BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B5
April 20, 2010
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PROSPECTUS SUPPLEMENT
(to prospectus dated February 6, 2009)

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-156839

2,824,858 Shares of Common Stock

Warrants to Purchase 1,412,429 Shares of Common Stock

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering an aggregate of 2,824,858 shares of our common stock directly to institutional investors pursuant to a Securities Purchase Agreement, dated April 20, 2010, at a price per share of $3.54. The purchasers in this offering will also receive warrants to purchase an aggregate of 1,412,429 shares of common stock with an exercise price of $4.67 per share. The warrants are exercisable immediately as of the date of issuance and expire five years from the date of issuance. There will be no trading market for the warrants.

Shares of our common stock are currently traded on the Nasdaq Capital Market under the symbol BDSI. On April 19, 2010, the closing sale price of our common stock was $4.21 per share.

As of the date of this prospectus supplement, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $67,626,089 based on 21,198,096 shares of outstanding common stock, of which 16,063,204 are held by non-affiliates, and a per share price of $4.21 which was based on the closing sale price of our common stock on April 19, 2010. We have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus supplement.

The net proceeds to us from this offering will be approximately $9.86 million. We have agreed to reimburse the purchasers for certain of their expenses in the amount of $25,000. We expect to deliver the shares and warrants to the purchasers on or about April 23, 2010.

Investing in our securities involves a high degree of risk. You should purchase our securities only if you can afford a complete loss of your investment. See Risk Factors beginning on page S-6 of this prospectus supplement.

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 this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is April 20, 2010

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Prospectus Supplement

Prospectus

You should rely only on the information contained in this prospectus supplement and the accompanying prospectus. We have not authorized anyone else to provide you with additional or different information. We are offering to sell, and seeking offers to buy, common stock and warrants only in jurisdictions where offers and sales are permitted. You should not assume that the information in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the common stock or warrants or possession or distribution of this prospectus supplement or the accompanying prospectus in that jurisdiction. Persons who come into possession of this prospectus supplement or the accompanying prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus supplement and the accompanying prospectus applicable to that jurisdiction.

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ABOUT THIS PROSPECTUS SUPPLEMENT

On January 21, 2009, we filed with the SEC a registration statement on Form S-3 (File No. 333-156839) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement was declared effective on February 6, 2009. Under this shelf registration process, we may, from time to time, sell up to $50 million in the aggregate of common stock, preferred stock, warrants, rights to purchase securities and units, of which approximately $40 million will remain available for sale following the offering and as of the date of this prospectus supplement.

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this common stock and warrant offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the prospectus. The second part, the accompanying prospectus, gives more general information, some of which does not apply to this offering. You should read this entire prospectus supplement as well as the accompanying prospectus and the documents incorporated by reference that are described under Where You Can Find More Information in this prospectus supplement and the accompanying prospectus.

If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in this prospectus supplement and the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement. We are not incorporating by reference any information submitted under Item 2.02 or Item 7.01 of any Current Report on Form 8-K into any filing under the Securities Act or the Exchange Act or into this prospectus supplement or the accompanying prospectus.

Any statement contained in a document incorporated by reference, or deemed to be incorporated by reference, into this prospectus supplement or the accompanying prospectus will be deemed to be modified or superseded for purposes of this prospectus supplement or the accompanying prospectus to the extent that a statement contained herein, therein or in any other subsequently filed document which also is incorporated by reference in this prospectus supplement or the accompanying prospectus modifies or supersedes that statement. Any such statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement or the accompanying prospectus.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in this prospectus supplement and the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Unless we have indicated otherwise, or the context otherwise requires, references in this prospectus supplement and the accompanying prospectus to BDSI, the Company, we, us and our or similar terms refer to refer to BioDelivery Sciences International, Inc., a Delaware corporation and its consolidated subsidiaries.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and information appearing elsewhere in this prospectus supplement and in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information that you should consider before investing. After you read this summary, to fully understand this offering and its consequences to you, you should read and consider carefully the more detailed information and financial statements and related notes that we include in and incorporate by reference into this prospectus supplement and the accompanying prospectus, especially the section entitled Risk Factors. If you invest in our common stock, you are assuming a high degree of risk.

Readers of this prospectus supplement are advised that our projected sales figures contained or incorporated by reference herein do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our market research and management s reasonable judgments, but readers are advised that such estimates may prove to be inaccurate.

Overview

We are a specialty pharmaceutical company that is utilizing licensed and owned proprietary drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, significant new formulations of proven therapeutics. Utilizing our drug delivery technologies, we have developed and are continuing to develop pharmaceutical products aimed principally in the areas of pain management and oncology supportive care.

Our patented drug delivery technologies include:

- **the BEMA® technology**, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek); and
- **the Bioral® cochleate drug delivery technology**, designed for the potential oral delivery of a broad base of products otherwise administered intravenously.

Our first FDA approved product, ONSOLIS®, as well as our pipeline of developmental stage products, predominately utilize our BEMA® technology. Our current development strategy focuses primarily on our ability to utilize 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, active therapeutics incorporated into our 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 expeditious, and have less regulatory approval risk, than other approval methods of the U.S. Food and Drug Administration, which we refer to herein as the FDA.

Our Products and Product Candidates

Our FDA approved product and principal product candidates include the following:

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BEMA® Formulated Products

ONSOLIS®

Approved by the FDA in July 2009 and commercially launched in October 2009, ONSOLIS® (fentanyl buccal soluble film) is an approved treatment for the management of breakthrough pain (pain that breaks through the effects of other medications being used to control persistent pain) in patients with cancer, eighteen years of age and older, who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain. ONSOLIS® is a formulation of the narcotic fentanyl delivered through our BEMA® technology.

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda AB (which we refer to herein as Meda), a leading international specialty pharmaceutical company based in Sweden with its U.S. headquarters in Somerset New Jersey. We receive a double digit royalty on the net sales of ONSOLIS® and also have the potential to receive milestone payments based on achieving certain predetermined sales targets. We estimate that ONSOLIS® has the potential to reach $200 million in annual peak sales.

In addition, we believe that ONSOLIS® may also have the potential for a broader indication that would allow for the treatment of chronic pain outside of breakthrough cancer pain. If approved by the FDA, this would extend the commercial opportunity for ONSOLIS® , and we will continue to evaluate this opportunity together with Meda.

BEMA® Buprenorphine (low dose for pain)

This product candidate utilizes the BEMA® technology to deliver the opioid analgesic buprenorphine for the treatment of moderate to severe pain conditions. A low dose formulation of BEMA® Buprenorphine was evaluated in a single dose, Phase 1 study that began in late November 2008. In March 2009, we announced favorable preliminary results from this Phase 1 study and our intention to commence a Phase 2 efficacy study in June 2009. In December 2009, we announced that the primary efficacy endpoint was achieved in this Phase 2 clinical study. We believe that this endpoint, called SPID 8 (summary of the pain intensity difference over 8 hours), is a good indicator of a product candidate s effectiveness in treating chronic pain.

We believe that buprenorphine is an attractive option for development given that it has demonstrated efficacy in the treatment of pain and is a Schedule III opioid, meaning there is a lower potential for abuse and addiction compared to Schedule II drugs such as morphine and oxycodone. We estimate that BEMA® Buprenorphine (low dose) has the potential to exceed $500 million in annual peak sales.

BEMA® Buprenorphine (high dose for opioid dependence)

We are also investigating a higher dose formulation of BEMA® Buprenorphine. Because of its lower propensity for abuse and addiction, BEMA® Buprenorphine (high dose) may also serve as a treatment for opioid dependence by preventing an opioid addicted patients withdrawal symptoms while at the same time maintaining pain control. Currently in the U.S. there are two buprenorphine products approved for this indication, and we believe BEMA® Buprenorphine (high dose) has the potential to offer advantages over these products. We estimate that BEMA® Buprenorphine for the treatment of opioid dependence has the potential to achieve between $200 to $300 million in annual peak sales.

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We anticipate securing a commercial distribution partnership, similar in structure as our agreement with Meda for ONSOLIS®, for one or both indications of BEMA® Buprenorphine as early as the end of 2010 or in 2011.

BEMA® Granisetron

This product candidate utilizes the BEMA® technology to deliver granisetron, an FDA approved antiemetic to prevent the nausea and vomiting often observed following chemotherapy. This product candidate is presently in initial formulation development and we intend to move BEMA® Granisetron into clinical trials in 2010. We believe that BEMA® Granisetron would have the potential for better tolerance than oral formulations in the presence of nausea and vomiting as well as potential for better and more consistent absorption in the presence of nausea and vomiting.

BEMA® Triptan

This product candidate utilizes the BEMA® technology to deliver a triptan, which refers to a class of compounds that FDA has approved for the treatment of migraine headaches. This product candidate is intended to move into formulation development in the second half of 2010. We believe that BEMA® Triptan has the potential for both earlier plasma concentrations and migraine response as well as the potential for better response in presence of nausea and vomiting based on more consistent absorption from the BEMA® technology compared to currently available oral formulations.

Bioral® Products

Bioral® Amphotericin B

Our lead Bioral® formulation is an encochleated version of Amphotericin B, a treatment for fungal infections. If this product gains regulatory approval it could become the first oral amphotericin product available in the world to treat systemic fungal infections. A single dose Phase I study has been performed with Bioral® Amphotericin B. We reported preliminary results in February 2009 where we indicated that plasma concentrations of Amphotericin B were detected in the sample of patients tested suggesting oral absorption from the Bioral® delivery system. On October 6, 2009, we announced our receipt of a $1.3 million grant from the Walter Reed Army Institute of Research to support the clinical study of Bioral® Amphotericin B product candidate in the treatment of Cutaneous Leishmaniasis, a skin infection typically found in third world countries.

Other Potential Bioral® Candidates.

We also believe our Bioral® technology has the potential to be applied to other types of pharmaceutical actives and also to other therapeutics such as small interfering RNA, or siRNA, and although we have not dedicated material corporate resources to these opportunities in recent years, we may seek to out-license these opportunities.

FDA Approval of ONSOLIS®

On July 16, 2009, we announced FDA approval of ONSOLIS®. ONSOLIS® will be marketed in Europe under the name BREAKYL™ if regulatory approvals are obtained. The FDA approval of ONSOLIS®, together with our satisfactory preparation of launch supplies of ONSOLIS®, triggered the payment by Meda to us of approval milestones aggregating $26.8 million and the termination of a security interest in the ONSOLIS® product and related assets which was held by CDC IV, LLC, or CDC, pursuant to a funding arrangement that we previously entered into with CDC in connection with the development of ONSOLIS®. Additionally, the FDA approval triggered a requirement by us to pay an approval milestone of $2.0 million to QLT USA Inc., from which we purchased the BEMA® delivery technology, which payment was made in August 2009.

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ONSOLIS® Commercial Partner

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda, a leading international specialty pharmaceutical company based in Sweden. Meda s U.S. division, located in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets, and sells branded prescription therapeutics. Although Meda was founded in 2001, it draws upon a long history, entering the U.S. market in 2007 through the acquisition of Medpointe Pharmaceuticals (previously known as Carter-Wallace, Inc.). Meda has an experienced, well trained and highly regarded sales force of over 400 representatives with a focus in specialty therapeutic areas including pain and central nervous system conditions. Meda has established a track record of commercializing products with their top two products, Astelin® and the more recently launched Soma® 250 mg. They have proven their ability to launch products and sustain growth in highly competitive pharmaceutical markets, as demonstrated by Astelin®, which has out-performed competitors in the anti-histamine, nasal steroid and rhinitis markets with regard to total prescription growth. We expect Meda to also effectively compete in the transmucosal opioid market. Meda has secured access to additional markets through acquisition of European businesses from Valeant, and a joint venture with Valeant covering Australia, Mexico and Canada.

Corporate Information

We are a Delaware corporation. Our executive offices are located at 801 Corporate Center Drive, suite 210, Raleigh, North Carolina, 27607, telephone number (919) 582-9050. We maintain an internet website at www.bdsi.com. The information on our website or any other website is not incorporated by reference into this prospectus supplement and does not constitute a part of this prospectus supplement.

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The Offering

Common stock offered by us	An aggregate of 2,824,858 shares of common stock
Warrants offered by us	Warrants to purchase an aggregate of 1,412,429 shares of common stock (50% of the shares of common stock offered hereby). This prospectus supplement also relates to the offering of the shares of common stock issuable upon the exercise of the warrants.
	The warrants have an exercise price of $4.67 per share and are exercisable immediately as of the date of issuance and expire five years from the date of issuance. There will be no trading market for the warrants.
Common stock to be outstanding after this offering (excluding common stock underlying the warrants offered hereby)	24,022,954 shares, based on 21,198,096 shares outstanding as of the date of this prospectus supplement.
Use of proceeds	The net proceeds of the sale of common stock and warrants to the purchasers, after expenses payable by us, is expected to be approximately $9.86 million. If and when all of the warrants are exercised, we will receive the proceeds from the exercise of the warrants. The purchasers are under no obligation to exercise the warrants. If the warrants are exercised in full, we will receive approximately $6,596,000.
	We intend to use the net proceeds from this offering for continued clinical development of our product candidate pipeline, including BEMA Buprenorphine, and for general corporate and working capital purposes,
Risk factors	See Risk Factors beginning on page S-6 for a discussion of factors you should consider carefully before deciding to invest in our securities.
NASDAQ Capital Market symbol	BDSI

Unless otherwise indicated, the number of shares of common stock presented in this prospectus supplement excludes the following:

- 3,861,208 shares of our common stock issuable upon exercise of stock options outstanding under our Amended and Restated 2001 Incentive Plan as of that date, at a weighted average exercise price of $3.81 per share and 1,348,389 shares of our common stock available for future grant or issuance pursuant to such plan; and

- 3,886,491 shares of our common stock issuable upon the exercise of warrants outstanding as of that date, at a weighted average exercise price of $3.95 per share.

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RISK FACTORS

Investing in our common stock and warrants involves a high degree of risk. Before purchasing our securities, you should carefully consider the following risk factors as well as all other information contained in this prospectus supplement and the accompanying prospectus and materials incorporated by reference, including our consolidated financial statements and the related notes. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Relating to Our Business

Since we have incurred significant losses since inception and have only generated minimal revenues from products sales. As such, you cannot rely upon our historical operating performance to make an investment decision regarding our company.

From our inception in January 1997 and through December 31, 2008, we have recorded significant losses. Our accumulated deficit at December 31, 2009 is approximately $59.2 million. As of December 31, 2009, we had working capital of only approximately $1.8 million. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates and product concepts, obtain the required regulatory approvals and manufacture, market and sell our proposed products. We may be unable to achieve any or all of these goals.

Although we have generated licensing-related and other revenue to date, we have only recently begun to generate revenue from the commercial sales of an approved product ONSOLIS® and such revenue has been minimal to date due to the fact that ONSOLIS® was only recently launched. Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel. Since 2005, we have also focused on commercialization activities, mostly relating to ONSOLIS®. This relatively 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. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive material revenues from our product candidates or product concepts in the timeframes we project, if at all, and our inability to do so would materially and adversely impact our viability as a company.

As a result of our current lack of financial liquidity, our auditors have expressed substantial doubt regarding our ability to continue as a going concern.

As a result of our current lack of financial liquidity, our auditors report for our 2009 financial statements, which are included as part of this Supplement, contains a statement concerning our ability to continue as a going concern. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a going concern is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include engaging in offerings of securities, negotiating up-front and milestone payments on pipeline products under development and royalties from

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sales of our products (like ONSOLIS®) which secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. However, we may be unable to achieve these goals and therefore may be unable to continue as a going concern.

We will likely need to raise additional capital to continue our operations, and our failure to do so would significantly impair our ability to fund our operations, develop our technologies and product candidates, attract commercial partners, retain key personnel or promote our products.

Our operations have been funded almost entirely by external financing. Such financing has historically come primarily from license and royalty fees, the sale of common and preferred stock and convertible debt to third parties, related party loans and, to a lesser degree, from grants and bank loans. At December 31, 2009, we had cash of approximately $23.9 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 our July 2009 receipt of milestone payments from Meda in connection with the FDA approval of ONSOLIS®, and not taking into account the net proceeds of this offering, that our current working capital will be sufficient to satisfy our contemplated cash requirements through the first quarter of 2011, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements.

Given our cash burn and lack of significant revenues, we will likely need to raise additional capital in the future to fund our anticipated operating expenses and progress our business plans. 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 the raising of capital more difficult or impossible and may also result in a lower price for our shares.

We may have difficulty raising any needed additional capital.

We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of material revenues from sales, as well as the inherent business risks associated with our company and present and future market conditions. Our business currently only generates a small amount of revenue from products sales, and such current sources of revenue will likely not be sufficient to meet our present and future capital requirements. Therefore, at least until we have a second product approved and have a second commercial partnerships in place, given we plan to continue to expend substantial funds in the research, development and non-clinical and clinical testing of our drug delivery technologies and product candidates as well as on other strategic initiatives, we will likely require additional funds to conduct research and development, establish and conduct non-clinical and clinical trials, secure clinical and commercial-scale manufacturing arrangements and provide for marketing and distribution. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs, product launches or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are subject to numerous risks.

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;

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progress with non-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, trademark and other intellectual property 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, insurance and other professional and business related costs.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources, which may have a material effect on our current or future business prospects.

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

The additional financings which we have undertaken and which we will likely in the future require, have and may be obtained through one or more transactions that 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.

The Risk Evaluation and Mitigation Strategy (REMS) that the FDA required for ONSOLIS® may have the effect of slowing sales and marketing efforts, which could impact our revenue from the product.

Because it contains the potent narcotic fentanyl, as part of its approval of ONSOLIS®, the FDA required that we and Meda put in place a detailed REMS. The REMS sets forth detailed procedures that seek to mitigate the risk of ONSOLIS® overdose, abuse, addiction and serious complications due to medication errors. These procedures have and will continue to place administrative burdens on our commercial partner Meda and potential prescribers of ONSOLIS®, which burdens could make it more difficult for Meda to market and sell ONSOLIS®. Meda s compliance with the REMS could lead to lower than expected revenue generation and could make it more difficult for us to achieve our annual peak sales projections for ONSOLIS®, which projections may take longer than expected to achieve or may not be achieved at all. Since our royalty revenue from Meda is dependent on sales by Meda of ONSOLIS®, Meda s inability to generate sales of this product would have a material adverse effect on our results of operations.

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Moreover, as of the date of this prospectus supplement, two products which compete directly with ONSOLIS®, namely Actiq® and Fentora® (each of which are marketed by Cephalon, Inc.), are currently being marketed without the requirement of compliance with a REMS. Instead, these products are currently marketed under a less onerous risk management plan that was in place prior to enactment of the 2007 legislation that granted FDA with REMS authorities. This condition currently puts ONSOLIS® at a material competitive disadvantage with these products, which may impact sales of ONSOLIS®. Additionally, two generic forms of Actiq® have been approved by the FDA. We are not aware that these products have been launched, but upon launch, we are not aware that the marketing of either of these products would be a subject to a REMS until such time that a REMS has been implemented and is in effect for Actiq®. This condition would also put ONSOLIS® at a potential material competitive disadvantage, which could impact Meda s ability to sell ONSOLIS®.

Acceptance of our technologies, product candidates or products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate material revenues.

Our future financial performance will depend, to a large extent, upon the introduction and physician and patient acceptance of our technologies, product candidates and products. Even if approved for marketing by the necessary regulatory authorities, our technologies, product candidates and products may not achieve market acceptance. This is especially true for our one existing approved product, ONSOLIS®.

The degree of market acceptance for our products and product candidates 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 payers 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;
- regulatory programs such as the REMS for ONSOLIS® or market (including competitive) forces that may make it more difficult for us to penetrate a particular market segment; and
- our, or our partners , ability to timely and effectively manufacture and market our products.

Physicians, various other health care providers, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our approved products or product candidates. If we are unable to obtain regulatory approval, or are unable (either on or own or through third parties) to manufacture, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

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

Use of our products and, if approved, our product candidates will require physicians to be informed regarding the intended benefits of our products and product candidates. The time and cost of such an educational process may be substantial. Inability to 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 products or product candidates are created, if at all.

We have been and expect to be significantly dependent on our collaborative agreements for the development of our product candidates, which exposes us to the risk of reliance on the performance of third parties.

In conducting our research and development activities, we currently rely, and expect to continue to rely, on numerous collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements is our U.S. and European commercialization agreements with Meda and our manufacturing development and supply agreement with Aveva Drug Delivery Systems, Inc., or Aveva, and LTS Lohmann Therapie-Systeme AG, or LTS, relating to ONSOLIS® and with LTS relating to BREAKYL (the brand name for ONSOLIS® in Europe) and BEMA® Buprenorphine. The loss of, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials and commercial sales. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation. This is particularly true with regard to our relationship with Meda, who is our worldwide (outside of Taiwan and South Korea) commercialization partner for our one approved product ONSOLIS®.

In addition, under our collaborative agreements with Meda, we are responsible for paying certain costs relating to ONSOLIS®. Our inability to adequately project or control such costs would have a material adverse effect on our potential profits from such agreements.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to likely product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims are likely to be asserted against us at some point. In addition, the use in our clinical trials of pharmaceutical formulations and products 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.

We currently have a general liability/product liability policy, which includes coverage for our clinical trials, with an annual aggregate limit of $2 million with a $2 million limit per occurrence. Under, our agreements, Meda is required to carry comprehensive general product liability and tort liability insurance, each in amounts not less than $2 million per incident and US $10 million annual aggregate and

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to name us as an additional insured thereon. However, we or our commercial partners may be unable to obtain or maintain adequate product liability insurance on acceptable terms, if at all, and there is a risk that our insurance will not provide adequate coverage against our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements 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 assets to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us or our partners could have a material adverse effect on our business, financial condition and results of operations.

Moreover, product liability insurance is costly, and due to the nature of the pharmaceutical products underlying ONSOLIS® and our product candidates, we or our partners may not be able to obtain such insurance, or, if obtained, we or our partners may not be able to maintain such insurance on economically feasible terms. If a product or product candidate related action is brought against us, or liability is found against us prior to our obtaining product liability insurance for any product or product candidate, or should we have liability found against us for any other matter in excess of any insurance coverage we may carry, we could face significant difficulty continuing operations.

We may be sued by third parties who claim that our products, and formulations, methods of manufacture or methods of use infringe on their intellectual property rights.

We may be exposed to future litigation by third parties based on claims that our technologies, processes, formulations, methods, or products 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 pharmaceutical patents is, in most instances, uncertain and highly complex. Any litigation or claims against us, whether or not valid, would result in substantial costs, could place a significant strain on our financial and human resources and could harm our reputation. Such a situation may force us to do one or more of the following:

- incur significant costs in legal expenses for defending against an intellectual property infringement suit;
- cease selling, making, importing, incorporating or using one or more or all 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.

With respect to our BEMA® delivery technology, the mucoadhesive erodible drug delivery device technology space is congested. There is a risk that a court of law in the United States or elsewhere could determine that ONSOLIS® or another of our BEMA® based products is in conflict with or covered by external patents. We have a been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market ONSOLIS® and BEMA® Buprenorphine within the countries of the European Union. We have not conducted freedom to operate searches and analyses for our other proposed products. Moreover, the possibility exists that a patent could issue that would cover one or more of our products, requiring us to defend a patent infringement suit or necessitating a patent validity challenge that would be costly, time consuming and possibly unsuccessful.

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With respect to our Bioral® technology, we are currently aware of United States patent 5,616,334 dealing with lipid formulations of Amphotericin B products. We do not believe that our Bioral® products are covered by or in conflict with this patent, although there is a risk that a court of law in the United States might determine otherwise. Accordingly, we do not believe that we require a license under this patent. If a court were, however, to determine that we were infringing this or other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B. We may be unable 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, there would be a material adverse effect upon our business plan to commercialize these products.

If a lawsuit were to be filed against us for patent infringement, we would incur significant legal costs to defend ourselves. Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our BEMA® and/or Bioral® products (including, without limitation, ONSOLIS®). We may be unable to obtain such licenses from the patent holders.

In addition, certain portions of the development of our cochleate technology were supported by funding from the United States government. This support provides the United States government certain rights in technologies developed solely by government employees. We believe to the extent the United States government would have rights in technologies developed under our agreements we may need to obtain a license, likely royalty bearing, relating to the United States government s rights in the technology. Rights to negotiate a license to any United States government rights are provided for in our agreements.

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, enforce, maintain or protect such rights.

Our ability to license, enforce and maintain 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 and access patented technologies. Without these licenses, the use of technologies would be limited and the sales of our products could be prohibited. Therefore, any disruption in access to the technologies could substantially delay the development and sale of our products.

The patent positions of biotechnology and pharmaceutical companies, including ours, which involve 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 patents, patent applications and licensed rights may not provide protection against competitive technologies or may be held invalid if challenged or could be circumvented. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements provide that 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 assign the ownership of relevant inventions created during the course of employment to us. 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, 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.

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In addition, we may have to resort to costly and time consuming litigation to protect or enforce our rights under certain intellectual property, or to determine their scope, validity or enforceability. Enforcing or defending our rights will be expensive, could cause significant 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.

We are dependent on third party suppliers for key components of our delivery technologies, products and product candidates.

Key components of our drug delivery technologies, products and product candidates 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 the active pharmaceutical component of our products, 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 non-clinical and clinical trials due to an inability to timely obtain a single or limited source component;
- our potential inability to timely obtain an adequate supply of required components; and
- the potential for reduced control over pricing, quality and timely delivery.

Except for our agreements with Aveva and LTS, we do not have long-term agreements with most of our suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. As it is the primary manufacturer of our only approved product, ONSOLIS®, our relationship with Aveva is particularly important to us, and any loss of or material diminution of Aveva s capabilities due to factors such as regulatory issues, accidents, acts of God or any other factor would have a material adverse effect on our company. We do not carry interruption insurance for any such loss. Any loss of or interruption in the supply of components from Aveva or other third party suppliers would require us to seek alternative sources of supply or require us to manufacture these components internally, which we are currently not able to do. If the supply of any components is lost or interrupted, product or components from alternative suppliers may not be available in sufficient quality or in volumes within required time frames, if at all, to meet our or our partners needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing; or cause us to lose sales, force us into breach of other agreements, incur additional costs, delay new product introductions or harm our reputation. Furthermore, product or components from a new supplier may not be identical to those provided by the original supplier. Such differences could have material effects on our overall business plan and timing, could fall outside of regulatory requirements, affect product formulations or the safety and effectiveness of our products that are being developed.

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We have limited manufacturing experience and therefore depend on third parties to formulate and manufacture our products. We may not be able to secure or maintain the manufacture of sufficient quantities or at an acceptable cost necessary to successfully commercialize or continue to sell our products.

Our management s expertise is primarily in the research and development, formulation development and non-clinical and clinical trial phases of pharmaceutical product development. Our management s experience in the manufacturing of pharmaceutical products is more limited and we have limited equipment and no facilities of our own from which these activities could be performed. Therefore, we are dependent on third parties for our formulation development, manufacturing and the packaging of our products. This is particularly true with respect to Aveva, the primary manufacturer of our only approved product, ONSOLIS®. This reliance exposes us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to formulate sufficient product to conduct clinical trials and, subsequently, to launch and maintain the marketing of our products. Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to commercialize our products.

There are risks associated with our reliance on third parties for marketing, sales, managed care and distribution infrastructure and channels.

We expect that we will be required to enter into agreements with commercial partners (such as our agreements with Meda) to engage in sales, marketing and distribution efforts around our products and product candidates. 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. If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, we will need to develop our own sales and marketing capabilities.

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.

We will be subject to risks if we seek to develop our own sales force.

If we choose at some point to develop our own sales and marketing capability, including in connection with any exercise by us of our co-promotion rights with respect to ONSOLIS® under our agreements with Meda, we may be impeded in these efforts given that our experience in developing a fully integrated commercial organization is limited. If we choose to establish a fully integrated commercial organization, we will likely incur substantial 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.

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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 or foreign regulatory clearance to market our proposed formulations and products, we will have to demonstrate that our formulations and products are safe and effective in 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, although we received FDA approval for one product, ONSOLIS®, we may not receive regulatory approval of our other proposed products and formulations. We may be unable to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and viability.

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:

a demonstration of the benefit from delivery of each specific drug through our drug delivery technologies;

a demonstration, through non-clinical and clinical trials, that our drug delivery technologies are safe and effective; and

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

The estimated required capital and time-frames necessary to achieve these developmental milestones is subject to inherent risks, many of which may be beyond our control. As such, we may not be able to achieve these or similar milestones for any of our proposed product candidates or other product candidates in the future. Our failure to meet these or other critical milestones would adversely affect the viability of our company.

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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 did 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 permanently 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 or use without FDA approval.

Moreover, it is our stated intention to seek to avail ourselves of the FDA s 505(b)(2) approval procedure where it is appropriate to do so. 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 commercializing 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 non-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later non-clinical studies and clinical trials. Moreover, non-clinical and clinical data is susceptible to multiple and 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 product candidate, resulting in delays to commercialization, and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

We depend on technology owned or 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 QLT, with respect to our BEMA® technology, and the University of Medicine and Dentistry of New Jersey with respect to our Bioral® technology. Although we have purchased the BEMA® technology from QLT, we may be unable to fulfill our obligations under such agreement. The loss of our key technologies would seriously impair our business and future viability, and 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 license 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.

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Competitors in the drug development or specialty pharmaceutical industries may develop competing technologies or products which outperform or supplant our technologies or products.

Drug companies and/or other technology companies have sought and may seek to develop and market mucosal adhesive, encapsulation or other drug delivery technologies and related pharmaceutical products which may compete with our technologies and products. Competitors may develop similar or different technologies or products which may become more accepted by the marketplace or which may supplant our technology entirely. In addition, these competitors may be larger and better financed than we are, thus giving them a significant advantage over us.

Should competing or dominating technologies or products come into existence and the owners thereof patent the applicable technological advances, we could also be required to license such technologies in order to continue to manufacture, market and sell our products. We may be unable to secure such licenses on commercially acceptable terms, or at all, and our resulting inability to manufacture, market and sell the affected products could have a material adverse effect on us.

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

Our FDA approved product, ONSOLIS®, and our lead product candidate, BEMA® Buprenorphine, contain tightly controlled and highly regulated 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, transportation 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. This is particularly true with respect to the REMS that FDA required for ONSOLIS®. 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. Any such current or new regulations may be difficult and expensive for us and our manufacturing and commercial partners 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 ONSOLIS® and certain of our product candidates 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 marketed product ONSOLIS® and in our lead product candidate BEMA® Buprenorphine (fentanyl and buprenorphine, respectively) are listed by the DEA as Schedule II and III substances, respectively, 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.

The DEA limits the availability of the active ingredients used in ONSOLIS®, BEMA® Buprenorphine and potentially other of our product candidates 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

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not establish procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides for public comment on the labeling, promotion, risk management plan and other documents associated with such product. A DEA review of such materials may result in potentially significant 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, product launches or sales of products, which could have a material adverse effect on our business and results of operations.

Risks Related to Our Industry

The market for our products and product candidates 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, our approved products and our product candidates 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 now existing or diversifying into the field is intense and is expected to increase. Many of these entities (including our competitors with respect to our one approved product, ONSOLIS®) have significantly greater research and development capabilities, human resources 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.

With respect to our drug delivery technologies, we may experience technical or intellectual property related 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 technologies. 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.

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

The continuing efforts of government and insurance companies, health maintenance organizations and other payers 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

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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 and related laws, rules and regulations (including the major Health Care and Education Reconciliation Act which was signed into law in March 2010) could materially harm our business, financial condition results of operations or stock price.

The ability of Meda to sell ONSOLIS® and our ability to commercialize our product candidates 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. Consumers and third-party payers 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 product 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. All of our clinical trials have been, and all of our proposed clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have a general liability/product liability policy that includes coverage for our clinical trials, with an annual aggregate limit of $2 million with a $2 million limit per occurrence. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our 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. 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 products and product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products. In addition, although third party partners like Meda are required to provide insurance in connection with specific products like ONSOLIS®, such partners may face similar insurance related risks.

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 or our partners research and development activities and the manufacture of materials and products, we and our partners 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. We and our partners may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development now and in the future may involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. 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.

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Risks Related to Our Management and Affiliate Transactions

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 ability to achieve our corporate objectives will depend to a significant degree upon the continued services of key management, technical and scientific personnel. 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 product development or approval, loss of sales and diversion of management resources. In addition, we 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 executives or any of our employees. 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 supplement, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 31% of our outstanding common stock. These figures do not reflect any future potential exercise of common stock purchase warrants (including those issued to Laurus Master Fund, Ltd., CDC and others) into shares of common stock.

The interests of our current officers, directors and affiliated stockholders may differ from the interests of other stockholders. As a result, these current officers, directors and affiliated stockholders could 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. Frank O Donnell, who is the Chairman of our board of directors and also is a substantial beneficial owner of our securities through Hopkins Capital Group II, LLC, has a financial interest in a number of other companies which have business relationships with us. These companies include Accentia

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Biopharmaceuticals (which we refer to 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. In addition, William Poole, a director of our company, is also a director of Accentia, and James A. McNulty, our Chief Financial Officer, is employed on a part-time basis 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. The risks associated with potential conflicts of interests were evidenced recently in a settlement, announced in late December 2009, of a potential dispute between us and Accentia relating to the development of Emezine.

Our business arrangement with Accentia may be impaired as a result of Accentia s bankruptcy filing.

We have commercial ties to Accentia, a related party, through our license agreement with them and the sharing of certain corporate resources. On November 10, 2008, Accentia and its subsidiaries, including Biovest International, Inc. filed voluntary petitions to reorganize under Chapter 11 of the United States Bankruptcy Code. As such, there is a risk that projects on which we are working with Accentia may not progress in the future and that we may not receive royalty payments which we are due from Accentia. In addition, certain payments due by us to Accentia under our December 2009 settlement of a potential dispute between us and Accentia relating to the development of Emezine will be triggered upon Accentia s exit from bankruptcy, including payments on the sale or licensing of our BEMA® Granisetron product candidate.

Risks Related to Our Common Stock and this Offering

Investors in this offering will experience immediate dilution in the book value per share of the common stock they purchase in this offering.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. After giving effect to the sale by us of 2,824,858 shares of common stock in this offering, and based on a public offering price of $3.54 per share in this offering and a pro forma net tangible book value per share of our common stock of $0.61 as of December 31, 2009, if you purchase shares in this offering, you will suffer immediate and substantial dilution of $2.93 per share in the net tangible book value of the common stock purchased. See Dilution for a more detailed discussion of the dilution you will incur in connection with this offering.

There is and will be no public market for the warrants to purchase common stock in this offering.

There is no established public trading market for the warrants being sold in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any securities exchange. Without an active market, the liquidity of the warrants will be limited.

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

Under our May 2006 Securities Purchase Agreement with CDC, as amended, until such time as our public share price reaches $9 for certain time periods, 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

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with CDC the terms of a financing for 30 days which must match the terms of the financing we present to them. If no terms are agreed to, we may pursue a financing with a third party for 60 days, but only on terms and conditions no less favorable to us than the terms and conditions presented to CDC. CDC has exercised similar rights to our detriment in the past, and it is possible that CDC will seek to exercise this right again in the future. The existence or alleged existence of CDC s right of first refusal, 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.

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 relatively limited public market for our securities and there is a risk that an active trading market in our securities may not be adequately 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.

We will have broad discretion in applying the net proceeds of this offering and may not use these proceeds in ways that will enhance the market value of our common stock or warrants.

We have broad discretion in applying the net proceeds we will receive in this offering. Such proceeds may be used to fund product development, corporate growth and for other general corporate purposes. For more information, see Use of Proceeds. As part of your investment decision, you will not be able to assess or direct how we apply these net proceeds.

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.

As of the date of this prospectus, our shares are listed on the NASDAQ Capital Market. In the future, however, 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. We have been subject to delisting proceedings and comments by NASDAQ in the past. 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 OTC 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 the date of this prospectus supplement, there are 21,213,587 shares of common stock issued and 21,198,096 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 outstanding options or warrants. To the extent such options (including options under our stock incentive plan) or warrants are exercised, the holders of our common stock may experience further dilution.

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In addition, 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 million authorized but undesignated shares of 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 have a material number of shares of common stock underlying securities of our company, the future sale of which could depress the price of our publicly-traded stock. As of the date of this prospectus supplement, (i) 3,958,156 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.81 per share, and (ii) 3,886,491 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.95 per share. If and when these securities are 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.

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, after satisfying a six month holding period: (i) affiliated stockholder (or stockholders whose shares are aggregated) 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 and (ii) non-affiliated stockholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one year holding period without any limitation or restriction. 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 and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing a staggered board of directors, which impairs the ability of our stockholders to remove our directors at annual or special meetings of stockholders;
- 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.

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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.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially greater or less than those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

We do not intend to pay dividends on our common stock.

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

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

The additional financings which we have undertaken and which we will in the future require, have and may 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.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus and the documents we have filed with the SEC that are incorporated by reference into this prospectus supplement and the accompanying prospectus contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, that involve risks and uncertainties. Any statements contained, or incorporated by reference, in this prospectus supplement and the accompanying prospectus that are not statements of historical fact may be forward-looking statements. When we use the words anticipate, believe, could, estimate, expect, intend, may, plan, predict, pro other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements.

A variety of factors, some of which are outside our control, may cause our operating results to fluctuate significantly. They include:

- our plans regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the BEMA and Bioral technology platforms and any proposed product candidates, including our sole approved product, ONSOLIS®;
- 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 BEMA and Bioral technology platforms and our proposed formulations and products;
- 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 patents and any interest in licensed patents, or our ability to enforce our rights under such patents or 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 commercial partners to market and sell the products we license to them, including Meda with respect to ONSOLIS®;
- our ability to retain members of our management team and our employees; and
- competition existing today or that will likely arise in the future.

The foregoing does not represent an exhaustive list of risks that may impact upon the forward-looking statements used herein or in the documents incorporated by reference herein. Please see Risk Factors for additional risks which could adversely impact our business and financial performance and related forward-looking statements.

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Moreover, new risks regularly emerge 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 supplement and the accompanying prospectus are based on information available to us on the date hereof. 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 supplement, the accompanying prospectus and the documents we have filed with the SEC.

USE OF PROCEEDS

We expect to receive net proceeds of approximately $9.86 million from the sale of 2,824,858 shares of common stock and warrants in this offering. If and when all of the shares underlying the warrants are exercised, we will receive the proceeds from the exercise of the warrants. The purchasers in this offering are under no obligation to exercise the warrants. If the warrants are exercised in full, we will receive up to approximately $6,596,000.

We intend to use the net proceeds from this offering and any warrant exercise for continued clinical development of our product candidate pipeline, including BEMA Buprenorphine, and for general corporate and working capital purposes. We have not determined with specificity the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering for any purpose. Pending application of the net proceeds as described above, we may initially invest the net proceeds in short-term, investment-grade securities.

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DILUTION

Our net tangible book value on December 31, 2009 was approximately $4,614,000, or approximately $0.22 per share of common stock. Net tangible book value is total assets minus the sum of liabilities and intangible assets. Net tangible book value per share is net tangible book value divided by the total number of shares of common stock outstanding.

After giving effect to the sale of 2,824,858 shares of common stock offered by us in this offering at a price of $3.54 per share, less estimated expenses of this offering payable by us, our adjusted net tangible book value on December 31, 2009 would have been approximately $14,474,000, or $0.61 per share of common stock. This represents an immediate increase in net tangible book value of $0.39 per share to our existing stockholders and an immediate dilution of $2.93 per share to anyone who purchases our common stock in the offering. The following table illustrates this calculation on a per share basis, assuming that we sell all of the shares we are offering:

Offering price per share		$ 3.54
Net tangible book value per share as of December 31, 2009	$ 0.22	
Increase per share attributable to the offering	$ 0.39	
Adjusted net tangible book value per share as of December 31, 2009 after giving effect to the offering		$ 0.61
Dilution per share to new investors		$ 2.93

The foregoing table is based on 21,166,363 shares of common stock outstanding at December 31, 2009, which does not take into effect further dilution to new investors that could occur upon the exercise of outstanding options and warrants having a per share exercise price less than the public offering price.

In addition, the calculations in the foregoing table do not take into account, as of December 31, 2009:

- 3,873,945 shares of our common stock issuable upon exercise of stock options outstanding under our Amended and Restated 2001 Incentive Plan as of that date, at a weighted average exercise price of $3.80 per share and 1,367,385 shares of our common stock available for future grant or issuance pursuant to such plan; and

- 3,886,491 shares of our common stock issuable upon the exercise of warrants outstanding as of that date, at a weighted average exercise price of $3.95 per share.

To the extent that any of our outstanding options or warrants are exercised, we grant additional options under our stock option plans or issue additional warrants, or we issue additional shares of common stock in the future, there may be further dilution.

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PRICE RANGE OF COMMON STOCK

Our common stock is quoted on the NASDAQ Capital Market under the symbol BDSI. The table below sets forth, for the calendar quarters indicated, the high and low bid prices for the securities as reported on the NASDAQ Capital Market.

Fiscal Year 2010, Quarter Ended:	**High**	**Low**
March 31, 2010	$ 4.31	$ 3.34
Fiscal Year 2009, Quarter Ended:	**High**	**Low**
March 31, 2009	$ 3.86	$ 2.42
June 30, 2009	$ 8.29	$ 3.29
September 30, 2009	$ 7.25	$ 4.23
December 31, 2009	$ 5.25	$ 3.82
Fiscal Year 2008, Quarter Ended:	**High**	**Low**
March 31, 2008	$ 3.10	$ 2.21
June 30, 2008	$ 3.12	$ 1.57
September 30, 2008	$ 4.74	$ 1.93
December 31, 2008	$ 2.90	$ 2.08

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We intend to retain any future earnings to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. Any dividends paid will be solely at the discretion of our Board of Directors.

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DESCRIPTION OF OUR SECURITIES WE ARE OFFERING

Common Stock

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

The securities purchase agreement entered into on April 20, 2010 with the purchasers in this offering contains certain covenants that we are required to comply with and certain consent rights of the purchasers, including:

- we will be precluded from engaging in securities offerings for a period of 60 days from the closing of the offering, subject to certain exceptions;
- we have granted the purchasers in the offering a 12 month right, subject to certain exceptions, to participate in our future financings up to an amount equal to 35% of such financings;
- we will be precluded, for a period of 12 months from the closing of the offering, to engage in any variable rate financing transactions;
- we are required to maintain our status as a publicly listed and reporting company, subject to certain exceptions;
- we are required to provide certain financial information to the purchasers in the event we are not a publicly reporting company in order to facilitate the use by the purchasers of SEC Rule 144 to dispose of their securities; and
- the following actions will require the consent of the holders of two-thirds of the shares underlying the warrants: (i) our engaging in any reverse stock split; (ii) amending the securities purchase agreement; and (iii) our assignment of our rights and obligations under the securities purchase agreement, subject to certain exceptions.

Warrants

The material terms and provisions of the warrants being offered pursuant to this prospectus supplement and the accompanying prospectus are summarized below. This summary is subject to, and qualified in its entirety by, the terms of the warrants as set forth in the form of warrant to be filed as an exhibit to our periodic report on Form 8-K, which we will file with the SEC in connection with the completion of this offering.

The warrants to which this prospectus supplement relates represent the right to purchase an aggregate of 1,412,429 shares of our common stock initially at an exercise price of $4.67 per share, subject to adjustment upon the occurrence of certain dilutive events. Each warrant may be exercised at any time from the date of issuance and expire five years from the date of issuance. The warrants may be exercised by means of cashless exercise in the event the registration statement of which this prospectus forms a part is no longer effective.

There is no established public trading market for the warrants, and we do not expect a market to develop. We do not intend to apply to list the warrants on any securities exchange. Without an active market, the liquidity of the warrants will be limited. In addition, in the event our common stock price does not exceed the per share exercise price of the warrants during the period when the warrants are exercisable, the warrants will not have any value.

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A warrant may be transferred by a holder in accordance with applicable securities laws. In order to validly exercise a warrant, a holder thereof other than the original holder must, concurrently with or prior to the delivery of an exercise notice, provide us with definitive documentation conclusively evidencing, in our reasonable discretion, that the person seeking to exercise the warrant is the actual owner of the warrant possessing the right to cause the exercise thereof.

The warrants are subject to customary pro rata anti-dilution provisions for stock splits or recapitalizations as well as full ratchet price-based anti-dilution protection. In addition, in the event of certain fundamental transactions, including, without limitation, any merger, consolidation, sale or other reorganization event in which our common stock is converted into or exchanged for securities, cash or other property or a sale of substantially all of our assets, then following that event, the holders of the warrants may be entitled to cause the repurchase of the warrant by us for cash at the Black-Scholes value of the warrant. Also, on our distribution, pro rata to our common stockholders, of assets or rights to purchase additional securities, the holders of warrants shall be entitled to participate in such distributions as if the warrants had been exercised (without regard to any limitations on exercise set forth therein).

The holders of the warrants will not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would, subject to limited exceptions, beneficially own in excess of 4.99% of the number of our common stock outstanding immediately after the exercise. The holder may elect to change this beneficial ownership limitation from 4.99% to up to 9.99% of the number of our common stock outstanding immediately after the exercise upon not less than 61 days prior written notice to us.

Upon receipt of payment and the form of exercise properly completed and duly executed, we will, on or before the third trading day follow our receipt of a warrant exercise notice, issue the shares purchasable upon exercise of the warrant.

Before the exercise of their warrants, except as provided for in the warrant, holders of warrants will not have any of the rights of stockholders, and will not be entitled to, among other things, vote or receive dividend payments or similar distributions on the shares purchasable upon exercise.

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PLAN OF DISTRIBUTION

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering an aggregate of 2,824,858 shares of our common stock directly to institutional investors pursuant to a Securities Purchase Agreement, dated April 20, 2010, at a price per share of $3.54. The purchasers in this offering will also receive warrants to purchase an aggregate of 1,412,429 shares of common stock with an exercise price of $4.67 per share. The price of the shares and the exercise price of the warrants issued in this offering were calculated with reference to the recent volume weighted average closing price of our publicly traded common stock.

No underwriter or placement agent has been involved in the preparation of, or has performed any review of, this prospectus supplement or the accompanying prospectus.

The offering price of the common stock, and the exercise price of the warrants, offered hereby was determined by reference to the recent trading price of our common stock on the Nasdaq Capital Market.

The expenses of this offering are estimated to be approximately $140,000 and are payable by us.

We have applied to list the common stock (and common stock underlying the warrants) sold in this offering on the Nasdaq Capital Market. Closing of this offering is subject to us obtaining Nasdaq approval for the listing of such common stock.

We currently anticipate that the closing of the sale of the shares and warrants offered hereby will take place on or before April 23, 2010. Such closing is subject to conditions which are provided for in the Securities Purchase Agreement.

LEGAL MATTERS

The validity of the securities offered in this prospectus has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements of the Company as of December 31, 2009 and 2008 and for the two years ended December 31, 2009 and 2008, incorporated in the prospectus by reference from the Company s Annual Report on Form 10-K, dated March 19, 2010, have been audited by Cherry, Bekaert & Holland, L.L.P., an independent registered public accounting firm, as stated in their reports, which are incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC for the securities we are offering by this prospectus supplement. This prospectus supplement does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. We are required to file annual and quarterly reports, special reports, proxy statements, and other information with the SEC. We make these documents publicly available, free of charge, on our website at http://www.bdsinternational.com/SEC.php as soon as reasonably practicable after filing such documents with the SEC. You can read our SEC filings, including the registration statement, on the SEC s website at http://www.sec.gov. You also may read and copy any document we file with the SEC at its public reference facility at Public Reference Room, 100 F Street N.E., Washington, DC 20549. Please call the SEC at 1-800-732-0330 for further information on the operation of the public reference facilities.

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INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We are incorporating by reference certain documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information in the documents incorporated by reference is considered to be part of this prospectus supplement. Statements contained in documents that we file with the SEC and that are incorporated by reference in this prospectus supplement will automatically update and supersede information contained in this prospectus supplement, including information in previously filed documents or reports that have been incorporated by reference in this prospectus supplement, to the extent the new information differs from or is inconsistent with the old information.

We have filed or may file the following documents with the SEC and they are incorporated herein by reference as of their respective dates of filing:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2009, as filed with the SEC on March 19, 2010;
- Our Proxy Statement on Form DEF 14A, as filed with the SEC on June 18, 2009;
- Our Current Report on Form 8-K, as filed with the SEC on March 23, 2010;
- the description of our common stock contained in our Form 8-A filed on June 19, 2002, as amended June 20, 2002, and as it may be further amended from time to time; and
- All documents filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and before the termination or completion of this offering of common stock shall be deemed to be incorporated by reference in this prospectus supplement and to be a part of it from the filing dates of such documents, except in each case for information contained in any such filing where we indicate that such information is being furnished and is not to be considered filed under the Securities Exchange Act of 1934, as amended.

You may request a copy of these filings at no cost (other than exhibits unless such exhibits are specifically incorporated by reference) by writing or telephoning us at the following address and telephone number:

BioDelivery Sciences International, Inc.

324 South Hyde Park Avenue, Suite 350

Tampa FL 33606

Telephone: (813) 864-2562

Attention: James A. McNulty

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Prospectus

$50,000,000

Common Stock **Preferred Stock**
Debt Securities **Warrants**
Rights **Units**

BioDelivery Sciences International, Inc. may offer and sell from time to time, in one or more series, any one of the following securities of our company:

- common stock;
- preferred stock;
- secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities;
- warrants to purchase our securities
- rights to purchase any of the foregoing securities; or
- units comprised of, or other combinations of, the foregoing securities.

Each time our securities are offered, we will provide a prospectus supplement containing more specific information about the particular offering and attach it to this prospectus. The prospectus supplements may also add, update or change information contained in this prospectus. **This prospectus may not be used to offer or sell securities without a prospectus supplement which includes a description of the method and terms of this offering.**

Our common stock is traded on the Nasdaq Capital Market under the symbol BDSI. As of January 19, 2009, the aggregate market value of our outstanding common stock held by non-affiliates is approximately $35,619,962, based on 19,163,538 shares of outstanding common stock, of which approximately 11,343,937 shares are held by non-affiliates, and a per share price of $3.14 based on the closing sale price of our common stock on January 16, 2009. As of the date hereof we have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on and includes the date hereof.

Investing in our securities involves a high degree of risk. See the section entitled Risk Factors in the accompanying prospectus supplement and in the documents we incorporate by reference in this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 6, 2009.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission utilizing a shelf registration process. Under this shelf registration statement, we may, from time to time, sell any combination of the securities referred to herein in one or more offerings for total gross proceeds of up to $50,000,000. This prospectus provides you with a general description of the securities we may offer.

If required, each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of the securities being offered. The prospectus supplement may add, update or change information contained in this prospectus and may include a discussion of any risk factors or other special considerations that apply to the offered securities. If there is any inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in that prospectus supplement. Before making an investment decision, it is important for you to read and consider the information contained in this prospectus and any prospectus supplement, together with the additional information described under the heading Where You Can Find More Information.

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 or incorporated by reference in this prospectus or in any prospectus supplement 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, project and other expressions which are predictions of or indicate future event 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 BEMA and Bioral technology platforms and any proposed formulations or products relating thereto (including, without limitation, ONSOLIS, formerly known as BEMA Fentanyl);
- 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 other similar international regulatory agencies, and the timing, status and results of pre-clinical work and clinical studies;
- our ability to manufacture and generate commercial viability and acceptance of our BEMA and Bioral technology platforms and our proposed formulations and products;
- 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 patents, or our interest in licensed patents, or our ability to enforce our rights under such patents or licenses;
- our ability to enter into and/or perform under strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and formulations;
- the ability of our sublicensed 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.

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The foregoing does not represent an exhaustive list of risks. Please see Risk Factors in any accompanying prospectus supplement or in our Annual Reports on Form 10-K 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 or the date of any prospectus supplement. 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 or in any prospectus supplement.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained or incorporated by reference 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 and any supplement hereto 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 pharmaceutical company that is utilizing licensed and owned 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 drug delivery technologies include:

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

Utilizing our patented and 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 candidate is ONSOLIS (formerly known as 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) in opioid tolerant patients. In December 2008, we resubmitted our New Drug Application, or NDA, for ONSOLIS to the U.S. Food and Drug Administration, or FDA, following our receipt of a complete response letter from FDA in August 2008. The only NDA deficiency that FDA noted in their complete response letter was the need for a Risk Evaluation and Mitigation Strategy (REMS) which the agency had not required prior to the submission of our ONSOLIS NDA in October 2007. We anticipate that final FDA approval of ONSOLIS will occur in the second quarter of 2009. We have granted commercialization and distribution rights for ONSOLIS on a worldwide basis (except in South Korea and Taiwan) to Meda AB, a leading international specialty pharmaceutical company based in Sweden.

Our follow on product to ONSOLIS is BEMA Buprenorphine, a treatment for moderate to severe pain conditions which is currently in Phase I trials.

Our lead Bioral formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for treating systemic fungal infections. This product is also currently in Phase I human testing. We also believe this drug delivery technology has the potential to be applied to other types of pharmaceuticals and also to other therapeutics such as small interfering RNA, or siRNA.

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Some of our products, such as ONSOLIS and BEMA Buprenorphine, may also have broader indications that would allow for chronic use. When such products present a viable commercial opportunity, we will also consider developing the product for chronic uses.

We currently generate revenue from licensing milestone payments and royalties, and have generated revenue from grants. Ultimately, if we secure approval from the FDA and other regulatory bodies throughout the world 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.

Our development strategy focuses on, but is not limited to, the utilization of the FDA 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 FDA.

Our principal executive offices are located at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina 27607. Our telephone number is (919) 582-9050.

The Securities We May Offer

We may offer and sell from time to time up to an aggregate of $50,000,000 of any of, or combinations of, the following securities:

Common Stock

We may issue shares of our common stock. Holders of common stock are entitled to receive ratably dividends if, as and when dividends are declared from time to time by our board of directors out of funds legally available for that purpose, after payment of dividends required to be paid on outstanding preferred stock or series common stock. Holders of common stock are entitled to one vote per share. Holders of common stock have no cumulative voting rights in the election of directors.

Preferred Stock

We may issue shares of our preferred stock in one or more series. Our board of directors will determine the dividend, voting, conversion and other rights of the series of preferred stock being offered.

Debt Securities

We may offer debt securities, which may be secured or unsecured, senior, senior subordinated or subordinated, may be guaranteed by our subsidiaries, and may be convertible into shares of our common stock. We may issue debt securities either separately, or together with, upon conversion of or in exchange for other securities. It is likely that the debt securities that we may issue will not be issued under an indenture.

Warrants

We may issue warrants for the purchase of preferred stock or common stock or debt securities of our company. We may issue warrants independently or together with other securities. Warrants sold with other securities as a unit may be attached to or separate from the other securities. To the extent the warrants are publicly-traded, we will issue warrants under one or more warrant agreements between us and a warrant agent that we will name in the applicable prospectus supplement.

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Rights

We may issue rights to purchase of preferred stock or common stock or debt securities of our company. We may issue rights independently or together with other securities. Rights sold with other securities as a unit may be attached to or separate from the other securities and may be (but shall not be required to be) publicly-listed securities.

Units

We may also issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security.

Prospectus Supplement

We will describe the terms of any such offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. Such prospectus supplement will contain the following information about the offered securities:

- title and amount;
- offering price, underwriting discounts and commissions or agency fees, and our net proceeds;
- any market listing and trading symbol;
- names of lead or managing underwriters or agents and description of underwriting or agency arrangements; and
- the specific terms of the offered securities.

This prospectus may not be used to offer or sell securities without a prospectus supplement which includes a description of the method and terms of this offering.

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RISK FACTORS

Investing in our securities involves a high degree of risk. The prospectus supplement relating to a particular offering will contain a discussion of risks applicable to an investment in the securities offered. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading Risk Factors in the applicable prospectus supplement together with all of the other information contained in the prospectus supplement or appearing or incorporated by reference in this prospectus.

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from these sales for general corporate purposes including the advancement of our product candidates, and to meet working capital needs. The amounts and timing of the expenditures will depend on numerous factors, such as the timing and progress of our clinical trials and research and development efforts, technological advances and the competitive environment for our drug candidates.

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DESCRIPTION OF SECURITIES AND SECURITIES WE MAY OFFER

General

The following description of our capital stock (which includes a description of securities we may offer pursuant to the registration statement of which this prospectus, as the same may be supplemented, forms a part) does not purport to be complete and is subject to and qualified in its entirety by our certificate of incorporation and bylaws and by the applicable provisions of Delaware law.

Our authorized capital stock consists of 45,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of the date of this prospectus, our outstanding capital stock consists of 19,163,538 shares of common stock, $0.001 par value, and no shares of preferred stock. These figures do not include securities to be issued: (i) pursuant to other unregistered warrants issued since our initial public offering or (ii) pursuant to our Amended and Restated 2001 Incentive Stock Option Plan.

We, directly or through agents, dealers or underwriters designated from time to time, may offer, issue and sell, together or separately, up to $50,000,000 in the aggregate of:

- common stock;
- preferred stock;
- secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities;
- warrants to purchase our securities;
- rights to purchase our securities; or
- units comprised of, or other combinations of, the foregoing securities.

We may issue the debt securities as exchangeable for or convertible into shares of common stock, preferred stock or other securities. The preferred stock may also be exchangeable for and/or convertible into shares of common stock, another series of preferred stock or other securities. The debt securities, the preferred stock, the common stock, the rights and the warrants are collectively referred to in this prospectus as the securities. When a particular series of securities is offered, a supplement to this prospectus will be delivered with this prospectus, which will set forth the terms of the offering and sale of the offered securities.

Common Stock

As of January 19, 2009, there were 19,179,029 shares of common stock issued and 19,163,538 shares of common stock outstanding, held of record by approximately 169 stockholders. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Subject to preferential rights with respect to any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefore. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and satisfaction of preferential rights of any outstanding preferred stock.

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Our common stock has no preemptive or conversion rights or other subscription rights. There are no sinking fund provisions applicable to the common stock. The outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our certificate of incorporation empowers our board of directors, without action by our shareholders, to issue up to 5,000,000 shares of preferred stock from time to time in one or more series, which preferred stock may be offered by this prospectus and supplements thereto. As of January 19, 2009, no shares of preferred stock were outstanding.

We are currently authorized to issue: (i) no shares of our previously designated Series A Convertible Preferred Stock, (ii) 600,001 shares of our previously designated Series B Convertible Preferred Stock and (iii) no shares of our previously designated Series C Convertible Preferred Stock. In addition, our board may fix the rights, preferences, privileges, and restrictions of our remaining 764,705 authorized but undesignated preferred shares, including:

- dividend rights and preferences over dividends on our common stock or any series of preferred stock;
- the dividend rate (and whether dividends are cumulative);
- conversion rights, if any;
- voting rights;
- rights and terms of redemption (including sinking fund provisions, if any);
- redemption price and liquidation preferences of any wholly unissued series of any preferred stock and the designation thereof of any of them; and
- to increase or decrease the number of shares of any series subsequent to the issue of shares of that series but not below the number of shares then outstanding.

You should refer to the prospectus supplement relating to the series of preferred stock being offered for the specific terms of that series, including:

- the title of the series and the number of shares in the series;
- the price at which the preferred stock will be offered;
- the dividend rate or rates or method of calculating the rates, the dates on which the dividends will be payable, whether or not dividends will be cumulative or noncumulative and, if cumulative, the dates from which dividends on the preferred stock being offered will cumulate;

the voting rights, if any, of the holders of shares of the preferred stock being offered;

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the provisions for a sinking fund, if any, and the provisions for redemption, if applicable, of the preferred stock being offered, including any restrictions on the foregoing as a result of arrearage in the payment of dividends or sinking fund installments;

the liquidation preference per share;

the terms and conditions, if applicable, upon which the preferred stock being offered will be convertible into our common stock, including the conversion price, or the manner of calculating the conversion price, and the conversion period;

the terms and conditions, if applicable, upon which the preferred stock being offered will be exchangeable for debt securities, including the exchange price, or the manner of calculating the exchange price, and the exchange period;

any listing of the preferred stock being offered on any securities exchange;

a discussion of any material federal income tax considerations applicable to the preferred stock being offered;

any preemptive rights;

the relative ranking and preferences of the preferred stock being offered as to dividend rights and rights upon liquidation, dissolution or the winding up of our affairs;

any limitations on the issuance of any class or series of preferred stock ranking senior or equal to the series of preferred stock being offered as to dividend rights and rights upon liquidation, dissolution or the winding up of our affairs; and

any additional rights, preferences, qualifications, limitations and restrictions of the series.

Upon issuance, the shares of preferred stock will be fully paid and nonassessable, which means that its holders will have paid their purchase price in full and we may not require them to pay additional funds.

Any preferred stock terms selected by our board of directors could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and power, including voting rights, of the holders of our common stock without any further vote or action by the stockholders. The rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued by us in the future. The issuance of preferred stock could also have the effect of delaying or preventing a change in control of our company or make removal of management more difficult.

Warrants

We may issue warrants for the purchase of our common stock, preferred stock or debt securities or any combination thereof. Warrants may be issued independently or together with our common stock, preferred stock or debt securities and may be attached to or separate from any offered securities. To the extent warrants that we issue are to be publicly-traded, each series of such warrants will be issued under a separate warrant agreement to be entered into between us and a bank or trust company, as warrant agent. The warrant agent will act solely as our agent in connection with such warrants. The warrant agent will

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not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. This summary of certain provisions of the warrants is not complete. For the terms of a particular series of warrants, you should refer to the prospectus supplement for that series of warrants and the warrant agreement for that particular series.

Debt Securities

As used in this prospectus, the term debt securities means the debentures, notes, bonds and other evidences of indebtedness that we may issue from time to time. The debt securities will either be senior debt securities, senior subordinated debt or subordinated debt securities. We may also issue convertible debt securities. Debt securities issued under an indenture (which we refer to herein as an Indenture) will be indenture entered into between us and a trustee to be named therein. It is likely that convertible debt securities will not be issued under an Indenture.

The Indenture or forms of Indentures, if any, will be filed as exhibits to the registration statement of which this prospectus is a part. The statements and descriptions in this prospectus or in any prospectus supplement regarding provisions of the Indentures and debt securities are summaries thereof, do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of the Indentures (and any amendments or supplements we may enter into from time to time which are permitted under each Indenture) and the debt securities, including the definitions therein of certain terms.

General

Unless otherwise specified in a prospectus supplement, the debt securities will be direct secured or unsecured obligations of our company. The senior debt securities will rank equally with any of our other unsecured senior and unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment to any senior indebtedness.

We may issue debt securities from time to time in one or more series, in each case with the same or various maturities, at par or at a discount. Unless indicated in a prospectus supplement, we may issue additional debt securities of a particular series without the consent of the holders of the debt securities of such series outstanding at the time of the issuance. Any such additional debt securities, together with all other outstanding debt securities of that series, will constitute a single series of debt securities under the applicable Indenture and will be equal in ranking.

Should an indenture relate to unsecured indebtedness, in the event of a bankruptcy or other liquidation event involving a distribution of assets to satisfy our outstanding indebtedness or an event of default under a loan agreement relating to secured indebtedness of our company or its subsidiaries, the holders of such secured indebtedness, if any, would be entitled to receive payment of principal and interest prior to payments on the senior indebtedness issued under an Indenture.

Prospectus Supplement

Each prospectus supplement will describe the terms relating to the specific series of debt securities being offered. These terms will include some or all of the following:

- the title of debt securities and whether they are subordinated, senior subordinated or senior debt securities;
- any limit on the aggregate principal amount of debt securities of such series;

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the percentage of the principal amount at which the debt securities of any series will be issued;

the ability to issue additional debt securities of the same series;

the purchase price for the debt securities and the denominations of the debt securities;

the specific designation of the series of debt securities being offered;

the maturity date or dates of the debt securities and the date or dates upon which the debt securities are payable and the rate or rates at which the debt securities of the series shall bear interest, if any, which may be fixed or variable, or the method by which such rate shall be determined;

the basis for calculating interest if other than 360-day year or twelve 30-day months;

the date or dates from which any interest will accrue or the method by which such date or dates will be determined;

the duration of any deferral period, including the maximum consecutive period during which interest payment periods may be extended;

whether the amount of payments of principal of (and premium, if any) or interest on the debt securities may be determined with reference to any index, formula or other method, such as one or more currencies, commodities, equity indices or other indices, and the manner of determining the amount of such payments;

the dates on which we will pay interest on the debt securities and the regular record date for determining who is entitled to the interest payable on any interest payment date;

the place or places where the principal of (and premium, if any) and interest on the debt securities will be payable, where any securities may be surrendered for registration of transfer, exchange or conversion, as applicable, and notices and demands may be delivered to or upon us pursuant to the applicable Indenture;

the rate or rates of amortization of the debt securities;

if we possess the option to do so, the periods within which and the prices at which we may redeem the debt securities, in whole or in part, pursuant to optional redemption provisions, and the other terms and conditions of any such provisions;

our obligation or discretion, if any, to redeem, repay or purchase debt securities by making periodic payments to a sinking fund or through an analogous provision or at the option of holders of the debt securities, and the period or periods within which and the price or prices at which we will redeem, repay or purchase the debt securities, in whole or in part, pursuant to such obligation, and the other terms and conditions of such obligation;

the terms and conditions, if any, regarding the option or mandatory conversion or exchange of debt securities;

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the period or periods within which, the price or prices at which and the terms and conditions upon which any debt securities of the series may be redeemed, in whole or in part at our option and, if other than by a board resolution, the manner in which any election by us to redeem the debt securities shall be evidenced;

any restriction or condition on the transferability of the debt securities of a particular series;

the portion, or methods of determining the portion, of the principal amount of the debt securities which we must pay upon the acceleration of the maturity of the debt securities in connection with any event of default if other than the full principal amount;

the currency or currencies in which the debt securities will be denominated and in which principal, any premium and any interest will or may be payable or a description of any units based on or relating to a currency or currencies in which the debt securities will be denominated;

provisions, if any, granting special rights to holders of the debt securities upon the occurrence of specified events;

any deletions from, modifications of or additions to the events of default or our covenants with respect to the applicable series of debt securities, and whether or not such events of default or covenants are consistent with those contained in the applicable Indenture;

any limitation on our ability to incur debt, redeem stock, sell our assets or other restrictions;

the application, if any, of the terms of the applicable Indenture relating to defeasance and covenant defeasance (which terms are described below) to the debt securities;

what subordination provisions will apply to the debt securities;

the terms, if any, upon which the holders may convert or exchange the debt securities into or for our common stock, preferred stock or other securities or property;

whether we are issuing the debt securities in whole or in part in global form;

any change in the right of the trustee or the requisite holders of debt securities to declare the principal amount thereof due and payable because of an event of default;

the depositary for global or certificated debt securities, if any;

any material federal income tax consequences applicable to the debt securities, including any debt securities denominated and made payable, as described in the prospectus supplements, in foreign currencies, or units based on or related to foreign currencies;

any right we may have to satisfy, discharge and defease our obligations under the debt securities, or terminate or eliminate restrictive covenants or events of default in the Indentures, by depositing money or U.S. government obligations with the trustee of the Indentures;

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the names of any trustees, depositories, authenticating or paying agents, transfer agents or registrars or other agents with respect to the debt securities;

to whom any interest on any debt security shall be payable, if other than the person in whose name the security is registered, on the record date for such interest, the extent to which, or the manner in which, any interest payable on a temporary global debt security will be paid if other than in the manner provided in the applicable Indenture;

if the principal of or any premium or interest on any debt securities is to be payable in one or more currencies or currency units other than as stated, the currency, currencies or currency units in which it shall be paid and the periods within and terms and conditions upon which such election is to be made and the amounts payable (or the manner in which such amount shall be determined);

the portion of the principal amount of any debt securities which shall be payable upon declaration of acceleration of the maturity of the debt securities pursuant to the applicable Indenture if other than the entire principal amount;

if the principal amount payable at the stated maturity of any debt security of the series will not be determinable as of any one or more dates prior to the stated maturity, the amount which shall be deemed to be the principal amount of such debt securities as of any such date for any purpose, including the principal amount thereof which shall be due and payable upon any maturity other than the stated maturity or which shall be deemed to be outstanding as of any date prior to the stated maturity (or, in any such case, the manner in which such amount deemed to be the principal amount shall be determined); and

any other specific terms of the debt securities, including any modifications to the events of default under the debt securities and any other terms which may be required by or advisable under applicable laws or regulations.

Unless otherwise specified in the applicable prospectus supplement, the debt securities will not be listed on any securities exchange. Holders of the debt securities may present registered debt securities for exchange or transfer in the manner described in the applicable prospectus supplement. Except as limited by the applicable Indenture, we will provide these services without charge, other than any tax or other governmental charge payable in connection with the exchange or transfer.

Debt securities may bear interest at a fixed rate or a variable rate as specified in the prospectus supplement. In addition, if specified in the prospectus supplement, we may sell debt securities bearing no interest or interest at a rate that at the time of issuance is below the prevailing market rate, or at a discount below their stated principal amount. We will describe in the applicable prospectus supplement any special federal income tax considerations applicable to these discounted debt securities.

We may issue debt securities with the principal amount payable on any principal payment date, or the amount of interest payable on any interest payment date, to be determined by referring to one or more currency exchange rates, commodity prices, equity indices or other factors. Holders of such debt securities may receive a principal amount on any principal payment date, or interest payments on any interest payment date, that are greater or less than the amount of principal or interest otherwise payable on such dates, depending upon the value on such dates of applicable currency, commodity, equity index or other factors. The applicable prospectus supplement will contain information as to how we will determine the amount of principal or interest payable on any date, as well as the currencies, commodities, equity indices or other factors to which the amount payable on that date relates and certain additional tax considerations.

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Rights

We may issue rights to purchase our securities. The rights may or may not be transferable by the persons purchasing or receiving the rights. In connection with any rights offering, we may enter into a standby underwriting or other arrangement with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering. Each series of rights will be issued under a separate rights agent agreement to be entered into between us and one or more banks, trust companies or other financial institutions, as rights agent, that we will name in the applicable prospectus supplement. The rights agent will act solely as our agent in connection with the rights and will not assume any obligation or relationship of agency or trust for or with any holders of rights certificates or beneficial owners of rights.

The prospectus supplement relating to any rights that we offer will include specific terms relating to the offering, including, among other matters:

- the date of determining the security holders entitled to the rights distribution;
- the aggregate number of rights issued and the aggregate amount of securities purchasable upon exercise of the rights;
- the exercise price;
- the conditions to completion of the rights offering;
- the date on which the right to exercise the rights will commence and the date on which the rights will expire; and
- any applicable federal income tax considerations.

Each right would entitle the holder of the rights to purchase for cash the principal amount of securities at the exercise price set forth in the applicable prospectus supplement. Rights may be exercised at any time up to the close of business on the expiration date for the rights provided in the applicable prospectus supplement. After the close of business on the expiration date, all unexercised rights will become void.

If less than all of the rights issued in any rights offering are exercised, we may offer any unsubscribed securities directly to persons other than our security holders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby arrangements, as described in the applicable prospectus supplement.

Anti-Takeover Law

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

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

Transfer Agent and Registrar

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock.

Listing

Our common stock is quoted on the Nasdaq Capital Market under the trading symbol BDSI.

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PLAN OF DISTRIBUTION

Pursuant to General Instruction I.B.6 of Form S-3, we are permitted to utilize the registration statement of which this prospectus forms a part to sell a maximum amount of securities equal to one-third (33.33%) of the aggregate market value of the outstanding voting and non-voting common equity held by our non-affiliates in any 12 month period. We may, from time to time, offer the securities registered hereby up to this maximum amount.

We may sell the securities offered through this prospectus: (i) to or through underwriters or dealers, (ii) directly to purchasers, including our affiliates, (iii) through agents, or (iv) through a combination of any these methods or any other permissible method. The securities may be distributed at a fixed price or prices, which may be changed, market prices prevailing at the time of sale, prices related to the prevailing market prices, or negotiated prices. The prospectus supplement used for any offering an sale of securities contemplated hereunder will include the following information:

- the terms of the offering;
- the names of any underwriters or agents;
- the name or names of any managing underwriter or underwriters;
- the purchase price of the securities;
- the net proceeds from the sale of the securities;
- any delayed delivery arrangements;
- any underwriting discounts, commissions and other items constituting underwriters compensation;
- any initial public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any commissions paid to agents.

Sale Through Underwriters or Dealers

If underwriters are used in the sale, the underwriters will acquire the securities for their own account, including through underwriting, purchase, security lending or repurchase agreements with us. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions. Underwriters may sell the securities in order to facilitate transactions in any of our other securities (described in this prospectus or otherwise), including other public or private transactions and short sales. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless otherwise indicated in the prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. The underwriters may change from time to time any initial public offering price and any discounts or concessions allowed or reallowed or paid to

dealers.

If dealers are used in the sale of securities offered through this prospectus, we will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale. The prospectus supplement will include the names of the dealers and the terms of the transaction.

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Direct Sales and Sales Through Agents

We may sell the securities offered through this prospectus directly. In this case, no underwriters or agents would be involved. Such securities may also be sold through agents designated from time to time. The prospectus supplement will name any agent involved in the offer or sale of the offered securities and will describe any commissions payable to the agent. Unless otherwise indicated in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. The terms of any such sales will be described in the prospectus supplement.

Delayed Delivery Contracts

If the prospectus supplement indicates, we may authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase securities at the public offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. The contracts would be subject only to those conditions described in the prospectus supplement. The applicable prospectus supplement will describe the commission payable for solicitation of those contracts.

Market Making, Stabilization and Other Transactions

Unless the applicable prospectus supplement states otherwise, each series of offered securities will be a new issue and will have no established trading market. We may elect to list any series of offered securities on an exchange. Any underwriters that we use in the sale of offered securities may make a market in such securities, but may discontinue such market making at any time without notice. Therefore, we cannot assure you that the securities will have a liquid trading market.

Any underwriter may also engage in stabilizing transactions, syndicate covering transactions and penalty bids in accordance with Rule 104 under the Securities Exchange Act. Stabilizing transactions involve bids to purchase the underlying security in the open market for the purpose of pegging, fixing or maintaining the price of the securities. Syndicate covering transactions involve purchases of the securities in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the securities to be higher than it would be in the absence of the transactions. The underwriters may, if they commence these transactions, discontinue them at any time.

Derivative Transactions and Hedging

We, the underwriters or other agents may engage in derivative transactions involving the securities. These derivatives may consist of short sale transactions and other hedging activities. The underwriters or agents may acquire a long or short position in the securities, hold or resell securities acquired and purchase options or futures on the securities and other derivative instruments with returns linked to or related to changes in the price of the securities. In order to facilitate these derivative

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transactions, we may enter into security lending or repurchase agreements with the underwriters or agents. The underwriters or agents may effect the derivative transactions through sales of the securities to the public, including short sales, or by lending the securities in order to facilitate short sale transactions by others. The underwriters or agents may also use the securities purchased or borrowed from us or others (or, in the case of derivatives, securities received from us in settlement of those derivatives) to directly or indirectly settle sales of the securities or close out any related open borrowings of the securities.

Electronic Auctions

We may also make sales through the Internet or through other electronic means. Since we may from time to time elect to offer securities directly to the public, with or without the involvement of agents, underwriters or dealers, utilizing the Internet or other forms of electronic bidding or ordering systems for the pricing and allocation of such securities, you will want to pay particular attention to the description of that system we will provide in a prospectus supplement.

Such electronic system may allow bidders to directly participate, through electronic access to an auction site, by submitting conditional offers to buy that are subject to acceptance by us, and which may directly affect the price or other terms and conditions at which such securities are sold. These bidding or ordering systems may present to each bidder, on a so-called real-time basis, relevant information to assist in making a bid, such as the clearing spread at which the offering would be sold, based on the bids submitted, and whether a bidder s individual bids would be accepted, prorated or rejected. For example, in the case of debt security, the clearing spread could be indicated as a number of basis points above an index treasury note. Of course, many pricing methods can and may also be used.

Upon completion of such an electronic auction process, securities will be allocated based on prices bid, terms of bid or other factors. The final offering price at which securities would be sold and the allocation of securities among bidders would be based in whole or in part on the results of the Internet or other electronic bidding process or auction.

General Information

Agents, underwriters, and dealers may be entitled, under agreements entered into with us, to indemnification by us against certain liabilities, including liabilities under the Securities Act. Our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with or perform services for us, in the ordinary course of business.

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LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements as of and for each of the two years in the period ended December 31, 2007, incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2007, have been audited by Cherry, Bekaert & Holland, L.L.P. as successor by merger to Aidman, Piser & Company, P.A., our former independent registered public accounting firm, as stated in their report incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

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. In addition, the documents we are incorporating by reference as of the date hereof are as follows:

- our Annual Report on Form 10-K for fiscal year ended December 31, 2007, as filed with the SEC on March 7, 2008, and as amended on March 17, 2008;

- our Quarterly Report on Form 10-Q for fiscal quarter ended March 31, 2008 (as filed with the SEC on May 15, 2008);

- our Quarterly Report on Form 10-Q for fiscal quarter ended June 30, 2008 (as filed with the SEC on August 14, 2008);

- our Quarterly Report on Form 10-Q for fiscal quarter ended September 30, 2008 (as filed with the SEC on November 19, 2008);

- our Current Reports on Form 8-K as filed with the SEC on May 8, 2008, May 30, 2008, June 6, 2008 (as amended June 11, 2008), July 28, 3008, August 28, 2008, October 9, 2008, November 7, 2008, November 21, 2008, December 16, 2008, and January 6, 2009;

- our Annual Proxy Statement (Schedule 14A) for our Annual Shareholders Meeting , filed with the SEC on June 18, 2008;

- the description of our common stock contained in our Form 8-A filed on June 19, 2002, as amended June 20, 2002, and as it may be further amended from time to time, under the caption Description of Capital Stock ; and

- all documents that we file with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this registration statement by reference and to be a part hereof from the date of filing of such documents.

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Any statement contained in a document we incorporate by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus (or in any other document that is subsequently filed with the Securities and Exchange Commission and incorporated by reference) modifies or is contrary to that previous statement. Any statement so modified or superseded will not be deemed a part of this prospectus except as so modified or superseded.

You may request a copy of these filings at no cost (other than exhibits unless such exhibits are specifically incorporated by reference) by writing or telephoning us at the following address and telephone number:

BioDelivery Sciences International, Inc.

324 South Hyde Park Avenue, Suite 350

Tampa FL 33606

Telephone: (813) 864-2562

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.

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.

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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.

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You should rely only on the information contained in this prospectus supplement. We have not authorized any dealer, broker, salesperson or any other person to provide you with information or to make any representations different from those contained in this prospectus or incorporated herein by reference. The information contained in this prospectus supplement is accurate only as of the date of this prospectus supplement, regardless of the time of delivery of this prospectus supplement or of any sale of the shares. This prospectus supplement does not constitute an offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorized or in which the person making such offer is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

2,824,858 Shares of Common Stock

Warrants to Purchase 1,412,429 Shares of Common Stock

PROSPECTUS SUPPLEMENT

April 20, 2010