, United States Patent No. 05,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we require a license under this patent. If a court were to determine that we infringe either of these patents, we might be required to seek to a license to commercialize Amphotericin B products. There can be no assurance that we would be able to obtain a license from either patent holder. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

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

40

rights in the technology, or have agreements with the United States government which would granting us exclusive rights.

We also rely on trade secrets and confidentiality agreements with collaborators, advisors, employees, consultants, vendors and other service providers. We cannot assure you that these agreements will not be breached or that our trade secrets will not otherwise become known or be independently discovered by competitors. Our business would be adversely affected if our competitors were able to learn our secrets or if we were unable to protect our intellectual property.

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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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. 05,643,574 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. 05,834,015, issued to the Universities. AUTOGENOUS VACCINE (HIV).
November	1998	U.S. Patent No. 05,840,707 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. 05,994,318 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.

41

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 0722,647 to the Universities. AUTOGENOUS VACCINE (HIV)
November	2000	U.S. Patent No. 06,153,217 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. 06,165,502, issued to the Universities. AUTOGENOUS VACCINE (cancer etc.).
December	2000	U.S. Patent No. 06,340,591, issued to the Universities.
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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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.
July	2001	European Patent No. 722338, issued to the Universities and the University of Maryland.
September	2001	Award of \$0.9 million, with an additional \$1.8 million expected to be awarded NIH(SBIR) Grant for Pre-clinical and Clinical development of Amphotericin B cochleates.

### 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 develop potentially competitive technologies. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing 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, and therefore we cannot know what research or progress has actually been made, we are not aware of any other drug delivery technology using a naturally occurring drug delivery vehicle (carrier) that can be used to simultaneously address two important clinical goals; oral delivery of drugs that normally require injection and targeted cell delivery once the drug is in the body.

42

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 of lipid soluble) compounds with limited customization for each specific drug.

We believe that our technology may have cell-targeted delivery attributes as well. Additional companies which are developing potentially competitive technologies in this area may include Valentis (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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

information regarding these potential competitors and their development status and strategy, we believe that our technology may be differentiated because unlike these potential competitors, we seek to use our cochleate to encapsulate the therapeutic to achieve drug delivery into the interior of the cells such as inflammatory cells.

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

We believe that competitors may also be working on patient-specific therapies for cancer. However, we are not aware of any competitors currently attempting to develop patient-specific therapies for HIV. This does not, however, mean to imply that there are not any now or that there will not be in the future. Vaccines can be used for prophylactic (prevention of infection), or therapeutic (treatment following infection) applications. The patient-specific therapeutic, which we are attempting to develop, is intended to boost or alter the immune response in patients already infected with HIV. For the most part, HIV vaccines in development, about which we are aware, are being targeted specifically to prevent infection, however, some of these vaccines may also prove useful for therapeutic applications. As such, these could prove to be competitive with our autologous therapeutic.

Our drug delivery technology, specific drugs encapsulated with our drug delivery technology and HIV autologous immunotherapeutics must compete with other existing technologies and/or technologies in development. Such potential competitive technologies may ultimately prove to be safer, more effective or less costly than any drugs which we are currently developing or may be able to develop. Additionally, our competitive position may be materially affected by our ability to develop or successfully commercialize our drugs and technologies before any such competitor.

### MANUFACTURING

During drug development and the regulatory approval process, we plan to rely on third-party manufacturers to produce our compounds for research purposes and for pre-clinical and clinical trials. 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 preclinical 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 established 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

suppliers of all required components although there may not actually be more than one at that time.

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

In addition to obtaining FDA approval for each product, each domestic product-manufacturing establishment must be registered with, and approved by,

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

44

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 may be effective and has an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to test for safety within an expanded patient population at geographically dispersed multi-center clinical study sites. Phase III frequently involves randomized controlled trials and, whenever possible, double blind studies. We, or the FDA, may suspend clinical trials at any time if it is believed that the individuals participating in such trials are being exposed to unacceptable health risks.



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

45

that any approval will be granted on a timely basis, if at all. The FDA may deny a New Drug Application if applicable regulatory criteria are not satisfied, require additional testing or information or require post-marketing testing (Phase IV) and surveillance to monitor the safety of a company's products if it does not believe the New Drug Application contains adequate evidence of the safety and efficacy of the drug. Notwithstanding the submission of such data, the FDA may ultimately decide that a New Drug Application does not satisfy its regulatory criteria for approval. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Post approval studies may be conducted to explore further intervention, new indications or new product uses.

Among the conditions for New Drug Application approval is the requirement that any prospective manufacturer's quality control and manufacturing procedures conform to Good Manufacturing Practices and the requirement specifications of the approved NDA. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of 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. Additionally, in the event of non-compliance, FDA may issue warning letters and seek criminal and civil penalties, enjoin manufacture, seize product or revoke approval.

### International Approval

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country at this time has its own procedures and requirements.

### Other Regulation

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

### EMPLOYEES

As of March 31, 2002, we had nine full-time employees, of which six are scientists and three 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.

### FACILITIES

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. These payments are expected to be approximately

46

\$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.

### LEGAL PROCEEDINGS

We are not subject to any pending legal actions other than described below. However, in May 2001, we settled litigation commenced against BioDelivery Sciences, Inc. by Irving A. Bernstein and certain of his family members and affiliates.

Mr. Bernstein was an officer, director and more than 10% stockholder of Biodelivery Sciences, Inc. A dispute arose between Mr. Bernstein 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. Bernstein's conduct as an officer and director of Biodelivery Sciences, Inc., the terms and enforceability of certain agreements between Mr. Bernstein and Biodelivery Sciences, Inc., the termination of employment of Mr. Bernstein as an employee and officer of Biodelivery Sciences, Inc. and the subsequent issuance of stock by

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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, which is being satisfied in full out of the proceeds of this offering. 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 will use part of the proceeds to fully satisfy debt owed pursuant to this litigation and remove the lien on our assets.

A lawsuit has been filed by Michael Pennessi d/b/a SSP Consultants, who is not affiliated with us, arising out of an introduction to BioDelivery Sciences, Inc. in 2000. Settlement discussions have been conducted. Informal telephonic settlement discussions prior to the filing of the lawsuit, have 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. 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 this litigation. It is our belief that the potential claim is neither material nor meritorious.

47

### MANAGEMENT

Our directors and executive officers and their ages as of June 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(1).....	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	Director of Business Development-Vaccines and Gene Therapy
L.M. Stephenson, Ph.D. ....	59	Director
William B. Stone.....	58	Director
James R. Butler.....	61	Director

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

John J. Shea..... 75 Director  
Robert G.L. Shorr..... 48 Director

-----  
(1) Dr. Zarif has notified us that she and her family have decided to move back to their native country of France and discontinue working with us. She has indicated to us that her departure is solely for personal reasons and not having any thing to do with this offering or any disagreement with us. We do not believe that Dr. Zarif's termination of employment will have a material adverse effect on our operations.

There are no family relationships between any director, executive officer, or person nominated or chosen to become a director or executive officer.

Francis E. O'Donnell, Jr., M.D., age 52, has been CEO, President, Chairman and Director on a full time basis since March 29, 2002 when Dr. O'Donnell executed an employment agreement with us to become full-time interim President and CEO. Following the offering, 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

48

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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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. Dr. Zarif has notified us that she and her family have decided to move back to their native country of France and discontinue working with us. She has indicated to us that her departure is solely for personal reasons and not having anything to do with this offering or any disagreement with us.

Christopher Chapman, M.D., 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 Director 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 Associate Professor (2001 to present),

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Assistant Professor (1991-2001), at University Of Medicine And Dentistry Of New Jersey, New Jersey Medical School, 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 Hematrophe 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Corporate Quality Assurance at Hexcel Corporation from 1980-1987. Mr. Shea has also served as the quality assurance person for other companies including, Teledyne Relays, Ortho Diagnostics, Inc. and Bio Reagents & Diagnostics, Inc. Mr. Shea earned a B.S. in Chemistry at Bethany College.

Robert G.L. Shorr, Ph.D., age 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

50

Business Development for the State University of New York at Stony Brook Center for Biotechnology, Dr. Shorr has been responsible for working with faculty and the university technology transfer office to establish grant funded entrepreneurial programs for promising commercializable technology. From 1991 to 1998, Dr. Shorr served as Vice President Science and Technology and as Vice President for Research and Development at Enzon Inc., a public company. Among his many accomplishments, Dr. Shorr was responsible for management of the co-development with Schering Plough of the product PEG INTRON A, which is now approved in the US and Europe. Dr. Shorr also served as chief scientist for another public company, United Therapeutics, Inc. since 1998 and continues to be a consultant. Dr. Shorr was also Associate Director for Molecular Pharmacology at SmithKline and French Upper Marion, PA; working under the direction of Stanley T. Crooke, M.D., Ph.D. and President of World Wide Research and Development. Dr. Shorr received his B.S. in Biology from the State University of New York (Buffalo) in 1975, his D.I.C. from Imperial College of Science & Technology in London, England in 1982, and his Ph.D., in Biochemistry from the University of London in 1981.

### 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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. One of the first acts of the audit committee was to review all related-party agreements and transactions which we had executed. The audit committee reviewed our related party transactions including agreements with RetinaPharma International, Inc., Tatton Technologies, LLC, and BioKeys Pharmaceuticals, Inc and subsequently ratified them on March 13, 2002.

51

### SCIENTIFIC ADVISORY BOARD

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

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

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

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

James M. Oleske, M.D., MPH is Francois-Xavier Bagnoud Professor of Pediatrics and Director, Division of Pulmonary, Allergy, Immunology and



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

52

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.

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

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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.

In addition, we will acquire directors' and officers' insurance providing indemnification for our directors, officers and certain employees for certain liabilities. We believe that these indemnification provisions and agreements are necessary to attract and retain qualified directors and officers.

The limited liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty and may reduce the likelihood of derivative litigation against directors and officers, even though a derivative action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment in us may be adversely affected to the extent we pay the costs of settlement and damage awards against our directors and officers under these indemnification provisions.

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.

53

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\*

(a)	(b)	ANNUAL COMPENSATION (1)			LONG TERM COMPENSA	
		(c)	(d)	(e)	(f)	(g)
NAME AND PRINCIPAL POSITION	YEAR	SALARY	BONUS	OTHER ANNUAL COMPENSATION	RESTRICTED STOCK AWARD (S)	SECURITIES UNDERLYING OPTIONS/SAR
		(\$)	(\$)	(\$)	(\$)	(#)
Francis E. O'Donnell, Jr., M.D.,.....	2001	--	--	--	--	8,009
CEO, President and Chairman	2000	--	--	--	--	--
709 The Hampton Lane	1999	--	--	--	--	--
Chesterfield, MO 63017						
James McNulty, CFO,.....	2001	\$ 40,000	--	--	--	--

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Secretary and Treasurer	2000	--	--	--	--	--
4419 W. Sevilla Street	1999	--	--	--	--	--
Tampa, Florida 33629						
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	--	--	--	96,110
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., (3) .....	2001	\$139,514	--	--	--	91,533
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						

54

(a)	(b)	ANNUAL COMPENSATION (1)			LONG TERM COMPENSA	
		(c)	(d)	(e)	(f)	(g)
NAME AND PRINCIPAL POSITION	YEAR	SALARY	BONUS	OTHER ANNUAL COMPENSATION	RESTRICTED STOCK AWARD (S)	SECURITIES UNDERLYING OPTIONS/SAR
		(\$)	(\$)	(\$)	(\$)	(#)
Susan Gould-Fogerite,	2001	\$ 40,800	--	--	--	34,324
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						

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

- (1) The annual amount of perquisites and other personal benefits, if any, did not exceed the lesser of \$50,000 or 10% of the total annual salary reported for each named executive officer and has therefore been omitted.
- (2) Reflects the increase in value of the permanent discount stock (a variable award) and the compensation expense recorded by us as a result of the agreement to remove the permanent discount and put rights.
- (3) Dr. Zarif has notified us that she and her family have decided to move back to their native country of France and discontinue working with us. She has indicated to us that her departure is solely for personal reasons and not having any thing to do with this offering or any disagreement with us.

OPTION GRANTS DURING YEAR ENDED DECEMBER 31, 2001

(a)	INDIVIDUAL GRANTS		POTENTIAL REALIZABLE VALUE AT ASS OF STOCK PRICE APPRECIATION FO		
	(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	5%
Francis E. O'Donnell, Jr. M.D. ....	8,009	0.96%	\$ 3.06	September 30, 2006	\$
Donald L. Ferguson.....	137,300	16.48%	\$ 3.06	September 30, 2006	\$ 1
	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	\$
	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	\$
	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	\$
	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	\$
	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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

NAME AND PRINCIPAL POSITION -----	SHARES ACQUIRED ON EXERCISE (#)	VALUE REALIZED (\$)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS/SARS AT FISCAL YEAR-END (#) EXERCISABLE/ UNEXERCISABLE	VALUE UNEXERCISED OPTIONS/ AT FISCAL YEAR END
(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	--	--	--	
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	--	--	--	

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

NAME AND PRINCIPAL POSITION	SHARES ACQUIRED ON EXERCISE (#)	VALUE REALIZED (\$)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS/SARS AT FISCAL YEAR-END (#) EXERCISABLE/ UNEXERCISABLE	VALUE OF UNEXERCISED OPTIONS/ AT FISCAL YEAR END (#) EXERCISABLE/ UNEXERCISABLE
(a)	(b)	(c)	(d)	(e)
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 Dr. Frank O'Donnell, 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 agreements with certain of these individuals at some point in the future. Under our employment at will arrangement, our officers received the following annualized salaries and other benefits in 2001:

(i) Dr. O'Donnell, President, CEO and Chairman - On March 29, 2002, Dr. O'Donnell executed an employment agreement to be our full-time President and CEO at an annual salary of \$150,000. Dr. O'Donnell's term of employment shall be no longer than three years or until another CEO candidate is appointed.

(ii) James 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. Notwithstanding his part-time status, he has been paid \$67,461 in 2002 through June 7 because we have been using his services on a more regular basis.

(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 \$90,000 and receives no benefits.

(v) Dr. Leila Zarif, Executive Vice President of Research and Development - Receives a salary of \$170,000. Under the terms of this agreement, she is also entitled to the following benefits: medical and dental. Dr. Zarif has notified us that she and her family have decided to move back to their native country of France and discontinue working with us. She has indicated to us that her departure is solely for personal reasons and not having any thing to do with this offering or any disagreement with us.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

(vi) Dr. Susan Gould-Fogerite, Director of Business Development - Receives a salary of \$40,800 and is entitled to the following benefits: a 401k Plan.

(vii) Christopher 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.

57

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 this offering, we are forgiving those notes and 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 978,355 shares of common stock have been granted under the 2001 stock option plan a portion of which is subject to shareholder approval. 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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Options and warrants to purchase 978,355 shares of our common stock at prices ranging from \$2.87 to \$17.48 have been granted as of April 23, 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 this offering registered with the SEC; or (ii) 24 months from the date of grant. None of our outstanding options have terms in excess of five (5) years from the date of grant.

### CERTAIN TRANSACTIONS

During 2001, we entered into agreements with RetinaPharma, Inc. and Tatton Technology LLC. Both are biotechnology companies which are developing neutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson's disease. To the extent that such drugs utilize Bioral cochleate technology, we will support drug development and will share in ten percent (10%) of all net revenue from such sales of Bioral encapsulated drugs. The Hopkins Capital Group II, LLC, one of our significant stockholders and Dr. Francis E. O'Donnell, Jr., our CEO, President and a director are affiliated as stockholders and a director of RetinaPharma, Inc. Additionally, Hopkins Capital Capital, LLC,

58

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 \$1,050,000 with a bank and other liabilities for our benefit at a rate of prime plus 2% of which \$850,000 matured in May 2002 but is being deferred pending the completion of this offering and \$200,000 will mature in June 2002. As of March 31, 2002, we used \$598,000 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 II, LLC, which is affiliated with Dr. Francis E. O'Donnell, Jr., our CEO and director, are affiliated as stockholders, and a member of the management, of Biotech Specialty Partners, LLC.

We have also entered into a letter agreement with BioKeys Pharmaceutical, Inc, a biotechnology company, which is developing several potential products which are vaccine based. To the extent that BioKeys Pharmaceutical, Inc. utilizes our Bioral drug delivery technology, we will earn a flat royalty which we will negotiate and be approved by our independent audit committee. Regent Court Technologies LLC, which is affiliated with one of our stockholders, and Dr. Francis E. O'Donnell, our CEO and director, and Donald L. Ferguson, our senior executive vice-president, are affiliated as stockholders and Dr. O'Donnell is a member of the board of directors of BioKeys Pharmaceutical, Inc. We 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 Secretary, Treasurer and part-time Chief



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 a stockholders, and former officer and director of BioDelivery Sciences, Inc. The settlement required that we pay \$150,000 in cash and \$125,000 by promissory note, which is being satisfied in full out of the proceeds of this offering. At the same time, we purchased the shares of BioDelivery Sciences, Inc. owned by these stockholders for \$500,000 which was paid \$200,000 in cash and \$300,000 by promissory note which is being satisfied in full out of the proceeds of this offering.

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

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.

59

As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to "promoters" as that term is commonly understood by the SEC and state securities authorities.

We believe that the terms of the above transactions with affiliates were as favorable to us or our affiliates as those generally available from unaffiliated third parties. 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.

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel. We intend to maintain at least two independent members on our Board of Directors.

PPDI has expressed its intent in purchasing up to 690,000 Units in this

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

offering, constituting approximately 34.5% of this offering (assuming an offering of 2,000,000 Units), at a price equal to the initial public offering price. The shares of common stock will be issued to PPDI with the voting and disposition rights vesting in its board of directors. The board may elect to delegate the voting and disposition rights to a member or members of PPDI's management. The current board of directors of PPDI consists of the following eight members: Stuart Bondurant, M.D., Fredric N. Eshelman, Frederick Frank, Catherine M. Klema, Terry Magnuson, Ernest Mario, John A. McNeill, Jr. and Paul J. Rizzo. There is one vacancy on PPDI's board resulting from a former director's decision not to stand for re-election. The vacancy will be filled as soon as practicable. We are also in the process of beginning stages of negotiation with PPDI as to the terms of one or more license agreements, pursuant to which we would be exploring the possibility of granting PPDI a non-exclusive license to our drug delivery technology. Although each side has expressed an interest in further negotiations to formalize the proposed licensing relationship, there is not currently a license agreement or any other document which reflects any definitive or binding arrangements. If PPDI purchases all of the Units for which it has expressed an interest, any negotiations with PPDI after the offering will be with a party that owns more than a 5% beneficial interest in our securities.

60

PRINCIPAL STOCKHOLDERS

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 of the effective date 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. Percentage ownership figures after the offering do not include shares that may be purchased by each person in this offering.

NAME OF BENEFICIAL OWNER	POSITION	NO. OF SHARES OF COMMON STOCK	PERCENTAGE OF CLASS PRIOR TO THIS OFFERING	PER OF AFT OF
-----	-----	-----	-----	-----

Hopkins Capital Group II,

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

LLC(1) 4419 W. Sevilla Street Tampa, FL 33629	Stockholder	3,111,579	62.22%	4
Francis E. O'Donnell, Jr., M.D.(2) CEO, President and Chairman 709 The Hampton Lane Chesterfield, MO 63017	Chief Executive Officer, Chairman and Director	3,161,922	63.23%	4
University of Medicine and Dentistry of New Jersey(3) 65 Bergen Street MB 1414 University Heights Newark, NJ 07103	Stockholder	139,522	2.79%	
Albany Medical College(3) Director of Research Admin 47 New Scotland Avenue Albany, NY 12202	Stockholder	2,222	0.04%	
John R. Williams, Sr.(4) 1 Starwood Lane Manakin-Sabot, VA 23103	Stockholder	3,203,112	64.05%	4
Dennis Ryll, M.D.(5) 1029 Speckledwood Manor Court Chesterfield, MO 63017	Stockholder	3,157,346	63.14%	4
James A. McNulty 4419 W. Sevilla Street Tampa, FL 33629	Chief Financial Officer Treasurer and Secretary	76,659	1.53%	

61

NAME OF BENEFICIAL OWNER -----	POSITION -----	NO. OF SHARES OF COMMON STOCK -----	PERCENTAGE OF CLASS PRIOR TO THIS OFFERING -----	PER OF AFT OF
Donald L. Ferguson(6) 11719 Old Ballas Road, Suite 110 St. Louis, MO 63141	Sr. Executive Vice President	91,533	1.83%	
Raphael J. Mannino, Ph.D.(7) 185 South Orange Avenue Building 4 Newark, NJ 07103	Executive Vice President, Chief Scientific Officer and Director	182,609	3.65%	
Susan Gould-Fogerite,				

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

<p>Ph.D.(8) 185 South Orange Avenue Building 4 Newark, NJ 07103</p>	<p>Director of Business Development -- Vaccines and Gene Therapy</p>	<p>152,174</p>	<p>3.04%</p>
<p>Leila Zarif, Ph.D.(9) 185 South Orange Avenue Building 4 Newark, NJ 07103</p>	<p>Executive Vice President of Research and Development</p>	<p>152,174</p>	<p>3.04%</p>
<p>Pharmaceutical Product Development, Inc.(10) 3151 South Seventeenth Street Wilmington, NC 28412</p>	<p>Stockholder</p>	<p>690,000</p>	<p>--</p>
<p>L.M. Stephenson, Ph.D.(11) University of Medicine and Dentistry of New Jersey 65 Bergen Street MB 1414 University Heights Newark, NJ 07103</p>	<p>Director</p>	<p>--</p>	<p>--</p>
<p>William Stone(12) 11120 Geyers Down Lane Frontenac, MO 63131</p>	<p>Director</p>	<p>--</p>	<p>--</p>
<p>James R. Butler(13) 109 Cutler Court Ponte Bedra Beach, FL 32082</p>	<p>Director</p>	<p>--</p>	<p>--</p>
<p>John J. Shea(13) 90 Poteskeet Trail Kitty Hawk, NC 27949</p>	<p>Director</p>	<p>--</p>	<p>--</p>
<p>Robert G. L. Shorr(13) 28 Brookfall Road Edison, NJ 08817</p>	<p>Director</p>	<p>--</p>	<p>--</p>
<p>All directors and officers as a group (2) (6) (7) (8) (9) (11) (12) (13)</p>		<p>3,817,071</p>	<p>76.33%</p>

-----

(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.

62

(2) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 1) and 45,767 shares of common stock, owned by his wife, as to which he disclaims beneficial interest of. Does not include options to purchase 8,009 shares of common stock at an exercise price of \$3.06 per share and 26,991 shares of common stock at an exercise price of \$5.50 per share exercisable 13 months from the date of this prospectus. The remaining 4,576 shares of common stock are personally owned by Dr. O'Donnell.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

- (3) Excludes warrants owned by both of the universities with each owning 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 this prospectus. These warrants were granted in October 2001.
- (4) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 1) and 45,767 shares of common stock, converted from preferred stock prior to this offering, owned by his wife, as to which he disclaims beneficial interest of. The remaining 45,766 shares of common stock are personally owned by Mr. Williams.
- (5) Includes the shares owned by Hopkins Capital Group II, LLC. The remaining 45,767 shares of common stock are personally owned by Mr. Ryll.
- (6) 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 this prospectus 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 this prospectus 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 this prospectus or October 2003.
- (7) 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 this prospectus 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 this prospectus 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 this prospectus or October 2003.
- (8) 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 this prospectus 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 this prospectus 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 this prospectus or October 2003.
- (9) 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 this prospectus 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 this prospectus 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 this prospectus or October 2003. Dr. Zarif has notified us that she and her family have decided to move back to their native country of France and discontinue working with us. She has indicated to us that her departure is solely for personal reasons and not having any thing to do with this offering or any disagreement with us.
- (10) Includes PPDI's intended purchase of up to 690,000 Units as part of this offering.
- (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 this prospectus.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

- (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 this prospectus.
- (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 this prospectus.

63

### DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 45,000,000 shares of common stock and 5,000,000 shares of preferred stock. Upon the completion of this offering, our outstanding capital stock will consist of 7,000,863 shares of common stock, \$.001 par value, and no shares of preferred stock, \$.001 par value. There will also be 2,000,000 outstanding Class A warrants to purchase 2,000,000 shares of common stock in the aggregate. These figures do not include securities to be issued as part of the exercise of the overallotment option, the Representative's unit purchase option or the 2001 Incentive Stock Option Plan.

#### UNITS

Each Unit consists of: (i) one share of our common stock, par value \$.001 per share; and (ii) one redeemable Class A common stock purchase warrant. The common stock and warrants will not trade as separate securities until 30 days after this offering unless the Representative of the underwriters determines that separate trading should occur earlier. After the 30 day period, the securities contained in the Units will automatically begin to trade separately and the Units will no longer trade as a security.

#### COMMON STOCK

There are 5,000,863 shares of common stock outstanding, held of record by approximately 227 stockholders. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Subject to preferential rights with respect to any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor. See "Dividend Policy." In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and satisfaction of preferential rights of any outstanding preferred stock.

Our common stock has no preemptive or conversion rights or other subscription rights. There are no sinking fund provisions applicable to the common stock. The outstanding shares of common stock are, and the shares of common stock to be issued upon completion of this offering will be, fully paid and non-assessable.

#### CLASS A WARRANTS

Each Class A warrant entitles the holder to purchase one share of our common stock at a price of \$6.30 (120% of the initial offering price of the Units). The exercise price of the Class A warrants is subject to adjustment, including anti-dilution provisions for corporate events, such as stock splits and for issuance of securities at less than the current exercise price. You may exercise your warrants at any time during the four years commencing one year after the date of this prospectus unless we have redeemed them.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

The Class A warrants are exercisable from June 24 2003 until June 24 2007. We may redeem the outstanding Class A warrants for \$.10 per warrant upon no less than 30 days written notice to the warrant holder; provided: (i) that there is then an effective registration statement under the Securities Act allowing the issuance of the shares issuable upon exercise of the Class A warrants; (ii) the average closing sale price of the common stock equals or exceeds 150% of the offering price of the Units for the 10 trading days prior to the date of the notice of redemption; and (iii) that 12 months has elapsed since the date of this prospectus.

The Class A warrants will be issued pursuant to a warrant agreement among us, Kashner Davidson Securities Corporation and American Stock Transfer and Trust Company, as warrant agent. The shares of common stock underlying the Class A warrants, when issued upon exercise of the Class A warrants, will be fully paid and non-assessable.

### PREFERRED STOCK

We have authorized 5,000,000 shares of preferred stock, none of which have been designated or are outstanding. Prior to this offering, all outstanding shares of preferred stock were rescinded and shares of common stock issued in replacement thereof. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including voting rights, of the

64

holders of common stock. In certain circumstances, such issuance could have the effect of decreasing the market price of the common stock. Notwithstanding the broad discretion granted to the Board of Directors with respect to designating the terms and conditions of any series of preferred stock, our Board of Directors has agreed to refrain from issuing shares of preferred stock, unless such designation and issuance are approved by a majority of our independent directors who do not have an interest in the transactions and who have access to and consulted with (at our expense) our counsel or counsel of their choosing.

### OPTIONS

We have outstanding options and warrants to purchase 978,355 shares of our common stock at exercise prices ranging from \$2.87 to \$17.48. Up to 121,645 additional shares of common stock may be subject to options granted in the future under the 2001 stock option plan. See "2001 incentive stock option plan."

In order for the holders of the rights to resell the common stock issuable upon exercise of the rights, there must be a current prospectus available under the Securities Act of 1933 and applicable state securities laws.

### REGISTRATION RIGHTS

Except for the registration rights granted to the underwriters pursuant to the underwriting agreement, there are no registration rights granted to investors. See "Underwriting."

### ANTI-TAKEOVER LAW

We are subject to Section 203 of the Delaware General Corporation Law, which restricts certain transactions and business combinations between a corporation and an "interested stockholder" (as defined in Section 203) owning 15% or more of the corporation's outstanding voting stock, for a period of three years from the date the stockholder becomes an interested stockholder. Subject to certain exceptions, unless the transaction is approved by the board of directors and the holders of at least two-thirds of our outstanding voting stock

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

(excluding shares held by the interested stockholder), Section 203 prohibits significant business transactions such as a merger with, disposition of assets to, or receipt of disproportionate financial benefits by the interested stockholder, or any other transaction that would increase the interest stockholder's proportionate ownership of any class or series of the corporation's stock. The statutory ban does not apply if, upon consummation of the transaction in which any person becomes an interested stockholder, the interested stockholder owns at least 85% of the outstanding voting stock of the corporation (excluding shares held by persons who are both directors and officers or by certain employee stock plans).

### TRANSFER AGENT AND REGISTRAR

American Stock Transfer & Trust Company will be our transfer agent and registrar for our common stock and warrant agent for the Class A warrants.

### LISTING

The Nasdaq SmallCap Market has accepted for quotation the Units, Class A warrants and common stock under the symbols "BDSIU", "BDSI", and "BDSIW", respectively. Also, the Boston Stock Exchange has accepted for quotation the Units, common stock and Class A warrants under the same symbols.

65

### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect prevailing market prices.

Upon consummation of the offering, we will have an aggregate of 7,000,863 shares of common stock outstanding, assuming that the underwriters do not exercise their over-allotment option and none of the outstanding options and warrants are exercised. Of the 7,000,863 shares outstanding after the offering, only the 2,000,000 shares sold in this offering (excluding an additional 300,000 shares included in the underwriter's overallotment option and shares underlying the Class A warrants) will be freely tradable without restriction under the Securities Act, except for any shares that may be sold or purchased by our "affiliates." Shares purchased by our affiliates will be subject to the volume and other limitations of Rule 144 of the Securities Act, or "Rule 144" described below. As defined in Rule 144, an "affiliate" of an issuer is a person who, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with the issuer. Of the outstanding shares, 3,934,237 shares are subject to the volume and other limitations of Rule 144 and 319,765 shares are subject to only the limitations of Rule 144(k). The remaining 746,861 shares will become eligible for sale at various times.

The Representative required as a condition to closing of the offering that all officers, directors, and certain stockholders agree to contractual restrictions for a period of twelve months (three years in the case of Dr. Francis O'Donnell and The Hopkins Group II, LLC.) from the effective date of this prospectus, as follows:

- such parties may not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

- such parties may not enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or other securities, in cash or otherwise.

These persons and entities own an aggregate of 4,955,442 shares of common stock, and 778,525 warrants and/or options. Upon the expiration of the applicable "lock-up" period, all these shares will be available for sale subject to Rule 144. Kashner Davidson Securities Corporation may choose to release some or all of these shares from such restrictions prior to the expiration of the applicable "lock-up" period, although it has no current intention of doing so.

### RULE 144

Under Rule 144 as currently in effect, a person who has beneficially owned restricted shares of common stock for at least one year, including the holding period of any prior owner who is not an affiliate, would be entitled to sell a number of the shares within any three-month period equal to the greater of 1% of the then outstanding shares of the common stock or the average weekly reported volume of trading of the common stock on the Nasdaq Small Cap Market during the four calendar weeks preceding such sale. Immediately after the offering, 1% of our outstanding shares of common stock would equal approximately 70,001 shares. Under Rule 144, restricted shares are subject to manner of sale and notice requirements and requirements as to the availability of current public information concerning us.

Under Rule 144(k), a person who is not deemed to have been an affiliate at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner who is not an affiliate, is entitled to sell such shares without regard to the volume or other limitations of Rule 144 just described.

66

### RULE 701

Immediately after this offering, excluding the underwriter's over-allotment, there will be options outstanding to purchase approximately 978,335 shares of common stock. Subject to the provisions of the lock-up agreements described above, holders of these options may rely on the resale provisions of Rule 701 under the Securities Act. Rule 701 permits non-affiliates to sell their shares without having to comply with the volume, holding period or other limitations of Rule 144 and permits affiliates to sell their shares without having to comply with the holding period limitation of Rule 144, in each case beginning 90 days after the consummation of this offering.

67

### UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement dated the date hereof, the underwriters named below through their representative Kashner Davidson Securities Corporation have severally agreed to purchase, and we have agreed to sell to them, severally and not jointly, the respective number of Units set forth opposite their names at the public offering price less the underwriting discounts and commission set forth on the cover page of this prospectus below:

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

UNDERWRITERS -----	NUMBER OF UNITS -----
Kashner Davidson Securities Corporation.....	700,000
Roan/Meyers Associates, L.P. ....	475,000
Investors Capital Corp. ....	370,000
Sterling Financial Investment Group, Inc. ....	370,000
Schneider Securities, Inc.....	85,000
Total.....	----- 2,000,000

The underwriters are collectively referred to as the "underwriters." The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the Units offered hereby are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the Units offered by this prospectus if any Units are taken except for those covered by the overallotment option. These conditions include requirements that no stop order be in effect and that no proceedings for such purpose be instituted or threatened by the Securities and Exchange Commission.

The Representative has informed us that the underwriters propose to offer the Units directly to the public at the public offering price set forth on the cover page hereof and part to certain dealers at a price that represents a concession not in excess of \$.225 a Unit under the public offering price. After the initial offering of the Units, the offering price and other selling terms may from time to time be changed by the representative.

We have granted to the Representative an option, exercisable for 45 days from the date of this prospectus, to purchase up to an aggregate of 300,000 additional Units at the public offering price set forth on the cover page hereof, less underwriting discounts and commissions. The underwriters may exercise such option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the Units offered hereby. To the extent such option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of such additional Units as the number set forth next to such underwriter's name in the preceding table bears to the total number of Units set forth next to the names of all underwriters in the preceding table.

We have also agreed to issue to the Representative a Unit Option Agreement granting the Representative the right to purchase up to 200,000 Units at an exercise price equal to 165% of the initial offering price of the Units. The exercise price and the number of underlying securities in the warrants contained in the Representative's Units are subject to adjustment upon the same terms as contained the Class A warrants being sold in the Units. The securities to be delivered upon exercise of the Representative's Unit Option are the same as the Units being sold to the public in this offering, and include the same provisions for redemption of the Class A warrants as being sold to the public. These Unit warrants are exercisable during the four year period beginning one year from the date of effectiveness of the registration statement of which this prospectus forms a part. The Representative's Unit Purchase Option will be restricted from sale, transfer, assignment or hypothecation for a period of one year from the effective date of the offering except to officers or partners (not directors) of the underwriter and members of the selling group and/or their officers or partners in compliance with NASD Rule 2710(c) (7) (A).

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

The representative's unit purchase option is not redeemable by us. In addition, we have agreed to certain "demand and piggyback" registration rights for the securities underlying the representative's unit purchase option. The holder of the representative's unit purchase option can demand, on one occasion, at anytime until

68

five years from the effective date of the registration statement, that we register the shares and warrants for resale under the Securities Act of 1933. The "piggyback" registration provision provides that we will include the underlying shares and Class A warrants in any registration statement filed by us during the five-year period commencing after the effective date.

The holders of the representative's unit purchase option will have, in that capacity, no voting, dividend or other stockholder rights. Any profit realized by the representative on the sale of the securities issuable upon exercise of the representative's unit purchase option may be deemed to be additional underwriting compensation. The securities underlying the representative's unit purchase option are being registered in the registration statement. During the term of the representative's unit purchase option, the holders thereof are given the opportunity to profit from a rise in the market price of our common stock. We may find it more difficult to raise additional equity capital while the representative's unit purchase option are outstanding. At any time at which the representative's unit purchase option are likely to be exercised, we may be able to obtain additional equity capital on more favorable terms.

We have also paid to an underwriter \$90,000 on account of the underwriters' expenses in connection with this offering to be applied to the non-accountable expense allowance equal to 3% of the gross proceeds of the offering (including proceeds from the sale, if any, of the over allotment option securities). In addition, an associated person of the Underwriters has received compensation of \$26,076 which will be included, pursuant to applicable NASD rules, as underwriter compensation. This compensation was paid in connection with a consulting agreement between us and the affiliated person. The agreement has been terminated in full.

The representative has informed us that sales to discretionary accounts by the underwriters will not exceed 5% of the securities offered in the offering.

We have agreed, in connection with the exercise of the Class A warrants, to pay to the representative a fee of 5% of the exercise price for each Class A warrants exercised; provided, however, that the representative will not be entitled to receive such compensation in warrant exercise transactions in which (i) the market price of common stock at the time of exercise is lower than the exercise price of the warrants; (ii) the warrants are held in any discretionary account; (iii) disclosure of compensation arrangements is not made, in addition to the disclosure provided in this Prospectus, in documents provided to holders of warrants at the time of exercise; (iv) the holder of the warrants has not confirmed in writing that the representative solicited such exercise; or (v) the solicitation of exercise of the warrants was in violation of Regulation M promulgated under the Securities Act. The Representative will not solicit the exercise of warrants prior to 12 months from the date of this prospectus and NASD members will not be compensated for solicitations sooner than such date. In addition, unless granted an exemption by the Commission from Regulation M under the Exchange Act, the representative will be prohibited from engaging in any market making activities or solicited brokerage activities until the later of the termination of such solicitations activity or the termination by waiver or otherwise of any right the representative may have to receive a fee for the exercise of the warrants following such solicitation. Such a prohibition, while in effect, could impair the liquidity and market price of the securities offered

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

pursuant to the offering.

The Representative required as a condition to closing of the offering that all officers, directors, and certain significant stockholders agree to contractual restrictions for a period of twelve months (three years in the case of Dr. Francis O'Donnell and The Hopkins Group II, LLC) from the effective date of this prospectus, as follows:

- such parties may not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any Unit or any securities convertible into or exercisable or exchangeable for common stock, or
- such parties may not enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise.

69

The restrictions described above do not apply to:

- the sale of Units to the underwriters;
- the issuance by us of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing, provided that purchasers enter into similar "lock-up" agreements; or
- transactions by any person other than us relating to the Units or other securities acquired in open market transactions after the completion of the offering of the shares.

PPDI, has expressed its interest in purchasing up to 690,000 Units as part of this offering. In the event that PPDI fails to consummate the purchase of 690,000 Units, then the Representative has the right to terminate the offering. The underwriters will receive the stated commission and expense allowance on the sale of these Units. Following this offering, and assuming PPDI purchases these Units, PPDI will beneficially own up to a 9.9% of our outstanding common stock (9.5% if the Underwriter's Over Allotment Option is exercised). PPDI will agree not to sell any Units, common stock or Class A warrants for a period of at least 180 days, following the date of the final Prospectus without the Representative's approval.

### REGULATION M

In order to facilitate the offering of the Units, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the Units. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of Units available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing Units in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of the Units compared to the price available under the over-allotment option. The

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

underwriters may also sell the Units in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the Unit in the open market after pricing that could adversely affect investors who purchase in the offering. As an additional means of facilitating the offering, the underwriters may bid for, and purchase, the Units in the open market to stabilize the price of the Unit. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing the Units in the offering, if the syndicate repurchases previously distributed Units to cover syndicate short positions or to stabilize the price of the Unit. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities, and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

### DETERMINATION OF OFFERING PRICE

Before this offering, there has been no public market for the units and the common stock and Class A warrants contained in the units. Accordingly, the initial public offering price of the units offered by this prospectus and the exercise price of the Class A warrants were determined by negotiation between us and the representative. Among the factors considered in determining the initial public offering price of the units and the exercise price of the warrants were:

- our history and our prospects;
- the industry in which we operate;
- the status and development prospects for our proposed products and services;
- our past and present operating results;
- the previous experience of our executive officers; and

70

- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the units. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the units, or the common stock and warrants contained in the units, can be resold at or above the initial public offering price.

### LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Ellenoff Grossman Schole & Cyruli, LLP, New York, New York. Goldstein & DiGioia LLP is acting as counsel for Kashner Davidson Securities Corporation as Representative, and the underwriters.

### EXPERTS

The financial statements for our company as of December 31, 2000 and 2001

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

and for the years ended December 31, 2000 and 2001 and the financial statements of BioDelivery Sciences, Inc. for the nine months ended September 30, 2000, included in this Prospectus and in the registration statement, have been audited by Grant Thornton LLP, independent certified public accountants, as stated in their reports included herein and in the registration statement, and are included herein in reliance upon the reports given upon the authority of that firm as experts in auditing and accounting.

### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form SB-2 under the Securities Act, and the rules and regulations promulgated thereunder, with respect to the common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits thereto. Statements contained in this prospectus as to the contents of any contract or other document that is filed as an exhibit to the registration statement are not necessarily complete and each such statement is qualified in all respects by reference to the full text of such contract or document. For further information with respect to us and the common stock, reference is hereby made to the registration statement and the exhibits thereto, which may be inspected and copied at the principal office of the Commission, 450 Fifth Street, N.W., Washington, D.C. 20549, and at the regional offices of the Commission located at Seven World Trade Center, Suite 1300, New York, New York 10048 and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and copies of all or any part thereof may be obtained at prescribed rates from the Commission's Public Reference Section at such addresses. Also, the Commission maintains a World Wide Web site on the Internet at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission.

Prior to filing this registration statement on Form SB-2, we have voluntarily complied with the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy and information statements and other information with the Commission. Such periodic reports, proxy and information statements and other information will be available for inspection and copying at the regional offices, public reference facilities and Web site of the Commission referred to above.

71

### INDEX TO FINANCIAL STATEMENTS

	PAGE
	----
BIODELIVERY SCIENCES INTERNATIONAL, INC.	
Report of Independent Certified Public Accountants.....	F-2
Consolidated Balance Sheets as of December 31, 2000 and 2001 and March 31, 2002 (unaudited).....	F-3
Consolidated Statements of Operations for the years ended December 31, 2000 and 2001, the period from January 6, 1997 (date of incorporation) to December 31, 2001, and the three months ended March 31, 2001 and 2002 (unaudited).....	F-4
Consolidated Statement of Stockholders' Equity (Deficit) for the period from January 6, 1997 (date of incorporation) to December 31, 1999, and the years	

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

ended December 31, 2000 and 2001, and the three months ended March 31, 2002 (unaudited).....	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2000 and 2001, the period from January 6, 1997 (date of incorporation) to December 31, 2001, and the three months ended March 31, 2001 and 2002 (unaudited).....	F-6
Notes to Consolidated Financial Statements.....	F-7
BIODELIVERY SCIENCES, INC.	
Report of Independent Certified Public Accountants.....	F-20
Statements of Operations for the nine months ended September 30, 2000.....	F-21
Statements of Cash Flows for the nine months ended September 30, 2000.....	F-22
Notes to Financial Statements.....	F-23

F-1

## 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

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

F-2

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

CONSOLIDATED BALANCE SHEETS

	DECEMBER 31,		MARCH 31,
	2000	2001	2002
			(UNAUDITED)
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents.....	\$ 950,939	\$ 75,513	\$ --
Prepaid expenses and other assets.....	54,481	111,684	247,553
Total current assets.....	1,005,420	187,197	247,553
EQUIPMENT, net.....	253,390	233,562	193,905
OTHER ASSETS, net.....	30,124	912,810	1,144,791
TOTAL ASSETS.....	\$1,288,934	\$ 1,333,569	\$ 1,586,249
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>			
<b>CURRENT LIABILITIES:</b>			
Accounts payable and accrued liabilities.....	\$ 394,020	\$ 814,279	\$ 1,085,738
Due to related parties.....	515,584	74,331	106,608
Line of credit.....	--	282,527	618,732
Deferred revenue.....	--	37,000	--
Current portion of capital lease payable.....	11,307	14,804	14,804
Current portion of notes payable.....	--	149,524	119,141
Total current liabilities.....	920,911	1,372,465	1,945,023
CAPITAL LEASE PAYABLE, LESS CURRENT PORTION.....	28,372	18,369	18,369
NOTES PAYABLE, less current portion.....	--	151,733	127,069
COMMITMENTS AND CONTINGENCIES.....	--	--	--
REDEEMABLE COMMON STOCK, net of notes receivable of approximately \$321,000.....	2,346	--	--
<b>STOCKHOLDERS' EQUITY (DEFICIT):</b>			
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 including issuable shares in 2000 and 2001, respectively.....	3,513	5,001	5,001
Additional paid-in capital.....	1,006,136	4,903,368	4,903,368
Deficit accumulated during development stage.....	(672,806)	(5,117,367)	(5,412,581)
Total stockholders' equity (deficit).....	337,305	(208,998)	(504,212)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT).....	\$1,288,934	\$ 1,333,569	\$ 1,586,249

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



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

CONSOLIDATED STATEMENTS OF OPERATIONS

	YEAR ENDED DECEMBER 31, 2000	YEAR ENDED DECEMBER 31, 2001	PERIOD FROM JANUARY 6, 1997 (DATE OF INCORPORATION) TO DECEMBER 31, 2001	THREE MONTHS ENDED 31, 2001 (UNAUDITED)	2002 (UNAUDITED)
Sponsored research revenues.....	\$ 56,000	\$ 478,385	\$ 534,385	\$ --	\$ 2,000
Expenses:					
Research and development...	312,736	1,663,932	1,976,668	331,483	4,000
General and administrative:					
General and administrative.....	265,239	679,883	945,197	74,394	2,000
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	405,877	6,000
Interest income (expense), net.....	21,772	(21,957)	(185)	13,406	--
Loss before income taxes and minority interest.....	(775,203)	(4,463,096)	(5,238,374)	(392,471)	(3,000)
Income tax benefit.....	--	18,535	18,535	--	--
Loss before minority interest.....	(775,203)	(4,444,561)	(5,219,839)	(392,471)	(2,000)
Minority interest in net loss of subsidiary.....	102,472	--	102,472	--	--
Net loss.....	\$ (672,731)	\$ (4,444,561)	\$ (5,117,367)	\$ (392,471)	\$ (2,000)
Net loss per common share:					
Basic and diluted.....	\$ (0.19)	\$ (1.15)		\$ (.11)	\$ --
Weighted average common stock shares outstanding (including issuable shares) -- basic and diluted.....	3,512,586	3,851,587		3,518,179	5,000

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

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL
	SHARES	AMOUNT	SHARES	AMOUNT	
BALANCE, JANUARY 6, 1997 (date of incorporation)					
Shares issued to founders.....	--	\$ --	80,091	\$ 80	\$ 31
Shares issued for services.....	--	--	1	--	--
Net loss.....	--	--	--	--	--
BALANCE, DECEMBER 31, 1999.....	--	--	80,092	80	31
Shares issued to founders.....	--	--	3,432,494	3,433	(3,433)
Preferred stock issued for cash.....	462,243	462	--	--	1,009,538
Net loss.....	--	--	--	--	--
BALANCE, DECEMBER 31, 2000.....	462,243	462	3,512,586	3,513	1,006,136
Shares issued for cash.....	--	--	368,421	369	804,631
Shares issued for satisfaction of debt.....	--	--	137,300	137	499,447
Shares issued in replacement of preferred stock.....	(462,243)	(462)	462,243	462	--
Shares issuable in merger with subsidiary.....	--	--	520,313	520	2,540,148
Issuance of stock options.....	--	--	--	--	53,006
Net loss.....	--	--	--	--	--
BALANCE, DECEMBER 31, 2001.....	--	--	5,000,863	\$5,001	\$4,903,368
Net loss (unaudited).....	--	--	--	--	--
BALANCE, MARCH 31, 2002 (unaudited).....	--	--	--	--	--
		\$ --	5,000,863	\$5,001	\$4,903,368

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

F-5

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

#### CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEAR ENDED DECEMBER 31, 2000	YEAR ENDED DECEMBER 31, 2001	PERIOD FROM
			JANUARY 6, 1997 (DATE OF INCORPORATION) TO DECEMBER 31, 2001
OPERATING ACTIVITIES:			

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 agreed to exchange 72,922 shares of its common stock for common shares of BioDelivery Sciences, Inc. previously held by minority stockholders. This agreement resulted in the recognition of goodwill of \$401,070. In addition, the Company agrees to exchange 447,391 shares of its common stock for outstanding redeemable permanent discount common shares of

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

BioDelivery Sciences, Inc. The variable nature of this underlying stock award, as modified by the removal of discount and redemption provisions resulted in the recognition of compensation expense of approximately \$2,140,000.

During 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.

F-6

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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

##### 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 Company considers December 31, 2001 to be the acquisition date for accounting purposes as the rights of ownership of BDS had been essentially transferred to BDSI, without restrictions, by that date. The agreement required an exchange of 1.33 shares of identical BDSI common stock for each share of BDS common stock outstanding, including redeemable common stock. The Company would also exchange 72,922 shares of common stock for 239,600 shares of BDS common stock and 447,391 shares of common stock for 1,470,000 shares of BDS redeemable common stock. The acquisition of the 239,600 shares of common stock represents the acquisition of minority interest which resulted in recorded goodwill of approximately \$401,000. Prior to the acquisition of the 1,470,000 shares of redeemable common stock the Company agreed to remove the permanent discount and redemption provisions and agreed to the forgiveness of the stockholder debt associated with these shares upon, or soon after, the 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 permanent discount and 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.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

F-7

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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) (INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

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

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.

#### 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

F-8

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

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

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.

#### 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 modification of the terms of this stock (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 rights, 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 is evaluating the effect, if any, of adopting

F-9

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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) (INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

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

SFAS 142, but 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 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 adopted this standard effective January 1, 2002, which did not have a material impact on the Company's financial statements.

### UNAUDITED FINANCIAL STATEMENTS

The unaudited financial statements and the related notes thereto for March 31, 2002 and 2001 include all normal and recurring adjustments which, in the opinion of management, are necessary for a fair presentation and are prepared on the same basis as audited annual statements. The interim results are not necessarily indicative of the results that may be expected for the full year.

### 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.

F-10

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

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) (INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

### NOTE 3 -- BUSINESS COMBINATION -- (CONTINUED)

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)
	=====



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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 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. For the three months ended March 31, 2000 and 2001, respectively, BDSI incurred costs of approximately \$260,000 and \$0 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. At March 31, 2002, the Company owes \$106,608 under this agreement.

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

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

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.

During 2001, the Company entered into agreements with RetinaPharma, Inc. and Tatton Technology LLC. Both are biotechnology companies which are developing 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 pay a royalty of ten percent (10%) on net revenues from such sales of Bioral encapsulated drugs. The CEO/director is affiliated with these companies. The Company incurred a de minimus 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 de minimus 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 de minimus amount of costs relating to this agreement in 2001.

F-12

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

## NOTE 5 -- OTHER ASSETS

Other assets consist of the following.

	YEAR ENDED		MARCH 31,
	DECEMBER 31,		2002
	2000	2001	2002
	-----	-----	-----
			(UNAUDITED)
Goodwill.....	\$ --	\$517,445	\$ 517,445
Deferred offering costs.....	--	365,340	598,022
Other.....	42,520	43,821	43,821
	-----	-----	-----
Less: Accumulated amortization.....	42,520	926,606	1,159,288
	(12,396)	(13,796)	(14,497)
	-----	-----	-----
Total other assets, net.....	\$ 30,124	\$912,810	\$1,144,791
	=====	=====	=====

The Company has incurred and capitalized offering costs of approximately \$366,000 and \$598,000 at December 31, 2001 and March 31, 2002, respectively, related to the anticipated proposed public offering (see Note 16).

## NOTE 6 -- EQUIPMENT

Equipment consists of the following:

	DECEMBER 31,		MARCH 31,
	2000	2001	2002
	-----	-----	-----
			(UNAUDITED)
Office and laboratory equipment.....	\$236,466	\$ 321,338	\$ 321,338
Leased equipment.....	39,679	39,679	39,679
	-----	-----	-----
Less accumulated depreciation and amortization...	276,145	361,017	361,017
	(22,755)	(127,455)	(167,112)
	-----	-----	-----
Net equipment.....	\$253,390	\$ 233,562	\$ 193,905
	=====	=====	=====

Depreciation and amortization expense related to equipment for the years ended December 31, 2000 and 2001 and the three month periods ended March 31, 2002 and 2001 was approximately \$23,000, \$104,000, \$23,000 and \$40,000, respectively.

## NOTE 7 -- COMMITMENTS AND CONTINGENCIES

### LITIGATION

During May 2001, the Company entered into a settlement agreement with a

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

F-13

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

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

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
	=====

The Company has received notification of a potential claim for a finder's fee, and a lawsuit has been filed by Michael J. Pennesi and SSP Consultants, who are not affiliated with the Company, arising out of an introduction to BioDelivery Sciences, Inc. in 2000. Settlement discussions have been conducted. Informal telephonic settlement discussions prior to the filing of the lawsuit, have ranged between an approximately \$120,000 cash demand upon the Company to the Company's counter-offer of approximately \$5,000 in cash and 5,000 shares of stock. The Company intends to vigorously defend this litigation. It is the Company's belief that the potential claim is neither material nor meritorious.

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

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

## 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

F-14

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

## NOTE 8 -- PREFERRED STOCK -- (CONTINUED)

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 \$950,000. Interest on the line of credit accrues at a rate of prime plus 2.0% (6.75% at December 31, 2001) and principally matures in May 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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

and does not recognize compensation expense based upon the fair value at the grant date for awards under these plans 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.

F-15

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

NOTE 10 -- STOCK OPTIONS -- (CONTINUED)

Activity related to options is as follows:

	NUMBER OF SHARES -----	WEIGHTED AVERAGE EXERCISE PRICE PER SHARE -----
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 -----

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

\$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 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.

F-16

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

NOTE 11 -- INCOME TAXES -- (CONTINUED)

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

YEAR ENDED DECEMBER 31,		THREE MONTHS ENDED MARCH 31,	
-----	-----	-----	-----
2000	2001	2001	2002
-----	-----	-----	-----
		(UNAUDITED)	(UNAUDITED)

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

Federal statutory income tax rate.....	34.00%	34.00%	34.00%	34.00%
State taxes, net of federal benefit.....	4.95	4.95	4.95	4.95
Permanent differences -- compensation expense.....	--	(21.23)	--	--
Valuation allowance.....	(38.95)	(17.30)	(38.95)	(14.44)
	-----	-----	-----	-----
	--%	0.42%	--%	24.51%
	=====	=====	=====	=====

In March 2002, a new tax law changed the carryback period from two to five years. This allowed the Company to carryback its net operating losses to 1996 and 1997, which resulted in an additional benefit of \$95,843.

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 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. The weighted average shares outstanding at December 31, 2001 includes the 520,313 shares of common stock exchanged in the Merger (see Note 1) which was consummated on January 7, 2002. The Company considers

F-17

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

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



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

December 31, 2001 to be the acquisition date as the rights of ownership of BDS had been essentially transferred to BDSI, without restrictions, by that date.

	YEAR ENDED DECEMBER 31,		THREE MONTHS ENDED MAR	
	2000	2001	2001	31, 2002
			(UNAUDITED)	(UNAUDITED)
Net loss -- (numerator).....	\$ (672,731)	\$ (4,444,561)	\$ (392,471)	\$ (295,000)
Basic:				
Weighted average Shares outstanding (denominator).....	3,512,586	3,851,587	3,518,179	5,000,000
Net loss per common share -- basic.....	\$ (0.19)	\$ (1.15)	(.11)	(0.10)
Diluted:				
Weighted average shares outstanding.....	3,512,586	3,851,587	3,518,179	5,000,000
Effect of dilutive options.....	--	--	--	--
Adjusted weighted average shares (denominator).....	3,512,586	3,851,587	3,518,179	5,000,000
Net loss per common share -- diluted.....	\$ (0.19)	\$ (1.15)	\$ (.11)	\$ (0.10)

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 and \$260,000 of costs related to this agreement in 2001 and the three month period ended March 31, 2002, respectively.

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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. During the three month period ended

F-18

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)  
(INCLUDING NOTES APPLICABLE TO UNAUDITED PERIODS)

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

March 31, 2002, the Company received \$148,000 and recognized revenue of \$259,000 from this grant. As awarded on September 19, 2001, the grant provided for reimbursement of, or advances for, future research and development efforts. During October 2001, the Company negotiated a lump sum payment of \$220,000. The terms that were negotiated in October 2001 allowed the Company to recover \$220,000 of costs principally incurred in the third quarter of 2001, which were recognized as revenue upon agreement of those negotiated terms in October 2001. Upon receiving funding under the grant and utilizing the funds as specified, no amounts are refundable.

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 April 2002, the Company filed 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.

F-19

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the 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

F-20

BIODELIVERY SCIENCES, INC.  
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS

	NINE MONTHS ENDED SEPTEMBER 30, 2000	PERIOD FROM MARCH 28, 1995 (DATE OF INCORPORATION) TO SEPTEMBER 30, 2000
	-----	-----
		(UNAUDITED)
Sponsored research revenues.....	\$ 614,001	\$7,338,501
EXPENSES:		
Research and development.....	820,551	6,816,444
General and administrative.....	62,480	423,233
	-----	-----
Total expenses.....	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	(183,925)
	-----	-----
Net income (loss).....	\$ (206,004)	\$ 102,073
	=====	=====

# Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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

F-21

BIODELIVERY SCIENCES, INC.  
(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CASH FLOWS

	NINE MONTHS ENDED SEPTEMBER 30, 2000	PERIOD FROM MARCH 28, 1995 (DATE OF INCORPORATION) TO SEPTEMBER 30, 2000
	-----	-----
		(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.

F-22

BIODELIVERY SCIENCES, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

### 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.

BIODELIVERY SCIENCES, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

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

## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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.

F-24

BIODELIVERY SCIENCES, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

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

F-25

BIODELIVERY SCIENCES, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

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



## Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 424B1

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.

F-26

[BIODELIVERY LOGO]