BIODELIVERY SCIENCES INTERNATIONAL INC
Form S-8
June 08, 2007
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**As filed with the Securities and Exchange Commission on June 8, 2007**

**Registration No. 333-_____**

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM S-8

**REGISTRATION STATEMENT UNDER**

**THE SECURITIES ACT OF 1933**

# BioDelivery Sciences International, Inc.

**(Exact name of registrant as specified in charter)**

**Delaware**

**(State or jurisdiction of incorporation or organization)**

**35-2089858**

**(I.R.S. Employer Identification No.)**

**2501 Aerial Center Parkway, Suite 205**

**Morrisville, North Carolina 27560**

**(919) 653-5160**

**(Address, including zip code, and telephone number, including area code,**

**of registrant s principal executive offices)**

**BioDelivery Sciences International, Inc.**

**Amended & Restated 2001 Stock Incentive Plan**

**(Full title of plan)**

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**Mark A. Sirgo, Pharm.D.**

**2501 Aerial Center Parkway, Suite 205**

**Morrisville, North Carolina 27560**

**(919) 653-5160**

**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

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**Copies to:**

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**CALCULATION OF REGISTRATION FEE**

| Title of each class of securities to be registered | Amount to be registered[1] | Proposed maximum offering price per unit[2] | Proposed maximum aggregate offering price | Amount of registration fee |
|---|---|---|---|---|
| common stock, par value $0.001 per share, underlying options | 60,000 shares | $ 1.63 (2)(a) | $ 97,800.00 | $ 3.00 |
| common stock, par value $0.001 per share, underlying options | 220,000 shares | $ 1.70 (2)(a) | $ 374,000.00 | $ 11.48 |
| common stock, par value $0.001 per share, underlying options | 315,085 shares | $ 2.05 (2)(a) | $ 645,924.25 | $ 19.83 |
| common stock, par value $0.001 per share, underlying options | 225,000 shares | $ 2.29 (2)(a) | $ 515,250.00 | $ 15.82 |
| common stock, par value $0.001 per share, underlying options | 30,000 shares | $ 2.32 (2)(a) | $ 69,600.00 | $ 2.14 |
| common stock, par value $0.001 per share, underlying options | 255,738 shares | $ 2.42 (2)(a) | $ 618,885.96 | $ 19.00 |
| common stock, par value $0.001 per share, underlying options | 33,750 shares | $ 2.76 (2)(a) | $ 93,150.00 | $ 2.86 |
| common stock, par value $0.001 per share, underlying options | 33,334 shares | $ 2.69 (2)(a) | $ 89,668.46 | $ 2.75 |
| common stock, par value $0.001 per share, underlying options | 1,560 shares | $ 2.80 (2)(a) | $ 4,368.00 | $ 0.13 |
| common stock, par value $0.001 per share, underlying options | 345,952 shares | $ 2.94 (2)(a) | $ 1,017,098.88 | $ 31.22 |
| common stock, par value $0.001 per share, underlying options | 113,000 shares | $ 3.03 (2)(a) | $ 342,390.00 | $ 10.51 |
| common stock, par value $0.001 per share, underlying options | 17,162 shares | $ 3.06 (2)(a) | $ 52,515.72 | $ 1.61 |
| common stock, par value $0.001 per share, underlying options | 11,792 shares | $ 3.18 (2)(a) | $ 37,498.56 | $ 1.15 |
| common stock, par value $0.001 per share, underlying options | 39,063 shares | $ 3.40 (2)(a) | $ 132,814.20 | $ 4.08 |
| common stock, par value $0.001 per share, underlying options | 10,944 shares | $ 3.74 (2)(a) | $ 40,930.56 | $ 1.26 |
| common stock, par value $0.001 per share, underlying options | 288,981 shares | $ 3.83 (2)(a) | $ 1,106,797.23 | $ 33.98 |
| common stock, par value $0.001 per share, underlying options | 30,000 shares | $ 5.50 (2)(a) | $ 165,000.00 | $ 5.07 |
| common stock, par value $0.001 per share, underlying options | 75,000 shares | $ 6.06 (2)(a) | $ 454,500.00 | $ 13.95 |
| common stock, par value $0.001 per share, underlying options | 634,000 shares | $ 6.63 (2)(a) | $ 4,203,420.00 | $ 129.04 |
| common stock, par value $0.001 per share, underlying options | 8,581 shares | $ 11.80 (2)(a) | $ 101,255.80 | $ 3.11 |
| common stock, par value $0.001 per share, underlying options | 8,581 shares | $ 17.48 (2)(a) | $ 149,995.88 | $ 4.60 |
| common stock, par value $0.001 per share, underlying options | 740,492 shares | $ 5.03 (2)(b) | $ 3,724,674.76 | $ 114.35 |
| Total | 3,500,000 shares | n/a | $ 14,150,266.11 | $ 437.49 |

(1) The aggregate amount of securities registered hereunder is 3,500,000 shares of common stock issuable upon the exercise of options which may be granted pursuant to our Amended and Restated 2001 Stock Incentive Plan. Pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended, this Registration Statement covers such indeterminate additional shares of common stock to be offered or issued to prevent dilution as a result of future stock splits, stock dividends, or other similar transactions.

(2) The offering price has been estimated solely for the purposes of the calculation of the registration fee. The offering price has been calculated in accordance with the manner described in paragraphs (h) and (c) of Rule 457 in the following manner:

(a) to the extent the exercise price of the options for which the underlying shares reoffered by this prospectus is known, the offering price is based upon the applicable exercise price; or

(b) to the extent the exercise price of the options for which the underlying shares reoffered by this prospectus is unknown, the offering price is based upon the average of high and low prices reported by the Nasdaq Capital Market on June 6, 2007, a date within five (5) business days prior to the date of the filing of this registration statement.

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**Explanatory Note**

This registration statement on Form S-8 of BioDelivery Sciences International, Inc. (this Registration Statement ) has been prepared in accordance with the requirements of Form S-8 under the Securities Act of 1933, as amended (the Securities Act ) to register up to 3,500,000 shares of our common stock, par value $0.001 per share (the Common Stock ), to be issued to participants in our Amended and Restated 2001 Stock Incentive Plan.

This Registration Statement includes the registration for reoffer and resale of up to 1,860,128 shares of our Common Stock that may be acquired in the future under this Registration Statement by participants in the Plans who are our affiliates as such term is defined in Rule 405 under the Securities Act of 1933, which shares constitute control securities as such term is defined in General Instruction C to Form S-8.

The materials that follow Part I and precede Part II of this Registration Statement constitute a reoffer prospectus. The reoffer prospectus filed as part of this Registration Statement on Form S-8 has been prepared in accordance with the requirements of Part I of Form S-3 and in accordance with General Instruction C of Form S-8.

**PART I**

**INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS**

**Item 1. Plan Information.***

**Item 2. Registrant Information and Employee Plan Annual Information.***

* Information required by Part I to be contained in the Section 10(a) Prospectus is omitted from the Registration Statement in accordance with Rule 428 under the Securities Act of 1933, as amended.

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**Reoffer Prospectus**

# 3,500,000 Shares

# Common Stock

This prospectus is being used in connection with the offering from time to time by certain selling stockholders of our company or their successors in interest of shares of the common stock issued or to be issued, or which may be acquired upon the exercise of stock options issued or to be issued, pursuant to our Amended and Restated 2001 Stock Incentive Plan, which we refer to herein as the Plan.

The common stock may be sold from time to time by the selling stockholders or by their pledgees, donees, transferees or other successors in interest. Such sales may be made in the over-the-counter market or otherwise at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. The common stock may be sold by one or more of the following: (a) block trades in which the broker or dealer so engaged will attempt to sell the shares as agent but may position and resell portions of the block as principal to facilitate the transaction; (b) purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus; (c) an exchange distribution in accordance with the rules of such exchange; and (d) ordinary brokerage transactions and transactions in which the broker solicits purchases. In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers will receive commissions or discounts from selling stockholders in amounts to be negotiated immediately prior to the sale. Such brokers or dealers and any other participating brokers or dealers may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, or the Act, in connection with such sales. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus. We will not receive any of the proceeds from the sale of these shares, although we have paid the expenses of preparing this prospectus and the related registration statement.

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 $5.2801 per share and the closing sales price for our warrants was $0.2898 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 7 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 June 8, 2007.**

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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.

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## 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

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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.

## 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; 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-8 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.

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## 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,

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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

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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.

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.

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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

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future revenues, the failure to ultimately achieve FDA approval of Emezine® 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.

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**The Offering**

| | |
|---|---|
| Outstanding Common Stock | 18,805,598 shares of our common stock issued and 18,790,107 shares issued and outstanding as of May 30, 2007 |
| Common Stock Offered | Up to 3,500,000 shares. |
| Proceeds | We will not receive any proceeds from the sale of our common stock by the selling shareholders. We would, however, receive proceeds upon the exercise of the stock options by those who receive options under the Plan and exercise such options for cash. Any cash proceeds will be used by us for general corporate purposes. |
| Risk Factors | The securities offered hereby involve a high degree of risk. See Risk Factors. |
| Nasdaq Capital Market/Boston Stock Exchange Symbols, Respectively | BDSI, BDSIW |

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## 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. 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 first 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

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connection with our August 2006 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;