BIODELIVERY SCIENCES INTERNATIONAL INC
Form S-8
August 24, 2011
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As filed with the Securities and Exchange Commission on August 24, 2011

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-8

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

801 Corporate Center Drive, Suite #210

Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

BioDelivery Sciences International, Inc. 2011 Equity Incentive Plan

BioDelivery Sciences International, Inc. Amended and Restated 2001 Incentive Plan

(Full title of plan)

Mark A. Sirgo, Pharm.D.

801 Corporate Center Drive, Suite 210

Raleigh, North Carolina 27607

(919) 653-5160

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

Copies to:

Lawrence A. Rosenbloom, Esq.

Ellenoff Grossman & Schole LLP

150 East 42nd Street, 11th Floor

New York, New York 10017

(212) 370-1300

Fax: (212) 370-7889

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Shares of common stock issuable under Amended and Restated 2001 Incentive Plan	1,821,179	$3.07	$5,591,019.53	$649.11
Shares of common stock issuable under 2011 Equity Incentive Plan	4,200,000	$3.07	$12,894,000.00	$1,496.99
Total	6,021,179		$18,485,019.53	$2,146.10

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended (the Securities Act), this Registration Statement shall also cover any additional shares of common stock, par value $.001 per share (the Common Stock), of BioDelivery Sciences International, Inc. (the Company) which become issuable under the employee benefit plans described herein by reason of stock dividends, stock splits, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of the outstanding shares of Common Stock.

(2) Pursuant to Rule 457(c), the average of the high and low prices reported in the consolidated reporting system within 5 business days prior to the date of filing the registration statement.

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Explanatory Note

This Registration Statement on Form S-8 of BioDelivery Sciences International, Inc. has been prepared in accordance with the requirements of Form S-8 under the Securities Act of 1933, as amended (which we refer to herein as the Securities Act), to register:

- an additional 1,821,179 shares of our common stock, par value $.001 per share, underlying options previously granted under our Amended and Restated 2001 Incentive Plan (which we refer to herein as the 2001 Plan), which shares are in addition to 3,500,000 shares underlying options granted under the 2001 Plan, such 3,500,000 shares having been previously registered on a Registration Statement on Form S-8 (No. 333-142590) as filed with the Securities and Exchange Commission on June 8, 2007 and supplemented on June 5, 2009 (which we refer to as the Previous S-8); and

- 4,200,000 shares of common stock issuable pursuant to our recently adopted 2011 Equity Incentive Plan (which we refer to herein as the 2011 Plan), of which 147,500 shares underlying options were granted to certain of our officers and directors under 2011 Plan in July 2011.

This Registration Statement also includes a prospectus (which we refer to as the reoffer prospectus) prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3. The reoffer prospectus may be used for reofferings and resales of shares of our common stock that may be deemed to be control securities and/or restricted securities under the Securities Act and the rules and regulations promulgated thereunder that have been acquired by certain of our officers and directors, who are the selling stockholders identified in the reoffer prospectus.

The 3,057,315 shares included in the reoffer prospectus represents the number of shares of our common stock that may be acquired by the selling stockholders, which shares are deemed to be control securities , pursuant to previous option awards made to the selling stockholders, under the 2001 Plan and 2011 Plan, and which are issuable upon the exercise of certain options granted under the 2001 Plan and the 2011 Plan to the selling stockholders.

Accordingly, (i) the reoffer prospectus included herein is a combined prospectus with the reoffer prospectus included as part of the Previous S-8 pursuant to Rule 429(a) under the Securities Act, and (ii) this Registration Statement, which is a new registration statement, also constitutes a post-effective amendment to the Previous S-8 pursuant to Rule 429(b) under the Securities Act.

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PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Item 1. Plan Information.*

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

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

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Reoffer Prospectus

3,057,315 Shares

Common Stock

This reoffer prospectus is a combined prospectus relating to shares of our common stock, par value $.001 per share, that have been registered with the Securities and Exchange Commission, or SEC, under the Securities Act of 1933, as amended, or the Securities Act, and that have been or may be acquired by certain of our prior, current and future officers and directors (or any of their respective assigns) (who we refer to herein as the selling stockholders) pursuant to option awards under our Amended and Restated 2001 Incentive Plan (which we refer to as the 2001 Plan) and our 2011 Equity Incentive Plan (which we refer to as the 2011 Plan and which we refer to together with the 2001 Plan, the Plans). The 3,057,315 shares included in this reoffer prospectus include certain shares of common stock previously registered on a registration statement on Form S-8 (No. 333-142590), as filed with the Securities and Exchange Commission on June 8, 2007, as supplemented on June 5, 2009.

The selling stockholders listed herein (who are the executive officers and directors of our company) are offering and selling up to 3,057,315 shares that have been or may hereafter be acquired by such selling stockholders upon the exercised of options to purchase our common stock that were granted to such selling stockholders under the 2001 Plan and 2011 Plan. We will not receive any proceeds from the sale of the shares hereunder. However, we will receive the proceeds, if any, from the exercise of the options granted under the Plans.

The common stock offered hereby may be sold from time to time by the selling stockholders or by their pledgees, donees, transferees or other successors in interest. Such sales may be made in the public market or otherwise at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. Such shares may be sold by one or more of the following: (a) block trades in which the broker or dealer so engaged will attempt to sell the shares as agent but may position and resell portions of the block as principal to facilitate the transaction; (b) purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus; (c) an exchange distribution in accordance with the rules of such exchange; and (d) ordinary brokerage transactions and transactions in which the broker solicits purchases. In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers will receive commissions or discounts from selling stockholders in amounts to be negotiated immediately prior to the sale. Such brokers or dealers and any other participating brokers or dealers may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. We have paid the expenses of preparing this prospectus and the related registration statement.

Our common stock is quoted on both the Nasdaq Capital Market under the symbol BDSI . On August 19, 2011, the closing sales price for the common stock on the Nasdaq Capital Market was $3.10 per share.

Our principal executive offices are located at 801 Corporate Center Drive, Suite 210, Raleigh, NC 27607. Our telephone number is 919 582 9050.

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Investing in our common stock involves a high degree of risk. You should read the Risk Factors section beginning on page 5 and in the documents incorporated by reference herein before you decide to purchase any shares of our common stock.

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

The date of this reoffer prospectus is August 24, 2011.

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You should rely only upon the information contained or incorporated by reference in this reoffer prospectus and the registration statement of which this reoffer 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. The selling stockholders 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 reoffer prospectus is accurate only as of the date on the front cover of this reoffer prospectus. Our business, financial condition, results of operations and prospects may have changed since that date. This reoffer 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 described or incorporated by reference in this reoffer 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 reoffer prospectus.

This reoffer 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 in this prospectus, including the documents referred to or incorporated by reference in this reoffer 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 other 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 in this reoffer 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 the BEMA® and Bioral® technology platforms and any proposed products, product candidates or marketed products, including our sole marketed product, ONSOLIS®;
- 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 filings with the U.S. Food and Drug Administration, (ii) the timing, status and results of non-clinical work and clinical studies and (ii) heavily regulated industry in which we operate our business generally;
- our ability to generate commercially viable products, acceptance of our BEMA® and Bioral® technology platforms and our proposed formulations 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 and any interest in licensed patents, or our ability to enforce our rights under such patents or licenses;
- litigation or other claims or disputes relating to our technologies, products or processes;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and product candidates;
- the ability of our commercial partners to market and sell the products we license to them and our expected revenues from such partnerships;

the ability of our manufacturing partners to supply us or our commercial parties with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner;

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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 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 reoffer 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 reoffer prospectus.

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PROSPECTUS SUMMARY

The following summary highlights selected information contained in this reoffer prospectus. This summary does not contain all of the information you should consider before investing in the securities. Before making an investment decision, you should read the entire prospectus carefully, including the risk factors section as well as the financial statements and the notes to the financial statements incorporated herein by reference.

In this reoffer prospectus and any amendment or supplement hereto, unless otherwise indicated, the terms BioDelivery Sciences International, Inc. , BDSI , the Company , we , us , and our refer and relate to BioDelivery Sciences International, Inc. and its consolidated subsidiaries.

Our Company

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.

We utilize two novel drug delivery technologies:

- *the BioErodible MucoAdhesive (BEMA®) technology*, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek); and

- *the Bioral® cochleate drug delivery technology*, designed for the potential oral delivery of a broad base of products otherwise administered intravenously. Other than patent costs, we are not currently utilizing our resources to pursue development of this technology or related product candidates.

Our first U.S. Food and Drug Administration, or FDA, approved product, ONSOLIS® (fentanyl buccal soluble film), as well as our pipeline of products candidates, predominately utilize our BEMA® technology.

Our current development strategy focuses primarily on our ability to utilize the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into our drug delivery technologies. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and expeditious, and have less regulatory approval risk, than other FDA approval approaches.

On July 16, 2009, we announced the U.S. approval of our first product, ONSOLIS®. In 2010, regulatory approvals were granted for Canada (May 2010), and most recently in the European Union (October 2010) where it will be marketed under the trade-name BREAKYL . Our commercial partner for ONSOLIS® is Meda AB, a leading international specialty pharmaceutical company based in Sweden (referred to herein as Meda). In addition to milestone payments we received from Meda, we began receiving royalties from Meda on net sales of ONSOLIS® following launch and anticipate additional royalty sales following launches in Canada and the E.U. in 2011, although our royalty revenue from this product remains below original projections due to certain regulatory conditions in the U.S. discussed below.

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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 herein 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.

Our next planned product utilizing the BEMA® technology 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. We believe that this endpoint, referred to as SPID 8 (sum of pain intensity difference over 8 hours), is a good indicator of this product candidate s effectiveness in treating chronic pain. In February 2010, we announced promising secondary data from this study. 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 July 25, 2011, we announced the completion of our Phase 3 clinical for BEMA® Buprenorphine. Study results are anticipated to be available in mid- to late September of 2011, and if positive, will potentially lead to an NDA filing in the first half of 2012.

In addition, 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. We confirmed that the 505(b)(2) regulatory pathway will be pursued for the clinical development of BEMA® Buprenorphine/Naloxone.

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. In this regard, in 2009 we began the development of BEMA® Granisetron for the prevention of chemotherapy-induced nausea and vomiting. We believe that this product candidate and other product concepts demonstrate the potential broad applicability of our BEMA® delivery technology.

Our lead Bioral® formulation is an encochleated version of Amphotericin B, a treatment for fungal infections. A single dose Phase 1 study has been performed with Bioral® Amphotericin B. We also believe our Bioral® technology has the potential to be applied to other types of pharmaceutical actives and other therapeutics such as small interfering RNA, or siRNA. However, although we continue to hold and prosecute our rights to the Bioral® technology, we are dedicating the vast majority of our resources to our BEMA® platform and related products and product candidates.

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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 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 has 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 2010, Meda submitted a new REMS program for review and approval by the FDA which provides for potential broader access to ONSOLIS® through retail pharmacies and reduces some of the administrative burdens placed on prescribers. This new REMS program follows the guidelines provided by FDA in November, 2010 to all companies that are or will be marketing fast acting fentanyl products in the future.

Additionally, substantial progress has recently been made by a cross-company collaboration, which includes Meda and us, on a class-wide REMS program for all fast-acting fentanyl products. Such a program would further streamline the REMS process by providing one single shared REMS program and process that would be used for all fast-acting fentanyl products. Such a program would put all fast-acting fentanyl products that are currently in the marketplace under the same requirements and into the same REMS program, finally resulting in a completely level playing field for ONSOLIS® and allowing ONSOLIS® to compete on its own merits. Importantly, a class-wide REMS will also substantially reduce the administrative burden on healthcare providers and patients and markedly increase the overall number of healthcare providers registered to prescribe fast-acting fentanyl products.

Based on the timing of approval of the ONSOLIS® retail REMS and the class-wide REMS, we will pursue a REMS implementation strategy that provides the best opportunity for access to ONSOLIS® and supports future growth. We anticipate approval of both REMS options in the second half of 2011.

Since inception and through June 30, 2011, we have recorded accumulated losses totaling approximately $86.4 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 below and elsewhere (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 Investigational New Drug Applications (known as INDs) or New Drug Applications (known as 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.

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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 Offering

Outstanding Common Stock	29,561,655 shares of our common stock are outstanding as of August 19, 2011.
Common Stock Offered	Up to 3,057,315 shares of common stock for sale by the selling stockholders (who are our executive officers and directors) for their own account pursuant to the 2001 Plan and the 2011 Plan.
Selling Stockholders	The selling stockholders are set forth in the section entitled Selling Stockholders of this reoffer prospectus on page 24.
Proceeds	We will not receive any proceeds from the sale of our common stock by the selling stockholders. We would, however, receive proceeds upon the exercise of the stock options by those who receive options under the Plans and exercise such options for cash. Any cash proceeds will be used by us for general corporate purposes.
Risk Factors	The securities offered hereby involve a high degree of risk. See Risk Factors.
Nasdaq Capital Market Symbol	BDSI

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RISK FACTORS

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

Risks Relating to Our Business

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

From our inception in January 1997 and through June 30, 2011, we have recorded significant losses. Our accumulated deficit at June 30, 2011 was approximately $86.4 million. As of June 30, 2011, we had working capital of approximately $0.9 million, including non-refundable deferred revenue of $12.5 million. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our product candidates and product concepts, obtain the required regulatory approvals and manufacture, market and sell our proposed products. We may be unable to achieve any or all of these goals.

Although we have generated licensing-related and other revenue to date, we have only recently begun to generate revenue from the commercial sales of an approved product ONSOLIS® and such revenue has been minimal to date due to the fact that ONSOLIS® has been adversely affected by a REMS program that has yet to be approved for the competitor products.

Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel. Since 2005, we have also focused on commercialization activities, mostly relating to ONSOLIS®. This relatively limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize our technologies and proposed formulations or products, obtain FDA approval and achieve market acceptance of our proposed formulations or products and respond to competition. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive material revenues from our product candidates or product concepts in the timeframes we project, if at all, and our inability to do so would materially and adversely impact our viability as a company.

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

As a result of our current lack of financial liquidity, our auditors report for our 2010 financial statements, which are incorporated by reference as part of this reoffer prospectus, contains a statement concerning our ability to continue as a going concern. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a going concern is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include engaging in offerings of securities, negotiating up-front and milestone payments on pipeline products under development and royalties from sales of our products (like ONSOLIS®) which secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. However, we may be unable to achieve these goals and therefore may be unable to continue as a going concern.

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Until we have a larger royalty revenue stream from ONSOLIS® and milestone payments from a partnership around BEMA® Buprenorphine, and perhaps even thereafter, 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 June 30, 2011, we had cash of approximately $21.2 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 second quarter of 2012, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could affect our cash requirements.

Depending on the timing of our certain potential commercial partnerships or financings, 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. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make the raising of capital more difficult or impossible and may also result in a lower price for our shares.

We may have difficulty raising any needed additional capital.

We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of material revenues from sales, as well as the inherent business risks associated with our company and present and future market conditions. Our business currently only generates a small amount of revenue from 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 and have a second commercial partnership in place, given we plan to continue to expend substantial funds in the research, development and non-clinical and clinical testing of our drug delivery technologies and product candidates as well as on other strategic initiatives, we will likely require additional funds to conduct research and development, establish and conduct non-clinical and clinical trials, secure clinical and commercial-scale manufacturing arrangements and provide for marketing and distribution. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs, product launches or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are subject to numerous risks.

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

- the number of potential formulations, products and technologies in development;
- continued progress and cost of our research and development programs;

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progress with non-clinical studies and clinical trials;

time and costs involved in obtaining regulatory (including FDA) clearance;

costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;

costs of developing sales, marketing and distribution channels and our ability to sell our drug formulations or products;

costs involved in establishing manufacturing capabilities for commercial quantities of our drug formulations or products;

competing technological and market developments;

market acceptance of our drug formulations or products;

costs for recruiting and retaining employees and consultants;

costs for training physicians; and

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

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

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

The additional financings which we have undertaken and which we will likely in the future require, have and may be obtained through one or more transactions that have diluted or will dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. On July 21, 2011, 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 per share, from 45,000,000 to 75,000,000 shares. We are also authorized to issue 5 million shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

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

Because it contains the potent narcotic fentanyl, as part of its approval of ONSOLIS®, the FDA required that we and Meda put in place a detailed REMS. The REMS sets forth detailed procedures that seek to mitigate the risk of ONSOLIS® overdose, abuse, addiction and serious complications due to medication errors. These procedures have and will continue to place administrative burdens on our commercial partner Meda and potential prescribers of ONSOLIS®, which burdens could make it more difficult for Meda to market and sell ONSOLIS®. Meda s compliance with the REMS has led and could 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.

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Moreover, as of the date of this reoffer prospectus, a modified retail REMS program for ONSOLIS® remains under review by FDA. As of recently, retail REMS programs have been approved by FDA for competing products, including Actiq and Fentora (Cephalon). Until a retail REMS is approved for ONSOLIS®, the product will continue to be available solely through limited distribution from a single source supplier, which will continue to hamper the product s competitiveness in the marketplace. No assurances can be given that the modified retail REMS for ONSOLIS® will be approved.

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

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

The degree of market acceptance for our products and product candidates will depend upon a number of factors, including:

- receipt of regulatory clearance of marketing claims for the uses that we are developing;
- establishment and demonstration of the advantages, safety and efficacy of our formulations, products and technologies;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our proposed formulations or products;
- regulatory programs such as the REMS for ONSOLIS® or market (including competitive) forces that may make it more difficult for us to penetrate a particular market segment; and
- our, or our partners , ability to timely and effectively manufacture and market our products.

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

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

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

We have been and expect to be significantly dependent on our collaborative agreements for the development, 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 is our U.S. and European commercialization agreements with Meda and our manufacturing development and supply agreements with Aveva or LTS relating to ONSOLIS® and with LTS relating to BREAKYL (the brand name for ONSOLIS® in Europe) and BEMA® Buprenorphine. The loss of, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials and commercial sales. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation. This is particularly true with regard to our relationship with Meda, who is our worldwide (outside of Taiwan and South Korea) commercialization partner for our one approved product ONSOLIS®.

This 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. Any future manufacturing interruptions or related supply issues could have a material adverse effect on our company.

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

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

Our business exposes us to 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 for general liability and $3 million with a $3 million limit per occurrence 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;
- cease selling, making, importing, incorporating or using one or more or all of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our formulations or products, which would be costly and time-consuming.

With respect to our BEMA® delivery technology, the mucoadhesive erodible drug delivery device technology space is congested. There is a risk that a court of law in the United States or elsewhere could determine that ONSOLIS® or another of our BEMA® based products is in conflict with or covered by external patents. This risk presently exists in our litigation with MonoSol Rx, which was filed by MonoSol in November 2010, wherein MonoSol claims that our and our partners 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 partners 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.

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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 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.

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

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

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

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

Our ability to license, enforce and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others will be important to our commercializing any formulations or products under development. The current and future development of our drug delivery technologies is contingent upon whether we are able to maintain licenses and access patented technologies. Without these licenses, the use of technologies would be limited and the sales of our products could be prohibited. Therefore, any disruption in access to the technologies could substantially delay the development and sale of our products.

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

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

In addition, we may have to resort to costly and time consuming litigation to protect or enforce our rights under certain intellectual property, or to determine their scope, validity or enforceability. Enforcing or defending our rights will be expensive, could cause significant diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technologies to develop or sell competing products.

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

Key components of our drug delivery technologies, products and product candidates may be provided by sole or limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs. Certain components used in our research and development activities, such as the active pharmaceutical component of our products, are currently purchased from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

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

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

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

Our management s expertise is primarily in the research and development, formulation development and non-clinical and clinical trial phases of pharmaceutical product development. Our management s experience in the manufacturing of pharmaceutical products is more limited and we have limited equipment and no facilities of our own from which these activities could be performed. Therefore, we are dependent on third parties for our formulation development, manufacturing and the packaging of our products. This is particularly true with respect to Aveva, the primary manufacturer of our only approved product, ONSOLIS®. This reliance exposes us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to formulate sufficient product to conduct clinical trials and, subsequently, to launch and maintain the marketing of our products.

Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production, 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. 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) to engage in sales, marketing and distribution efforts around our products and product candidates. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors. If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, we will need to develop our own sales and marketing capabilities.

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

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

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

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

If we choose at some point to develop our own sales and marketing capability, including in connection with any exercise by us of our co-promotion rights with respect to ONSOLIS® under our agreements with Meda, we may be impeded in these efforts given that our experience in developing a fully integrated commercial organization is limited. If we choose to establish a fully integrated commercial organization, we will likely incur substantial expenses in developing, training and managing such an organization. We may be unable to build a fully integrated commercial organization on a cost effective basis, or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

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®, we may not receive regulatory approval of our other proposed products and formulations. We may be unable to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and viability.

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

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

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

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

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

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

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

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

Moreover, it is our stated intention to seek to avail ourselves of the FDA s 505(b)(2) approval procedure where it is appropriate to do so. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

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

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

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

We rely, in large part, on drug delivery technologies that we have purchased from third parties such as QLT with respect to our BEMA® technology, and the University of Medicine and Dentistry of New Jersey with respect to our Bioral® technology. Although we have purchased the BEMA® technology from QLT, we may be unable to fulfill our remaining payment obligations under such agreement. The loss of our key technologies would seriously impair our business and future viability, and could result in delays in developing, introducing or maintaining our products and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the technology we license could prevent the implementation or impair the functionality of our products or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

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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 marketed 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 FDA required for ONSOLIS®. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. Any such current or new regulations may be difficult and expensive for us and our manufacturing and commercial partners to comply with, may delay the introduction of our products, may adversely affect our net sales, if any, and may have a material adverse effect on our results of operations.

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

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in our marketed product ONSOLIS® and in our lead product 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.

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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 procurement quota in order to obtain these substances. The DEA may not establish procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides for public comment on the labeling, promotion, risk management plan and other documents associated with such product. A DEA review of such materials may result in potentially significant delays in obtaining procurement quota for controlled substances, a reduction in the quota issued to us or an elimination of our quota entirely. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or sales of products, which could have a material adverse effect on our business and results of operations.

Risks Related to Our Industry

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

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

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

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

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

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

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. All of our clinical trials have been, and all of our proposed clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have a general liability/product liability policy that includes coverage for our clinical trials, with an annual aggregate limit of $2 million per occurrence. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products and product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products. In addition, although third party partners like Meda are required to provide insurance in connection with specific products like ONSOLIS®, such partners may face similar insurance related risks.

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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.

Risks Related to Our Management and Affiliate Transactions

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

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

Additionally, we do not currently maintain key person life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

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

As of the date of this reoffer prospectus, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 24.53% of our outstanding common stock. These figures do not reflect any future potential exercise of common stock purchase warrants (including those issued to Laurus Master Fund, Ltd., CDC and others) into shares of common stock.

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

- approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets and material financing transactions;
- election of directors;

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adoption of or amendments to stock option plans;

amendment of charter documents; or

issuance of blank check preferred stock.

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

Dr. Frank O Donnell, who is the Chairman of our board of directors and also is a substantial beneficial owner of our securities through Hopkins Capital Group II, LLC, has a financial interest in a number of other companies which have business relationships with us. These companies include Accentia, RetinaPharma Technologies, Inc. and Biotechnology Specialty Partners, Inc. We have entered into license agreements with Accentia and RetinaPharma International, Inc. with regard to proposed products incorporating our Bioral® technology. We have entered into a non-exclusive distribution agreement with Biotechnology Specialty Partners, Inc. In addition, William Poole, a director of our company, is also a director of Accentia, and James A. McNulty, our Chief Financial Officer, is employed on a part-time basis by Accentia. These relationships and agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and such members of our management. The risks associated with potential conflicts of interests were evidenced recently in a settlement, announced in late December 2009, of a potential dispute between us and Accentia relating to the development of Emezine .

Risks Related to Our Common Stock

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.

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.

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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 reoffer prospectus, our shares are listed on the NASDAQ Capital Market. In the future, however, we may not be able to meet the listing maintenance requirements of the NASDAQ Capital Market and NASDAQ rules, which require, among other things, maintaining a minimum bid price per share, minimum stockholders equity of $2.5 million or a minimum market capitalization of $35 million and a majority of independent directors on our board of directors. We have been subject to delisting proceedings and comments by NASDAQ in the past. If we are unable to satisfy the NASDAQ criteria for maintaining listing, our securities could again be subject to delisting. Trading, if any, of our securities would thereafter be conducted in the over-the-counter market, in the so-called pink sheets or on the OTC Bulletin Board. As a consequence of any such delisting, our stockholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the prices of our securities.

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

As of June 30, 2011, there are 29,577,146 shares of common stock issued and 29,561,655 shares of common stock outstanding. On July 21, 2011, 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, 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 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 August 19, 2011: (i) 4,548,388 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) 4,197,801 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.63 per share. If and when these securities are exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

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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;
- eliminating the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent;
- 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 reoffer prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

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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.

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USE OF PROCEEDS

The shares which may be sold under this reoffer prospectus will be sold for the respective accounts of each of the selling stockholders listed herein (who are our executive officers and directors). Accordingly, we will not realize any proceeds from the sale of the shares of our common stock. We will receive proceeds from the exercise of the options; however, no assurance can be given as to when or if any or all of the options will be exercised. If any options are exercised, the proceeds derived therefrom will be used for working capital and general corporate purposes. All expenses of the registration of the shares will be paid by us. See Selling Stockholders and Plan of Distribution.

SELLING STOCKHOLDERS

This reoffer prospectus relates to the shares of our common stock that are being registered for reoffers and resales by selling stockholders who have acquired or may acquire shares pursuant to the 2001 Plan and 2011 Plan. Offers and sales by selling stockholders who are our affiliates (as such term is defined in Rule 405 under the Securities Act) are also covered by this prospectus.

The selling stockholders are our prior, current and future officers and directors (or any of their respective assigns) who have acquired or may acquire in the future shares of our common stock under the 2001 Plan and 2011 Plan. The selling stockholders may, from time to time, resell all, a portion or none of the shares of our common stock covered by this reoffer prospectus. There is no assurance that any of the selling stockholders will sell any or all of the shares offered by them under this reoffer prospectus. The address for each of the selling stockholders listed below is c/o BioDelivery Sciences International, Inc., 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina 27607.

Any changed information will be set forth in an amendment to the registration statement or supplement to this reoffer prospectus, to the extent required by law.

Name	Position, Office, or Other Material Relationship	Number of Shares Owned (1)	Number of Shares to be Offered for the Account of the Selling Stockholder (2)(3)	Number of Shares to be Owned After Offering	% Owned After Offering
Andrew L. Finn	(4)	766,413	349,812[5]	766,413	2.56%
James A. McNulty	(6)	43,159	438,855[7]	43,159	*
Francis E. O Donnell, Jr.	(8)	157,689	280,000[9]	157,689	*
William S. Poole	(10)	8,190	245,000[11]	8,190	*
John J. Shea	(12)	26,300	283,700[13]	26,300	*
Mark A. Sirgo	(14)	856,721	971,628[15]	856,721	2.81%
William B. Stone	(16)	35,000	400,000[17]	35,000	*
Benny Ward	(18)		88,320[19]		*

* Less than 1%

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(1) Represents common stock owned.
(2) Represents vested and unvested options.
(3) These shares constitute control securities as such term is defined in General Instruction C to Form S-8.
(4) Andrew L. Finn, Pharm.D., is our Executive Vice President of Product Development.
(5) Includes options to purchase 300,422 shares of common stock, all of which are currently exercisable. Includes options to purchase 49,390 shares of common stock which are not currently exercisable. All options have been granted under the 2001 Plan.
(6) James A. McNulty is our Secretary, Treasurer and Chief Financial Officer.
(7) Includes options to purchase 350,595 shares of our common stock, all of which are currently exercisable. Includes options to purchase 88,260 shares of common stock which are not currently exercisable. All options have been granted under the 2001 Plan.
(8) Francis E. O Donnell, Jr., M.D. is the Chairman of our Board of Directors.
(9) Includes options to purchase 280,000 shares of our common stock, all of which is currently exercisable. Of the 280,000 options, 247,500 and 32,500 have been granted under the 2001 Plan and 2011 Plan, respectively.
(10) William Poole is a member of our Board of Directors.
(11) Includes options to purchase 245,000 shares of our common stock, all of which are currently exercisable. Of the 245,000 options, 220,000 and 25,000 have been granted under the 2001 Plan and 2011 Plan, respectively.
(12) John J. Shea is a member of our Board of Directors.
(13) Includes options to purchase 283,700 shares of our common stock, all of which are currently exercisable. Of the 283,700 options, 258,700 and 25,000 have been granted under the 2001 Plan and 2011 Plan, respectively.
(14) Mark A. Sirgo, Pharm.D., is our President and Chief Executive Officer and a member of our Board of Directors.
(15) Includes options to purchase 865,125 shares of common stock, all of which are currently exercisable. Includes options to purchase 106,503 shares of common stock which are not currently exercisable. Of the total options, 946,628 and 25,000 have been granted under the 2001 Plan and 2011 Plan, respectively.
(16) William B. Stone is a member of our Board of Directors and our Lead Director.
(17) Includes options to purchase 400,000 shares of our common stock, all of which are currently exercisable. Of the 400,000 options, 360,000 and 40,000 have been granted under the 2001 Plan and 2011 Plan, respectively.
(18) Benny Ward is our Executive Vice President of Business and Strategic Development.
(19) Includes options to purchase 28,000 shares of common stock, all of which are currently exercisable. Includes options to purchase 60,320 shares of common stock which are not currently exercisable. All options have been granted under the 2001 Plan.

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PLAN OF DISTRIBUTION

In this section of the reoffer prospectus, the term selling stockholder means and includes:

- the persons identified in the table above as the selling stockholders; and
- any of the donees, pledgees, distributees, transferees or other successors in interest of the selling stockholders who may: (a) receive any of the shares of our common stock offered hereby after the date of this reoffer prospectus and (b) offer or sell those shares hereunder.

The shares of our common stock offered by this reoffer prospectus may be sold from time to time directly by the selling stockholders. Alternatively, the selling stockholders may from time to time offer such shares through underwriters, brokers, dealers, agents or other intermediaries. The selling stockholders as of the date of this reoffer prospectus have advised us that there were no underwriting or distribution arrangements entered into with respect to the common stock offered hereby. The distribution of the common stock by the selling stockholders may be effected: in one or more transactions that may take place on the Nasdaq Capital Market (including one or more block transaction) through customary brokerage channels, either through brokers acting as agents for the selling stockholders, or through market makers, dealers or underwriters acting as principals who may resell these shares on the Nasdaq Capital Market; in privately-negotiated sales; by a combination of such methods; or by other means. These transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at other negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling stockholders in connection with sales of our common stock.

The selling stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares of our common stock in the course of hedging the positions they assume with the selling stockholders. The selling stockholders also may sell shares short and redeliver the shares to close out such short positions. The selling stockholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of shares of our common stock. The broker-dealer may then resell or otherwise transfer such shares of common stock pursuant to this reoffer prospectus.

The selling stockholders also may lend or pledge shares of our common stock to a broker-dealer. The broker-dealer may sell the shares of common stock so lent, or upon a default the broker-dealer may sell the pledged shares of common stock pursuant to this reoffer prospectus. Any securities covered by this reoffer prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this reoffer prospectus.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares of common stock the selling stockholders.

Although the shares of common stock covered by this reoffer prospectus are not currently being underwritten, the selling stockholders or their underwriters, brokers, dealers or other agents or other intermediaries, if any, that may participate with the selling security holders in any offering or distribution of common stock may be deemed underwriters within the meaning of the Act and any profits realized or commissions received by them may be deemed underwriting compensation thereunder.

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Under applicable rules and regulations under the Exchange Act, any person engaged in a distribution of shares of the common stock offered hereby may not simultaneously engage in market making activities with respect to the common stock for a period of up to five days preceding such distribution. The selling stockholders will be subject to the applicable provisions of the Exchange Act and the rules and regulations promulgated thereunder, including without limitation Regulation M, which provisions may limit the timing of purchases and sales by the selling stockholders.

In order to comply with certain state securities or blue sky laws and regulations, if applicable, the common stock offered hereby will be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the common stock may not be sold unless they are registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained.

We will bear all costs, expenses and fees in connection with the registration of the common stock offered hereby. However, the selling stockholders will bear any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the shares of common stock offered pursuant to this reoffer prospectus. We have agreed to indemnify certain of the selling security holders against certain liabilities, including liabilities under the Act, or to contribute to payments to which any of those security holders may be required to make in respect thereof.

There can be no assurance that the selling stockholders will sell any or all of the securities offered by them hereby.

LEGAL MATTERS

The validity of the shares of our common stock being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP of New York, New York.

EXPERTS

The consolidated financial statements as of and for each of the two years in the period ended December 31, 2010, incorporated in this reoffer 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., our independent registered public accounting firm, as stated in their report incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

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 reoffer prospectus. This reoffer 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 reoffer prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as an exhibit to the registration statement, and these statements are hereby qualified in their entirety by reference to the contract or document. The registration statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission s Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and may also be obtained from the web site that the Securities and Exchange Commission maintains at http://www.sec.gov. You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission s public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

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DISCLOSURE OF COMMISSION POSITION ON

INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our certificate of incorporation, 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. However, insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

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

1. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2010, filed on March 11, 2011;
2. Our Current Report on Form 8-K, filed on March 16, 2011;
3. Our Current Report on Form 8-K, filed on March 21, 2011;
4. Our Current Report on Form 8-K, filed on April 5, 2011;
5. Our Current Report on Form 8-K, filed on May 13, 2011;
6. Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011, filed on May 13, 2011;
7. Our Current Report on Form 8-K/A, filed May 17, 2011;
8. Our Definitive Proxy Statement on Schedule 14A, filed June 6, 2011, and additional proxy materials filed on June 29, 2011;
9. Our Current Report on Form 8-K, filed June 3, 2011;
10. Our Current Report on Form 8-K, filed July 25, 2011;

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11. Our Current Report on Form 8-K, filed July 26, 2011;
12. Our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011, filed on August 15, 2011;
13. Our Current Report on Form 8-K, filed August 22, 2011;
14. 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
15. All documents that we filed with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this registration statement by reference and to be a part hereof from the date of filing of such documents.

All documents filed by the registrant after the date of filing the initial registration statement on Form S-3 of which this reoffer prospectus forms a part and prior to the effectiveness of such registration statement pursuant to Section 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 shall be deemed to be incorporated by reference into this reoffer prospectus and to be 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 reoffer prospectus (or in any other document that is subsequently filed with the Securities and Exchange Commission and incorporated by reference) modifies or is contrary to that previous statement. Any statement so modified or superseded will not be deemed part of this reoffer prospectus except as so modified or superseded.

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

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

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

BioDelivery Sciences International, Inc.

3,057,315 shares

Common Stock

REOFFER PROSPECTUS

August 24, 2011

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PART II

INFORMATION REQUIRED IN PROSPECTUS

Item 3. Incorporation of Documents by Reference

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

1. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2010, filed on March 11, 2011;
2. Our Current Report on Form 8-K, filed on March 16, 2011;
3. Our Current Report on Form 8-K, filed on March 21, 2011;
4. Our Current Report on Form 8-K, filed on April 5, 2011;
5. Our Current Report on Form 8-K, filed on May 13, 2011;
6. Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011, filed on May 13, 2011;
7. Our Current Report on Form 8-K/A, filed May 17, 2011;
8. Our Definitive Proxy Statement on Schedule 14A, filed June 6, 2011, and additional proxy materials filed on June 29, 2011;
9. Our Current Report on Form 8-K, filed June 3, 2011;
10. Our Current Report on Form 8-K, filed July 25, 2011;
11. Our Current Report on Form 8-K, filed July 26, 2011;
12. Our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011, filed on August 15, 2011;
13. Our Current Report on Form 8-K, filed August 22, 2011;
14. 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
15. All documents that we filed with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this registration statement by reference and to be a part hereof from the date of filing of such documents.

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

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

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

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

Item 4. Description of Securities

Included in the prospectus which is part of this registration statement.

Item 5. Interests of Named Experts and Counsel.

N/A.

Item 6. Indemnification of Officers and Directors.

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.

Item 7. Exemption from Registration Claimed.

All shares of common stock registered hereunder for reoffer or resale will be issued upon exercise of options granted or to be granted pursuant to the Plans. The options are non-transferable and the underlying shares will be issued in transactions not involving a public offering. Upon exercise of an option, the optionee is required to execute an undertaking not to resell such shares except pursuant to an effective registration statement or other exemption under the Securities Act, a restrictive legend is placed on the certificates for the shares of common stock purchased and transfer stops are placed against such certificates. Such shares may only be reoffered and sold pursuant to registration under the Act or pursuant to an applicable exemption under the Act. As a result, such offers and sales are exempt from the registration requirements of the Act pursuant to the provisions of Section 4(2) of the Act.

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Item 8. Exhibits.
The following exhibits are filed with this Registration statement.

Number	Description
4.1	Registrant s Amended and Restated 2001 Stock Incentive Plan(1)
4.2	Registrant s 2011 Equity Incentive Plan(2)
5.1	Opinion of Ellenoff Grossman & Schole LLP*
23.1	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.1)*
23.2	Consent of Cherry, Bekaert & Holland, L.L.P.*

(1) Filed as part of the Company s Form SB-2, Amendment No. 2, February 1, 2002.
(2) Filed as part of the Company s 2011 Schedule 14A, July 13, 2011
* Filed herewith.

Item 9. Undertakings.
(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement.

(i) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.

(5) That every prospectus (i) that is filed pursuant to paragraph (4) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act of 1933 and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) To respond to requests for information that is incorporated by reference into the joint proxy statement/prospectus pursuant to Item 4, 10(b), 11 or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

(8) To supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Raleigh, State of North Carolina, on August 24, 2011.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer

BioDelivery Sciences International, Inc. and each of the undersigned do hereby appoint Mark A. Sirgo and James A. McNulty and each of them severally, its or his true and lawful attorney to execute on behalf of BioDelivery Sciences International, Inc. and the undersigned any and all amendments to this Registration Statement on Form S-8 and to file the same with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission; each of such persons shall have the power to act hereunder with or without the other.

In accordance with the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates stated.

Person	Capacity	**Date**
/s/ Francis E. O Donnell, Jr. Francis E. O Donnell, Jr.	Chairman of the Board and Director	August 24, 2011
/s/ Mark A. Sirgo Mark A. Sirgo	President and Chief Executive Officer (Principal Executive Officer)	August 24, 2011
/s/ James A. McNulty James A. McNulty	Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)	August 24, 2011
/s/ Raphael J. Mannino Raphael J. Mannino	Executive Vice President, Chief Scientific Officer and Director	August 24, 2011
/s/ William B. Stone William B. Stone	Director	August 24, 2011
/s/ John J. Shea John J. Shea	Director	August 24, 2011
/s/ William S. Poole William S. Poole	Director	August 24, 2011