BIODELIVERY SCIENCES INTERNATIONAL INC
Form S-8
August 12, 2015
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As filed with the Securities and Exchange Commission on August 12, 2015

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.)**

4131 ParkLake Ave., Suite #225

Raleigh, NC	**27612**
(Address of principal executive offices)	**(Zip Code)**

BioDelivery Sciences International, Inc. Amended and Restated 2001 Incentive Plan (as amended)

BioDelivery Sciences International, Inc. 2011 Equity Incentive Plan (as amended)

(Full title of plan)

Mark A. Sirgo, Pharm.D.

President and Chief Executive Officer

BioDelivery Sciences International, Inc.

4131 ParkLake Ave., Suite #225

Raleigh, North Carolina 27612

(919) 582-9050

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

Copies to:

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

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 2011 Equity Incentive Plan	4,722,860	$7.41	$34,996,392.60	$4,066.58
Total	**4,722,860**		**$34,996,392.60**	**$4,066.58**

(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) This calculation is made solely for the purpose of determining the registration fee pursuant to Rule 457(c) under the Securities Act based on the 5 day average of the high and low prices of the registrant s common stock on the NASDAQ Capital Market ending on August 10, 2015.

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Explanatory Note

This Registration Statement on Form S-8 of BioDelivery Sciences International, Inc. has been prepared in accordance with General Instruction E 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 4,722,860 shares of our common stock, par value $.001 per share, issuable pursuant to our 2011 Equity Incentive Plan (as amended and approved by our stockholders on July 16, 2015, and which we refer to herein as the 2011 Plan), of which 2,733,105 shares underlying options or restricted stock units were granted to certain of our officers and directors under the 2011 Plan from February 2014 through August 2015. Shares of our common stock underlying options or restricted stock units granted pursuant to our Amended and Restated 2001 Incentive Plan (which we refer to as the 2001 Plan) and the 2011 Plan were previously registered Form S-8 (No. 333-190796, filed on August 9, 2013, and which we refer to as the 2013 S-8); and

- Update the reoffer prospectus included in the 2013 S-8 and that forms a part of this Registration Statement relating to the resale of control securities and/or restricted securities that have been or will be acquired under the 2001 Plan and the 2011 Plan by certain of our officers and directors, who are the selling stockholders identified in the reoffer prospectus.

The reoffer prospectus contained herein has been prepared in accordance with the requirements of General Instruction C of Form S-8 and Part I of Form S-3. The 7,795,386 shares included in the reoffer prospectus are the number of shares of our common stock underlying options or restricted stock units that have been or may be acquired by the selling stockholders under the 2001 Plan and the 2011 Plan.

Accordingly: (i) the reoffer prospectus included herein is a combined prospectus with the reoffer prospectus included as part of the 2013 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 2013 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

7,795,386 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, as amended (which we refer to as the 2011 Plan).

The selling stockholders listed herein (which include the executive officers and directors of our company) are offering and selling up to 7,795,386 shares that have been or may hereafter be acquired by such selling stockholders upon the exercise of options to purchase our common stock that were granted to such selling stockholders under the 2001 Plan and the 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 2001 Plan and the 2011 Plan.

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 the Nasdaq Capital Market under the symbol BDSI . On August 10, 2015, the closing sales price for the common stock on the Nasdaq Capital Market was $7.05 per share.

Our principal executive offices are located at 4131 ParkLake Ave, Suite #225, Raleigh, NC 27612. Our telephone number is 919 582 9050.

Investing in our common stock involves a high degree of risk. You should read the Risk Factors section beginning on page 8 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 12, 2015.

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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 reoffer 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 reoffer prospectus, including the documents referred to or incorporated by reference in this reoffer prospectus or statements of our management referring to or summarizing the contents of this reoffer 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 th 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 our research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® drug delivery technology platform and any of our approved products or product candidates;

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

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

- our ability, or the ability of our commercial partners to actually develop, commercialize, manufacture or distribute our products and product candidates, including BUNAVAIL®, which is the first product we are self-commercializing;

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

- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;

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

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

the outcome of ongoing or potential future litigation (and related activities, including inter-partes reviews and inter-partes reexaminations) or other claims or disputes relating to our business, technologies, products or processes;

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

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

our ability to retain members of our management team and our employees; and

competition existing today or that will likely arise in the future.

The foregoing does not represent an exhaustive list of 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 anticipated in our forward-looking statements. Please see Risk Factors for additional risks which could adversely impact our business and financial performance.

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

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 approved 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 addiction. We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002.

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

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we have licensed, and will continue to seek to acquire or license, additional drug delivery technologies or drugs utilizing the delivery or other technologies of other companies. Clonidine Topical Gel, which we licensed from Arcion Therapeutics (or Arcion) in 2013, and our 2015 agreement with Evonik Corporation (or Evonik) to develop a buprenorphine depot injection formulation, do not utilize the BEMA® technology and allowed us to diversify our portfolio while maintaining a focus in pain and addiction. As we gain access to such technologies, we seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace.

Our current development strategy focuses primarily on our ability to utilize the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into our drug delivery technology. 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.

An overview of our approved products and key products in development or awaiting approval is set out below:

BELBUCA (BEMA® Buprenorphine) for Chronic Pain

BELBUCA is a partial mu-opioid agonist and a potential treatment for the management of pain severe enough to require daily, around the clock, long-term opioid treatment for which alternative treatment options are inadequate. As

described further below, our commercial partner for this product has filed a New Drug Application (or NDA) with the FDA for BELBUCA and we are awaiting the outcome of the FDA s review.

In January 2012, we announced the signing of a worldwide licensing and development agreement for BELBUCA (which we refer to herein as the Endo Agreement) with Endo Pharmaceuticals, Inc. (or Endo) under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BELBUCA for the

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treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront, non-refundable license fee, which we received in January 2012; (ii) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events (some of which we have received); (iii) $55 million in potential sales threshold payments upon achievement of designated sales levels; and (iv) a tiered, mid- to upper-teen royalty on net sales of BELBUCA in the United States and a mid- to high-single digit royalty on net sales of BELBUCA outside the United States. Endo is one of the premier companies in the area of pain management and has demonstrated significant achievements in the pain space, particularly with the development, launch and commercialization of a portfolio of pain therapeutics including Opana ® ER, Lidoderm ® and Voltaren ® Gel. We believe BELBUCA is an excellent fit with Endo s pain portfolio and will, if approved, add a Schedule III opioid to their branded pain franchise. BELBUCA would complement Endo s pain therapeutics portfolio providing the company with an opportunity to offer a ladder of pain products, aligned with pain severity and opioid scheduling. In particular, BELBUCA would potentially be aligned with the needs of pain specialists and primary care physicians who seek an alternative to Schedule II opioids for the treatment of moderate to severe chronic pain that is not adequately controlled with commonly prescribed first-line therapies (e.g., NSAIDs).

One of the key intellectual property milestones under our Endo Agreement was achieved in February 2012, when the U.S. Patent and Trademark Office (or USPTO) issued a Notice of Allowance regarding one of our patent applications (No. 13/184306) which, once the patent was granted in April 2012, extended the exclusivity of the BEMA® drug delivery technology for BELBUCA (as well as BUNAVAIL®, as discussed below) from 2020 to 2027. As a result, we received a milestone payment from Endo in the amount of $15 million in May 2012, and also related to the issuance of the patent, will receive an additional milestone payment of $20 million at the time of approval of a NDA by the FDA for BELBUCA for the treatment of chronic pain. Such amounts are included in the aforementioned $95 million in potential milestone payments based on intellectual property and clinical development and regulatory events.

In May 2012, in close collaboration with Endo, we initiated two Phase 3 clinical studies one in opioid naïve and one in opioid experienced populations. The Phase 3 clinical trials were enriched-enrollment, double-blind, randomized withdrawal studies to evaluate the efficacy and safety of BELBUCA in the treatment of chronic lower back pain in opioid naive and opioid experienced populations. Patients titrated to a well-tolerated, effective dose were randomized to either continue on that dose of BELBUCA , or receive placebo (BEMA® film with no active drug), with treatment continuing for 12 weeks. The primary efficacy endpoint was the mean change in the daily average pain numerical rating scale (NRS-Pain) scores from baseline (just prior to randomization) to week twelve of the double-blind treatment period. Pain was self-reported daily on an 11-point numeric rating scale (daily NRS; 0=no pain, 10=worst possible pain).

Interim analyses were conducted as part of the Phase 3 protocol in both the opioid naïve and opioid experienced studies to allow for adjustments to the sample size in order to maintain appropriate study power to detect statistically significant differences between BELBUCA and placebo. The analyses were conducted by an independent biostatistician. We and Endo announced in September 2013 that, as a result of the interim analyses, no sample size adjustment would be necessary to the opioid naïve study and that additional patients would be added to the ongoing opioid experienced study. The outcomes of the interim analyses were significant because they utilized actual study data to confirm or adjust sample sizes, and importantly, maintain probability of a successful outcome.

On January 23, 2014, we announced with Endo positive top-line results from the Phase 3 efficacy study of BELBUCA in opioid- naïve subjects. The trial successfully met its primary efficacy endpoint in demonstrating that BELBUCA resulted in significantly ($p<0.005$) improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BELBUCA compared to placebo. The most commonly reported adverse events in patients treated with BELBUCA compared to placebo were nausea (10% vs. 8%, respectively), vomiting (4% vs. 2%, respectively) and constipation (4% vs. 2%, respectively). The locking of the database for the opioid naïve study

triggered a $10 million milestone payment from Endo per the terms of the license agreement, which we received in February 2014.

On July 7, 2014, we announced with Endo positive top-line results from the Phase 3 efficacy study of BELBUCA in opioid- experienced subjects. The trial successfully met its primary efficacy endpoint in demonstrating that BELBUCA resulted in significantly ($p<0.0001$) improved chronic pain relief compared to

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placebo. Additional secondary endpoints were supportive of the efficacy of BELBUCA compared to placebo. The most commonly reported adverse events in patients treated with BELBUCA compared to placebo were nausea (7.5% vs. 7.4%, respectively) and vomiting (5.5% vs. 2.3%, respectively). Locking of the database for the opioid experienced study triggered an additional $10 million milestone payment from Endo per the terms of the license agreement, which we received July 2014.

On December 23, 2014, we and Endo announced the NDA submission for BELBUCA , which was accepted by FDA in February 2015. Acceptance of the filing of the NDA by FDA triggered an additional $10 million milestone payment from Endo, to be received within 60 days of acceptance (received March 2015). BELBUCA is subject to a ten month FDA review, which could result in an approval in the fourth quarter of 2015 and allow for product launch in early 2016.

BUNAVAIL® (buprenorphine and naloxone) buccal film

We believe that the widespread use of buprenorphine for the treatment of opioid dependence and the need for improved means of delivery to address existing administration challenges present an additional commercial opportunity. Therefore, we developed a BEMA® formulation of buprenorphine and naloxone specifically for the treatment of opioid dependence. The product combines a high dose of buprenorphine along with an abuse deterrent agent, naloxone. BUNAVAIL ® provides us with an opportunity to compete in the growing opioid dependence market which, according to Symphony Health, approached $1.8 billion in sales in the U.S in 2014.

In September 2012, we announced the positive outcome of the pivotal pharmacokinetic study comparing BUNAVAIL® to Suboxone ® sublingual tablets. The study was designed to compare the relative bioavailability of buprenorphine and naloxone between BUNAVAIL ® and the reference product, Suboxone ® tablets. The results demonstrated that the two key pharmacokinetic parameters, maximum drug plasma concentration (Cmax) and total drug exposure (AUC), for buprenorphine were comparable to Suboxone ® sublingual tablet, and that the same parameters for naloxone were similar or less than Suboxone ® tablet. This was followed by initiation of the safety study requested by FDA, assessing the safety and tolerability of BUNAVAIL ® in patients converted from a stable dose of Suboxone ® (buprenorphine/naloxone) sublingual tablets or films. A total of 249 patients were enrolled in the study, (191 patients completed) which completed in December 2012. Results of the study showed a very favorable safety and tolerability profile along with strong study subject retention and high dose form acceptability ratings. Data showed that over 91% of patients who switched from Suboxone ® film or tablets considered the taste of BUNAVAIL ® to be very pleasant, pleasant or neutral and over 82% rated the ease of use of BUNAVAIL® as very easy, easy or neutral. The study also showed a decrease in the incidence of constipation symptoms from 41% at baseline, before conversion of patients from Suboxone tablets or films to BUNAVAIL ®, to 13% following 12 weeks of treatment with BUNAVAIL ®.

On July 31, 2013, we submitted the NDA for BUNAVAIL® to the FDA for review, and on June 6, 2014, we announced the FDA approval of BUNAVAIL for the maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support.

Following thorough review and analysis of a variety of commercialization strategies, which included entertaining commercial partnerships, a decision was made to commercialize BUNAVAIL ® utilizing both internal and external resources. In March 2014, we announced we had entered into an agreement with Quintiles to support the launch and commercialization of BUNAVAIL ®. Under terms of the agreement, Quintiles provides a range of services to support the commercialization of BUNAVAIL ® in the U.S., including recruiting and training a field sales force. Separately, we entered into an agreement with Ashfield Market Access to provide managed markets and trade support for BUNAVAIL ®. Ashfield Market Access, which is led by industry veterans including those who led GlaxoSmithKline s

managed markets group for more than 20 years, took responsibility for executing a payer strategy aimed at maximizing patient access to BUNAVAIL ®.

On November 3, 2014, we announced the availability of BUNAVAIL® in the U.S. where it is being supported by a 60-person field sales force and a full marketing effort targeting the nearly 5,000 physicians who are responsible for approximately 90% of prescriptions for buprenorphine products for the treatment of opioid dependence, according to Symphony Health.

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ONSOLIS® (fentanyl buccal soluble film)

On July 16, 2009, we announced the U.S. approval of our first product, ONSOLIS® (fentanyl buccal soluble film). ONSOLIS ® is indicated for the treatment of breakthrough pain (i.e., pain that breaks through the effects of other medications being used to control persistent pain) in opioid tolerant patients with cancer. In May 2010, regulatory approvals were granted for Canada, and in October 2010, approval was obtained in the European Union (which we refer to herein as E.U.) through the E.U. s Decentralized Procedure, with Germany acting as the reference member state. ONSOLIS ® is marketed in Europe under the trade-name BREAKYL .

The FDA approval of ONSOLIS®, together with our satisfactory preparation of launch supplies of ONSOLIS®, triggered the payment to us by our commercial partner, Meda AB, a leading international specialty pharmaceutical company based in Sweden (which we refer to herein as Meda), of approval milestones aggregating $26.8 million. The first national approval of BREAKYL in the E.U. resulted in a milestone payment of $2.5 million from Meda. A second milestone payment of $2.5 million was subsequently realized at the time of first commercial sale in the E.U. in October 2012. We began receiving royalties from Meda on net sales of ONSOLIS ® in the U.S. and Canada following launch and from BREAKYL following launch in the E.U. Our royalty revenue from this product remains below original projections due to certain regulatory conditions in the U.S., which are discussed below.

We 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 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 Co., Ltd. (or Kunwha), for South Korea and TTY Biopharm Co., Ltd. (or TTY) for Taiwan where the product will be marketed as PAINKYL .

Although we have generated licensing-related and other revenue to date from the commercial sales of an approved product ONSOLIS® /BREAKYL such revenue has been minimal to date due to multiple factors, including a highly restrictive Risk Evaluation and Mitigation Strategy (REMS) imposed by the FDA and certain formulation issues described below. The lack of approved REMS programs for our direct competitors resulted in an un-level playing field, which created an unfavorable selling environment for ONSOLIS ® into 2012. In the E.U., BREAKYL began to be launched on a country by country basis starting in the fourth quarter of 2012.

On December 29, 2011, the FDA approved a class-wide REMS program covering all transmucosal fentanyl products under a single risk management program. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The TIRF REMS program was implemented in March 2012. The approved program covers all marketed transmucosal fentanyl products under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. One common program also ended the disparity in prescribing requirements for ONSOLIS ® compared to similar products and provided ONSOLIS ® with the opportunity for retail and inpatient facility access.

On March 12, 2012, we announced the postponement of the U.S. re-launch of ONSOLIS® following the initiation of the class-wide REMS until the product formulation could be modified to address two appearance-related issues. Such appearance-related issues involved the formation of microscopic crystals and a fading of the color in the mucoadhesive layer, raised by the FDA during an inspection of our North American manufacturing partner for

ONSOLIS ®, Aveva Drug Delivery Systems, Inc. (or Aveva). While the appearance issues do not affect the product s underlying integrity, safety or performance, the FDA believes that the fading of the color in particular may potentially confuse patients, necessitating a modification of the product and its specification before it can be manufactured and distributed. The source of microcrystal formation and the potential for fading of ONSOLIS ® was found to be specific to a buffer used in its formulation. We modified the formulation and as of the date of this prospectus have 12 months of stability data on the reformulated product that shows no signs of microcrystal formation or color changes.

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On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Meda to return to us the marketing authorization for ONSOLIS ® for the U.S. and the right to seek marketing authorizations for ONSOLIS ® in Canada and Mexico. Following return of the US marketing authorization from Meda, we submitted a prior approval supplement for the new formulation to the FDA in March 2015 that provided responses to earlier questions and requests. The FDA s review of the application may take up to 6 months; therefore, it is possible to have a decision before the end of 2015.

Clonidine Topical Gel

In March 2013, we announced our entry into a worldwide Exclusive License Agreement (which we refer to as the Arcion Agreement) with privately held Arcion, under which we will develop and commercialize Clonidine Topical Gel (formerly ARC4558) for the treatment of painful diabetic neuropathy (or PDN) and potentially other indications. Under the terms of the agreement, we made an upfront payment of $2 million to Arcion in the form of unregistered shares of our common stock. Additional financial terms of the licensing agreement include a milestone payment to Arcion of $2.5 million in unregistered shares of our common stock upon acceptance by the FDA of a NDA for Clonidine Topical Gel and a cash payment to Arcion of between $17.5 and $35 million upon NDA approval, depending on certain regulatory and commercial considerations. In addition, the licensing agreement includes sales milestones and low single-digit royalties on net worldwide sales.

We believe that the PDN market is highly under-served by existing products and therefore there is a strong scientific rationale for developing a topical treatment for PDN that delivers analgesia in a way that avoids systemic side effects. Evidence has shown that clonidine stimulates an inhibitory receptor in the skin associated with pain fibers. Arcion has assessed its effectiveness in reducing pain in PDN in a double-blind, placebo-controlled, Phase 2 study where the primary study endpoint was the change in pain intensity over a 3 month treatment period in diabetic foot pain. A significant treatment difference was seen in the planned subset analysis of diabetic patients who had documented evidence of functioning pain receptors in the skin of the lower leg (p=0.01, n=63) thus, at a minimum, supporting the effectiveness of topical clonidine in diabetic patients with functioning pain receptors of the skin. In the overall population that included patients without functioning nerve receptors , there was a trend favoring topical Clonidine Topical Gel (p=0.07, n= 182), though the overall results did not reach statistical significance. Oral medications that are approved for the treatment of PDN include anticonvulsants such as Lyrica (pregabalin), the antidepressant Cymbalta ® (duloxetine) and the opioid Nucynta ® ER (tapentadol ER), with sales for the treatment of neuropathic pain totaling over $3 billion in the U.S. according to Datamonitor. These treatments are modestly effective in relieving symptoms and their use can be limited by adverse effects and drug interactions.

On March 30, 2015, we announced that the primary efficacy endpoint in its initial Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance. Analyses of the trial results indicated significant differences in patient response between centers and among patient subpopulations. Based on review of these analyses with statistical and clinical consultants, we have elected to initiate an additional placebo-controlled study with entry criteria and design features that attempt to control for the challenges of assay sensitivity and accuracy of pain assessment in diabetic patients with neuropathic pain. The additional study is planned to start in fourth quarter of 2015. We will be discussing the design of this study with the European Medicines Agency to assess its adequacy as the single study required for EU submission.

Buprenorphine Depot Injection

In 2014, we entered into an exclusive agreement with Evonik to develop and commercialize a proprietary, injectable microparticle formulation of buprenorphine potentially capable of providing 30 days of continuous therapy following a single subcutaneous injection. Microsphere-based, long acting, buprenorphine injectable depot has the ability to

change the treatment paradigm in opioid dependence. Such a dosage form has the opportunity to improve therapy compliance through continuous delivery of drug for up to 30 days and addresses challenges regarding patient adherence to long-term buprenorphine treatment, which is critical to successfully manage opioid dependence and the potential for misuse and diversion.

While we plan to pursue an indication for the maintenance treatment of opioid dependence, we have also secured the rights and plans to develop a product for the treatment of chronic pain in patients requiring continuous

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opioid therapy. As part of the agreement, we will have the right to license the product(s) following the attainment of Phase 1 ready formulations. At that point, Evonik could receive downstream payments for milestones related to regulatory filings and subsequent NDA approvals as well as product royalties. Evonik has the exclusive rights to develop the formulation and manufacture the product(s).

We plan to submit an Investigational New Drug application (or IND) for this product candidate to FDA in the second half of 2015.

Additional Information

From our inception through June 30, 2015, we have recorded accumulated losses totaling approximately $232.9 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 intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- commercializing our approved products such as BUNAVAIL®;
- partnering with other pharmaceutical companies such as Meda and Endo to assist in the distribution of our products like ONSOLIS® and BELBUCA , for which we would expect to receive an upfront payment, milestones and royalty payments; and
- securing proceeds from public and private financings and other strategic transactions.

We have based our estimates of development costs, market size estimates, peak annual sales projections and similar matters described below and elsewhere in this prospectus on our market research, third party reports and publicly available information which we consider reliable. However, readers are advised that the projected dates for filing and approval of our INDs or NDAs with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding BUNAVAIL ® , ONSOLIS ® , BELBUCA , Clonidine Topical Gel, Buprenorphine Depot Injection or any other product candidates discussed below and elsewhere in this prospectus and any accompanying prospectus supplement 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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The Offering

Outstanding Common Stock	52,461,435 shares of our common stock are outstanding as of August 12, 2015.
Common Stock Offered	Up to 7,795,386 shares of common stock for sale by the selling stockholders (which include 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 9.
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

We have included discussions of the risks, uncertainties and assumptions under the heading Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2014 (as updated in our subsequently filed Quarterly Reports on Form 10-Q), which risk factors are incorporated by reference into this reoffer prospectus. See Where You Can Find More Information for an explanation of how to get a copy of this report.

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should carefully consider the risk factors we describe herein and in any document incorporated herein by reference, including our Annual Report on Form 10-K for the year ended December 31, 2014, or any Annual Report on Form 10-K or Quarterly Report on Form 10-Q that is incorporated by reference into this reoffer prospectus after the date of this reoffer prospectus. Although we discuss key risks in those risk factor descriptions, additional risks not currently known to us or that we currently deem immaterial also may impair our business. Our subsequent filings with the SEC may contain amended and updated discussions of significant risks. We cannot predict future risks or estimate the extent to which they may affect our financial performance.

Please also read carefully the section above entitled Cautionary Note Regarding Forward-Looking Statements.

DIVIDENDS

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

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.

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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 reoffer 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., 4131 ParkLake Ave, Suite 225, Raleigh, North Carolina 27612.

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)(5)	626,745	325,426	626,745	1.19%
Ernest R. De Paolantonio	(6)(7)	7,733	55,659	7,733	*
Francis E. O Donnell, Jr.	(8)(9)	151,228	220,000	151,228	*
Charles J. Bramlage	(10)	1,800		1,800	*
John J. Shea	(11)(12)	33,305	12,500	33,305	*
Mark A. Sirgo	(13)(14)	1,069,119	987,604	1,069,119	2.04%
William B. Stone	(15)(16)	79,175	215,000	79,175	*
Thomas W. D Alonzo	(17)(18)	51,851	65,000	51,851	*
Samuel P. Sears	(19)(20)	27,000	17,363	27,000	*
Barry I. Feinberg	(21)(22)	36,000		36,000	*

* Less than 1%
(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 325,426 shares of common stock, all of which are currently exercisable. Of the total options, 276,133 and 49,293 have been granted under the 2001 Plan and 2011 Plan, respectively.

(6) Ernest R. De Paolantonio is our Secretary, Treasurer and Chief Financial Officer.
(7) Includes options to purchase 18,553 shares of our common stock, all of which are currently exercisable. Includes options to purchase 37,106 shares of common stock which are not currently exercisable. Of the total options, all 55,659 have been granted under the 2011 Plan.
(8) Francis E. O Donnell, Jr., M.D. is our Executive Chairman.
(9) Includes options to purchase 220,000 shares of our common stock, all of which is currently exercisable. Of the total options, 177,500 and 42,500 have been granted under the 2001 Plan and 2011 Plan, respectively.
(10) Charles J. Bramlage is a member of our Board of Directors.
(11) John J. Shea is a member of our Board of Directors.

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(12) Includes options to purchase 12,500 shares of our common stock, all of which are currently exercisable. Of the total options, all 12,500 have been granted under the 2011 Plan.
(13) Mark A. Sirgo, Pharm.D., is our President and Chief Executive Officer and a member of our Board of Directors.
(14) Includes 2,480 shares owned by Dr. Sirgo s spouse. Includes options to purchase 987,604 shares of common stock, all of which are currently exercisable. Of the total options, 884,157 and 103,447 have been granted under the 2001 Plan and 2011 Plan, respectively.
(15) William B. Stone is a member of our Board of Directors and our Lead Director.
(16) Includes options to purchase 215,000 shares of our common stock, all of which are currently exercisable. Of the total options, 155,000 and 60,000 have been granted under the 2001 Plan and 2011 Plan, respectively.
(17) Thomas W. D Alonzo is a member of our Board of Directors.
(18) Includes options to purchase 65,000 shares of our common stock, all of which are currently exercisable. All options have been granted under the 2001 Plan.
(19) Samuel P. Sears is a member of our Board of Directors.
(20) Includes options to purchase 17,363 shares of our common stock, all of which are currently exercisable. All Options have been granted under the 2011 Plan.
(21) Barry I. Feinberg is a member of our Board of Directors.
(22) Includes 31,000 shares held in the Joint Revocable Living Trust and 5,000 shares held in the BIF Family Trust.

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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 those persons referenced above 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 of 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.

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.

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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 financial statements of BioDelivery Sciences International, Inc. as of December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014 appearing in our Annual Report on Form 10-K and the effectiveness of our internal control over financial reporting as of December 31, 2014 have been audited by Cherry Bekaert LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm 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:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the SEC on March 16, 2015;

Our Definitive Proxy Statement on Schedule 14(a), as filed with the SEC on June 5, 2015;

Our Current Reports on Form 8-K, as filed with the SEC on January 28, 2015, February 23, 2015, March 17, 2015, March 30, 2015, May 11, 2015, May 28, 2015, June 4, 2015, July 16, 2015 and August 10, 2015;

Our Quarterly Reports on Form 10-Q, as filed with the SEC on May 11, 2015 and August 10, 2015;

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

All documents filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and before the termination or completion of this offering of common stock shall

be deemed to be incorporated by reference in this prospectus supplement and to be a part of it from the filing dates of such documents, except in each case for information contained in any such filing where we indicate that such information is being furnished and is not to be considered filed under the Securities Exchange Act of 1934, as amended.

All documents filed by the registrant after the date of filing the initial registration statement on Form S-8 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.

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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., 4131 ParkLake Avenue, Suite 225, Raleigh, North Carolina 27612, Attention: Ernest R. De Paolantonio.

You should rely only on the information incorporated by reference or provided in this reoffer prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this reoffer prospectus 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.

7,795,386 shares

Common Stock

REOFFER PROSPECTUS

August 12, 2015

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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:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the SEC on March 16, 2015;

Our Definitive Proxy Statement on Schedule 14(a), as filed with the SEC on June 5, 2015;

Our Current Reports on Form 8-K, as filed with the SEC on January 28, 2015, February 23, 2015, March 17, 2015, March 30, 2015, May 11, 2015, May 28, 2015, June 4, 2015, July 16, 2015 and August 10, 2015;

Our Quarterly Reports on Form 10-Q, as filed with the SEC on May 11, 2015 and August 10, 2015;

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

All documents filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and before the termination or completion of this offering of common stock shall be deemed to be incorporated by reference in this prospectus supplement and to be a part of it from the filing dates of such documents, except in each case for information contained in any such filing where we indicate that such information is being furnished and is not to be considered filed under the Securities Exchange Act of 1934, as amended.

Item 4. Description of Securities

N/A

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 2011 Plan. 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

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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.

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)
4.3	Amendment No. 1 to Registrant s 2011 Equity Incentive Plan(3)
4.4	Amendment No. 2 to Registrant s 2011 Equity Incentive Plan(4)
4.5	Amendment No. 3 to Registrant s 2011 Equity Incentive Plan(5)
5.1	Opinion of Ellenoff Grossman & Schole LLP (6)
5.2	Opinion of Ellenoff Grossman & Schole LLP(7)
5.3	Opinion of Ellenoff Grossman & Schole LLP*
23.1	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.3)*
23.2	Consent of Cherry Bekaert LLP*

(1) Filed as part of the Registrant s Form SB-2, Amendment No. 2, February 1, 2002.
(2) Filed as part of the Registrant s 2011 Schedule 14A, June 13, 2011.
(3) Filed as part of the Registrant s 2013 Schedule 14A, June 12, 2013.
(4) Filed as part of the Registrant s 2014 Schedule 14A, June 10, 2014.
(5) Filed as part of the Registrant s 2015 Schedule 14A, June 5, 2015.
(6) Filed as part of the Company s Registration Statement on Form S-8, filed with the SEC on August 24, 2011.
(7) Filed as part of the Company s Registration Statement on Form S-8, filed with the SEC on August 23, 2013
* 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

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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.

(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 12, 2015.

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 Ernest R. De Paolantonio 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 (including post-effective 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.	Executive Chairman	August 12, 2015
/s/ Mark A. Sirgo Mark A. Sirgo	President and Chief Executive Officer (Principal Executive Officer)	August 12, 2015
/s/ Ernest R. De Paolantonio Ernest R. De Paolantonio	Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	August 12, 2015
/s/ William B. Stone William B. Stone	Lead Director	August 12, 2015
/s/ John J. Shea	Director	August 12, 2015

John J. Shea		
/s/ Samuel P. Sears, Jr.	Director	August 12, 2015
Samuel P. Sears, Jr.		
/s/ Thomas W. D Alonzo	Director	August 12, 2015
Thomas W. D Alonzo		
/s/ Charles J. Bramlage	Director	August 12, 2015
Charles J. Bramlage		
/s/ Barry I. Feinberg, M.D	Director	August 12, 2015
Barry I. Feinberg, M.D.		