

BIODELIVERY SCIENCES INTERNATIONAL INC

Form S-8

January 26, 2018

Table of Contents

As filed with the Securities and Exchange Commission on January 26, 2018

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-8
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

35-2089858
(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)

Ernest R. De Paolantonio

Chief Financial Officer, Treasurer and Secretary

BioDelivery Science 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:

Lawrence A. Rosenbloom, Esq.

Ellenoff Grossman & Schole LLP

1345 Avenue of the Americas, 11th Floor

New York, New York 10105

(212) 370-1300

Fax: (212) 370-7889

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
 Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Emerging growth company
 If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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	7,100,000	\$2.49	\$17,679,000.00	\$2,201.04
Total	7,100,000		\$17,679,000.00	\$2,201.04

- (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 on the basis of the average of the high and low prices of the Registrant's common stock on the NASDAQ Capital Market (rounded up to the nearest cent) on January 24, 2018.

Table of Contents

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 7,100,000 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 December 7, 2017, and which we refer to herein as the 2011 Plan). 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. 333-206326, filed on August 12, 2015, and which we refer to as the 2015 S-8); and

Update the reoffer prospectus included in the 2015 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, will be or may 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 15,854,707 shares included in the reoffer prospectus are the number of shares of our common stock underlying options or restricted stock units that have been, will be 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 2015 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 2015 S-8 pursuant to Rule 429(b) under the Securities Act.

Table of Contents

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.

Table of Contents

Reoffer Prospectus

15,854,707 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 15,854,707 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 January 24, 2018, the closing sales price for the common stock on the Nasdaq Capital Market was \$2.45 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 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 January 26, 2018.

Table of Contents**TABLE OF CONTENTS**

<u>Cautionary Note Regarding Forward Looking Statements</u>	ii
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	5
<u>Dividends</u>	5
<u>Use of Proceeds</u>	5
<u>Selling Stockholders</u>	6
<u>Plan of Distribution</u>	8
<u>Legal Matters</u>	9
<u>Experts</u>	9
<u>Where You Can Find More Information</u>	9
<u>Disclosure of Commission Position on Indemnification for Securities Law Violations</u>	10
<u>Incorporation of Certain Documents By Reference</u>	10

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.

Table of Contents

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 our 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 that express expectations or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements included or incorporated by reference 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 commercialize our products, notably BELBUCA[®] and BUNAVAIL[®], our related ability to gain market acceptance of our BEMA[®] technology platform, and our ability to enter into and maintain manufacturing and similar arrangements in connection therewith;

our ability, or the ability of commercial partners with whom we have or may license our products to develop, commercialize, manufacture or distribute such products;

our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing 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 patents or other intellectual property that we license, or our or our partners' ability to enforce our rights under such owned or

licensed patents or other intellectual property;

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 payment and royalty revenues) from our products or product candidates and any related commercial agreements of ours;

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

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.

Table of Contents

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.

Table of Contents

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 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 U.S. Food and Drug Administration (which we refer to as the FDA) approved products include BELBUCA[®] (buprenorphine) buccal film, BUNAVAIL[®] (buprenorphine and naloxone buccal film), and ONSOLIS[®] (fentanyl buccal soluble film). Each of these products utilize our BEMA[®] technology.

Our strategy is to:

Focus our commercial and development efforts in the areas of pain management and addiction within the U.S. pharmaceutical marketplace;

Identify and acquire rights to products that we believe have potential for near-term regulatory approval through the 505(b)(2) approval process of the FDA or are already FDA approved; and

Market our products through specialty sales teams by primarily focusing on high-prescribing U.S. physicians working with patients in the pain and addiction space.

We believe this strategy will allow us to increase our revenues, improve our margins and profitability and enhance stockholder value.

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

BELBUCA[®] is indicated for the management of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. This product was licensed on a worldwide basis to Endo Pharmaceuticals (or Endo) in 2012. On October 26, 2015, we announced with Endo that the FDA approved BELBUCA[®]. BELBUCA[®] was launched by Endo in February 2016. On

December 7, 2016, we entered into an agreement with Endo terminating Endo's licensing of rights for BELBUCA®. This followed a strategic decision made by Endo to discontinue commercial efforts in the branded pain business. On January 6, 2017, we announced the closing of the transaction to reacquire the license to BELBUCA® from Endo. As a result, the worldwide rights to BELBUCA® were transferred back to us. Going forward, we are not responsible for future royalties or milestone payments to Endo and Endo will not be obligated to any future milestone payments to us. Behind a revised commercialization plan based on market research conducted primarily by Endo that took into consideration the current climate for prescribing opioids for chronic pain, we are leveraging our existing sales force to capitalize on commercial synergies with BUNAVAIL®. This effort is a focused commercial approach targeting identified healthcare providers which we believe create the potential to incrementally grow BELBUCA® sales

Table of Contents

without the requirement for significant resources. We also will explore other options for longer-term growth for BELBUCA[®]. In mid-February 2017, we completed the expansion and training of our sales force, allowing for promotion of BELBUCA[®] to commence in full in late February. BELBUCA[®] and BUNAVAIL[®] are supported by our own field force of sales representatives and regional sales managers. As previously disclosed, the launch has been more challenging because of the increased scrutiny over the prescribing of opioids that is driven by the Centers for Disease Control and Prevention guidelines issued in March 2016. The difference that BELBUCA[®] offers over the Schedule II opioids, such as oxycodone, hydrocodone, morphine, etc., include less addiction and abuse potential along with a ceiling effect on respiratory depression. The approval of BELBUCA[®] carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BELBUCA[®] on QT prolongation (i.e. an abnormal lengthening of the heartbeat). Also required is a study assessing the safety and efficacy of BELBUCA[®] in pediatric patients and participation in a consortium with other holders of NDAs for long-acting opioids to assess and better understand the risk of abuse, misuse, addiction and overdose with opioids. Prescription sales of BELBUCA have significantly increased since promotion began.

On July 12, 2017, we, along with Purdue Pharma, an Ontario limited partnership (or Purdue), announced the execution of an exclusive agreement granting to Purdue the licensing, distribution, marketing and sale rights related to BELBUCA[®] in Canada. Financial terms of the Purdue agreement include: (i) total upfront and other cash milestone payments (relating to marketing authorization transfer and certain other marketing- and sales-related milestones) of up to an aggregate of CAD 4.5 million, including approximately CAD 1.5 million (0.5 million CAD and 1.0 million CAD received August 2017 and October 2017, respectfully); (ii) a low double digit percent royalty payable quarterly by Purdue to the Company based on Canadian net sales of BELBUCA[®], which royalty rate is subject to adjustment in certain circumstances; (iii) an annual royalty fee commencing a period of time after the commercial launch of BELBUCA[®] in Canada, which fee is creditable against royalties payable by Purdue and subject to reduction in certain circumstances; and (iv) payment by Purdue of certain costs incurred to obtain and transfer the marketing authorization for BELBUCA[®] in Canada, a portion of which will be reimbursed by the Company as a reduction of royalties payable by Purdue. On September 12, 2017, the Company announced Health Canada had granted market authorization to formally transfer the Drug Identification Number (DIN) ownership of BELBUCA[®] in Canada to Purdue.

BUNAVAIL[®] was approved by the FDA in June 2014 and is indicated for the treatment of opioid dependence. BUNAVAIL[®] uses our BEMA[®] technology combined with buprenorphine in tandem with naloxone, an opioid antagonist. We are commercializing BUNAVAIL[®] ourselves and launched the product during the fourth quarter of 2014. We have been actively engaged in efforts to optimize our commercialization of BUNAVAIL[®] with particular emphasis in 2016 on better aligning costs with revenue and reducing spending. We will seek to continue to manage our BUNAVAIL[®] business by focusing sales efforts on those healthcare providers who have been prescribers of BUNAVAIL. And we will continue to use published data evidencing diversion (i.e., the illicit use of a legally prescribed controlled substance) associated with the market leader's product and highlight the other attributes of BUNAVAIL[®] as we seek to win additional managed care contracts. We also believe there will be an opportunity to introduce more patients to BUNAVAIL[®] with the lifting of the long-standing limit from 100 to 275 (as outlined in the final ruling by the Department of Health and Human Services and effective on August 8, 2016), the number of patients per physician that can be treated at any given time with buprenorphine and more recent legislation allowing nurse practitioners and physician assistants to prescribe buprenorphine for opioid dependence. We will continue to closely monitor commercial efforts and seek to increase revenue and profitability, as well as evaluate all options available to preserve the long-term prospects for and maximize the value of BUNAVAIL[®]. Separately, as with all other buprenorphine containing products for opioid dependence, the approval of BUNAVAIL[®] carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BUNAVAIL[®] on QT prolongation.

ONSOLIS[®] is approved in the U.S., the EU (where it is marketed as **BREAKYL**) and Taiwan (where it is marketed as **PAINKYL**), for the management of breakthrough pain in opioid tolerant adult patients with cancer.

ONSOLIS[®] utilizes our **BEMA**[®] drug delivery technology in combination with the narcotic fentanyl. The commercial rights to **ONSOLIS**[®] were originally licensed to Meda, a subsidiary of Mylan N.V., in 2006 and 2007 for all territories worldwide except for Taiwan (where it is licensed to TTY Biopharm Co., Ltd. (or TTY)). The marketing authorization for **ONSOLIS**[®] was returned to us in early 2015 as part of an assignment and revenue sharing agreement with Meda for the United States, Canada and Mexico. Such agreement also facilitated the

Table of Contents

approval of a new formulation of ONSOLIS® in the U.S. On May 11, 2016, we executed a License Agreement with Collegium Pharmaceutical, Inc. (or Collegium) under which we granted to Collegium the exclusive rights to develop and commercialize ONSOLIS® in the U.S. On December 8, 2017, we received the required 90-day notice from Collegium regarding termination of such license agreement. Collegium's decision to terminate the license involved their recent execution of a separate license agreement to commercialize Nucynta® (tapentadol) Immediate Release and Nucynta® ER (tapentadol). Termination of the license agreement will be effective on March 8, 2018, and there are no early termination penalties incurred by us pursuant to the license agreement. We will be assessing our commercial options for ONSOLIS®, but we do not currently believe that the return of ONSOLIS® will have a material impact on our business.

Sustained Release Buprenorphine Injection is in development as an injectable, extended release, microparticle formulation of buprenorphine for the treatment of opioid dependence and chronic pain, the rights to which we secured when we entered into a definitive development and exclusive license option agreement from Evonik in October 2014. In 2015, we completed initial development work and preclinical studies which have resulted in the identification of a formulation we believe is capable of providing 30 days of continuous buprenorphine treatment. During a pre-IND meeting with FDA in November 2015, FDA requested an additional study to assess the fate of the polymers used in the formulation. In 2016, we completed this study as well as additional preclinical work and other activities to support a planned Phase 1 clinical study. We submitted an Investigational New Drug application (or IND) for this product candidate to FDA in December 2016.

We expect to continue our research and development of pharmaceutical products and related drug delivery technologies, some of which will be funded by our commercialization agreements. We will continue to seek additional license agreements, which may include upfront payments. We anticipate that funding for the next several years will come primarily from earnings from sales of BELBUCA® and BUNAVAIL®, milestone payments and royalties from Meda and TTY, potential sales of securities and collaborative research agreements, including those with pharmaceutical companies.

Additional Information

From our inception through September 30, 2017, we have recorded accumulated losses totaling approximately \$288.8 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 products, our goal (which we began to achieve in 2017) 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;

partnering with other pharmaceutical companies to assist in the distribution of our products, 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 BELBUCA[®], BUNAVAIL[®], ONSOLIS[®] or any other product candidates discussed below and elsewhere in this reoffer prospectus and documents incorporated herein by reference 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.

Table of Contents

The Offering

Outstanding Common Stock	57,477,815 shares of our common stock are outstanding as of January 26, 2018.
Common Stock Offered	Up to 15,854,707 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 6.
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

Table of Contents

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, 2016 (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, 2016, 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."

Table of Contents**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(4)
Thomas W. D Alonzo	(5)(6)	161,379	45,000	161,379	*
Ernest R. De Paolantonio	(7)(8)	96,464	373,098	96,464	*
Barry I. Feinberg	(9)(10)	121,000	45,000	121,000	*
Frank E. O Donnell, Jr.	(11)(12)	271,299	1,143,912	271,299	*
Scott M. Plesha	(13)(14)	130,031	134,765	130,031	*
Samuel P. Sears	(15)(16)	82,863	57,500	82,863	*
Mark A. Sirgo	(17)(18)	2,300,661	608,086	2,300,661	4.00%
Timothy C. Tyson	(19)(20)	4,658	7,315	4,658	*
W. Mark Watson	(21)(22)	1,500		1,500	*

* Less than 1%

(1) Represents common stock owned.

(2) Represents vested and unvested options or restricted stock units.

(3) These shares constitute control securities as such term is defined in General Instruction C to Form S-8.

(4) Based on 57,477,815 shares of common stock outstanding as of January 26, 2018.

(5) Thomas W. D Alonzo is a member of our Board of Directors.

(6) Includes options to purchase 30,000 shares of our common stock, of which 22,500 are currently exercisable and 7,500 are unvested. Also includes 15,000 shares of unvested RSUs which will vest in August 2018. Of the total options and RSUs, respectively, all have been granted under the 2011 Plan.

(7) Ernest R. De Paolantonio is our Secretary, Treasurer and Chief Financial Officer.

(8)

Includes options to purchase 55,659 shares of our common stock, of which all 55,659 are currently exercisable. Also includes 284,391 shares of unvested RSUs which vests from February 2018 to March 2020, a portion of which vests if certain pre-determined company revenue targets are achieved and 33,048 shares of unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved. Of the total options and RSUs, respectively, all have been granted under the 2011 Plan.

- (9) Barry I. Feinberg is a member of our Board of Directors.
- (10) Includes options to purchase 30,000 shares of our common stock, of which 22,500 are currently exercisable and 7,500 are unvested. Also includes 15,000 shares of unvested RSUs which will vest in August 2018. Of the total options and RSUs, respectively, all have been granted under the 2011 Plan.
- (11) Frank E. O Donnell, Jr., M.D. is our Chairman of the Board.

Table of Contents

- (12) Includes options to purchase 145,000 shares of our common stock, of which all 145,000 are currently exercisable. Also includes 828,084 shares of unvested RSUs which vests from February 2018 to March 2020, a portion of which vests if certain pre-determined company revenue targets are achieved and 170,828 shares of unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved. Of the total options and RSUs, 42,500 options and all RSUs have been granted under the 2011 Plan. 102,500 options have been granted under the Amended and Restated 2001 Incentive Plan.
- (13) Scott M. Plesha is our President.
- (14) Includes 134,765 shares of unvested RSUs which vests from February 2018 to March 2020, a portion of which vests if certain pre-determined company revenue targets are achieved. Of the total RSUs, all have been granted under the 2011 Plan.
- (15) Samuel P. Sears, Jr. is a member of our Board of Directors.
- (16) Includes options to purchase 42,500 shares of our common stock, of which 35,000 are currently exercisable and 7,500 are unvested. Also includes 15,000 shares of unvested RSUs which will vest in August 2018. Of the total options and RSUs, respectively, all have been granted under the 2011 Plan.
- (17) Mark A. Sirgo, Pharm.D. is our Vice Chairman.
- (18) Includes options to purchase 267,340 shares of our common stock, of which all 267,340 are currently exercisable. Also includes 340,746 shares of unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved. Of the total options and RSUs, 28,658 options and all RSUs have been granted under the 2011 Plan. 242,340 options have been granted under the Amended and Restated 2001 Incentive Plan.
- (19) Timothy C. Tyson is a member of our Board of Directors.
- (20) Includes options to purchase 3,658 shares of our common stock, of which 1,829 are currently exercisable and 1,829 are unvested. Also includes 3,657 shares of unvested RSUs which will vest in August 2018. Of the total options and RSUs, respectively, all have been granted under the 2011 Plan.
- (21) W. Mark Watson is a member of our Board of Directors.
- (22) Mr. Watson was elected to our Board of Directors December 2017.

Table of Contents

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.

Table of Contents

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 and financial statement schedule incorporated in this reoffer prospectus by reference from BioDelivery Sciences International, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2016 and the effectiveness of BioDelivery Sciences International, Inc.'s internal control over financial reporting have been audited by Cherry Bekaert LLP, an independent registered public accounting firm, as stated in their reports, which are incorporated by reference herein. Such consolidated financial statements and financial statement schedule have been so incorporated in reliance upon the reports of such firm, given upon their authority as experts in auditing and accounting.

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.

Table of Contents

**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 Second 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, 2016, as filed with the SEC on March 16, 2017;

Our Definitive Proxy Statement on Schedule 14(a), as filed with the SEC on November 11, 2017, as supplemented on November 22, 2017;

Our Current Reports on Form 8-K, as filed with the SEC on March 17, 2017, March 24, 2017, March 31, 2017, May 2, 2017, May 16, 2017, June 1, 2017, June 21, 2017, June 23, 2017, July 18, 2017, August 1, 2017, August 10, 2017, August 29, 2017, September 1, 2017, September 12, 2017, October 6, 2017, October 12, 2017, November 13, 2017, November 17, 2017, November 27, 2017, December 8, 2017, December 14, 2017, December 18, 2017, December 22, 2017, December 29, 2017, and January 18, 2018;

Our Quarterly Reports on Form 10-Q, as filed with the SEC on May 15, 2017, August 9, 2017 and November 11, 2017;

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.

Table of Contents

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., 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.

Table of Contents

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.

15,854,707 shares

Common Stock

REOFFER PROSPECTUS

January 26, 2018

Table of Contents

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, 2016, as filed with the SEC on March 16, 2017;

Our Definitive Proxy Statement on Schedule 14(a), as filed with the SEC on November 11, 2017, as supplemented on November 22, 2017;

Our Current Reports on Form 8-K, as filed with the SEC on March 17, 2017, March 24, 2017, March 31, 2017, May 2, 2017, May 16, 2017, June 1, 2017, June 21, 2017, June 23, 2017, July 18, 2017, August 1, 2017, August 10, 2017, August 29, 2017, September 1, 2017, September 12, 2017, October 6, 2017, October 12, 2017, November 13, 2017, November 17, 2017, November 27, 2017, December 8, 2017, December 14, 2017, December 18, 2017, December 22, 2017, December 29, 2017, and January 18, 2018;

Our Quarterly Reports on Form 10-Q, as filed with the SEC on May 15, 2017, August 9, 2017 and November 11, 2017;

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 Second 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.

II-1

Table of Contents**Item 7. Exemption from Registration Claimed.**

All shares of common stock registered hereunder for reoffer or resale will be issued upon vesting of restricted stock units or upon exercise of options granted or to be granted pursuant to the 2011 Plan. Such securities are non-transferable and the underlying shares will be issued in transactions not involving a public offering. Upon receipt of the applicable shares of common stock, the holder 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.

Item 8. Exhibits.

The following exhibits are filed with this Registration statement.

Number	Description
4.1	<u>Registrant's Amended and Restated 2001 Stock Incentive Plan(1)</u>
4.2	<u>Registrant's 2011 Equity Incentive Plan(2)</u>
4.3	<u>Amendment No. 1 to Registrant's 2011 Equity Incentive Plan(3)</u>
4.4	<u>Amendment No. 2 to Registrant's 2011 Equity Incentive Plan(4)</u>
4.5	<u>Amendment No. 3 to Registrant's 2011 Equity Incentive Plan(5)</u>
4.6	<u>Amendment No. 4 to Registrant's 2011 Equity Incentive Plan(6)</u>
5.1	<u>Opinion of Ellenoff Grossman & Schole LLP (7)</u>
5.2	<u>Opinion of Ellenoff Grossman & Schole LLP(8)</u>
5.3	<u>Opinion of Ellenoff Grossman & Schole LLP(9)</u>
5.4	<u>Opinion of Ellenoff Grossman & Schole LLP*</u>
23.1	<u>Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.4)*</u>
23.2	<u>Consent of Cherry Bekaert LLP*</u>

(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 Registrant's 2017 Schedule 14A, November 1, 2017, as supplemented.

(7) Filed as part of the Registrant's Registration Statement on Form S-8, filed with the SEC on August 24, 2011.

(8) Filed as part of the Registrant's Registration Statement on Form S-8, filed with the SEC on August 23, 2013.

(9) Filed as part of the Registrant's Registration Statement on Form S-8, filed with the SEC on August 12, 2015.

* 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.

II-2

Table of Contents

(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.

(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.

II-3

Table of Contents**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 January 26, 2018.

**BIODELIVERY SCIENCES
INTERNATIONAL, INC.**

By: /s/ Scott M. Plesha

Name: Scott M. Plesha

Title: President

BioDelivery Sciences International, Inc. and each of the undersigned do hereby appoint Scott M. Plesha 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/ Frank E. O Donnell, Jr. Francis E. O Donnell, Jr.	Chairman of the Board	January 26, 2018
/s/ Scott M. Plesha Scott M. Plesha	President (Principal Executive Officer)	January 26, 2018
/s/ Ernest R. De Paolantonio Ernest R. De Paolantonio	Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	January 26, 2018
/s/ Mark A. Sirgo Mark A. Sirgo	Vice Chairman	January 26, 2018
/s/ Timothy C. Tyson Timothy C. Tyson	Director	January 26, 2018
/s/ Samuel P. Sears, Jr. Samuel P. Sears, Jr.	Director	January 26, 2018
/s/ Thomas W. D Alonzo	Director	January 26, 2018

Thomas W. D Alonzo

/s/ W. Mark Watson

Director

January 26, 2018

W. Mark Watson

/s/ Barry I. Feinberg, M.D

Director

January 26, 2018

Barry I. Feinberg, M.D.

II-4