BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B3
November 28, 2012
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PROSPECTUS SUPPLEMENT
(to prospectus dated February 24, 2012)

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-179257

6,791,887 Shares of Common Stock

2,709,300 Shares of Series A Non-Voting Convertible Preferred Stock

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering an aggregate of (i) 6,791,887 shares of our common stock, par value $.001 per share and (ii) 2,709,300 shares of our Series A Non-Voting Convertible Preferred Stock, par value $.001 per share (which we refer to as the Series A Preferred Stock). The shares of common stock and Series A Preferred Stock will be issued separately. This offering also includes an aggregate of 2,709,300 shares of our common stock initially issuable upon the conversion of the Series A Preferred Stock. We refer to the shares of common stock and Series A Preferred Stock issued hereunder and the share of common stock issuable upon conversion of the Series A Preferred Stock collectively as the securities.

Shares of our common stock are currently traded on the Nasdaq Capital Market under the symbol BDSI. On November 27, 2012, the consolidated closing bid price of our common stock was $4.21 per share. There is no established public trading market for the Series A Preferred Stock and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or any trading system.

Each share of Series A Preferred Stock is convertible into one share of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting shares of Series A Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of our common stock then issued and outstanding. In the event of our liquidation, dissolution or winding up, holders of our Series A Preferred Stock will receive a payment equal to $.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of our common stock. Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock. For a more detailed description of our Series A Preferred Stock, see the section entitled Description of Series A Preferred Stock beginning on page S-39.

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-9 of this prospectus supplement.

We have retained William Blair & Company, L.L.C. to act as the sole lead placement agent for this offering. We also retained JMP Securities LLC and Roth Capital Partners, LLC to act as co-placement agents in the offering. We have agreed to pay the placement agents an aggregate cash fee equal to 4% of the gross proceeds of the offering and pay the sole lead placement agent a corporate finance fee of 0.5% of the gross proceeds of the offering; provided, however, that the placement agents will not receive any fee, including the 0.5% corporate finance fee, or other remuneration in connection with any funds invested by a specific, agreed upon investor. We have also agreed to reimburse the placement agents for certain of its expenses as described under Plan of Distribution in this prospectus supplement. The placement agents are not required to arrange for the sale of any specific number of securities or dollar amount but will use reasonable best efforts to arrange for the sale of the securities.

We estimate the total expenses of this offering, excluding the placement agent fees and the corporate finance fee, will be approximately $310,000. It is anticipated that the securities will be delivered against payment thereon on or about December 3, 2012.

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.

William Blair

Sole Lead Placement Agent

JMP Securities — *Co-Placement Agent*

Roth Capital Partners — *Co-Placement Agent*

The date of this prospectus supplement is November 27, 2012

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Prospectus Supplement

Prospectus

You should rely only on the information contained in this prospectus supplement and the accompanying prospectus or incorporated by reference herein. 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 Series A Preferred Stock 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.

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ABOUT THIS PROSPECTUS SUPPLEMENT

On January 31, 2012, we filed with the SEC a registration statement on Form S-3 (File No. 333-179257) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement was declared effective on February 24, 2012. Under this shelf registration process, we may, from time to time, sell up to $40 million in the aggregate of common stock, preferred stock, debt securities, warrants and rights to purchase securities and units, of which approximately all of such $40 million will be sold in this offering.

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this common stock and Series A Preferred Stock offering and also adds to, updates or changes 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 information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement. 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

The following summary highlights selected information contained or incorporated by reference in this prospectus supplement and the accompanying 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 this entire prospectus supplement and the accompanying prospectus carefully, including the risk factors section as well as the financial statements, the notes to the financial statements and other documents incorporated herein by reference.

Overview

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of proven therapeutics to address important unmet medical needs using both proven and new 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. We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002.

In formulating our products and product candidates, we utilize the novel, patent protected and proprietary *BioErodible MucoAdhesive (BEMA®)* drug delivery technology, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek). Our first U.S. Food and Drug Administration (which we refer to as the FDA) approved product, ONSOLIS® (fentanyl buccal soluble film), as well as our pipeline of products candidates, utilize our BEMA® technology.

In addition to our FDA-approved product ONSOLIS®, our lead products in development are:

BEMA® Buprenorphine, a potential treatment for moderate to severe chronic pain, which is currently in Phase 3 trials and which is partnered on a worldwide basis to Endo Pharmaceuticals, Inc. (which we refer to herein as Endo), and

BEMA® Buprenorphine/Naloxone, a high dose formulation of buprenorphine along with an abuse deterrent agent naloxone, which is a potential treatment for opioid dependence and which is also in Phase 3 trials.

ONSOLIS ® and our product candidates such as BEMA® Buprenorphine may also have broader indications. When presented with viable commercial opportunities for broader indications of our products, we will consider developing the product for those uses. We also continue to explore the use of the BEMA® technology with additional pharmaceutical products that may fulfill an unmet medical need.

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we may seek to acquire or license additional drug delivery technologies or other development stage products in novel technologies. Should we gain access to such technologies, we would seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through commercial partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace. We plan to follow the same strategy should we acquire or license other development stage products in novel technologies.

Our current development strategy focuses primarily on our ability to utilize the FDA s 505(b)(2) regulatory 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)

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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 FDA approval approaches.

Our Lead Product Candidates and Our Marketed Product

We are currently focusing most of our efforts on advancing our two lead product candidates, BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone, and supporting our commercial partner on our FDA approved product, ONSOLIS®.

BEMA® Buprenorphine

Our first lead product candidate, currently in Phase 3 trials, is BEMA® Buprenorphine, a potential treatment for moderate to severe chronic pain. In December 2009, we announced that the primary efficacy endpoint was achieved in a Phase 2 clinical study evaluating the safety and efficacy of a range of doses of BEMA® Buprenorphine. Completion of this Phase 2 study led to the initiation of a Phase 3 double-blind, randomized, placebo-controlled clinical study which was initiated in the fourth quarter of 2010. On September 28, 2011, we announced the preliminary findings of our randomized, placebo-controlled, Phase 3 clinical study of BEMA® Buprenorphine for the treatment of moderate to severe chronic pain in a mixed opioid naïve and opioid experienced population. The primary endpoint of the study, overall pain intensity difference between BEMA® Buprenorphine and placebo, was not achieved. However, we believe the totality of the study results favor BEMA® Buprenorphine, and the trial has provided a wealth of knowledge that will assist us in the final design of what we believe will be positive future clinical studies.

We believe that our outlook on BEMA® Buprenorphine was validated when, in January 2012, we announced the signing of a worldwide licensing and development agreement for BEMA® Buprenorphine with Endo under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BEMA® Buprenorphine for the treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront payment, which we received in January 2012; (ii) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events; (iii) $55 million in potential sales milestones upon achievement of designated sales levels; and (iv) a tiered, mid- to upper-teen royalty on net sales of BEMA® Buprenorphine in the United States and a mid- to high-single digit royalty on net sales of BEMA® Buprenorphine outside the United States. We expect to use portions of our Endo milestone payments to fund our development obligations under the Endo agreement with respect to BEMA® Buprenorphine.

One of the key intellectual property milestones under our Endo agreement was achieved when, in February 2012, the U.S. Patent and Trademark Office (or USPTO) issued a Notice of Allowance regarding one of our patent applications, US Application No. 13/184306. In April 2012, the USPTO formally awarded this patent, now US Patent No. 8,147,866, entitled *Transmucosal Delivery Devices with Enhanced Uptake.* The issue of this patent extends our existing patent protection for BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone by seven years to July 2027. As a result of the issue of the patent, we received a milestone payment in the amount of $15 million and we will receive an additional future milestone payment if we achieve approval of a New Drug Application (or NDA) by the FDA for BEMA® Buprenorphine for the treatment of chronic pain.

In August 2012, we announced with Endo the initiation of the Phase 3 clinical program for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain. The Phase 3 program consists of two efficacy studies, one in opioid naïve and one in opioid experienced subjects. We have started recruitment for both studies. Both are anticipated to be completed by late 2013 or early 2014. Both are double-blind, randomized, placebo-controlled, enriched-enrollment studies in patients with chronic lower back pain. Based on our agreement with Endo, we will receive milestone payments from Endo upon the achievement of two specified milestones, and subsequently, for the acceptance of filing of the NDA by the FDA.

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BEMA® Buprenorphine/Naloxone

We believe that the widespread use of buprenorphine for the treatment of opioid dependence presents an additional commercial opportunity for the product, and we are developing a formulation of BEMA® Buprenorphine specifically for the treatment of opioid dependence. The product will combine a high dose of buprenorphine along with an abuse deterrent agent, naloxone. A BEMA® Buprenorphine/Naloxone (which we call BNX) product would provide us with an opportunity to compete in a rapidly growing opioid dependence market which, according to Wolters Kluwer, currently exceeds $1.4 billion in annual sales in the U.S.

We currently retain all rights to develop and commercialize BNX, which is not included within the scope of our agreement with Endo.

The leading approved product for the treatment of opioid dependence is Suboxone®, which is marketed by Reckitt Benckiser. We believe our market prospects for BNX may have improved when, in September 2012, Reckitt Benckiser announced the voluntary discontinuation of Suboxone® tablets.

Our previous pharmacokinetic studies have demonstrated the ability of the BEMA® technology to deliver the high doses of buprenorphine necessary for the treatment of opioid dependence, including studies for which we announced positive results in September and December 2011. We held a meeting with the FDA in early February 2012, and following the meeting, we announced that we had reached an agreement with the FDA on the development plan for BNX, which includes a pivotal pharmacokinetic study comparing BNX to Suboxone® in normal volunteers and a supporting safety study in opioid dependent patients. The FDA concurred with our strategy while requesting one additional, non-comparative pharmacokinetic study examining the effects of multiple films administered concurrently.

During 2012, positive results were obtained from a pharmacokinetic study (BNX-106) examining the effects of multiple BNX films administered concurrently. The study confirmed that the buprenorphine pharmacokinetics were nearly identical following multiple BNX films applied at one time compared to an equivalent dose administered as a single film. Additionally, there was a linear relationship in buprenorphine pharmacokinetics across the dose range of BNX administered. Regarding the naloxone component of BNX, this study demonstrated that the exposure of naloxone is similar to the reference standard, Suboxone®.

The Results of BNX-106 allowed for initiation of both the pivotal pharmacokinetic study and the safety study. The pivotal pharmacokinetic study (BNX-103) was designed to compare the relative bioavailability of buprenorphine and naloxone between BNX and Suboxone. Based on the FDA agreed upon 505(b)(2) pharmacokinetic regulatory pathway for the BNX program, the goals of the study were to demonstrate that two key pharmacokinetic parameters: that maximum drug plasma concentration (Cmax) and total drug exposure (area under the curve or AUC), for buprenorphine were comparable to Suboxone, and that the same parameters for naloxone were similar or less than Suboxone. In September 2012, we announced a positive outcome of this study. Based on this positive outcome, we anticipate that we will be in a position to submit an NDA to the FDA for BNX during the second quarter of 2013.

We are presently determining the optimal commercialization strategy for BNX. Such strategies could include: (i) partnering (as we did with ONSOLIS® and BEMA® Buprenorphine), (ii)

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commercializing on our own (which would require us to develop capabilities such as a sales force and manufacturing capability) or (iii) co-promotion, where we would use another company s sales force to promote the product along side of our own sales force, which we would first need to develop.

ONSOLIS

On July 16, 2009, we announced the U.S. approval of ONSOLIS®, a transmucosal formulation of the narcotic fentanyl utilizing our BEMA® technology. ONSOLIS® is indicated for the treatment of breakthrough pain (i.e., pain that breaks through the effects of other medications being used to control persistent pain) in opioid tolerant patients with cancer. In May 2010, regulatory approval was granted for Canada, and in October 2010, approval was obtained in the European Union through the E.U. s Decentralized Procedure, with Germany acting as the reference member state. In the E.U., ONSOLIS® will be marketed under the trade-name BREAKYL . ONSOLIS was commercially launched in Canada in 2011 and in the E.U. in October 2012. However, as a result of certain appearance and related formulation issues relating to ONSOLIS® as described further below, manufacturing and distribution of ONSOLIS® were suspended in March 2012 in the U.S and Canada. We intend to relaunch the product in the U.S. and Canada once the formulation and manufacturing issues are resolved.

Our commercial partner for ONSOLIS® is Meda AB, a leading international specialty pharmaceutical company based in Sweden (which we refer to as Meda). In addition to milestone payments we received and may in the future receive from Meda, we began receiving royalties from Meda on net sales of ONSOLIS® following the product s commercial launch in the U.S. and Canada. Under the terms of its E.U. agreement with Meda, we received a final milestone payment in October 2012 of $2.5 million. We will also receive a royalty on net sales of BREAKYL in the E.U.

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Meda s U.S. subsidiary, Meda Pharmaceuticals, based in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets and sells branded prescription therapeutics. Meda has secured access to additional markets through acquisition of European businesses from Valeant Pharmaceuticals International, Inc. (which we refer to as Valeant) and a joint venture with Valeant covering Australia, Mexico and Canada.

In 2010, we secured commercialization rights for ONSOLIS® for the remaining worldwide territories through execution of licensing agreements with Kunwha Pharmaceutical Ltd. for South Korea and TTY Biopharm Ltd. for Taiwan.

Although we have generated licensing-related and other revenue to date, we only began to generate revenue from the commercial sales of an approved product (ONSOLIS®) in late 2009 and such revenue has been minimal to date due to multiple factors, including a highly restrictive Risk Evaluation and Mitigation Strategy (REMS) imposed by the FDA and the suspension of manufacturing and distribution in the U.S and Canada where the product is approved but has faced certain appearance and related formulation issues. The lack of approved REMS programs for our direct competitors has resulted in an unlevel playing field, which created an unfavorable selling environment for ONSOLIS®. Furthermore, increasing pressure from payers and the availability of generic competitors have further impacted the market.

On December 29, 2011, the FDA approved a class-wide REMS program covering all transmucosal fentanyl products under a single risk management program. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all marketed

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transmucosal fentanyl products under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program also ends the disparity in prescribing requirements for ONSOLIS® compared to similar products and provides ONSOLIS® with both retail and inpatient facility access. Prescribers and patients enrolled by our commercial partner Meda or any other company selling a transmucosal fentanyl product will be eligible to prescribe ONSOLIS®. In addition to consistency in educational materials, technological advances will simplify the process of participation and verification of program participation. It is anticipated that ONSOLIS® will be in a better position to compete on its own merits as a result of the TIRF.

In March 2012, we announced the postponement of the U.S. and Canadian relaunch of ONSOLIS® until the product formulation can be modified to address two appearance issues (described further below) noted by FDA following an inspection of the manufacturing facility of our North American manufacturing partner for ONSOLIS®, Aveva Drug Delivery Systems, Inc. (which we refer to herein as Aveva). Therefore, the U.S. and Canadian relaunch and additional manufacturing of ONSOLIS® has been postponed until such product appearance issues have been resolved.

Subsequent to our announcement regarding the postponement of the U.S. and Canadian relaunch of ONSOLIS®, we have been working on various formulation adjustments to resolve (i) certain color fading and (ii) crystal formation issues observed with this product, although neither had any impact on product performance. The positive reformulation efforts led to the results being submitted to FDA in October 2012 with a request for a Type A meeting to review our findings and what we believe to be a pathway forward. This meeting, scheduled for mid-December 2012, will provide us with an opportunity: (1) for FDA to review with us the data we generated from the reformulation work to hopefully resolve the concerns FDA had regarding the two issues noted above (2) to determine the content of the formal submission package that FDA will require for their formal review; and (3) to establish the formal submission classification and its associated review time. This Type A meeting and its outcome will enable us to better predict with greater certainty the potential timing of the U.S. and Canadian relaunch of ONSOLIS®.

Other Information

Open SEC Comments Regarding Endo Revenue Recognition

On September 5, 2012, we received a comment letter from the staff of the Securities and Exchange Commission (or SEC) relating to our revenue recognition accounting under our licensing agreement for BEMA Buprenorphine with Endo. Since that date, we have been in discussions with the SEC staff regarding the terms of the Endo agreement and our accounting treatments related thereto and we are continuing to work with the staff to answer any remaining questions or comments they may have in order to resolve this matter satisfactorily.

We believe that our revenue recognition relating to the Endo agreement has been undertaken in accordance with generally accepted accounting principles and related current accounting literature. In addition, we believe that the types of questions being asked by the SEC staff are not unusual for these types of clinical development and license agreements.

Importantly, and particularly in light of the earned and non-refundable nature of the $45 million in payments we have received in 2012 from Endo, we believe that our cash position and operations will not be impacted by the outcome of our discussions with the staff, regardless of the ultimate revenue recognition treatment afforded such $45 million of payments or any future payments we may receive under our agreement with Endo.

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As of the date of this prospectus supplement, we cannot determine with certainty what impact the SEC staff s comments will have on our previous or future disclosures and related policies regarding the revenue recognition treatment of our payments from Endo, including the financial information contained in our annual and quarterly reports for the year 2012. Based on the ultimate outcome of our discussions with the Staff, we may reach a determination to supplement our future financial disclosure, or restate prior financial disclosures, which could have a material impact on our aforementioned revenue recognition and policies related thereto, but not, as stated above, on our cash position or ability to continue and progress ongoing operations.

For risk associated with the open SEC comment, please see Risk Factors- Risks Related to Our Common Stock and This Offering- *We are currently engaged in an SEC comment letter process regarding our revenue recognition treatment of our license agreement with Endo, which process could lead to future supplements to or restatements of our financial disclosure*.

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:	
Common stock offered by us	6,791,887 shares of common stock
Common stock to be outstanding after this offering	37,482,212 shares, based on 30,690,325 shares outstanding as of November 26, 2012.
Series A Preferred Stock:	
Series A Preferred Stock offered by us	2,709,300 shares of Series A Preferred Stock. This prospectus supplement also relates to the offering of the shares of common stock issuable upon conversion of the Series A Preferred Stock.
Conversion	Each share of Series A Preferred Stock is convertible into one share of our common stock at any time at the option of the holder, except that the Series A Preferred Stock provides that a holder will be prohibited from converting shares of Series A Preferred Stock into shares of Common Stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of our Common Stock then issued and outstanding.
Liquidation Preference	In the event of our liquidation, dissolution or winding up, holders of the Series A Preferred Stock will receive a payment equal to $.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock, the holders of Series A Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.
Voting Rights	Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock.
Dividends	Holders of Series A Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

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Use of proceeds	The net proceeds of the sale of common stock and Series A Preferred Stock to the purchasers, after deducting placement agent fees, the corporate finance fee and estimated offering expenses payable by us, will be approximately $38.3 million. We intend to use the net proceeds from this offering for continued clinical development of our product candidate pipeline, including BEMA Buprenorphine for chronic pain and BEMA Buprenorphine/Naloxone for the treatment of opioid dependence, for potential product or technology acquisitions and for general corporate and working capital purposes. We are not presently a party to any definitive agreements to make any product or technology acquisitions. See Use of Proceeds.
Risk factors	Our business and an investment in our securities involve a high degree of risk. See Risk Factors beginning on page S-9 for a discussion of factors you should consider carefully before deciding to invest in our securities.
Listing	Our common stock is listed on the NASDAQ Capital Market under the symbol BDSI. There is no established public trading market for the Series A Preferred Stock and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or any trading system.

The number of shares of our common stock to be outstanding after this offering as reflected above is based on 30,690,325 shares of our common stock outstanding as of November 26, 2012. This number excludes the 2,709,300 shares of common stock issuable upon the conversion of the Series A Preferred Stock to be issued in this offering. This number also excludes (as of the close of business on November 26, 2012):

- 3,493,565 shares of our common stock issuable upon exercise of stock options outstanding under our Amended and Restated 2001 Incentive Plan which had at a weighted average exercise price of $3.90 per share as of September 30, 2012 and 746,797 shares of our common stock issuable upon exercise of stock options outstanding under our 2011 Incentive Plan which had a weighted average exercise price of $2.58 per share as of September 30, 2012 and 1,008,123 shares of our common stock available for future grant or issuance pursuant to such 2011 Incentive Plan as of September 30, 2012; and

- 2,246,301 shares of our common stock issuable upon the exercise of warrants outstanding as of September 30, 2012 at a weighted average exercise price of $3.82 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

We have incurred significant losses since inception, have relatively limited working capital and have only generated minimal revenues from actual 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 September 30, 2012, we have recorded significant losses. Our accumulated deficit at September 30, 2012 was approximately $92,044,389 million. As of September 30, 2012, we had working capital of approximately $0.1 million, including non-refundable deferred revenue of $15.1 million, but we do not generate meaningful recurring revenue or cash flow and thus use our working capital to maintain our operations. 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 products if approved. 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® has been adversely affected by: (i) the lack of a uniform REMS program, and (ii) certain post-FDA approval appearance issues associated with ONSOLIS® which have led to the temporary suspension of manufacturing and marketing of ONSOLIS® in the US and Canada.

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 clinical and commercialization activities, mostly relating to ONSOLIS® and more recently with BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone. 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 historical lack of financial liquidity, our auditors have previously expressed substantial doubt regarding our ability to continue as a going concern .

As a result of our historical lack of liquidity, our auditors have previously issued opinions, on our 2010 audited financial statements which are incorporated by reference in this prospectus supplement, which expressed substantial doubt with respect to our ability to continue as a going concern. As a result

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of our cash position at September 30, 2012, the receipt of an upfront and additional milestones from Endo in 2012 on our BEMA® Buprenorphine product which are to be used on clinical trials for and development of this product and not for general working capital, we believe that we will be able to fund planned operations and product development into the second quarter of 2013. Additionally, we believe that the timing of certain planned expenditures is discretionary and such expenditures could be deferred if needed.

Our auditors have included an emphasis of a matter paragraph in their 2011 report to our audited financial statements to highlight our current liquidity position and operating plans and, the fact that we will need, absent improvements in revenues from the sales of our products, to obtain additional capital before or during the first quarter of 2013 to fund our operations through the end of 2013 and into 2014. If we are unable to obtain such funding, we may be required to scale back operations (perhaps significantly), which could have a material adverse effect on our business and results of operations.

Until we have a larger royalty revenue stream from Meda on ONSOLIS® and reach the NDA approval milestone payment under the Endo licensing agreement for BEMA® Buprenorphine for chronic pain, we will likely need to raise additional capital to continue our operations from time to time, 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 September 30, 2012, we had cash of approximately $31.3 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) that our current working capital will be sufficient to satisfy our contemplated cash requirements through the first quarter of 2013, although this excludes the additional capital that will be required for additional clinical trials of BEMA® Buprenorphine for chronic pain and further assumes 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. This also excludes capital raised in this offering.

Depending on the timing and receipt of milestone payments from our commercial partnership with Meda and Endo, and given our anticipated cash usage 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. This may include the potential need to fund additional Phase 3 clinical trials for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain, which are required because, as announced in late September 2011, our initial Phase 3 trial for this product failed to meet its primary endpoint. As a result, the further development of BEMA® Buprenorphine will require significant additional capital to complete. It is anticipated that the majority of these costs will come from certain predetermined milestone payments that are part of the Endo agreement, including the $30 million upfront and $15 million milestone payments we have received to date. It is anticipated that these funds are to be used primarily on clinical trials and to develop BEMA® Buprenorphine, and not for general working capital. 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 raising additional capital more difficult or impossible and may also result in a lower price for our shares.

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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 product 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, 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;
- progress and cost of our research and development programs;
- progress with non-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) approval and addressing regulatory and other issues that may arise post-approval (such as we have experienced with ONSOLIS®);
- 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;
- costs we may incur in acquiring new technologies or products;
- competing technological and market developments;
- market acceptance of our drug formulations or products;
- costs for recruiting and retaining employees, consultants and experts;

costs for training physicians; and

legal, accounting, insurance and other professional and business related costs.

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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 75 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. In particular, we have on file with the SEC a universal shelf registration statement that allows us (subject to certain limitations) to issue up to $40 million of our common stock, preferred stock, notes, warrants and other securities of our company.

The Risk Evaluation and Mitigation Strategy (REMS) that the FDA required for ONSOLIS® and the subsequent classwide REMS for all transmucosal fentanyl products may continue slow sales and marketing efforts for ONSOLIS®, which could impact our royalty 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 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® once the outstanding appearance and related formulation issues have been resolved and manufacturing and distribution of the product in the U.S. and Canada has resumed. Meda s compliance with the REMS has led and could (should the product be relaunched in the U.S. and Canada) continue to 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.

Moreover, until recently, two products that compete directly with ONSOLIS®, namely Actiq® and Fentora® (each of which are marketed by Teva), were being marketed without the requirement of compliance with a REMS. This condition put ONSOLIS® at a material competitive disadvantage with these products, which likely impacted sales of ONSOLIS®.

On December 29, 2011, FDA approved a REMS program covering all transmucosal fentanyl products. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all approved transmucosal fentanyl products under a single program and was implemented in March 2012. There is a risk that healthcare providers may respond negatively to the new classwide REMS program in a manner similar to the original ONSOLIS® REMS program. Should this occur, Meda s ability to generate revenue from sales of ONSOLIS® in the U.S. and Canada, once the appearance and related formulation issues have been resolved and the product is relaunched in the U.S. and Canada, could be materially compromised, which would result in low royalty payments to us.

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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:

- regulatory clearance of marketing claims for the uses that we are developing;
- 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;
- 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
- 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 our 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.

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.

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We have been and expect to be significantly dependent on our collaborative agreements for the development, manufacturing and sales of our products and 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 are our commercialization agreements with Meda and Endo as well as our manufacturing development and supply agreements with Aveva and LTS relating to ONSOLIS® and with LTS relating to BREAKYL . The termination of these relationships, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under their applicable agreements or arrangements with us, 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®.

The risks associated with reliance on key third parties was demonstrated in 2010 when Aveva experienced certain adverse equipment and regulatory issues leading to the temporary stoppage of manufacturing of all products at that site, which left us exposed to delays in our and our partners commercial plans. In addition, in March 2012 Meda temporarily suspended distribution of ONSOLIS® following discussions with the FDA regarding issues with the product s appearance. Specifically, the FDA raised concerns about two cosmetic issues that may have originated from the formulation used in the manufacturing of ONSOLIS® following an inspection of Aveva, which manufactures ONSOLIS® on our behalf. On March 12, 2012, we announced the postponement of the U.S. and Canadian relaunch of ONSOLIS® until the product formulation can be modified to address these issues. Therefore, ONSOLIS® is not currently being marketed in the U.S. and Canada and the relaunch and additional manufacturing of ONSOLIS® has been postponed until such product issues have been resolved. Any future manufacturing interruptions or related supply issues could have a material adverse effect on our company.

Under our collaborative agreements with Meda, we are responsible for paying certain costs relating to ONSOLIS®. In addition, under our licensing and development agreement with Endo, we are responsible for supporting the clinical development of BEMA® Buprenorphine for pain by conducting certain specified clinical trials in the United States. Our inability to adequately project or control our costs under these agreements could 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 potential 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.

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We currently have a general liability/product liability policy which includes coverage for our clinical trials. Annual aggregate limits include $7 million with a $6 million limit per occurrence, with $5 million with a $5 million limit per occurrence specifically for product liability. 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 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 are presently a party to a lawsuit by a third party who claims that our products, methods of manufacture or methods of use infringe on their intellectual property rights, and we may be exposed to these types of claims in the future.

We are presently and may continue to be exposed to 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;
- delay the launch of, or 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 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

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ONSOLIS® or another of our BEMA® based products is in conflict with or covered by external patents. This risk presently exists in our litigation with MonoSol which was filed by MonoSol in November 2010, wherein MonoSol claims that our and our partner s trade secreted manufacturing process for ONSOLIS® is infringing upon MonoSol s patented manufacturing process. If the court in that case were to rule against us and our partner in that case, we could be forced to license technology from MonoSol or otherwise incur liability for damages, which could have a material adverse effect on our company.

We have 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 are required to pay a low single digit royalty on sales of products that are covered by this patent in 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.

Our lawsuit with MonoSol has caused us to incur significant legal costs to defend ourselves, and we would be subject to similar costs if we are a party to similar lawsuits in the future. 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® products (including, without limitation, ONSOLIS®). We may be unable to obtain such licenses from the patent holders, which could materially and adversely impact our business.

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, 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,

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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.

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:

- 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;
- inability to timely obtain an adequate supply of required components; and
- 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. Such risks were demonstrated when certain manufacturing issues were experienced at Aveva in 2010-2011 and when, subsequently and separately, the FDA identified certain product appearance issues with ONSOLIS®, which resulted in the March 2012 postponement of the U.S. and Canadian relaunch of the product until such issues are resolved. 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, which could leave our commercial partners, such as Meda, with inadequate supplies of product to sell, especially when regulatory requirements or customer demand necessitate the need for additional product supplies. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes, and the inability of third party manufacturers like Aveva to consistently supply quality product when required would have a material adverse effect on our ability to commercialize and sell our products.

This risks associated with reliance on key third manufacturers was demonstrated in 2010 when Aveva experienced certain adverse equipment and regulatory issues leading to the temporary stoppage of manufacturing of all products at that site, which impacted our and our partners commercial plans. Additionally, in March 2012, Meda temporarily suspended distribution of ONSOLIS® following discussions with the FDA regarding certain appearance issues with the product. Specifically, the FDA raised concerns about two appearance issues with ONSOLIS® following an inspection of Aveva s manufacturing facility. On March 12, 2012, we announced the postponement of the U.S. and Canadian relaunch of ONSOLIS® until the product formulation can be modified to address these issues. Therefore, ONSOLIS® is not currently being marketed in the US and Canada and the relaunch and additional manufacturing of ONSOLIS® for those jurisdictions has been postponed until such product issues have been resolved. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including loss of sales and royalty revenue and claims by or against us or our partners for breach of contract.

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 and Endo) 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.

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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 or with respect to our BEMA® Buprenorphine product under our agreements with Endo, 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.

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 products and product candidates 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®, the product is not currently being marketed in the U.S. and Canada pending resolution of certain appearance and related formulation issues, and we may not receive regulatory approval for any required changes to the ONSOLIS® formulation or of our other product candidates. 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.

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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:

- demonstration of the benefit from delivery of each specific drug through our drug delivery technologies;
- demonstration, through non-clinical and clinical trials, that our drug delivery technologies are safe and effective; and
- 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.

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny as well as the risk of failing to meet the primary endpoint of such trials. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a drug product, the FDA requires the submission of an investigational new drug application, or IND. The FDA has 30 days to review the IND and, unless the FDA raises an issue or concern about the clinical trial plan during that time period, the IND becomes effective at the end of that 30 days and sponsors may proceed with their clinical trial plans. The FDA can suspend or terminate clinical trials at any time due to a number of factors, including for safety or efficacy reasons, because we or our clinical investigators did not comply with the FDA s requirements for conducting clinical trials, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If the FDA does not permit us to proceed with our planned clinical trials or the trials are suspended or permanently terminated by us, the FDA or any institutional review boards overseeing the trials, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, 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. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file a NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA s findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. If this approval pathway is not available to us with respect to a

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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. For example, in December 2011, the FDA received a Citizen Petition requesting that it refuse to file any Section 505(b)(2) NDA or abbreviated new drug application, or ANDA, for buprenorphine/naloxone drugs intended to be applied to the oral mucosal membranes unless such application refers to the sublingual film formulation of Suboxone, rather than the tablet formulation, as the reference listed drug, or RLD. Further, in September 2012, the manufacturer of Suboxone tablets announced its intention to withdraw from the market and discontinue Suboxone tablets due to increasing concerns with pediatric exposure relating to how Suboxone is currently packaged. Our proposed Section 505(b)(2) marketing application for BEMA® Buprenorphine/Naloxone is expected to reference the tablet formulation of Suboxone rather than the film formulation as the RLD, and the data we have generated has been based off of the tablet formulation of Suboxone. If the FDA grants the Citizen Petition and requires us to reference the film formulation of Suboxone in our marketing application, our studies comparing our BEMA® Buprenorphine/Naloxone product candidate to the Suboxone tablet may be rendered unsuitable to support our marketing application and we may be required to conduct additional studies of BEMA® Buprenorphine/Naloxone, which would require additional resources and time.

Moreover, we may be required to conduct additional costly and time-consuming clinical studies beyond those that we originally anticipate in the event that our clinical trials fail to meet their primary endpoints or for other reasons, which would render them inadequate to support approval by the FDA. For example, in September 2011, we announced that our Phase 3 clinical trial for BEMA® Buprenorphine did not meet its primary endpoint and therefore we will be required to conduct one or more new trials. In our licensing and development agreement with Endo, we are responsible for the conduct of planned clinical studies leading up to the submission of a NDA for BEMA® Buprenorphine. Conducting a new clinical trial in accordance with the FDA requirements will require significant additional capital, and we will not be able to commercialize and sell our BEMA® Buprenorphine product until we are able to meet our primary endpoint and obtain subsequent FDA approval.

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

Data already obtained, or data we may obtain in the future, 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 are 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. In additional, 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.

Finally, if any of our clinical trials do not meet their primary endpoints, or for a variety of other reasons, we may be required to conduct additional clinical trials in order to progress development of the subject product. These additional trials would be costly and time-consuming, and would divert resources from other projects. The foregoing risks were evidenced by the failure of our Phase 3 trial for BEMA® Buprenorphine for the treatment of moderate to severe chronic pain to meet its primary endpoint, which we announced September 2011.

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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 have purchased from third parties such as Tolmar with respect to our BEMA® technology. 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.

We compete with larger and better capitalized companies, and 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 developed (and are currently marketing in competition with us), have sought to develop and may in the future seek to develop and market mucosal adhesive, encapsulation or other drug delivery technologies and related pharmaceutical products which do and may compete with our technologies and products. Competitors have developed and may in the future develop similar or different technologies or products which may become more accepted by the marketplace or which may supplant our technology entirely. In addition, many of our current competitors are, and future competitors may be, significantly larger and better financed than we are, thus giving them a significant advantage over us.

We and our partners may be unable to respond to competitive forces presently in the marketplace (including competition from larger companies), which would severely impact our business. Moreover, 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 approved product and lead product candidates 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 candidates, BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone, 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 the 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.

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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 approved product ONSOLIS® and in our lead product candidates BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone (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, BEMA® Buprenorphine/Naloxone 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 a procurement quota in order to obtain these substances. The DEA may not establish a 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

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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 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 could materially harm our business, financial conditions results of operations or stock price. Moreover, the passage of the Patient Protection and Affordable Care Act in 2010, and efforts to amend or repeal such law, has created significant uncertainty relating to the scope of government regulation of healthcare and related legal and regulatory requirements, which could have an adverse impact on sales of our products.

The ability of Meda to sell ONSOLIS® (if, in the U.S. and Canada, the appearance and related formulation issues described elsewhere herein have been resolved and distribution has resumed), 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 drugs and medical 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 product liability policy that includes coverage for our clinical trials, with an annual aggregate limit of $5 million with a $5 million limit per occurrence. Should we decide to

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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 and product candidates.

In connection with our or our partners research and clinical development activities, as well as 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 clinical development, as well as the activities of our manufacturing and commercial partners, both 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.

Government and other efforts to reform the healthcare industry could have adverse effects on our company, including the inability of users of our current and future approved products to obtain adequate reimbursement from third-party payers, which could lead to diminished market acceptance of, and revenues from, such products.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (the PPACA). The Healthcare and Education Reconciliation Act of 2010 (the Reconciliation Act), which contains a number of amendments to the PPACA, was signed into law on March 30, 2010. Two primary goals of the PPACA, combined with the Reconciliation Act (collectively referred to as the Health Reform Legislation), are to provide for increased access to coverage for healthcare and to reduce healthcare-related expenses. On June 28, 2012, the United States Supreme Court upheld the constitutionality of the requirement in PPACA that individuals maintain health insurance or pay a penalty.

The Healthcare Reform Legislation contains a number of provisions that are expected to impact our business and operations or those of our commercial partners, including provisions governing enrollment in federal healthcare programs, reimbursement and discount programs and fraud and abuse prevention and control. The impact of these programs on our business is presently uncertain and may have unexpected consequences for our company. For example, expansion of health insurance coverage under the Health Reform Legislation may result in a reduction in uninsured patients and increase in the number of patients with access to healthcare that have either private or public program coverage, and subsequently prescription drug coverage, including coverage for those products currently approved or in

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development by us or our partners. However, this outcome, along with any other potential benefits of the Health Reform Legislation which could prove a benefit for us or our commercial partners, is uncertain and may not occur.

In addition to the Health Reform Legislation, we expect that there will continue to be proposals by legislators or new laws, rules and regulations at both the federal and state levels, as well as actions by healthcare and insurance regulators, insurance companies, health maintenance organizations and other payers of healthcare costs aimed at keeping healthcare costs down while expanding individual healthcare benefits. Certain of these changes (including, without limitation, those enacted in connection with the federal or state implementation of the Health Reform Legislation) could impose limitations on the prices we or our commercial partners will be able to charge for any of our approved products or the amounts of reimbursement available for these products from governmental agencies or third-party payors, or may increase the tax obligations on life sciences companies such as ours. Any or all of these changes (which are presently unclear and subject to potential modification on an ongoing basis) could impact the ability of users of our approved products to obtain insurance reimbursement for the use of such products or the ability of healthcare professionals to prescribe such products, any of which could have a material adverse effect on our revenues (royalty or otherwise), potential profitability and results of operations.

Furthermore, the ability of Meda to sell ONSOLIS® (once it is reformulated and placed back on the market in the U.S. and Canada) and our ability to commercialize our product candidates with partners such as Endo or otherwise 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, managed care, and other organizations and may all result in lower prices for or rejection of our products, which could further have a material adverse effect on our revenues (royalty or otherwise) and results of operations.

We may also be subject to healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

Although we currently do not directly market or promote any of our products, we may also be subject to several healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996 (or HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

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federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

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 November 26, 2012, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 23.21% of our outstanding common stock. These figures do not reflect the issuance of securities in this offering or any future potential exercise of outstanding common stock purchase warrants 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 substantial influence 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;

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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 our Executive Chairman 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, 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, which we no longer maintain. 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 .

Risks Related to Our Common Stock and This Offering

We are currently engaged in an SEC comment letter process regarding our revenue recognition treatment of our license agreement with Endo, which process could lead to future supplements to or restatements of our financial disclosure.

On September 5, 2012, we received a comment letter from the staff (which we refer to as the Staff of the Securities and Exchange Commission (which we refer to as the SEC) relating to our revenue recognition accounting under our agreement with Endo as disclosed in our periodic reports filed with the SEC during 2012. Since that date, we have been engaged in a dialogue with the Staff to familiarize the Staff with the terms of the Endo agreement and our accounting treatments related thereto. As of the date of this prospectus supplement, the Staff s comments remain unresolved, and until these comments are resolved, we cannot determine if we will be required to supplement our disclosures or restate or make other changes to our historical consolidated financial statements, including the financial information contained in our annual and quarterly reports.

Based on the ultimate outcome of our discussions with the Staff, we may reach a determination to supplement our future financial disclosure, or restate prior financial disclosure, related to such revenue recognition. In particular, we may be required to restate our previously reported financial statements to defer all or a portion of the $45 million in revenue we recognized during the first three quarters of 2012 upon payments we received from Endo which, in turn, would reduce or eliminate any earnings we produced during such periods. If we determine to so restate our previously reported financial statements in any way, it could have a material adverse effect on our results of operations (particularly related to our previously reported revenue) and our public stock price could decline. A reduction in our stock price could lower the value of the securities purchased in the offering described in this prospectus supplement.

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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 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.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase our common stock in this offering (including the shares of common stock issuable upon conversion of the Series A Preferred Stock), you will incur an immediate dilution in net tangible book value of $0.95 per share, after giving effect to the sale by us of 9,501,187 shares of our common stock (which includes the 2,709,300 shares of common stock issuable upon conversion of the Series A Preferred Stock) at the per share purchase price of $4.21, less the placement agent fees, corporate finance fee and estimated offering expenses payable by us.

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.

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 supplement, our shares are listed on the NASDAQ Capital Market. In the future, however, we may not be able to meet the continued listing requirements of the NASDAQ Capital Market and NASDAQ rules, which require, among other things, maintaining a minimum bid price per share of $1.00, 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, and during 2011

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our stock price declined to levels that put us at risk of not being able to maintain the required minimum bid price or market capitalization levels or both. If we are unable to satisfy the NASDAQ criteria for continued listing, especially at our current stock price levels, 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.

Our Series A Non-Voting Convertible Preferred Stock has never been publicly traded and active trading markets for these securities are not expected to develop.

Prior to this offering, there has been no public trading market for our Series A Preferred Stock and we do not expect a market to develop. We do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or any trading system. Without an active market, the liquidity of the Series A Convertible Preferred Stock and warrants will be significantly limited.

Our Series A Preferred Stock will rank junior to all our liabilities to third-party creditors, and to any class or series of our capital stock created after this offering specifically ranking by its terms senior to the Series A Preferred Stock, in the event of a bankruptcy, liquidation or winding up of our assets.

In the event of our bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Series A Preferred Stock only after all our liabilities have been paid. Our Series A Preferred Stock will effectively rank junior to all existing and future liabilities held by third-party creditors. The terms of our Series A Preferred Stock do not restrict our ability to raise additional capital in the future through the issuance of debt. Our Series A Preferred Stock will also rank junior to any class or series of our capital stock created after this offering specifically ranking by its terms senior to the Series A Preferred Stock, and we will have the ability and discretion to designate and issue securities (including classes of preferred stock) that rank senior to the Series A Preferred Stock. In the event of our bankruptcy, liquidation or winding up, there may not be sufficient assets remaining, after paying our liabilities, to pay amounts due on any or all of our Series A Preferred Stock then outstanding.

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

As of November 26, 2012, there were 30,705,816 shares of common stock issued and 30,690,325 shares of common stock outstanding. At our 2011 Annual Meeting of Stockholders, our stockholders approved an amendment to our certificate of incorporation to increase the number of authorized shares of common stock, par value $.001, of our common stock from 45,000,000 to 75,000,000 shares. This increase in our authorized shares of common stock provides us with the flexibility to issue more shares in the future, which might cause dilution to our stockholders. In addition, 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.

Moreover, 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 would experience additional dilution. Finally, 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

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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 September 30, 2012: (i) 4,240,362 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.67 per share, and (ii) 2,246,301 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.82 per share. Additionally, each share of Series A Preferred Stock is convertible into one share of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting shares of Series A Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of our common stock then issued and outstanding.

If and when these securities are exercised or converted 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 report may have a material adverse effect on the market price of our securities.

Our certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our amended and restated bylaws (which were adopted in 2010) and Delaware law contain provisions that may have the effect of preserving our current management, such as:

providing for 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;

limiting the ability of stockholders to call special meetings of stockholders;

permitting stockholder action by written consent;

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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;

requiring a super-majority vote of our stockholders to remove directors of our company; and

providing that our stockholders may only remove our directors for cause (as defined in our bylaws).

These provisions affect your rights as a stockholder since they permit our board of directors to make it more difficult for common stockholders to replace members of the board or undertake other significant corporate actions. 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 different from than those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus supplement 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 75 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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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.

We currently intend to use the net proceeds from this offering for continued clinical development of our product candidate pipeline, including BEMA Buprenorphine for chronic pain and BEMA Buprenorphine/Naloxone for the treatment of opioid dependence, for potential product or technology acquisitions and for general corporate and working capital purposes. For more information, see Use of Proceeds.

However, we will have broad discretion in applying the net proceeds we will receive in this offering. It is possible that we may allocate the proceeds differently than investors in this offering desire, or that we will fail to maximize our return on these proceeds. As part of your investment decision, you will not be able to assess or direct how we apply these net proceeds. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for our company.

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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 and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® drug delivery technology platform and any proposed products, product candidates or approved products, including our sole approved and approved product, ONSOLIS®, our partnered product candidate, BEMA® Buprenorphine and our other lead product candidate, BEMA® Buprenorphine/Naloxone (BNX);

- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including: (i) the timing, status and results of our or our commercial partners filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies, including regulatory review thereof and (ii) the heavily regulated industry in which we operate our business generally;

- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates;

- our ability, or the ability of our commercial partners to actually develop, commercialize, manufacture or distribute our products and product candidates;

- our ability to generate commercially viable products and the market acceptance of our BEMA® technology platform and our proposed products and product candidates;

- 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 or commercialization partnerships;

- our expectations about the potential market sizes and market participation potential for our approved or proposed products;

- the protection and control afforded by our patents or other intellectual property, and any interest patents or other intellectual property that we license, or our or our partners ability to enforce our rights under such owned or licensed patents or other intellectual property;

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- the outcome of ongoing or potential future litigation or other claims or disputes relating to our business, technologies, products or processes;

- our expected revenues (including sales, milestone payment and royalty revenues) from our products or product candidates and any related commercial agreements of ours;

- the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to address any regulatory issues that have arisen or may in the future arise;

- 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.

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.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of the securities offered by us in this offering will be approximately $38.3 million, after deducting placement agent fees, the corporate finance fee and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for continued clinical development of our product candidate pipeline, including BEMA Buprenorphine for chronic pain and BEMA Buprenorphine/Naloxone for the treatment of opioid dependence, for potential product or technology acquisitions and for general corporate and working capital purposes. We are not presently a party to any definitive agreements to make any product or technology acquisitions.

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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PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

The following table shows the high and low sales prices per share of our common stock, as reported on the Nasdaq Capital Market, for the periods indicated:

	High	Low
Fiscal Year Ended December 31, 2010		
1st Quarter	$ 4.31	$ 3.34
2nd Quarter	4.21	2.13
3rd Quarter	3.00	2.20
4th Quarter	3.70	2.67
Fiscal Year Ended December 31, 2011		
1st Quarter	$ 3.82	$ 3.22
2nd Quarter	3.89	3.23
3rd Quarter	3.99	1.09
4th Quarter	1.13	0.78
Fiscal Year Ending December 31, 2012		
1st Quarter	$ 2.55	$ 0.80
2nd Quarter	4.54	2.39
3rd Quarter	6.48	4.26
4th Quarter (through November 26, 2012)	6.89	4.10

On November 26, 2012, the last reported trading price of our common stock was $4.41. As of November 26, 2012, there were approximately 132 holders of record of our common stock.

We have never paid or declared cash dividends on our capital stock. We currently intend to retain our future earnings, if any, to finance the growth and development of our business. Payment of future dividends, if any, will be at the discretion of our board of directors.

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DILUTION

If you purchase shares of common stock in this offering (including the shares of common stock issuable upon conversion of the Series A Preferred Stock), your interest will be diluted to the extent of the difference between the public offering price and the net tangible book value per share of our common stock after this offering. We calculate net tangible book value per share by subtracting our total liabilities from our total tangible assets and dividing the difference by the number of outstanding shares of our common stock.

Our net tangible book value at September 30, 2012 was $1.9 million, or $0.06 per share, based on approximately 30,393,017 shares of common stock then outstanding. After giving effect to the sale by us of 9,501,187 shares of common stock in this offering (including the 2,709,300 shares of common stock issuable upon conversion of the Series A Preferred Stock) at the per share public offering price of $4.21, less the placement agent fees, the corporate finance fee and estimated offering expenses payable by us, our net tangible book value at September 30, 2012 would be $40.2 million, or $1.01 per share. This represents an immediate increase in net tangible book value of $0.95 per share to existing stockholders and an immediate dilution of $3.20 per share to investors in this offering. The following table illustrates this per share dilution:

Public offering price per share		$ 4.21
Net tangible book value per share as of September 30, 2012	$ 0.06	
Increase per share attributable to new investors purchasing shares in this offering	$ 0.95	
Net tangible book value per share after this offering	$ 1.01	
Dilution per share to new investors	$ 3.20	

The foregoing table is based on 30,393,017 shares of common stock outstanding at September 30, 2012, 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 September 30, 2012:

- 3,493,565 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 $3.90 per share, 746,797 shares of our common stock issuable upon exercise of stock options outstanding under our 2011 Incentive Plan and 1,008,123 shares of our common stock available for future grant or issuance pursuant to such 2011 Incentive Plan; and

- 2,246,301 shares of our common stock issuable upon the exercise of warrants outstanding as of that date, at a weighted average exercise price of $3.82 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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CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2012:

- on an actual basis, without giving effect to this offering and the use of net proceeds as discussed in Use of Proceeds ; and
- on an as adjusted basis to reflect this offering and the use of net proceeds as discussed in Use of Proceeds .

This capitalization table should be read in conjunction with management s discussion and analysis of results of operations and our consolidated financial statements and related notes included in our Quarterly Report on Form 10-Q for the period ended September 30, 2012, and the other financial information included and incorporated by reference in this prospectus supplement.

	As of September 30, 2012 (in thousands, except share data)	
	Actual (unaudited)	**Pro forma as Adjusted (unaudited)**
Cash and cash equivalents	$ 31,319	$ 69,614
Stockholders equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized and 0 shares issued and outstanding, actual; 5,000,000 shares authorized and 2,709,300 shares issued and outstanding, as adjusted	0	3
Common stock, $.001 par value; 75,000,000 shares authorized and 30,393,017 shares outstanding, actual; 75,000,000 shares authorized and 37,184,904 shares outstanding, as adjusted(1)	30	37
Additional paid-in capital	103,091	141,444
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(92,044)	(92,112)
Total stockholders equity	$ 11,030	$ 49,325

(1) Outstanding shares of common stock as of September 30, 2012 excludes:

- outstanding options as of that date representing the right to purchase a total of 4,240,362 shares of our common stock at a weighted average exercise price of $3.67 per share;
- 1,008,123 shares of our common stock which are reserved for future equity awards that may be granted in the future under our 2011 Incentive Plan; and
- outstanding warrants as of that date representing the right to purchase a total of 2,246,301 shares of our common stock at a weighted average exercise price of $3.82 per share.

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DESCRIPTION OF SERIES A PREFERRED STOCK

The material terms and provisions of the shares of the Series A Preferred Stock are summarized below. The following description is subject to, and qualified in its entirety by, the certificate of designation for the Series A Preferred Stock, the form of which will be filed as an exhibit to a Current Report on Form 8-K to be filed with the SEC contemporaneously with the filing of this prospectus supplement. You should review a copy of the certificate of designation for a complete description of the powers, preferences, rights, qualifications, limitations and restrictions applicable to the Series A Preferred Stock.

General

Under the terms of our certificate of incorporation, as amended, our board of directors is authorized to issue up to 5,000,000 shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Our board of directors has designated 2,709,300 of the 5,000,000 authorized shares of preferred stock as our Series A Non-Voting Convertible Preferred Stock, par value $0.001 per share.

Rank

The Series A Preferred Stock will rank:

- senior to our common stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A Preferred Stock; and
- junior to any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock,

in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion

Each share of Series A Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the certificate of designation for the Series A Preferred Stock) at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of our common stock then issued and outstanding, which percentage may be increased or decreased by on sixty-five days notice from the holder of Series A Preferred Stock to us.

Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series A Preferred Stock will receive a payment equal to $.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by

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its terms senior to the Series A Preferred Stock and holders of Series A Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

Voting Rights

Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock or the certificate of designation for the Series A Preferred Stock.

Dividends

Holders of Series A Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption

We are not obligated to redeem or repurchase any shares of Series A Preferred Stock. Shares of Series A Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing

There is no established public trading market for the Series A Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions

If, at any time that shares of Series A Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series A Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of one share of common stock.

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PLAN OF DISTRIBUTION

Pursuant to a placement agency agreement, dated November 27, 2012, we have engaged William Blair & Company, L.L.C. as the sole lead placement agent, JMP Securities LLC, as co-placement agent and Roth Capital Partners, LLC, as co-placement agent, in connection with this offering. The placement agents are not purchasing or selling any of the securities we are offering, and they are not required to arrange the purchase or sale of any specific number of securities or dollar amount, but the placement agents have agreed to use reasonable best efforts to arrange for the sale of the securities.

The placement agency agreement provides that the obligations of the placement agents are subject to certain conditions precedent, including, among other things, the absence of any material adverse change in our business and the receipt of customary opinions, letters and closing certificates.

The placement agents propose to arrange for the sale of the securities we are offering pursuant to this prospectus supplement to one or more investors through subscription agreements directly between the purchasers and us. All of the securities will be sold at the same price and, we expect, at a single closing. We established the price following negotiations with prospective investors and with reference to the prevailing market price of our common stock, recent trends in such price and other factors. It is possible that not all of the securities we are offering pursuant to this prospectus supplement will be sold at the closing, in which case our net proceeds would be reduced. We expect that the sale of the securities will be completed on the date indicated on the cover page of this prospectus supplement.

We will pay the placement agents a placement agent fee equal to 4% of the gross proceeds of this offering and pay the sole lead placement agent a corporate finance fee of 0.5% of the gross proceeds of the offering; provided, however, that the placement agents will not receive any fee, including the corporate finance fee, or other remuneration in connection with any funds invested by a specific, agreed upon investor.

We estimate the total expenses of this offering, which will be payable by us, excluding the placement agent fees and corporate finance fee, will be approximately $310,000, which includes up to $10,000 that we have agreed to reimburse to the placement agents for certain out of pocket fees and legal expenses reasonably incurred by them.

We have agreed to indemnify the placement agents against certain liabilities, including liabilities under the Securities Act of 1933, as amended. We have also agreed to contribute to payments the placement agents may be required to make in respect to such liabilities.

The placement agency agreement is included as Exhibit 1.1 to our Current Report on Form 8-K filed with the SEC in connection with this offering.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol BDSI. There is no established public trading market for the Series A Preferred Stock and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or any trading system.

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Electronic Distribution

This prospectus supplement and the accompanying prospectus may be made available in electronic format on websites or through other online services maintained by the placement agents, or by an affiliate. Other than this prospectus supplement and the accompanying prospectus in electronic format, the information on the placement agents website and any information contained in any other websites maintained by the placement agents are not part of this prospectus supplement or the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus forms a part, has not been approved and/or endorsed by us or the placement agents, and should not be relied upon by investors.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agency agreement and subscription agreements. A copy of the placement agency agreement and the form of subscription agreements with the investors are included as exhibits to our Current Report on Form 8-K filed with the SEC in connection with this offering. See Where You Can Find More Information and Incorporation by Reference.

Regulation M Restrictions

The placement agents may be deemed to be an underwriters within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by them and any profit realized on the resale of the securities sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agents would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of securities by the placement agents acting as a principal. Under these rules and regulations, the placement agents:

- must not engage in any stabilization activity in connection with our securities; and
- must not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Affiliations

The placement agents and their affiliates may provide various investment banking, financial advisory and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees. In the course of their businesses, the placement agents and their affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the placement agents and their affiliates may at any time hold long or short positions in such securities or loans.

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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. Latham & Watkins LLP, Chicago, Illinois, is counsel for the sole lead placement agent in connection with this offering.

EXPERTS

The consolidated financial statements of the Company as of December 31, 2011 and 2010 and for the two years ended December 31, 2011 and 2010, incorporated in the prospectus by reference from the Company s Annual Report on Form 10-K, dated March 19, 2012, 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.

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, 2011, as filed with the SEC on March 19, 2012;

Our Current Report on Form 8-K, as filed with the SEC on March 20, 2012;

Our Current Report on Form 8-K, as filed with the SEC on April 5, 2012;

Our Current Report on Form 8-K, as filed with the SEC on April 17, 2012;

Our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2012, as filed with the SEC on May 10, 2012;

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Our Current Report on Form 8-K, as filed with the SEC on May 11, 2012;

Our Current Report on Form 8-K, as filed with the SEC on May 21, 2012;

Our Proxy Statement on Form DEF 14A, as filed with the SEC on June 13, 2012;

Our Current Report on Form 8-K, as filed with the SEC on June 28, 2012;

Our Current Report on Form 8-K, as filed with the SEC on July 23, 2012;

Our Current Report on Form 8-K, as filed with the SEC on August 2, 2012;

Our Current Report on Form 8-K, as filed with the SEC on August 3, 2012;

Our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2012, as filed with the SEC on August 9, 2012;

Our Current Report on Form 8-K, as filed with the SEC on August 10, 2012;

Our Current Report on Form 8-K, as filed with the SEC on August 20, 2012;

Our Current Report on Form 8-K, as filed with the SEC on September 13, 2012;

Our Current Report on Form 8-K, as filed with the SEC on September 19, 2012;

Our Current Report on Form 8-K, as filed with the SEC on October 15, 2012;

Our Current Report on Form 8-K, as filed with the SEC on October 18, 2012;

Our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012, as filed with the SEC on November 9, 2012;

Our Current Report on Form 8-K, as filed with the SEC on November 9, 2012;

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.

801 Corporate Center Drive, Suite 210

Raleigh, North Carolina 27607

Telephone: (813) 864-2562

Attention: James A. McNulty

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$40,000,000

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 26, 2012, the aggregate market value of our outstanding common stock held by non-affiliates is approximately $49,981,288, based on 29,561,655 shares of outstanding common stock, of which approximately 24,381,116 shares are held by non-affiliates, and a per share price of $2.05 based on the closing sale price of our common stock on January 26, 2012. 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 that the registration statement of which this prospectus is a part was first filed with the Securities and Exchange Commission.

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 24, 2012.

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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 $40,000,000. 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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CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS

Certain statements contained or incorporated by reference in this prospectus, including the documents referred to or incorporated by reference in this prospectus or statements of our management referring to our summarizing the contents of this prospectus, include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and related releases issued by the U.S. Securities and Exchange Commission, or 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). We have based these forward-looking statements on our current expectations and projections about future events. Our actual results may differ materially or perhaps significantly from those discussed herein, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, expect, anticipate, intend, estimate, plan, project and c similar expressions. In addition, any statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements included or incorporated by reference in this prospectus or our other filings with the SEC include, but are not necessarily limited to, those relating to:

- our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® drug delivery technology platform and any proposed products, product candidates or marketed products, including our sole approved and marketed product, ONSOLIS®, and our partnered product candidate, BEMA® Buprenorphine;

- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including (i) the timing, status and results of our or our commercial partners filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies and (ii) the heavily regulated industry in which we operate our business generally;

- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates;

- our ability, or the ability of our commercial partners to actually develop, commercialize, manufacture or distribute our products and product candidates;

- our ability to generate commercially viable products and the market acceptance of our BEMA® technology platform and our proposed products and product candidates;

- 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 or commercialization partnerships;

- our expectations about the potential market sizes and market participation potential for our approved or proposed products;

- the protection and control afforded by our patents or other intellectual property, and any interest patents or other intellectual property that we license, or our or our partners ability to enforce our rights under such owned or licensed patents or other intellectual property;

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- the outcome of ongoing or potential future litigation or other claims or disputes relating to our business, technologies, products or processes;
- our expected revenues (including sales, milestone payment and royalty revenues) from our products or product candidates and any related commercial agreements of ours;
- the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner;
- 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 matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. Please see Risk Factors in our reports filed with the SEC or in a prospectus supplement related to this prospectus for additional risks which could adversely impact our business and financial performance.

Moreover, new risks regularly emerge and it is not possible for our management to predict or articulate all risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this prospectus are based on information available to us on the date of this prospectus. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout (or incorporated by reference in) this prospectus.

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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.

Overview

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of proven therapeutics to address important unmet medical needs using both proven and new 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. We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002.

In formulating our products and product candidates, we utilize the novel, patent protected and proprietary *BioErodible MucoAdhesive (BEMA®)* drug delivery technology, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek). Our first U.S. Food and Drug Administration (which we refer to as the FDA) approved product, ONSOLIS® (fentanyl buccal soluble film), as well as our pipeline of products candidates, utilize our BEMA® technology.

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we may seek to acquire or license additional drug delivery technologies. Should we gain access to such technologies, we would seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through commercial partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace.

Our current development strategy focuses primarily on our ability to utilize the FDA s 505(b)(2) regulatory 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 FDA approval approaches.

Our Products

ONSOLIS®

On July 16, 2009, we announced the U.S. approval of our first product, ONSOLIS®, a transmucosal formulation of the narcotic fentanyl utilizing our BEMA® technology. ONSOLIS® is indicated for the treatment of breakthrough pain (i.e., pain that breaks through the effects of other medications being used to control persistent pain) in opioid tolerant patients with cancer. In May 2010, regulatory approval was granted for Canada, and in October 2010, approval was obtained in the European Union through the E.U. s Decentralized Procedure, with Germany acting as the reference member state. In the E.U., ONSOLIS® will be marketed under the trade-name BREAKYL . ONSOLIS® was commercially launched in Canada in 2011 and is expected to launch in the E.U. in 2012.

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Our commercial partner for ONSOLIS® is Meda AB, a leading international specialty pharmaceutical company based in Sweden (which we refer to as Meda). In addition to milestone payments we received and may in the future receive from Meda, we began receiving royalties from Meda on net sales of ONSOLIS® following the product s commercial launch in the U.S. and Canada. We anticipate additional royalty sales following launches in the E.U. in 2012, although our royalty revenue from this product remains below original projections due to certain regulatory conditions in the U.S. discussed below.

We have granted commercialization and distribution rights for ONSOLIS® on a worldwide basis (except in South Korea and Taiwan) to Meda. Meda s U.S. subsidiary, Meda Pharmaceuticals, based in Somerset, New Jersey, is a specialty pharmaceutical company that develops, markets and sells branded prescription therapeutics. Meda has an experienced, well trained and highly regarded sales force with a focus in specialty therapeutic areas including pain, allergy and central nervous system conditions. Meda has established a track record of successfully commercializing products. Meda has secured access to additional markets through acquisition of European businesses from Valeant Pharmaceuticals International, Inc. (which we refer to as Valeant) and a joint venture with Valeant covering Australia, Mexico and Canada.

In 2010, we secured commercialization rights for ONSOLIS® for the remaining worldwide territories through execution of licensing agreements with Kunwha Pharmaceutical Ltd. for South Korea and TTY Biopharm Ltd. for Taiwan.

Although we have generated licensing-related and other revenue to date, we only began to generate revenue from the commercial sales of an approved product (ONSOLIS®) in late 2009 and such revenue has been minimal to date due to multiple factors, including a highly restrictive Risk Evaluation and Mitigation Strategy (REMS) imposed by the FDA. The lack of approved REMS programs for our direct competitors has resulted in an unlevel playing field, which created an unfavorable selling environment for ONSOLIS®. Furthermore, increasing pressure from payers and the availability of generic competitors have further impacted the market.

In December 2011, the FDA approved a class-wide REMS covering all transmucosal fentanyl products under a single risk management program. The program, which will be referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. We believe that a single risk management program will help to enhance patient safety while limiting the potential administrative burden on prescribers of transmucosal fentanyl products and their patients. This common program also ends the disparity in prescribing requirements for ONSOLIS® compared to other similar products. Based on the FDA s approval of the class-wide REMS, we and Meda will pursue a REMS implementation strategy that will seek to provide the best opportunity for access to ONSOLIS® and support future growth.

BEMA® Buprenorphine

Our next product, currently in development, is BEMA® Buprenorphine, a potential treatment for moderate to severe chronic pain. In December 2009, we announced that the primary efficacy endpoint was achieved in a Phase 2 clinical study evaluating the safety and efficacy of a range of doses of BEMA® Buprenorphine. Completion of this Phase 2 study led to the initiation of a Phase 3 double-blind, randomized, placebo-controlled clinical study which was initiated in the fourth quarter of 2010. On

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September 28, 2011, we announced that the primary endpoint of this Phase 3 study, overall pain intensity difference between BEMA® Buprenorphine and placebo, was not achieved. Despite this result, we believe that the totality of the study results favors the continued development of BEMA® Buprenorphine, including a near statistically significant difference between BEMA® Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). In addition, in this same group of opioid experienced patients, when eliminating those that did not titrate beyond the starting dose, a statistically significant difference between BEMA® Buprenorphine and placebo (p=0.025) was identified in this study.

Furthermore, we believe that our outlook on BEMA® Buprenorphine was validated when, in January 2012, we entered into a license and development agreement with Endo Pharmaceuticals, Inc. (which we refer to as Endo) under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BEMA® Buprenorphine for the treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront payment, which we received in January 2012; (ii) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events; (iii) $55 million in potential sales milestones upon achievement of designated sales levels; and (iv) a tiered, mid- to upper-teen royalty on net sales of BEMA® Buprenorphine in the United States and a mid- to high-single digit royalty on net sales of BEMA® Buprenorphine outside the United States. We expect to use portions of our Endo milestone payments to fund our development obligations under the Endo agreement with respect to BEMA® Buprenorphine.

Pursuant to our agreement with Endo, we are responsible for the completion of all clinical trials regarding BEMA® Buprenorphine necessary to submit a New Drug Application (or NDA) to the FDA in order to obtain approval of BEMA® Buprenorphine in the United States, pursuant to a development plan set forth in the Endo agreement. We are responsible for all development activities through the filing of the NDA in the U.S., while Endo is responsible for the development following the NDA submission as well as the manufacturing, distribution, marketing and sales of BEMA® Buprenorphine on a worldwide basis. In addition, Endo is responsible for all filings (including the NDA filing with the FDA) required in order to obtain regulatory approval of BEMA® Buprenorphine.

BEMA® Buprenorphine/Naloxone

In addition to our proposed use of BEMA® Buprenorphine to treat moderate to severe chronic pain, we believe that the widespread use of buprenorphine for the treatment of opioid dependence presents an additional commercial opportunity for the product, and we are developing a formulation of BEMA® Buprenorphine specifically for the treatment of opioid dependence. The product will combine a high dose of buprenorphine along with an abuse deterrent agent, naloxone. Preliminary pharmacokinetic studies have demonstrated the ability of the BEMA® technology to deliver the high doses of buprenorphine necessary for the treatment of opioid dependence. In March 2011, we announced the positive outcome of a pre-Investigational New Drug (pre-IND) meeting with the FDA on the development program for BEMA® Buprenorphine/Naloxone, at which we confirmed that the 505(b)(2) regulatory pathway will be pursued for the clinical development of BEMA® Buprenorphine/Naloxone. In December 2011, we announced positive results from our confirmatory study for this product which assessed the pharmacokinetics of our BEMA® Buprenorphine/Naloxone formulation compared to Suboxone, an FDA-approved treatment for opioid dependence with annual sales in excess of $1 billion. The results confirm the final formulation for the product and provide the basis for moving forward into the pivotal comparative pharmacokinetic study versus Suboxone, which we expect will take place in 2012.

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ONSOLIS® and our product candidates such as BEMA® Buprenorphine may also have broader indications. When presented with viable commercial opportunities for broader indications of our products, we will consider developing the product for those uses.

We also continue to explore the use of the BEMA® technology with additional pharmaceutical products that may fulfill unmet medical needs, such as in the areas of nausea and vomiting and migraines.

Additional Information

Since inception and through September 30, 2011, we have recorded accumulated losses totaling approximately $91.5 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for our product candidates, our goal will be to augment our current sources of revenue and, as applicable, deferred revenue (principally licensing fees), with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

We have based our estimates of development costs, market size estimates, peak annual sales projections and similar matters described or incorporated by reference in this prospectus on our market research, third party reports and publicly available information which we consider reliable. However, readers are advised that the projected dates for filing and approval of our INDs or NDAs with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding ONSOLIS®, BEMA® Buprenorphine, BEMA® Buprenorphine/Naloxone or any other product candidates discussed elsewhere (or incorporated by reference) in this prospectus are merely estimates and subject to many factors, many of which may be beyond our control, which will likely cause us to revise such estimates. Readers are also advised that our projected sales figures 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 management s reasonable judgments given the information available and their previous experiences, although such estimates may not prove to be accurate.

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 $40,000,000 of any of, or units comprised of, or other 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.

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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.

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, as amended, and our amended and restated bylaws and by the applicable provisions of Delaware law.

Our authorized capital stock consists of 75,000,000 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 29,561,655 shares of common stock, $0.001 par value, and no shares of preferred stock. These figures do not include securities that may be issued: (i) pursuant to outstanding warrants to purchase shares of our common stock, (ii) pursuant to our Amended and Restated 2001 Incentive Plan or (iii) pursuant to our 2011 Equity Incentive Plan.

We, directly or through agents, dealers or underwriters designated from time to time, may offer, issue and sell, together or separately, up to $40,000,000 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 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 26, 2012, there were 29,577,146 shares of common stock issued and 29,561,655 shares of common stock outstanding, held of record by approximately 136 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, as amended, 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 26, 2012, no shares of preferred stock were designated or outstanding. Our board may fix the rights, preferences, privileges, and restrictions of our 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;

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;

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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 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.

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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 issued pursuant to an indenture entered into between us and a trustee to be named therein and in the applicable prospectus supplement. It is likely that convertible debt securities will not be issued under an Indenture.

We have filed a form of Indenture as an exhibit to the registration statement of which this prospectus is a part. Amended, restated and/or supplemental Indentures and forms of debt securities containing the specific terms of the debt securities that we may offer in the future will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC. 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;
- 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;

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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;

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;

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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;

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;

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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.

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 our outstanding, publicly held voting and non-voting common equity 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.

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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.

The maximum amount of compensation to be received by any FINRA member or independent broker-dealer for the sale of any securities registered under this prospectus will not be greater than 8.0% of the gross proceeds from the sale of such securities.

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 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.

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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 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.

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.

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EXPERTS

The consolidated financial statements as of and for each of the two years in the period ended December 31, 2010, incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2010, have been audited by Cherry, Bekaert & Holland, L.L.P., 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 Exchange Act 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:

1. Our Current Report on Form 8-K, filed January 10, 2011;
2. Our Current Report on Form 8-K, filed February 17, 2011;
3. Our Current Report on Form 8-K, filed March 2, 2011;
4. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed on March 11, 2011;
5. Our Current Report on Form 8-K, filed on March 16, 2011;
6. Our Current Report on Form 8-K, filed on March 21, 2011;
7. Our Current Report on Form 8-K, filed on April 5, 2011;
8. Our Current Report on Form 8-K, filed on May 13, 2011;
9. Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011, filed on May 13, 2011;
10. Our Current Report on Form 8-K/A, filed May 17, 2011;
11. Our Definitive Proxy Statement on Schedule 14A, filed June 6, 2011, and supplemental proxy materials filed on June 29, 2011;
12. Our Current Report on Form 8-K, filed June 3, 2011;
13. Our Current Report on Form 8-K, filed July 25, 2011;
14. Our Current Report on Form 8-K, filed July 26, 2011;
15. Our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011, filed on August 15, 2011;
16. Our Current Report on Form 8-K, filed August 22, 2011;
17. Our Current Report on Form 8-K, filed September 6, 2011;
18. Our Current Report on Form 8-K, filed September 30, 2011;
19. Our Current Report on Form 8-K, filed October 25, 2011;
20. Our Current Report on Form 8-K, filed November 7, 2011;

21. Our Current Report on Form 8-K, filed November 10, 2011;

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22. Our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2011, filed on November 14, 2011;

23. Our Current Report on Form 8-K, filed November 14, 2011;

24. Our Current Report on Form 8-K, filed November 28, 2011;

25. Our Current Report on Form 8-K, filed December 21, 2011;

26. Our Current Report on Form 8-K, filed December 30, 2011;

27. Our Current Report on Form 8-K, filed January 11, 2012;

28. Our Current Report on Form 8-K, filed February 16, 2012;

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

30. All documents that we filed with the SEC 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.

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 SEC 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.

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WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered by this prospectus. This prospectus is part of that registration statement and does not contain all the information included in the registration statement.

For further information with respect to our common stock and us, you should refer to the registration statement, its exhibits and the material incorporated by reference therein. Portions of the exhibits have been omitted as permitted by the rules and regulations of the Securities and Exchange Commission. Statements made in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as an exhibit to the registration statement, and these statements are hereby qualified in their entirety by reference to the contract or document.

The registration statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission s Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and may also be obtained from the web site that the Securities and Exchange Commission maintains at http://www.sec.gov. You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission s public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

DISCLOSURE OF COMMISSION POSITION ON

INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our certificate of incorporation, as amended, 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 Amended and Restated 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.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

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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.

6,791,887 Shares Common Stock

2,709,300 Shares of Series A Non-Voting Convertible Preferred Stock

PROSPECTUS SUPPLEMENT

William Blair

Sole Lead Placement Agent

JMP Securities
Co-Placement Agent

Roth Capital Partners
Co-Placement Agent

November 27, 2012