BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B1
June 01, 2007
Table of Contents

Prospectus **Filed Pursuant to Rule 424(b)(1)**

Registration No. 333-72872

2,485,000 Shares of Common Stock

In June 2002, we conducted an initial public offering of Units, with each Unit consisting of: (i) one share of our common stock and (ii) one Class A Warrant. The common stock and Class A Warrants currently trade as separate securities. Each Class A Warrant entitles the holder to purchase one share of our common stock at a price of $6.11 (originally $6.30 per share, but adjusted downward because of issuances of our securities at below the market price on the date of the issuance).

We are filing the registration statement of which this notice and prospectus forms a part in order to update the registration of the shares of common stock underlying our Class A Warrants and the 400,000 shares of our common stock underlying the representative s unit purchase option, which we refer to herein as the Kashner Option, received by Kashner Davidson Securities Corporation, the representative of the underwriters in our 2002 initial public offering, and its assignees. We refer to Kashner Davidson Securities Corporation and such assignees collectively as Kashner.

To the extent the Class A warrants are exercised in full, we will receive $12,739,350 in gross proceeds. To the extent the Kashner Option is exercised in full, we will receive an additional $1,682,000 in proceeds. To the extent the warrants underlying the Kashner Option are exercised in full, we will receive an additional $1,222,000 in proceeds. Such proceeds, if any, will be used by us to fund our general corporate and working capital requirements.

If our Class A Warrants are not exercised by June 24, 2007, they will expire worthless. **Neither we nor our board of directors makes any recommendation to you as to whether you should exercise or refrain from exercising your Class A Warrants.**

Our common stock and warrants are quoted on both the Nasdaq Capital Market and the Boston Stock Exchange under the symbols BDSI and BDSIW , respectively. On May 31, 2007, the closing sales price for the common stock on the Nasdaq Capital Market was $5.28 per share and the closing sales price for our warrants was $0.29 per warrant.

Our principal executive offices are located at 2501 Aerial Center Parkway, Suite 205, Morrisville, North Carolina 27560. Our telephone number is (919) 653-5160.

An investment in the shares of our common stock being offered by this prospectus involves a high degree of risk. You should read the Risk Factors section beginning on page 6 before you decide to purchase any shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is May 31, 2007.

Table of Contents

TABLE OF CONTENTS

Incorporation of Certain Documents By Reference	-ii-
Note on Forward Looking Statements	-iii-
Prospectus Summary	1
Our Company	1
Risk Factors	6
Use of Proceeds	24
Plan of Distribution	24
Legal Matters	24
Experts	24
Where You Can Find More Information	25
Disclosure of Commission Position on Indemnification for Securities Law Violations	25

You should rely only upon the information contained in this prospectus and the registration statement of which this prospectus is a part. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date. This prospectus is based on information provided by us and other sources that we believe are reliable. We have summarized certain documents and other information in a manner we believe to be accurate, but we refer you to the actual documents for a more complete understanding of what we discuss in this prospectus. In making an investment decision, you must rely on your own examination of our business and the terms of the offering, including the merits and risks involved.

We obtained statistical data, market data and other industry data and forecasts used throughout, or incorporated by reference in, this prospectus from market research, publicly available information and industry publications. Industry publications generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy and completeness of the information. Similarly, while we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information. We have not sought the consent of the sources to refer to their reports appearing or incorporated by reference in this prospectus.

This prospectus contains, or incorporates by reference, trademarks, tradenames, service marks and service names of BioDelivery Sciences International, Inc. and other companies.

Table of Contents

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The following documents, heretofore filed by us with the U.S. Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended, are hereby incorporated by reference, except as superseded or modified herein:

1. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed on April 17, 2007, as amended on May 30, 2007;

2. Our Quarterly Report on Form 10-QSB for the quarterly period ended March 31, 2007, filed on May 15, 2007

3. Our Current Report on Form 8-K, filed on February 8, 2007;

4. Our Current Report on Form 8-K, filed on February 23, 2007;

5. Our Current Report on Form 8-K, filed on March 16, 2007;

6. Our Current Report on Form 8-K, filed on April 6, 2007;

7. Our Current Report on Form 8-K, filed on April 27, 2007;

8. Our Current Report on Form 8-K, filed on May 8, 2007;

9. Our Current Report on Form 8-K, filed on May 14, 2007; and

10. The description of our common stock contained in our registration statement on Form 8-A filed on June 19, 2002, as amended June 20, 2002, and as it may be further amended from time to time.

All documents filed by the registrant after the date of filing the initial registration statement on Form S-3 of which this prospectus forms a part and prior to the effectiveness of such registration statement pursuant to Section 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 shall be deemed to be incorporated by reference into this prospectus and to be part hereof from the date of filing of such documents.

We will provide without charge to each person to whom a copy of this prospectus is delivered, upon the written or oral request of any such person, a copy of any document described above (other than exhibits). Requests for such copies should be directed to BioDelivery Sciences International, Inc., 324 South Hyde Park Avenue, Suite 350, Tampa FL 33606, Attention: James A. McNulty.

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front page of those documents.

Table of Contents

NOTE ON FORWARD LOOKING STATEMENTS

Certain statements contained in this prospectus constitute forward-looking statements as that term is defined under the Private Securities Litigation Reform Act of 1995 and releases issued by the SEC and within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, (the Exchange Act). The words believe, expect, anticipate, intend, estimate, plan an expressions which are predictions of or indicate future events and trends and which do not relate to historical matters identify forward-looking statements. Reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance or achievements to differ materially from anticipated future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to:

- our plans regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the Bioral® and BEMA technology platforms and any proposed formulations or products relating thereto;
- the domestic and international regulatory process relating to our technologies and proposed products and formulations, including the timing, status and results of our filings with the FDA, and the timing, status and results of pre-clinical work and clinical studies;
- our ability to generate commercial viability and acceptance of our Bioral® and BEMA technology platforms and our proposed formulations and products, including Emezine®;
- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing partnerships;
- the protection and control afforded by our interest in licensed patents, or our ability to enforce our rights under such licenses;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and formulations;
- the ability of our sublicense partners to commercially exploit our drug delivery platforms and our ability to enter into sublicenses and to receive royalty and other payments from parties to whom we have sublicensed our technologies;
- our ability to retain members of our management team and our employees;
- our ability to receive federal, state, government or private grants; and
- the competition that may arise in the future.

The foregoing does not represent an exhaustive list of risks. Please see Risk Factors for additional risks which could adversely impact our business and financial performance. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this prospectus are based on information available to us on the date of this prospectus. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the

cautionary statements contained throughout this prospectus.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights selected information contained in this prospectus. This summary does not contain all of the information you should consider before investing in the securities. Before making an investment decision, you should read the entire prospectus carefully, including the risk factors section as well as the financial statements and the notes to the financial statements incorporated herein by reference. In this prospectus and any amendment or supplement hereto, unless otherwise indicated, the terms BioDelivery Sciences International, Inc. , BDSI , the Company , we , us , and our refer and relate to BioDelivery Sciences International, Inc. and its consolidated subsidiaries.

Our Company

We are a specialty biopharmaceutical company that is utilizing its licensed, owned and proprietary patented drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, clinically-significant new formulations of proven therapeutics.

Our development strategy focuses on the utilization of the U.S. Food and Drug Administration s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved therapeutics which incorporate our licensed drug delivery technologies. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and less time consuming than other approval methods of the U.S. Food and Drug Administration, which we refer to herein as the FDA.

Our drug delivery technologies include:

- the patented BEMA (transmucosal, or applied to the inner cheek membrane) drug delivery technology, and
- the patented Bioral® nanocochleate drug delivery technology, designed for a potentially broad base of applications.

Utilizing our licensed delivery technologies, we are currently developing formulations of pharmaceuticals aimed principally at acute (i.e., short term) conditions occurring in cancer and surgical patients, mostly notably in the areas of pain and fungal infections. Our lead product, currently in Phase III clinical trials, is BEMA Fentanyl, a treatment for breakthrough cancer pain (i.e., episodes of severe pain which break through the medication used to control the persistent pain). We also believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals and also to other therapeutics such as small interfering RNA, or siRNA.

We currently generate revenue from licensing milestone payments and royalties, and have generated revenue from grants. Ultimately, if we secure approval from the FDA for our licensed and/or proprietary products and formulations, our goal will be to augment these revenues from sales of such products and formulations, on which we will also pay royalties or other fees to our licensors and/or third-party collaborators where they exist.

We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- applying our licensed technologies to existing therapeutics to create our own proprietary formulations, which we will then seek to obtain FDA approval for and subsequently commercialize,

Table of Contents

licensing and joint venture arrangements with third parties, including pharmaceutical companies whose own proprietary pharmaceutical products may benefit from our drug delivery technologies,

partnering with pharmaceutical companies to assist in the distribution of our products for which we will receive milestone and royalty payments, and

proceeds raised from our public and private financings and strategic transactions.

BEMA Technology and Products in Development

Our BEMA drug delivery technology consists of a small, dissolvable polymer disc for application to mucosal (inner lining of cheek) membranes. BEMA discs deliver a rapid, reliable dose of drug across mucous membranes for time-critical conditions like breakthrough cancer pain or trauma cases where intravenous lines or injections are unavailable or not practical. We license the BEMA drug delivery technology in the United States on an exclusive basis from Atrix Laboratories, Inc. (now a wholly-owned subsidiary of QLT Inc.), which we refer to herein as QLT. In August 2006, we entered into an agreement with QLT to purchase the non-U.S. rights to the BEMA technology. This agreement includes an exclusive option to purchase the U.S. rights within 12 months of the effective date of this agreement. After purchasing the intellectual property rights from QLT, we will not owe any future milestone payments or royalties.

Our lead BEMA product under development is BEMA Fentanyl, a treatment for breakthrough cancer pain. This product entered into Phase III trials for breakthrough cancer pain in the second half 2005. In February of 2006, enrollment in the Phase III clinical program commenced. In April and May 2006, we announced results from pharmacokinetic studies demonstrating dose proportionality and reproducibility with BEMA Fentanyl. In September 2006, we conducted a second meeting with the FDA to discuss the status of the BEMA Fentanyl development program. At such meeting, we received confirmation from the FDA regarding the process being undertaken for the BEMA Fentanyl program.

On April 25, 2007, we announced that we achieved statistically significant results with BEMA Fentanyl in cancer patients with breakthrough pain in our Phase III efficacy clinical trial for the product. The results are based on achievement of the primary efficacy endpoint of the trial, Summary of Pain Intensity Difference (SPID), compared to placebo. We plan to submit a New Drug Application, or NDA, to the FDA regarding BEMA Fentanyl with an indication for the treatment of breakthrough cancer pain in the third quarter of 2007. On May 7, 2007, we announced the results of a bioavailability study for BEMA Fentanyl and on May 14, 2007, we announced the results of certain secondary efficacy data points from the Phase III BEMA Fentanyl study.

On July 15, 2005, we entered into a clinical development and licensing agreement (which agreement we refer to herein as the CDLA) with Clinical Development Capital, LLC, which we refer to herein as CDC, under which CDC has provided $7 million toward the Phase III clinical development of BEMA Fentanyl. The CDLA was subsequently assigned to CDC IV, LLC, an affiliate entity of Clinical Development Capital, LLC. On February 16, 2006, we announced that, as a result of our achievement of certain milestones called for under the CDLA, CDC made an initial $2 million payment to us.

On May 17, 2006, we consummated a transaction with CDC pursuant to which $7 million in funds previously committed by CDC under the CDLA to fund our clinical development of BEMA Fentanyl was converted into shares of our common stock at a value of $3.50 per share. As a result of this transaction, CDC was issued 2 million shares of our common stock in return for accelerating the funding of the $4.2 million balance of $7 million of aggregate commitment under the CDLA and for eliminating the $7 million milestone payable to CDC upon the approval by the FDA of BEMA Fentanyl which had been required under the CDLA.

Table of Contents

In August 2006, we entered into a definitive agreement with Meda AB, or Meda, to license the European development and commercial rights to BEMA Fentanyl to Meda AB. We received an upfront license payment of $2.5 million, are eligible to earn up to $7.5 million more upon achievement of certain milestones and will receive a double digit royalty on net sales of BEMA Fentanyl in Europe.

A second product under development, BEMA Long Acting Analgesic, which we refer to herein as BEMA LA, is a BEMA formulation of an already approved product in the U.S. that will target a broader range of pain conditions including post operative and, potentially, chronic pain due to osteoarthritis, lower back disorders and rheumatoid arthritis. In early December 2005, we submitted an Investigational New Drug Application, or IND, with FDA for BEMA LA. In mid-2006, we conducted our first Phase I study with BEMA LA in normal volunteers. The data from this study confirmed that we can deliver the active ingredient of BEMA LA at therapeutic plasma (blood) concentrations based on other work done in other deliver forms of the active ingredient. We therefore expect that we will be able to demonstrate efficacy with BEMA LA for the treatment of certain types of pain. Additional formulation work with BEMA LA is ongoing and we project to start Phase II trials by the end of 2007 or early in 2008.

A third product under development, BEMA Zolpidem, is a BEMA formulation of the most widely prescribed drug for the treatment of insomnia. Given funding constraints and our focus on applying the majority of our resources to the Phase III BEMA Fentanyl program, the initiation of the BEMA Zolpidem program was delayed in 2006. The timing of the restart of this program will be evaluated in 2007.

Bioral® Technology and Products in Development

Our Bioral® (cochleate) drug delivery technology encapsulates (encochleates) the selected drug or therapeutic in a nanocrystalline structure termed a cochleate cylinder. All of the components of the cochleate cylinder are naturally occurring substances. We believe that the cochleate cylinder provides an effective delivery mechanism without forming a chemical bond, or otherwise chemically altering, the selected drug. We believe this technology will allow us to take certain drugs that were only available by intravenous injection and convert them to formulations that can be taken orally. Our Bioral® drug delivery technology was developed in collaboration with The University of Medicine and Dentistry of New Jersey, which we refer to herein as UMDNJ, and the Albany Medical College, which we refer to herein, collectively with UMDNJ, as the Universities, each of which has granted us the exclusive worldwide licenses under applicable patents.

Our lead Bioral® formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for treating systemic fungal infections. A Bioral® formulation of Amphotericin B (which we refer to as CAMB) would have the potential for oral delivery of a drug that is currently only given by intravenous injection. Following the completion of preclinical testing in 2006, we submitted an IND to the FDA for CAMB in December 2006 which was accepted by the FDA. We believe that the opportunity to move forward with testing a Bioral® formulation in humans represents a major milestone for us given the time and resources we have spent in developing the technology. The next step for CAMB will be to manufacture clinical supplies and proceed with our first Phase I trial in normal volunteers to evaluate the safety of the product and its pharmacokinetics. If financing permits, we expect to begin this program in 2007.

Table of Contents

A second Bioral® formulation for the intranasal administration of Amphotericin B to treat chronic rhinosinusitis, or CRS, is now in initial in vitro studies. These studies suggest that CAMB may provide enhanced efficacy and stability. In April 2004, we licensed this second opportunity to Accentia Biopharmaceuticals, Inc., an affiliate of ours which we refer to herein as Accentia, for the use in the treatment of CRS and asthma. Certain of our officers and directors are officers, directors and/or stockholders of Accentia or its subsidiaries.

We have also explored other potential applications of our Bioral® encochleation technology, including the creation of cochleate formulations of siRNA therapeutics, other therapeutics, certain vaccines and important nutrients. In 2005 and 2006, we entered into agreements with third parties for the evaluation of cochleate formulations of siRNA therapeutics. The results of one of these collaborations demonstrated that the Bioral® technology showed the potential to deliver the siRNA resulting in the knock down of the targeted enzyme (meaning the siRNA positively effected the enzyme in question in such a way so as to potentially achieve a therapeutic effect). This was established in two sets of experiments (which we announced in August 2006) in a mouse model of influenza where intra-nasally and intravenously administered Bioral® siRNAs reduced the viral titer significantly. We believe this may represent a significant opportunity to deliver these therapeutics, which are normally difficult to use and which are easily destroyed in the plasma by the body s natural enzymes, to patients. We have an ongoing evaluation agreement with a major companies developing siRNA therapeutics and we are seeking additional collaborations and strategic partners in this area.

Additionally, we have ongoing evaluation agreements in place with other companies to evaluate their proprietary molecules in the Bioral® delivery system. In 2006, we signed a master research agreement with a major pharmaceutical company where we can evaluate a series of compounds from the sponsor company with predefined terms. If any of the evaluations from this agreement are positive, we will have an option to license the Bioral® technology for use with the specified compound. To date, no opportunity for such an option has arisen.

Emezine®

We have also been developing Emezine®, a formulation of prochlorperazine, which we believe would be the first drug to be delivered transmucousally for treatment of nausea and vomiting. In February 2005, we announced that we completed the clinical studies required for our Emezine® NDA, and on April 29, 2005, we submitted such NDA. The FDA accepted our NDA for filing on June 30, 2005. On February 28, 2006, however, we received a non-approvable letter from the FDA regarding our Emezine® NDA. The non-approvable letter stated that additional information would be required to address remaining questions. On May 17, 2006, we met with the Gastroenterology Division of the FDA to discuss the nonapprovable letter we received for Emezine®. The FDA s position was that while a 505(b)(2) submission is still an acceptable regulatory pathway for Emezine®, additional clinical trials would be required to support the use of Emezine® in the target population of the proposed indication. The FDA further suggested that a Special Protocol Assessment could potentially fulfill the remaining requirements. Based on the FDA feedback, on July 14, 2006, we submitted two draft pharmacokinetic protocols for review as a Special Protocol Assessment along with a proposal as to how the data from these protocols would address the deficiencies noted in the non-approvable letter. We are currently involved in discussions with clinical consultants to determine how and whether we will proceed with the continued development of Emezine® based on the feedback we received from FDA on the information we submitted on July 14, 2006. Given the opportunity that the BEMA Fentanyl and BEMA LA products currently present to us in terms of potential commercial value, any continued spending on Emezine® based on the challenges of meeting FDA s requirements for the ultimate approval of Emezine® may not be warranted. We therefore plan to continue to monitor, but not spend material resources, on the Emezine® project for the foreseeable future. Despite the fact Emezine® represents a relatively small portion of our potential future revenues, the failure to ultimately achieve FDA approval of Emezine®

Table of Contents

could have an adverse effect on our business. We do not, however, expect that such failure would seriously impair our overall potential future revenue growth. We license Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

During 2006, we actively pursued strategic financings and related partnerships regarding certain of our proposed formulations and products as we attempt to move them through the development, approval and commercialization phases. Unfortunately, the FDA non-approvable notification regarding Emezine® meant that revenues we had previously projected as potentially being generated upon the launch of Emezine® in 2006 were not realized. Therefore, in part to offset the potential loss of projected Emezine® revenue but primarily due to our interest in securing distribution partners for our products, we aggressively pursued these types of transactions in 2006 and will continue to do so in 2007. As a result, we were able to execute a European transaction involving the distribution rights of BEMA Fentanyl with Meda (European based pharmaceutical company with a focus in pain) that included a signing milestone payment of $2.5 million. We are currently in discussions with several companies regarding the same distribution rights for BEMA Fentanyl in the U.S.

The Offering

Outstanding Common Stock	18,805,598 shares of our common stock issued and 18,790,107 shares outstanding as of May 30, 2007.
Common Stock Offered	Up to 2,485,000 shares of common stock. These shares include: (i) up to 2,085,000 shares of our common stock issuable upon the exercise of the Class A Warrants; (ii) up to 200,000 shares of our common stock issuable upon the exercise of the Kashner Option; and (iii) up to 200,000 shares of our common stock issuable upon the exercise of the warrants underlying the Kashner Option.
Proceeds	We will receive up to $12,739,350 in gross proceeds upon the exercise of the Class A Warrants, up to $1,682,000 upon the exercise of the Kashner Option, and up to $1,222,000 upon the exercise of the warrants underlying the Kashner Option.
Risk Factors	The securities offered hereby involve a high degree of risk. See Risk Factors.
Nasdaq Capital Market Symbols	BDSI, BDSIW

Table of Contents

RISK FACTORS

An investment in our company is extremely risky. You should carefully consider the following risks, in addition to the other information presented in this prospectus before deciding to buy or exercise our securities. If any of the following risks actually materialize, our business and prospects could be seriously harmed, the price and value of our securities could decline and you could lose all or part of your investment.

Risks 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, 2007, we have recorded accumulated losses totaling approximately $60.2 million. As of March 31, 2007, we had negative working capital of approximately $18.7 million (which includes $15.2 million of derivative liability associated with warrants previously issued to Laurus Master Fund, Ltd., which we refer to herein as Laurus, and CDC). Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed formulations and products, obtain the required regulatory approvals and manufacture, market and sell our proposed formulations and products. No assurances can be given that we will be able to achieve these goals.

Although we have generated some licensing-related and other revenue to date, we have not generated any revenue from the commercial sale of products. Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel, although since 2005 we have shifted our focus towards commercialization activities, mostly relating to BEMA Fentanyl. This limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize our technologies and proposed formulations or products, obtain FDA approval and achieve market acceptance of our proposed formulations or products and respond to competition. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and derive material revenues from our proposed formulations or products in development.

We will need to raise additional capital to continue our operations, and our failure to do so would impair our ability to fund our operations, develop our technologies or promote our formulations or products.

Our operations have relied almost entirely on external financing to fund our operations. Such financing has historically come primarily from the sale of common and preferred stock and convertible debt to third parties and to a lesser degree from grants, loans and revenue from license and royalty fees. At March 31, 2007, we had cash of approximately $1.35 million. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) and financings we have undertaken prior to the date of this prospectus, that our current working capital and available financing will be sufficient to satisfy our contemplated cash requirements into approximately the second quarter of 2008, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events or contingencies, any of which could effect our cash requirements. Thereafter, and given that our current cash on hand will not fully fund all development costs of our leading product formulations, we will need to raise additional capital to fund our anticipated operating expenses and future expansion. Among other things, external financing will be required to allow us to pay, by March 31, 2007 (which we paid March 30, 2007), $1 million to QLT in connection with our August 2006

Table of Contents

acquisition of the non-U.S. BEMA assets and also cover the further development of our product formulations and other operating costs. While we expect that we will be able to find the needed capital to progress our business plan, we cannot assure you that financing, whether from external sources or related parties, will be available. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make capital raising more difficult and may also result in a lower price for our securities.

We may have difficulty raising needed capital in the future as a result of, among other factors, our limited operating history and business risks associated with our company. Our business currently does not generate any sales, and current sources of revenue are limited and will not be sufficient to meet our present and future capital requirements. We do not know when this will change. We have expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of our drug delivery technologies and product formulations incorporating such technologies. 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. While we expect that we will have access to financial resources so that we will be able to progress with our business plan, if adequate funds are unavailable, we may have to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs or product launches or marketing efforts which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are expected to depend on many factors, including, among others:

- the number of potential formulations, products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drug formulations or products;
- costs involved in establishing manufacturing capabilities for commercial quantities of our drug formulations or products;
- competing technological and market developments;
- market acceptance of our drug formulations or products;
- costs for recruiting and retaining employees and consultants;
- costs for training physicians; and

legal, accounting and other professional costs.

Table of Contents

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through the exercising of our public warrants, equity or debt financings, collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. If adequate funds are not available, we may be required to significantly reduce or refocus our development and commercialization efforts with regards to our delivery technologies and our proposed formulations and products. Additionally, investors are cautioned that the total projected development costs for BEMA Fentanyl will exceed the maximum amounts CDC has funded to us. As a result, we have and will continue to require additional financial resources to complete the development of BEMA Fentanyl, which resources may not be available to us.

Our additional financing requirements could result in dilution to existing stockholders.

The additional financings which we have undertaken and which we will require have and may in the future be obtained through one or more transactions which have diluted or will dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 45 million shares of common stock and 5 million shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

CDC has claimed that we have breached the CDLA and has sought to gain control of our BEMA® Fentanyl asset.

In August 2006, CDC provided us with a written notice in which they claimed that we had materially breached the CDLA. Such notice also contained a demand that we transfer to CDC all rights associated with BEMA Fentanyl. Although we settled this dispute in March 2007, such resolution was without prejudice to CDC s or our claims, and no assurances can be given however that CDC will not in the future make similar or additional claims against us. Our dispute with CDC has forced us to spend corporate resources in our defense and has distracted management s attention from key projects. Moreover, under our agreements with CDC, if we do not meet certain conditions, CDC can assume control of the BEMA Fentanyl project and related intellectual property assets. F or example, in the event that we do not diligently pursue the development and regulatory approval of BEMA Fentanyl or encounter certain specified negative circumstances regarding the development of BEMA Fentanyl, CDC has the right to pursue development and commercialization of BEMA Fentanyl pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of our BEMA Fentanyl assets to CDC. In addition to the time and cost associated with defending ourselves from CDC, which have negatively impacted us, if CDC were to prevail, our loss of BEMA Fentanyl to CDC would have a material adverse effect on our business.

CDC s right of first negotiation on future financings of ours could impede our ability to raise capital.

Under our May 2006 Securities Purchase Agreement, until such time as we achieve a market capitalization of $85 million, in the event that we seek to raise money through the offer and sale of debt or equity securities, we must first offer CDC an opportunity to provide financing to us. If CDC elects to exercise its right to such opportunity, we must negotiate exclusively with CDC the terms of a financing for 60 days. If no terms are agreed to, we may pursue a financing with a third party for 120 days, but only on terms superior and similar in structure to those offered by CDC. CDC has exercised this right of first negotiation to our detriment in the

Table of Contents

past, and the right of first negotiation was the subject of a now settled litigation between us and CDC in October 2006. No assurances can be given that CDC will not seek to exercise the right again in the future. The existence or alleged existence of CDC s right of first negotiation, or CDC s exercise thereof or claims related thereto, has and may in the future deter potential investors from providing us needed financing, which would have a material adverse effect on our operations and viability as a company.

Acceptance of our formulations or products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

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

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

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

We are dependent on our collaborative agreements for the development of our drug delivery technologies and business development which exposes us to the risk of reliance on the viability of third parties.

In conducting our research and development activities, we currently rely, and will continue to rely, on numerous collaborative agreements with universities, governmental agencies, manufacturers, contract research organizations and corporate partners for both strategic and financial resources. Our inability to secure such relationships as needed, or the loss of or failure to perform by us or our partners under any applicable agreements or arrangements, may substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

Table of Contents

We are exposed to product liability, clinical and pre-clinical liability risks which could place a substantial financial burden upon us, should we be sued, because we do not currently have product liability insurance above and beyond our general insurance coverage.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. Such claims may be asserted against us. In addition, the use in our clinical trials of pharmaceutical formulations and products that our potential collaborators may develop and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

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

We may be sued by third parties who claim that our drug formulations or products infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents.

We may be exposed to future litigation by third parties based on claims that our technologies, formulations, products or activities infringe the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether or not valid, could result in substantial costs, 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, importing, incorporating or using any of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our formulations or products, which would be costly and time-consuming.

Other parties could have patent rights which may block our products. We are aware of two issued United States patents dealing with lipid formulations of Amphotericin B products. The first of these patents, United States Patent No. 4,978,654, claims an Amphotericin B liposome product. We do not believe that our patent or technology are in conflict with this existing patent, although there can be no assurance that a court of law in the United States patent authorities might determine otherwise. Our belief is based

Table of Contents

upon the fact that our cochleate product does not contain liposomes, which is required by the issued claims of this patent. The second of these patents, United States Patent No. 5,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our Bioral® nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we require a license under this patent.

We are also aware of United States Patent No. 6,585,997, related to mucoadhesive erodible drug delivery devices. We do not believe that our BEMA Fentanyl product is in conflict with the existing patent, at least because there are limitations recited in the issued claims that are not met by our product. Accordingly, we do not believe that we require a license under this patent for BEMA Fentanyl. We have not, however, conducted any patent searches with respect to our other proposed BEMA-based products. We are further aware of U.S. Patents Nos. 5,948,430, 6,177,096 and 6,284,264, and European Patent No. 949 925, which are owned by LTS Lohmann and which also relate to mucoadhesive erodible drug delivery devices.

If a court were to determine that we infringe any of these or other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B and/or our BEMA products. There can be no assurance that we would be able to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, we might be precluded from developing or commercializing these products, which would likely have a material adverse effect on our results of operations and business plans.

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

If we are unable to adequately protect or enforce our rights to intellectual property or secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect such rights.

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

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

Table of Contents

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

Although our trade secrets and technical know-how are important, our continued access to the patents is a significant factor in the development and commercialization of our drug delivery technologies. Aside from the general body of scientific knowledge from other drug delivery processes and lipid technology, these patents, to the best of our knowledge and based upon our current scientific data, are the only intellectual property necessary to develop and apply our Bioral® and BEMA drug delivery systems to the drugs to which we are attempting to apply them.

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

Key components of our drug delivery technologies may be provided by sole or limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs.

Certain components used in our research and development activities, such as lipids, are currently purchased from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

- potential delays associated with research and development and pre-clinical and clinical trials due to an inability to timely obtain a single or limited source component;
- potential inability to timely obtain an adequate supply of required components; and
- potential for reduced control over pricing, quality and timely delivery.

Except for our agreement with Aveva, 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 time frames, if at all, to meet our needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing; or cause us to lose sales, incur additional costs, delay new product introductions or harm our reputation. Furthermore, components from a new supplier may not be identical to those provided by the original supplier. Such differences if they exist could affect product formulations or the safety and effectiveness of our products that are being developed.

Table of Contents

We have limited manufacturing experience, and once our drug formulations or products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost.

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, once our proposed formulations or products are approved for commercial sale, we will need to establish, most likely through third parties, the capability to commercially manufacture our formulations or products in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our formulations or products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our proposed formulations or products. We presently plan to rely on third party contractors to manufacture part or all of our proposed formulations or products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanic shut downs, employee strikes, or any other unforeseeable acts that may delay production.

Due to the fact that we must build our marketing, sales, managed care, and distribution infrastructure and channels, we may be unsuccessful in our efforts to sell our formulations or products.

We expect that we will be required to enter into agreements with commercial partners to engage in sales, marketing and distribution efforts around our products in development. Except for our non-exclusive distribution agreement with BioTech Specialty Partners, Inc., a development-stage company affiliated with Dr. Francis E. O Donnell, a member of our management and significant beneficial owner of our securities, and the agreement between us and TEAMM Pharmaceuticals, also an affiliate of Dr. O Donnell, relating to Emezine®, we have yet to establish marketing, sales or distribution capabilities for our proposed formulations or products. Even though our proposed formulations or products have not been approved by the regulatory authorities, we devote meaningful time and resources in this regard. At the appropriate time, we intend to enter into agreements with third parties to sell our proposed formulations or products, or we may (in the future, resources permitting) 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. In particular, our inability to secure a commercial partner for our lead product, BEMA Fentanyl, would seriously compromise our ability to bring this product to market.

If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, especially our lead product BEMA Fentanyl, we will need to develop our own sales and marketing capabilities. Given the late stage of the clinical development of BEMA Fentanyl, it is highly unlikely that we will have the time or resources to develop such capabilities with respect to such product and will have to rely on securing a commercial partner. Moreover, even if we were to develop our own sales and marketing capability, our experience in developing a fully integrated commercial organization is very limited. If we choose to establish a fully integrated commercial organization, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a fully integrated commercial organization on a cost effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

Table of Contents

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

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

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

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

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

We currently rely on the facilities of the University of Medicine and Dentistry of New Jersey for all of our research activities relating to our Bioral® technology, which activities could be materially delayed should we lose access to those facilities.

We have no research and development facilities of our own. As of the date of this prospectus, we are entirely dependent on third parties to use their facilities to conduct research and development. To date, we have relied on UMDNJ for this purpose in relation to our Bioral® technology, as well as third party providers of testing and trial services. Additionally, the Universities own certain of the patents to our encochleation drug delivery technology. Our inability to conduct research and development, or our inability to find suitable third party providers of research and development services on an outsourcing basis, may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technologies, formulations and products.

We leased our research facility from UMDNJ, which lease expired December 31, 2005. We are currently leasing the space on a month to month basis, but are in negotiations to renew the lease. No assurances can be given that we will be able to enter into, extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations. Should the lease expire or if we are otherwise are required to relocate on short notice, we do not currently have an alternate facility where we could relocate. The cost and time to establish or locate an alternative research and development facility to develop our technologies, other than through the Universities, or to find suitable third party providers of research and development services on an outsourcing basis, could be substantial and might delay gaining FDA approval and commercializing our formulations and products, assuming that we have not defaulted on the terms of our intellectual property licenses and can continue with our approval process.

Table of Contents

We may be unable to obtain, or elect not to pursue, extensions of our NIH grants and we may not be able to secure new NIH or similar grants in the future, which could deny us important funding.

In 2001, the NIH awarded us a Small Business Innovation Research Grant, or SBIR, which we utilized in our research and development efforts relating to our Bioral® Amphotericin B formulation. We have received all anticipated funding under this grant to date, and this grant expired in August 2004. In 2002, the NIH awarded us a second SBIR grant which we have utilized in our research and development efforts relating to a proposed encochleated HIV subunit vaccine. This grant expired in December 2005 but was extended by the NIH in February 2006 until July 31, 2006, and we believe this will be the final extension for this grant. As a result of this extension, we expect to receive approximately $74,000 in additional funds from the NIH for this project. In 2005, we subcontracted the responsibilities under the NIH grant for this project to UMDNJ. Also, in late July 2005, we received an indication from the NIAID, which is affiliated with the NIH, that the NIAID would, at its expense and following our achievement of certain milestones, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. No assurances can be given that NIAID will proceed with or actually pay for this testing.

Moreover, although we may seek additional NIH funding for either of these or other programs, we may choose not to seek such funding or such funding may be unavailable to us even should we desire it. The absence of additional funding from the NIH could impair our ability to further develop our Bioral® Amphotericin B formulation or other projects. Furthermore, as a result of these expirations, we incurred a decline in sponsored research revenue with associated NIH grant expenditures in 2005.

Risks Related to Our Products in Development and Regulation

Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our technologies and proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.

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

Moreover, we may never receive regulatory approval of our proposed products and formulations. No assurances can be given that we will be able to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and viability. For example, on February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. We subsequently have had interactions with the FDA regarding Emezine®, and at the present time, given our level of resources and our focus on other initiatives, it is not likely that we will proceed with Emezine® in the foreseeable future.

Table of Contents

Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair the viability of our company.

In order to be commercially viable, we must research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute formulations or products incorporating our technologies. For each drug that we formulate with our drug delivery technologies, we must meet a number of critical developmental milestones, including:

- demonstrate benefit from delivery of each specific drug through our drug delivery technologies;
- demonstrate through pre-clinical and clinical trials that our drug delivery technologies are safe and effective; and
- establish a viable Good Manufacturing Process capable of potential scale-up.

The required capital and time-frame necessary to achieve these developmental milestones is uncertain, and we may not able to achieve these milestones for any of our proposed formulations or products in development. Our failure to meet these or other critical milestones would adversely affect the viability of our company.

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

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

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

Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

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

Table of Contents

We depend on technology licensed to us by third parties, and the loss of access to this technology would terminate or delay the further development of our products, injure our reputation or force us to pay higher royalties.

We rely, in large part, on drug delivery technologies that we license from third parties such as the Universities, QLT and Reckitt. The loss of these licenses would seriously impair our business and future viability. After the expiration of these licenses, this technology may not continue to be available on commercially reasonable terms, if at all, and may be difficult to replace. The loss of any of these technology licenses could result in delays in developing, introducing or maintaining our products and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the technology we may license in the future could prevent the implementation or impair the functionality of our products or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

Competitors in the drug development or specialty pharmaceutical industries may develop competing technology.

Drug companies and/or other technology companies may seek to develop and market nanoencapsulation, mucosal adhesive or other technologies which may compete with our technologies. While we believe that our technologies have certain advantages over potential competitors, competitors may develop similar or different technologies which may become more accepted by the marketplace. In addition, these competitors may be larger and better financed than we are, thus giving them a significant advantage over us.

Our lead product candidates contain narcotic ingredients. The development, manufacturing and sale of such products are subject strict regulation, including the necessity of risk management programs, which may prove difficult or expensive to comply with.

Our lead product candidates, most notably BEMA Fentanyl and BEMA LA, contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. The FDA or the U.S. Drug Enforcement Administration, or DEA, currently impose and may impose additional regulations concerning the development manufacture and sale of prescription narcotics. Such regulations include labeling requirements, the development and implementation of risk management programs, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such current or new regulations may be difficult and expensive for us to comply with, may delay the introduction of our products, may adversely affect our net sales, if any, and may have a material adverse effect on our results of operations.

The DEA limits the availability of the active ingredients used in our products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in our lead products in development, including fentanyl and the active ingredient in BEMA LA, are listed by the DEA as Schedule II or III substances

Table of Contents

under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active ingredients used in our products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to complete clinical trials or meet commercial demand. We must annually apply to the DEA for procurement quota in order to obtain these substances. The DEA may not establish procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides public comment on the labeling, promotion, risk management plan and other documents associated with such product. No assurance can be given that the DEA review of such materials may not result in delays in obtaining procurement quota for controlled substances, a reduction in the quota issued to us or an elimination of our quota entirely. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches which could have a material adverse effect on our business and results of operations.

Risks Related to Our Industry

The market for our proposed formulations and products is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

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

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

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

Table of Contents

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

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

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

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

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. We currently have a general liability policy with an annual aggregate limit of $2 million with a $1 million limit per occurrence which does not provide coverage for product liability for commercial products. All of our pre-clinical trials have been and all of our proposed clinical and pre-clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have insurance relating to product liability or insurance related to clinical or pre-clinical trials only with respect to our developmental product portfolio, for which we have a clinical trial liability policy providing for a $2 million aggregate limit. We intend to seek additional insurance against such risks before our product sales are commenced, although there can be no assurance that such insurance can be obtained at such time, or even if it is available, that the cost will be affordable. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs. The cost and availability of such insurance are unknown. Product liability claims or other claims related to our proposed formulations and products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our drug delivery technology. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products.

Table of Contents

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 UMDNJ. UMDNJ also disposes these chemicals from our premises as part of our agreement to use the facilities and carries general liability insurance in this regard. Although we believe that our safety procedures for storing, handling and disposing of such materials will comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Our Management and Key Employees

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

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

Additionally, we do not currently maintain key person life insurance on the lives of our Chairman of the Board, Dr. Frank O Donnell, our President and Chief Executive Officer, Dr. Mark Sirgo, or any of our other executive officers. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Executive officers, directors and entities affiliated with them have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders.

As of the date of this prospectus, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 35.5% of our outstanding common stock. These figures do not reflect any future potential exercise of our Class A warrants or other outstanding warrants (including those issued to Laurus, CDC and others) into shares of common stock or the increased percentages that our officers and directors may have in the event that they exercise any of the options granted to them under our Amended and Restated 2001 Stock Incentive Plan or if they otherwise acquire additional shares of common stock generally.

Table of Contents

The interests of our current officer and director stockholders may differ from the interests of other stockholders. As a result, these current officer and director stockholders would have the ability to exercise significant control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

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

Certain of our management team have relationships which may potentially result in conflicts of interests.

Dr. O Donnell, who is the Chairman of 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 Accentia, RetinaPharma Technologies, Inc. and Biotechnology Specialty Partners, Inc. We have entered into license agreements with Accentia and RetinaPharma International, Inc. with regard to proposed products incorporating our Bioral® technology. We have entered into a non-exclusive distribution agreement with Biotechnology Specialty Partners, Inc. Each of these business arrangements was approved (with Dr. O Donnell abstaining) by our board of directors and our predecessor s board of directors. In addition, Dr. Mannino is a member of the board of directors of Biovest International, Inc. (OTC BB:BVTI), a subsidiary of Accentia, and Mr. McNulty is employed by Accentia. These relationships and agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and such members of our management.

Risks Related to Our Publicly-Traded Securities

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

Since our initial public offering in June 2002, there has only been a limited public market for our securities and there can be no assurance that an active trading market in our securities will be maintained. In addition, the overall market for securities in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies. In particular, the market prices of securities of biotechnology and pharmaceutical companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our securities, which could cause a decline in the value of your securities. These fluctuations, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

Table of Contents

If we cannot meet the Nasdaq Capital Market s continuing listing requirements and Nasdaq rules, Nasdaq may delist our securities, which could negatively affect our company, the price of our securities and your ability to sell our securities.

In 2004, according to rules of the Nasdaq Capital Market (then known as the Nasdaq SmallCap Market), our shares of common stock were subject to potential delisting from such market because we did not meet certain requirements. Also, on September 15, 2005, the Nasdaq Stock Market informed us of its view that we did not meet continuing listing requirements as a result of the non-independent status of Donald L. Ferguson, a former director of our company. These issues have been resolved and we believe that we are currently in compliance with Nasdaq listing requirements. Although, as of the date of this prospectus, our shares are still listed on the Nasdaq Capital Market, in the future, we may not be able to meet the listing maintenance requirements of the Nasdaq Capital Market and Nasdaq rules, which require, among other things, minimum stockholders equity of $2.5 million or a minimum market capitalization of $35 million and a majority of independent directors on our board of directors. If we are unable to satisfy the Nasdaq criteria for maintaining listing, our securities could again be subject to delisting. Trading, if any, of our securities would thereafter be conducted in the over-the-counter market, in the so-called pink sheets or on the National Association of Securities Dealers, Inc. s electronic bulletin board. As a consequence of any such delisting, our stockholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the prices of our securities.

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

We are authorized to issue 45 million shares of our common stock. As of May 30, 2007, there were 18,805,598 shares of common stock issued and 18,790,107 shares of common stock outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. We will likely, subject to the approval of our stockholders, increase the size of our option plan at our next annual meeting of stockholders. To the extent such options (including options under our larger, amended option plan) or warrants are exercised, the holders of our common stock may experience further dilution.

In addition, as in the case of our February and May 2005 financings with Laurus, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution. Moreover, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5,000,000 shares of authorized preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

Shares eligible for future sale may adversely affect the market for our common stock.

We presently have a significant number of convertible securities outstanding, including: (i) 2,768,698 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.80 per share, and (ii) 7,580,765 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $4.27 per share and (iv) 2,085,000 shares underlying our publicly-traded warrants, which expire on June 24, 2007, currently have an exercise price at $6.11 per share (originally $6.30 per share, but adjusted downward because of issuances of our securities at below the market price on the date of the issuance). If and when these securities are converted or exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

Table of Contents

In addition, from time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, which we refer to herein as the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one year holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a two year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that preserve our current management.

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

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

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

Table of Contents

USE OF PROCEEDS

We will receive $12,739,350 in gross proceeds if all of our Class A Warrants are exercised. If the Kashner Option is exercised, we will receive $1,682,000 in proceeds. Thereafter, assuming all of the Kashner Options are exercised, we will receive no proceeds from Kashner s sale of the common stock underlying the Kashner Options; however, we will receive $1,222,000 in proceeds if all of the warrants underlying the Kashner Options are exercised. We intend to use such proceeds, should we receive any, for general corporate and working capital purposes.

PLAN OF DISTRIBUTION

The shares of common stock offered by this prospectus will be sold by persons exercising our publicly-traded Class A Warrants to purchase such shares of our common stock. The Class A Warrants were initially issued in connection with our initial public offering in June 2002.

Pursuant to the terms of the Class A Warrants, shares of common stock will be distributed to those warrant holders who surrender the certificates representing the Class A Warrants and provide payment of the exercise price through their brokers to our warrant agent, American Stock Transfer & Trust Company.

In connection with our June 2002, we issued the Kashner Unit to Kasher, which granted to Kashner and its assignees the right to purchase up to 200,000 Units at an exercise price of $8.66 per Unit, with each Unit consisting of one share of common stock and one Class A Warrant. The Kashner Option may be exercised in the manner described in the underwriting agreement entered into by us and Kashner in June 2002.

The exercise price of the Class A Warrants (including the Class A Warrants underlying the Kashner Option) is currently $6.11 per share (originally $6.30 per share, but adjusted downward because of issuances of our securities at below the market price on the date of the issuance). The exercise price of the Kashner Option is currently $8.41 per share (originally $8.66 per share, but adjusted downward because of issuances of our securities at below the market price on the date of the issuance).

Our Class A Warrants and the Kashner Option expire on June 24, 2007.

LEGAL MATTERS

The validity of the shares of our common stock being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP of New York, New York. On July 19, 2002, we issued Ellenoff Grossman & Schole LLP 25,000 options to purchase shares of our common stock at $7.00 per share. In 2004, we issued Ellenoff Grossman & Schole LLP 44,510 shares of our common stock as compensation for services rendered. Ellenoff Grossman & Schole LLP is also counsel to our subsidiary, Bioral Nutrient Delivery, LLC. During 2003, Bioral Nutrient Delivery, LLC issued 37,500 Class B Shares of BND to Ellenoff Grossman & Schole LLP. These Class B Shares were issued at the inception of Bioral Nutrient Delivery, LLC at nominal value.

EXPERTS

The financial statements as of and for each of the two years in the period ended December 31, 2006, incorporated in this prospectus by reference from our Annual Report on Form 10-KSB for the year ended December 31, 2006 have been audited by Aidman, Piser & Company, P.A., independent registered public accounting firm, as stated in their report incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Table of Contents

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered by this prospectus. This prospectus is part of that registration statement and does not contain all the information included in the registration statement. For further information with respect to our common stock and us, you should refer to the registration statement, its exhibits and the material incorporated by reference therein. Portions of the exhibits have been omitted as permitted by the rules and regulations of the Securities and Exchange Commission. Statements made in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as an exhibit to the registration statement, and these statements are hereby qualified in their entirety by reference to the contract or document. The registration statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission s Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and may also be obtained from the web site that the Securities and Exchange Commission maintains at http://www.sec.gov. You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission s public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

DISCLOSURE OF COMMISSION POSITION ON

INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our certificate of incorporation provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted under the Delaware General Corporation Law, provided that they acted in good faith and that they reasoned their conduct or action was in, or not opposed to, the best interest of our company. Our Bylaws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the Delaware General Corporation Law. Further, we maintain officer and director liability insurance. However, insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Table of Contents

You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

TABLE OF CONTENTS

Incorporation of Certain Documents By Reference	-ii-
Note on Forward Looking Statements	-iii-
Prospectus Summary	1
Our Company	1
Risk Factors	6
Use of Proceeds	24
Plan of Distribution	24
Legal Matters	24
Experts	24
Where You Can Find More Information	25
Disclosure of Commission Position on Indemnification for Securities Law Violations	25

BioDelivery Sciences International, Inc.

2,485,000

shares of common stock

PROSPECTUS

May 31, 2007