BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B3
May 17, 2018
Table of Contents

Prospectus Supplement
(to Prospectus dated July 13, 2015)

Filed Pursuant to Rule 424(b)(3)
Registration No 333-205483

5,000 Shares

Series B Non-Voting Convertible Preferred Stock

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering an aggregate of 5,000 shares of Series B Non-Voting convertible preferred stock, par value $0.001 per share (which we refer to as the Series B Preferred Stock) to institutional and accredited investors pursuant to a Securities Purchase Agreement, dated May 17, 2018, at a price per share of $10,000 for aggregate gross proceeds of $50.0 million. This offering also includes an aggregate of 27,777,778 shares of our common stock initially issuable upon the conversion of the Series B Preferred Stock. We refer to the shares of Series B Preferred Stock issued hereunder and the shares of common stock issuable upon conversion of the Series B Preferred Stock collectively as the securities.

Shares of our common stock are currently traded on the Nasdaq Capital Market under the symbol BDSI. On May 16, 2018, the last reported sale price of our common stock was $1.95 per share. There is no established public trading market for the Series B Preferred Stock and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series B Preferred Stock on any national securities exchange or any trading system. The conversion of the Series B Preferred Stock into shares of common stock will be contingent upon our obtaining certain approvals from our stockholders. For a detailed description of the Series B Preferred Stock, see the section entitled Description of Series B Preferred Stock beginning on page S-15.

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

We have retained William Blair & Company, L.L.C. to act as our exclusive placement agent for this offering. We have agreed to pay the placement agent an aggregate cash fee equal to 3% of the gross proceeds of the offering. The placement agent is not required to arrange for the sale of any specific number of securities or dollar amount but will use reasonable best efforts to arrange for the sale of the securities.

We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately $500,000.

It is anticipated that the securities will be delivered against payment thereon on or about May 21, 2018.

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

Placement Agent

William Blair

The date of this prospectus supplement is May 17, 2018.

Table of Contents

TABLE OF CONTENTS

Prospectus Supplement

Prospectus

You should rely only on the information we have provided or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus supplement or the accompanying prospectus.

This prospectus supplement and the accompanying prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so.

You should assume that the information contained in this prospectus supplement and the accompanying prospectus is accurate only as of their respective dates and that any information we have incorporated by

reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement or the accompanying prospectus or any sale of securities.

Table of Contents

ABOUT THIS PROSPECTUS SUPPLEMENT

On July 2, 2015, we filed with the Securities and Exchange Commission (or SEC) a registration statement on Form S-3 (File No. 333-205483) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement was declared effective on July 13, 2015. Under this shelf registration process, we may, from time to time, sell up to $150 million in the aggregate of common stock, preferred stock, debt securities, warrants and rights to purchase securities and units, of which approximately $50.0 million will be sold in this offering.

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

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

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

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

Table of Contents

PROSPECTUS SUPPLEMENT SUMMARY

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

Overview

We are a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. We have built a portfolio of products utilizing our novel 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), which we currently commercialize in the U.S. utilizing our own sales force while working in partnership with third parties to commercialize our products outside the U.S. We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002.

BELBUCA® (buprenorphine) buccal film incorporates buprenorphine in our BEMA technology and was approved by the U.S. Food and Drug Administration (or FDA) on October 26, 2015, for the management of pain severe enough to require daily, around the clock, long-term opioid treatment for which alternative treatment options are inadequate. BELBUCA® is designated by the U.S. Drug Enforcement Agency as a Schedule III product, meaning it has moderate to low potential for physical and psychological dependence, but less abuse and addiction potential compared to Schedule II products such as morphine, oxycodone and hydrocodone. BELBUCA® is also commercially available in Canada following market authorization from Health Canada in June 2017 and our subsequent exclusive agreement with Purdue Pharma (Canada) in July 2017 for the licensing and distribution rights of BELBUCA® in Canada.

Along with BELBUCA®, we utilize our sales force to commercialize BUNAVAIL® (buprenorphine and naloxone) buccal film, which was approved by the FDA on June 6, 2014. BUNAVAIL® utilizes our BEMA technology to deliver higher doses of buprenorphine along with the abuse deterrent, naloxone, for the treatment of opioid dependence and as part of a complete treatment plan to include counseling and psychosocial support.

Our third approved product, ONSOLIS® (fentanyl buccal soluble film), is currently marketed outside the U.S. through partnerships, and we are currently assessing strategic options for the reintroduction of ONSOLIS® to the U.S. market following the termination during 2017 of a licensing agreement with Collegium Pharmaceutical, Inc.

Although our intention is to focus our efforts mainly on driving sales of our approved products, as part of our corporate growth strategy, we have licensed, and will continue to explore opportunities to acquire or license additional drug delivery technologies or drugs utilizing the delivery or other technologies of other companies. If and when we gain access to such drugs and technologies, we will seek to 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 clinical and regulatory development strategy has focused 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.

Table of Contents

Recent Developments and Additional Information

Change in Board of Directors

On May 1, 2018, Broadfin Healthcare Master Fund Ltd. (or Broadfin) filed a Schedule 13D amendment with the SEC disclosing that it had nominated three individuals for election to our board of directors at our 2018 Annual Meeting of Stockholders (or the 2018 Annual Meeting). The date of such meeting has not been scheduled as of the date of this prospectus supplement. Prior to and subsequent to such filing, we have engaged in discussions with Broadfin regarding the financing and governance of our company.

As a condition to the closing of the financing contemplated by this prospectus supplement, we have entered into an agreement with Broadfin (which we refer to as the Broadfin Agreement) that provides for the following, all to occur effective at the closing of the financing: (i) three new directors identified by Broadfin, Kevin Kotler (the Director of Broadfin), Todd C. Davis and Peter S. Greenleaf, will be appointed to our board of directors (we refer to these persons herein as the New Directors); (ii) four current directors, Thomas W. D Alonzo, Barry I. Feinberg, Samuel P. Sears, Jr. and Timothy C. Tyson (who we refer herein to as the Retiring Directors), will voluntarily resign from our board of directors; and (iii) Broadfin will withdraw its director nominations for the 2018 Annual Meeting.

In addition, the Broadfin Agreement will provide that: (i) we will be required to hold the 2018 Annual Meeting no later than seventy-five (75) days after the closing of this financing and place on the agenda for that meeting the approval of an increase in our authorized common stock and of the transactions described herein under applicable Nasdaq Stock Market Rules; (ii) during the period from the closing of this financing through the thirtieth day prior to the deadline for stockholder nominations for our 2019 Annual Meeting of Stockholders (which we refer to as the Standstill Period), Broadfin will be subject to customary standstill provisions, including with respect to proxy fights, voting of shares and transactions with third parties that seek to circumvent the standstill provisions and amendments to the Broadfin Agreement following its execution; and (iii) during the Standstill Period, Broadfin will have customary replacement rights for any New Director who ceases to serve as a director of our company for any reason during the Standstill Period; provided that only one of the New Directors serving on our board of directors at any time can be an employee, or otherwise not independent, of Broadfin. The Broadfin Agreement will also contain mutual non-disparagement provisions and releases of claims.

Also as part of the financing contemplated by this prospectus supplement, the Retiring Directors have each entered into an agreement with us and Broadfin to memorialize their retirement terms, which will include two (2) quarters of customary board fees, continued vesting and exercise rights for previously awarded equity grants, issuance of new equity awards for services prior to the retirement date and mutual non-disparagement provisions and releases of claims. These agreements are effective as of the closing of this offering.

Following the changes in our board of directors pursuant to the Broadfin Agreement, our board of directors will be set at seven (7) individuals, who will be seated in the following board classes:

Class I Directors (serving until the 2018 Annual Meeting): Todd C. Davis and Peter S. Greenleaf, each identified by Broadfin.

Class II Directors (serving until the 2019 Annual Meeting of Stockholders): Mark A. Sirgo (Vice Chairman of the Board), Herm Cukier and Kevin Kotler (the Director of Broadfin).

Class III Directors (serving until the 2020 Annual Meeting of Stockholders): Frank E. O Donnell, Jr. (Chairman of the Board) and W. Mark Watson.

The following are the biographies of the New Directors:

Kevin Kotler, age 46, has over 25 years of experience as an investor and analyst following the healthcare industry. He is the founder and Managing Member of Broadfin Capital, which is the investment advisor for Broadfin Healthcare Master Fund, Ltd., a healthcare focused investment fund which he launched in 2005. Mr. Kotler has served as a Director of Novelion Therapeutics, Inc. since November 2016 and has served as a director of InnerSpace Neuro Solutions, Inc., a privately-held medical device company since 2014. Mr. Kotler earned a B.S. in economics from the Wharton School at the University of Pennsylvania in 1993. We believe Mr. Kotler is qualified to serve on our board of directors due to his experience in managing biotechnology investments.

Table of Contents

Todd C. Davis, age 57, has served as the Founder, Managing Partner and President of RoyaltyRx Capital, LLC, special opportunities investment firm focused on pharmaceuticals, since January 2018. Mr. Davis previously served as Founding Managing Director and Managing Partner of HealthCare Royalty Partners, a global healthcare investment firm, from 2007 to December 2017. Previously, Mr. Davis was a partner at Paul Capital Partners, an investment firm where he co-managed royalty investments, from 2004 to 2006, and a partner at Apax Partners, a private equity investment group where he was responsible for biopharmaceutical growth investments, from 2001 to 2004. Prior to that, Mr. Davis held various sales and product management roles at Abbott Laboratories and worked in business development, operations and licensing at Elan Pharmaceuticals. Mr. Davis has served on the boards of directors of Ligand Pharmaceuticals Incorporated (NASDAQ: LGND), a biopharmaceutical company where he is a member of the audit and compensation committees, since March 2007, and Palvella Therapeutics, a rare-disease biopharmaceutical company serving patients with monogenic rare diseases, since June 2017. Mr. Davis previously served on the boards of directors of TearScience, a maker of ophthalmic medical devices where he was a member of the compensation committee, from February 2016 to October 2017, Acufocus, an ophthalmic medical device company, from April 2017 to December 2017, Suneva Medical, Inc., an aesthetics company where he was a member of the compensation committee, from January 2009 to September 2017, Helomics, Inc., an integrated clinical contract research organization where he was a member of the compensation committee, from September 2014 to June 2017, and Artes Medical, Inc. (NASDAQ: ARTE), a medical aesthetics company, from January 2008 to December 2008. Mr. Davis also is a board member of the Harvard Business School Healthcare Alumni Association. Mr. Davis earned a Bachelor of Science from the U.S. Naval Academy and an M.B.A. from Harvard Business School. We believe Mr. Davis is qualified to serve on our board of directors due to his experience as a biotechnology investor and his service as a board member of biotechnology companies.

Peter S. Greenleaf, age 48, has served as the Chief Executive Officer of Cerecor, Inc. (NASDAQ: CERQ), an integrated biopharmaceutical company focused on pediatric healthcare, since March 2018. Mr. Greenleaf previously served as Chief Executive Officer of Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP), a biopharmaceutical company focused on medical applications of a class of ion channel modulators, from March 2014 to February 2018, when Sucampo was sold to Mallincrodt PLC (NYSE: MNK). Prior to that, Mr. Greenleaf served as Chief Executive Officer of Histogenics Corporation, a regenerative medicine company, from June 2013 to March 2014, as President of MedImmune, Inc., an fully integrated biologics division of AstraZeneca Group and President of MedImmune Ventures, a venture capital fund within the AstraZeneca Group, a global, science-led biopharmaceutical business, from January 2010 to June 2013, and Senior Vice President, Commercial Operations of MedImmune, from 2006 to 2010. Mr. Greenleaf also held senior commercial roles at Centocor Biotech, Inc. (now Jansen Biotechnology, Johnson & Johnson), a biotechnology company founded with the goal of developing new diagnostic assays using monoclonal antibody technology, from 1998 to 2006, and at Boehringer Mannheim G.m.b.H. (now Roche Holdings), a diagnostics and pharmaceuticals business, from 1996 to 1998. Mr. Greenleaf has served on the board of directors of Cerecor, where he has been a member of its audit committee, since May 2017. Previously, he served on the boards of directors of Sucampo, including as Chairman, from March 2013 to February 2018, Mast Therapeutics, Inc. (NYSE MKT: MSTX), a clinical-stage biopharmaceutical company where he was a member of its audit committee and compensation committee, from November 2015 to April 2017, Mirna Therapeutics, Inc. (NASDAQ: MIRN), a clinical-stage biopharmaceutical company engaged in the development of microRNA-based oncology therapeutics where he was a member of the audit committee, from February 2016 to August 2017, and Histogenics, from June 2013 to March 2014. Mr. Greenleaf also previously served on the boards of directors of Rib-X Pharmaceuticals, a biopharmaceutical firm that focuses on the design and development of novel broad-spectrum antibiotics for the treatment of antibiotic-resistant infections in hospital and community settings, from 2009 to 2010, LigoCyte Pharmaceuticals, an immunology company focused on developing vaccines and monoclonal antibodies for gastrointestinal and respiratory indications, from 2010 to 2011 and Corridor Pharmaceuticals, a biopharmaceutical company dedicated to developing and commercializing novel therapeutic Arginase inhibitors, from 2010 to 2013. Mr. Greenleaf currently chairs the Maryland Venture Fund Authority, whose vision is to oversee implementation of

InvestMaryland, a public-private partnership to spur venture capital investment in the state. He is also a member of the board of directors of the Biotechnology Industry Organization, the largest trade organization in the world representing the biotechnology industry, where he serves on the Governing Boards of the Emerging Companies and Health Sections. Mr. Greenleaf previously served on the boards of PhARMA, the Tech Council of Maryland, a technology trade

Table of Contents

association for companies with operations in Maryland, Washington, D.C. and Virginia, and the University of Maryland Baltimore Foundation, Inc., which advises the President of the University of Maryland, Baltimore on matters affecting programs, students, faculty, employees, and the community. Mr. Greenleaf earned a M.B.A degree from St. Joseph s University and a B.S. degree from Western Connecticut State University. We believe Mr. Greenleaf is qualified to serve on our board of directors due to his experience in leading and serving on the board of directors of biotechnology companies.

Amendment to CRG Term Loan

Concurrently with the closing of the offering described herein, we expect to enter into an amendment to our Term Loan Agreement, dated February 21, 2017 (or the Loan Agreement), with CRG Servicing LLC (or CRG), as administrative agent and collateral agent, and the lenders named in the Loan Agreement.

Pursuant to such amendment: (i) the interest only period of the loan will be extended by one year, and certain milestones previously required for the extended interest only period have been removed; (ii) the PIK period (under which a portion of the interest accrued under the loan can be deferred to maturity) will also be extended for a year; (iii) amortization of the loan principal can be deferred until maturity (making the payment of the loan a balloon payment) if we achieve and maintain a market capitalization of $200 million as of the conclusion of the interest only period (provided that if we achieve, and thereafter fall below a $200 million market capitalization, amortization of the loan principal will resume; and (iv) certain revenue targets, the failure of which would create an event of default under the loan, have been lowered.

New Chief Executive Officer

Effective May 8, 2018, our board of directors appointed Herm Cukier to the position of Chief Executive Officer of our company and as a member of our board of directors. As Chief Executive Officer, subject to the direction and oversight of our board of directors, Mr. Cukier will serve as our principal executive officer.

Table of Contents

The Offering

Securities offered by us	An aggregate of 5,000 shares of newly designated Series B Preferred Stock at a price per share of $10,000.
	Each share of Series B Preferred Stock shall be convertible into a number of shares of our common stock determined by dividing $10,000 by a conversion price of $1.80 per share. As such, the Series B Preferred Stock is initially convertible into 27,777,778 shares of our common stock. The Series B Preferred Stock does not contain any price-based anti-dilution protection.
	The Series B Preferred Stock is not convertible until the date that we receive approval of our stockholders (i) for an increase in our authorized common stock to a number of shares of common stock sufficient for the conversion in full of the Series B Preferred Stock and (ii) of the transactions contemplated by this offering under applicable Nasdaq Stock Market rules (which we refer to herein, collectively, as the Stockholder Approval). We have agreed to hold our 2018 Annual Meeting of Stockholders no later than seventy-five (75) days after the closing of the offering and include on the agenda for that meeting proposals for the Stockholder Approval.
	We do not intend to apply for listing of the Series B Preferred Stock on any national securities exchange or any trading system.
	For a further description of the Series B Preferred Stock, see Description of Series B Preferred Stock on page S-15 of this prospectus supplement.
Use of proceeds	We expect that the net proceeds of the offering of Series B Preferred Stock will be $48.0 million, after expenses payable by us.
	Although we have not yet identified specific uses for the net proceeds we may receive from the sale of the Series B Preferred Stock offered under this prospectus supplement, we currently anticipate using such proceeds to fund (i) commercialization efforts related to BELBUCA and BUNAVAIL

and (ii) for general working capital purposes.

We have not determined the amount of net proceeds to be used specifically for such purposes. As a result, management will retain broad discretion over the allocation of the net proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short-term, interest-bearing instruments.

See Use of Proceeds on page S-11 of this prospectus supplement.

Risk factors

Investing in our preferred stock involves a high degree of risk. Please read the information contained in and incorporated by reference under the heading Risk Factors on page S-6 of this prospectus supplement, and under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement.

Table of Contents

RISK FACTORS

Investing in our securities involves a high degree of risk. *Before deciding whether to invest in our securities, you should carefully consider 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, 2017, and in our Quarterly Report for the three month period ended March 31, 2018, which risk factors are incorporated by reference into this prospectus supplement. See Where You Can Find More Information for an explanation of how to get a copy of these reports. Please also read carefully the section above entitled Cautionary Note Regarding Forward-Looking Statements.*

In addition, you are advised to consider the following additional risk factors related specifically to the offering contemplated by this prospectus supplement.

Additional Risks Related to This Offering

Our management will have broad discretion as to the use of the proceeds from this offering, and may not use the proceeds effectively.

Because we have not designated the amount of net proceeds from this offering to be used for any particular purpose, our management will have broad discretion as to the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value. See Use of Proceeds .

There is a material risk that we will be unable to utilize a significant portion of our net operating loss or research tax credit carryforwards or other tax attributes.

At December 31, 2017, we had U.S. federal net operating loss and research and development tax credit carryforwards of approximately $263 million and $11 million, respectively. Such operating losses and tax credits could be used by us to reduce any future taxable income and tax liabilities of ours. These losses and tax credits will expire at various dates between 2024 and 2037. We also had state net operating loss carryforwards as of December 31, 2017 of approximately $297 million. Such operating losses could also be used to reduce any future taxable income and tax liabilities of ours, and these losses and tax credits will expire at various dates between 2024 and 2030.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50 percentage point change (by value)) in its equity ownership by certain stockholders over a three-year period, the corporation s ability to use its pre-change U.S. federal net operating losses and other pre-change tax attributes (such as research and development tax credit carryforwards) to offset its post-change income or taxes may be limited. Our U.S. federal net operating loss carryforwards generated prior to May 2006 are subject to this limitation in an amount equal to approximately $1.5 million on an annual basis.

We have not undertaken a formal study of ownership changes in our company in several years. However, there is a material risk that this offering (due to its size) and/or past or future issuances or sales of our stock (including certain transactions involving our stock that are beyond our control) may cause us to experience one or more ownership changes, thereby limiting our ability to utilize our U.S. federal net operating loss and other tax attributes. Similar provisions of state tax law may also apply to limit our use of state net operation loss carryforwards, as well as other state tax attributes.

In addition, changes in law, including legislation commonly known as the Tax Cuts and Jobs Act of 2017, may further limit our ability to use our net operating loss carryforwards. As a result, if we achieve profitability in the future (of

which no assurances can be given), we may be unable to use a material portion of our net operating loss carryforwards and other tax attributes, which would require us to pay federal and state income tax, which in turn would likely adversely affect our future cash flows.

Table of Contents

If you purchase the Series B Preferred Stock sold in this offering, assuming it is converted into shares of our common stock, you will experience immediate and substantial dilution in your investment.

The offering price of the Series B Preferred Stock in this offering will be substantially higher than the net tangible book value per share of our common stock upon conversion of the Series B Preferred Stock. Therefore, if you purchase our Series B Preferred Stock in this offering (assuming conversion of the Series B Preferred Stock into common stock), you will incur an immediate dilution in net tangible book value of $1.73 per share, after giving effect to the sale by us of shares of our Series B Preferred Stock (assuming the conversion of 5,000 shares of the Series B Preferred Stock into 27,777,778 shares of our common stock) at the per share purchase price of $10,000, less the placement agent fees and estimated offering expenses payable by us.

We will not apply to list the Series B Preferred Stock offered hereby, and an active trading market for the Series B Preferred Stock is not expected to develop.

We do not intend to apply for listing of the Series B Preferred Stock on any national securities exchange or any trading system and we do not expect a market to develop. Without an active market, the liquidity of and your ability to sell the Series B Convertible Preferred Stock will be significantly limited.

Our Series B Preferred Stock will rank junior to all our liabilities to third-party creditors in the event of a bankruptcy, liquidation or winding up of our assets.

In the event of our bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Series B Preferred Stock only after all our liabilities have been paid. Our Series B Preferred Stock will effectively rank junior to all existing and future liabilities held by third-party creditors, most notably our current senior lender CRG. The terms of our Series B Preferred Stock do not restrict our ability to raise additional capital in the future through the issuance of debt. In the event of our bankruptcy, liquidation or winding up, there may not be sufficient assets remaining, after paying our liabilities, to pay amounts due on any or all of our Series B Preferred Stock then outstanding.

The shares of Series B Preferred Stock sold in this offering carry no voting rights, meaning that the holders of Series B Preferred Stock will have no rights to vote on matters brought before our common stockholders.

The shares of Series B Preferred Stock being sold in this offering carry no voting rights (other than customary protective provisions relating to changes to the terms of the Series B Preferred Stock, the issuance of securities with rights that are senior to the Series B Preferred Stock, the issuance of dividends, and the redemption of securities). Therefore, you should not invest in the Series B Preferred Stock in the expectation that you will able to vote with our common stockholders on any matter or proposal brought before our common stockholders.

The shares of Series B Preferred Stock sold in this offering carry no mandatory dividend, and we do not intend to pay dividends in the foreseeable future.

The shares of Series B Preferred Stock being sold in this offering carry no mandatory dividend rights, and therefore you should not invest in the Series B Preferred Stock in the expectation that you will ever receive dividends from our company. Moreover, we have never paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and currently do not plan to pay any cash dividends in the foreseeable future.

The terms of the offering contemplated hereby require stockholder approval at our 2018 Annual Meeting.

Under applicable Nasdaq Stock Market rules, the terms of this offering require approval of our stockholders, which we will seek at our 2018 Annual Meeting. If such stockholder approval is not obtained, we will be required to continue to seek stockholder approval at successive stockholders meetings. Failure to obtain stockholder approval of the transactions contemplated hereby will deny investors

Table of Contents

the ability to convert their Series B Preferred Stock into shares of our common stock as well as the contemplated benefits of the securities offered hereby.

We are nearing the limit on our authorized common stock, and in order to accommodate the full conversion of our Series B Preferred Stock into common stock, we will need to amend our certificate of incorporation to increase our authorized shares of common stock. Also, additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market for our common stock.

As of May 10, 2018, there are 59,288,804 shares of common stock issued and 59,273,313 shares of common stock outstanding and there were 2,709,300 shares issued and 2,093,155 outstanding of Series A Non-Voting Convertible Preferred Stock issued and outstanding. We also have 2,504,206 shares of common stock reserved for future issuance under our equity incentive plan, outstanding equity awards and outstanding warrants. Our certificate of incorporation currently provides for 75,000,000 authorized shares of common stock. As such, we are nearing the limit of our authorized common stock, and given the size of the offering described herein, we will be required to ask our stockholders to approve an amendment to our certificate of incorporation to increase the number of authorized shares of common stock at the 2018 Annual Meeting. Prior to such meeting, or after if such amendment in not approved, holders of our Series B Preferred Stock will be unable to convert such shares into shares of our common stock, and additionally we may be unable to issue common stock for a variety of purposes, including most importantly for financing purposes. This limitation on our ability to issue common stock will impair the holders of Series B Preferred Stock from converting such shares into common stock, and could generally have a material adverse effect on our ability to finance and operate our business.

Moreover, and even if our certificate of incorporation is amended to increase our authorized shares of common stock, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors would experience dilution, and sales of common stock by stockholders in the market could lower the price of our common stock and the value of our company.

Finally, in addition to the above referenced authorized shares of common stock (which available authorized may be issued without stockholder approval), we have 5 million shares of authorized preferred stock, of which 2,709,300 shares have been designated as Series A Non-Voting Convertible Preferred Stock and 5,000 will be designated as Series B Preferred Stock. The remaining 2,285,700 shares of preferred stock will remain undesignated shares of preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® drug delivery technology platform and any 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 (ii) the heavily regulated industry in which we operate our business generally;

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

- our ability, or the ability of our commercial partners, to actually develop, commercialize, manufacture or distribute our products and product candidates, including for BELBUCA® and BUNAVAIL®, which 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, of 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, inter partes reexaminations and Paragraph IV litigations) or other claims or disputes relating to our business, technologies, patents, 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;

Table of Contents

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

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

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

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

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

Table of Contents

USE OF PROCEEDS

Although we have not yet identified specific uses for the net proceeds we may receive from the sale of the Series B Preferred Stock offered under this prospectus supplement, we currently anticipate using such proceeds to fund (i) commercialization efforts related to BELBUCA and BUNAVAIL and (ii) for general working capital purposes.

We are not presently a party to any definitive agreements to make any product or technology acquisitions, although we reserve the right to use portions of the net proceeds of this offering to make such acquisitions.

The amounts and timing of our use of the net proceeds from this offering will depend on a number of factors, such as the timing and progress of our commercialization efforts and the competitive operational and regulatory environment for our products. Accordingly, our management will have broad discretion in the timing and application of these proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short-term, interest-bearing instruments.

Table of Contents

PRICE RANGE OF COMMON STOCK

Our common stock is listed on The Nasdaq Capital Market under the symbol BDSI. The following table shows the high and low per share sale prices of our common stock for the periods indicated.

Fiscal Year Ended December 31, 2016	High	Low
1st Quarter	$ 4.90	$ 2.53
2nd Quarter	$ 4.00	$ 1.86
3rd Quarter	$ 3.10	$ 2.23
4th Quarter	$ 2.70	$ 1.50

Fiscal Year Ended December 31, 2017	High	Low
1st Quarter	$ 2.15	$ 1.65
2nd Quarter	$ 3.05	$ 1.55
3rd Quarter	$ 3.60	$ 2.30
4th Quarter	$ 3.10	$ 2.05

Fiscal Year Ending December 31, 2018	High	Low
1st Quarter	$ 3.08	$ 1.90

On May 16, 2018, the last sale price reported on The Nasdaq Capital Market for our common stock was $1.95 per share.

Table of Contents

DILUTION

If you invest in our Series B Preferred Stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share and the adjusted net tangible book value per share of our common stock after this offering.

Our net tangible book value on March 31, 2018 was approximately $(41.9) million, or $(0.69) per share. Net tangible book value is total assets minus the sum of liabilities and intangible assets. Net tangible book value per share is net tangible book value divided by the total number of shares outstanding.

After giving effect to the sale of 5,000 shares of our Series B Preferred Stock at the public offering price of $10,000 per share, assuming the conversion of 5,000 shares of the Series B Preferred Stock into 27,777,778 shares of our common stock, and after deducting estimated offering commissions and expenses payable by us, our net tangible book value as of March 31, 2018 would have been approximately $6.1 million, or $0.07 per share of common stock. This represents an immediate increase in net tangible book value of $0.76 per share to our existing stockholders and an immediate dilution in net tangible book value of $1.73 per share to investors participating in this offering. The following table illustrates this dilution per share to investors participating in this offering:

offering price per share		$ 1.80
Net tangible book value per share as of March 31, 2018	$ (0.69)	
Increase per share attributable to new investors	$ 0.76	
Net tangible book value per share after giving effect to this offering	$ 0.07	
Dilution per share to new investors		$ 1.73

The number of shares outstanding as of the date of this prospectus, as used throughout this prospectus, unless otherwise indicated, excludes the following, all as of March 31, 2018:

2,093,155 of common stock underlying our Series A Non-Voting Convertible Preferred Stock;

outstanding options as of that date representing the right to purchase a total of 3,065,844 shares of our common stock at a weighted average exercise price of $3.41 per share;

3,556,263 shares of our common stock which are reserved for future equity awards that may be granted in the future under our 2011 Equity Incentive Plan, as amended;

outstanding warrants as of that date representing the right to purchase a total of 2,136,020 shares of our common stock at a weighted average exercise price of $2.60 per share; and

27,777,778 shares of common stock underlying our Series B Non-Voting Convertible Preferred Stock.

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

Table of Contents

CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2018:

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

This capitalization table should be read in conjunction with management s discussion and analysis of results of operations and our consolidated financial statements and related notes included in our Quarterly Report on Form 10-Q for the period ended March 31, 2018, and the other financial information included and incorporated by reference in this prospectus supplement.

	As of March 31, 2018 (in thousands, except share data)	
	Actual (unaudited)	**Pro forma as Adjusted (unaudited)**
Cash and cash equivalents	$ 12,090	$ 60,090
Stockholders equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,093,155 shares of Series A Non-Voting Convertible Preferred Stock outstanding, as adjusted for the issuance of 5,000 shares of Series B Non-Voting Convertible Preferred Stock	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 58,646,522 shares issued; 58,631,031 shares outstanding	59	59
Additional paid-in capital	316,970	364,970
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(315,630)	(315,630)
Total stockholders equity	$ 1,354	$ 49,354

Outstanding shares of common stock as of March 31, 2018 excludes:

- 2,093,155 shares of common stock underlying our Series A Non-Voting Convertible Preferred Stock;

outstanding options as of that date representing the right to purchase a total of 3,065,844 shares of our common stock at a weighted average exercise price of $3.41 per share;

3,556,263 shares of our common stock which are reserved for future equity awards that may be granted in the future under our 2011 Equity Incentive Plan, as amended;

outstanding warrants as of that date representing the right to purchase a total of 2,136,020 shares of our common stock at a weighted average exercise price of $2.60 per share; and

27,777,778 shares of common stock underlying our Series B Non-Voting Convertible Preferred Stock.

Table of Contents

DESCRIPTION OF SERIES B PREFERRED STOCK

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

General

Under the terms of our certificate of incorporation, as amended, our board of directors is authorized to issue up to 5,000,000 shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. We have 2,093,155 of Series A Non-Voting Convertible Preferred Stock outstanding, and our board of directors has designated 5,000 of the remaining 2,290,700 authorized shares of preferred stock as our Series B Non-Voting Convertible Preferred Stock, par value $0.001 per share (which are the securities being issued in this offering).

Rank

The Series B Preferred Stock will rank:

- on par with our outstanding Series A Non-Voting Convertible Preferred Stock;
- senior to our common stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series B Preferred Stock; and
- junior to any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series B Preferred Stock,

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

Conversion

Each share of Series B Preferred Stock shall be convertible into a number of shares of our common stock determined by dividing $10,000 by a conversion price of $1.80 per share (subject to adjustment as provided in the certificate of designation for the Series B Preferred Stock) at any time following the Stockholder Approval. As such, the Series B Preferred Stock is initially convertible into an aggregate of 27,777,778 shares of our common stock. The Series B Preferred Stock does not contain any price-based anti-dilution protection. The Series B Preferred Stock is convertible at any time after Stockholder Approval at the option of the holder, except that a holder will be prohibited from

converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of our common stock then issued and outstanding, which percentage may be increased or decreased on sixty-one (61) days notice from the holder of Series B Preferred Stock to us provided that, until Stockholder Approval, such beneficial ownership limitation may only be increased to up to 19.99% of the total number of shares of our common stock then issued and outstanding.

We have agreed to hold our 2018 Annual Meeting of Stockholders no later than seventy-five (75) days after the closing of the offering and include on the agenda for that meeting proposals for the Stockholder Approval. Within ten days following the date of Stockholder Approval, we have the right to deliver a notice to the holders of the Series B Preferred Stock to require conversion of the Series B Preferred Stock into common stock, provided that certain conditions with respect to our common stock is satisfied. Such forced conversion shall be subject to a holder s beneficial ownership limitation of 9% of the total number of shares of our common stock then issued and outstanding. Following an initial forced conversion of the Series B Preferred Stock, every ninety days thereafter, we have the right to require the forced conversion of still outstanding shares of Series B Preferred Stock up to the beneficial ownership limitation of 9% of the total number of shares of our common stock then issued and outstanding.

Table of Contents

Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series B Preferred Stock will receive a payment equal to $.001 per share of Series B Preferred Stock pari passu with the holders of our Series A Non-Voting Convertible Preferred Stock and before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series B Preferred Stock, the holders of Series B Preferred Stock will participate ratably in the distribution of any remaining assets with the holders of our Series A Non-Voting Convertible Preferred Stock and the holders of our common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

Voting Rights

Shares of Series B Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of 80% of the outstanding Series B Preferred Stock will be required to amend the terms of the Series B Preferred Stock or the certificate of designations for the Series B Preferred Stock, to authorize any class of securities that is senior to the Series B Preferred Stock with respect to distribution of assets upon liquidation, the payment of dividends or rights of redemption.

Dividends

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

Redemption

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

Listing

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

Fundamental Transactions

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

Registration Rights

In connection with the issuance of Series B Preferred Stock, we have entered into a registration rights agreement with Broadfin, who will be an affiliate (as such term is defined in SEC Rule 144) of our company as of the closing. In the registration rights agreement, we have granted demand registration rights and piggyback registration rights to Broadfin in connection with shares of common stock underlying the Series B Preferred Stock and other securities held by Broadfin that are subject to volume and manner of sale limitations under Rule 144.

Table of Contents

PLAN OF DISTRIBUTION

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering an aggregate of 5,000 shares of our Series B Preferred Stock to institutional and accredited investors pursuant to a securities purchase agreement, dated May 17, 2018, at a price per share of $10,000.

In addition, pursuant to a placement agency agreement, dated May 17, 2018, between us and William Blair & Company, L.L.C., we have engaged William Blair & Company, L.L.C. as the exclusive placement agent in connection with this offering. The placement agent is not purchasing or selling any of the securities we are offering, and it is not required to arrange the purchase or sale of any specific number of securities or dollar amount, but the placement agent has agreed to use reasonable best efforts to arrange for the sale of the securities.

The securities purchase agreement and the placement agency agreement provide that the obligations of the purchasers in this offering and of the placement agent are subject to certain conditions precedent, including, among other things, the absence of any material adverse change in our business and the receipt of customary opinions, letters and closing certificates.

All of the securities will be sold in this offering at the same price and at a single closing. We established the conversion price of the Series B Preferred Stock following negotiations with prospective investors and with reference to the prevailing market price of our common stock, recent trends in such price and other factors. It is possible that not all of the securities we are offering pursuant to this prospectus supplement will be sold at the closing, in which case our net proceeds would be reduced. We expect that the sale of the securities will be completed on the date indicated on the cover page of this prospectus supplement.

We will pay the placement agent a placement agent fee equal to 3% of the gross proceeds of this offering. The placement agent has agreed to reimburse us for our offering-related expenses up to $20,000.

We estimate the total expenses of this offering, which will be payable by us, excluding the placement agent fees, will be approximately $500,000. We are not responsible for the expenses incurred by the placement agent.

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

The placement agency agreement is included as Exhibit 1.1, and the securities purchase agreement is included as Exhibit 10.1, to our Current Report on Form 8-K filed with the SEC in connection with this offering.

Listing

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

Electronic Distribution

This prospectus supplement and the accompanying prospectus may be made available in electronic format on websites or through other online services maintained by the placement agent, or by an affiliate. Other than this prospectus supplement and the accompanying prospectus in electronic format, the information on the placement agent s website

and any information contained in any other websites maintained by the placement agent are not part of this prospectus supplement or the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus forms a part, has not been approved and/or endorsed by us or the placement agent, and should not be relied upon by investors.

Table of Contents

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

Regulation M Restrictions

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

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

Affiliations

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

Table of Contents

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, to support our business strategy and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, operating results, capital requirements and any plans for expansion.

LEGAL MATTERS

The validity of the securities offered in this prospectus has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York. Latham & Watkins LLP, Chicago, Illinois, is counsel for the placement agent in connection with this offering.

EXPERTS

The financial statements and management s assessment of the effectiveness of internal control over financial reporting (which is included in Management s Report on Internal Control over Financial Reporting) incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2017, have been so incorporated in reliance on the report of Cherry Bekaert LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

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

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as filed with the SEC on March 15, 2018;

Our Current Reports on Form 8-K, as filed with the SEC on March 16, 2018, May 3, 2018, May 8, 2018 and May 11, 2018;

Our Quarterly Report on Form 10-Q, as filed with the SEC on May 10, 2018; and

Table of Contents

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

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

BioDelivery Sciences International, Inc.

4131 ParkLake Avenue, Suite # 225

Raleigh, North Carolina 27612

Telephone: (919) 582-9050

Attention: Ernest R. De Paolantonio, Chief Financial Officer

Table of Contents

Prospectus

$150,000,000

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

We may offer and sell from time to time, in one or more series, any one of the following securities of our company, for total gross proceeds up to $150,000,000:

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

We will provide specific terms of these offerings and securities in one or more supplements to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement, and any documents incorporated by reference, may also add, update or change information contained in this prospectus. You should read this prospectus, the applicable prospectus supplement, any documents incorporated by reference and any related free writing prospectus carefully before buying any of the securities being offered.

We may offer and sell these securities to or through one or more underwriters, dealers and agents, or directly to purchasers, on a continuous or delayed basis.

Our common stock is traded on The NASDAQ Capital Market under the symbol BDSI. The last reported sale price of our common stock on The NASDAQ Capital Market on July 13, 2015 was $9.64 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors contained in the applicable prospectus supplement and in any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus or any prospectus supplement before making a decision to purchase our securities.

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

The date of this prospectus is July 13, 2015.

Table of Contents

TABLE OF CONTENTS

You should rely only on the information we have provided or incorporated by reference in this prospectus or in any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus or in any prospectus supplement.

This prospectus and any prospectus supplement is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so.

You should assume that the information contained in this prospectus and in any prospectus supplement is accurate only as of their respective dates and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospective supplement or any sale of securities.

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. Under this shelf registration process, we may offer and sell, either individually or in combination, in one or more offerings, any combination of the securities described in this prospectus, for total gross proceeds of up to $150,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change any of the information contained in this prospectus or in the documents that we have incorporated by reference into this prospectus.

We urge you to read carefully this prospectus, any applicable prospectus supplement and any free writing prospectuses we have authorized for use in connection with a specific offering, together with the information incorporated herein by reference as described under the heading Incorporation of Certain Information by Reference, before investing in any of the securities being offered. You should rely only on the information contained in, or incorporated by reference into, this prospectus and any applicable prospectus supplement, along with the information contained in any free writing prospectuses we have authorized for use in connection with a specific offering. We have not authorized anyone to provide you with different or additional information. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so.

The information appearing in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section entitled Where You Can Find More Information.

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

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our plans and expectations regarding the timing and outcome of 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 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;

Table of Contents

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; and

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

Moreover, new risks regularly emerge and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this prospectus and any accompanying prospectus supplement 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 prospectus, any accompanying prospectus and the documents we have filed with the SEC.

Table of Contents

PROSPECTUS SUMMARY

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

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

Overview

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of 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 treatment of chronic pain. The financial terms of our

Table of Contents

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 New Drug Application (or 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 placebo. Additional secondary endpoints were supportive of the efficacy of BELBUCA compared to placebo. The most commonly reported adverse events in patients treated with

Table of Contents

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 triggers an additional $10 million milestone payment from Endo, to be received within 60 days of acceptance. 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.

Table of Contents

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.

Table of Contents

On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Meda to return back to us the marketing authorizations for ONSOLIS ® for the U.S. and the right to seek marketing authorizations for ONSOLIS ® in Canada and Mexico. Once the NDA has been returned, we will have the right to work directly with the FDA and submit a prior approval supplement that responds to FDA questions and requests and will hopefully lead to the re-introduction of the product. 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.

In late March 2015, we announced that the primary efficacy endpoint in our Phase 3 clinical study of Clonidine Topical Gel for PDN compared to placebo for the treatment of PDN did not meet statistical significance. Certain secondary endpoints showed statistically significant improvement over the placebo. In addition, a strong safety profile for the product was observed. Based on our ongoing analysis, we believe that the data from this study supports continued development of this product. Our analysis showed an unusually high placebo response in the cohort of patients that entered the trial following our previously announced interim analysis of the study. Generally speaking, we believe there may be study design features that might be able to mitigate this response in all patients that would enter a subsequent study of Clonidine Topical Gel, and we are presently considering these features as we evaluate the potential for additional study of this product candidate. We are therefore currently in the process of determining what the next steps in the development pathway should be and whether our decision may require FDA consultation. One possibility is that we would do a small scale study that takes into account the design features that we believe could mitigate the placebo response we saw in our initial Phase 3 trial. If we decide to pursue this type of study or any next study, it would not likely occur before fourth quarter of 2015.

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.

Table of Contents

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 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 March 31, 2015, we have recorded accumulated losses totaling approximately $213.7 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.

The Securities We May Offer

We may offer and sell from time to time up to an aggregate of $150,000,000 of any of, or units comprised of, or other combinations of, the following securities:

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

Table of Contents

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

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

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

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

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

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

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

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

7

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, 2014, which risk factors are incorporated by reference into this prospectus. See Where You Can Find More Information for an explanation of how to get a copy of this report. Additional risks related to our securities may also be described in a prospectus supplement and in any related free writing prospectus that we may authorize to be provided to you.

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 in any prospectus supplement and in any related free writing prospectus that we may authorize to be provided to you or in any report incorporated by reference into this prospectus or such prospectus supplement, 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 prospectus or such prospectus supplement after the date of this 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.

RATIO OF EARNINGS TO FIXED CHARGES

The following table sets forth our ratio of fixed charges and preference dividends to earnings for each of the periods indicated. You should read this table in conjunction with the financial statements and notes incorporated by reference in this prospectus.

	For Fiscal Year Ended				
	December 31, 2014	December 31, 2013	December 31, 2012	December 31, 2011	December 31, 2010
Ratios of fixed charges and preference dividends to earnings	N/A	N/A	45.10	N/A	N/A

We have computed the ratio of fixed charges and preference dividends to earnings set forth above by dividing pre-tax loss before fixed charges and preference dividends by fixed charges and preference dividends. Fixed charges are the sum of the following:

- interest expensed and capitalized;
- amortized premiums related to indebtedness; and
- an estimate of the interest within rental expense.

We did not pay any cash dividends on any shares of our capital stock during the periods set forth above.

We did not record earnings for the fiscal years ended December 31, 2014, 2013, 2011 and 2010. Accordingly, our earnings were insufficient to cover fixed charges for such periods and we are unable to disclose a ratio of fixed charges and preference dividends to earnings for such periods. The dollar amount of the deficiency in earnings available for fixed charges and preference dividends for the fiscal years ended December 31, 2014, 2013, 2011 and 2010 was approximately $54.2 million, $57.4 million, $23.3 million and $13.0 million, respectively.

Table of Contents

USE OF PROCEEDS

Except as otherwise disclosed in the applicable prospectus supplement, we intend to use the net proceeds from the sales of securities hereunder for the clinical and regulatory advancement of our product candidates; for commercialization of our products, including potential sales and marketing of products on our own behalf; to support of our partnered products; for potential acquisitions of new technologies and products or related companies, and to meet working capital needs. The amounts and timing of our use of the net proceeds from this offering will depend on a number of factors, such as the timing and progress of our research and development efforts, the timing and progress of any partnering and commercialization efforts, technological advances and the competitive environment for our products. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from the sale of the securities offered by us hereunder and the applicable prospectus supplement. Accordingly, our management will have broad discretion in the timing and application of these proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short-term, interest-bearing instruments.

DESCRIPTION OF CAPITAL STOCK AND SECURITIES WE MAY OFFER

General

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

Our authorized capital stock consists of 75,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of the date of this prospectus, our outstanding capital stock consists of 52,421,435 shares of common stock, $.001 par value, and 2,093,155 shares of Series B Preferred Stock, par value $.001 per share. These figures do not include securities that may be issued: (i) pursuant to outstanding warrants to purchase shares of our common stock, (ii) pursuant to our Amended and Restated 2001 Incentive Plan or (iii) pursuant to our 2011 Equity Incentive Plan, as amended.

We, directly or through agents, dealers or underwriters designated from time to time, may offer, issue and sell, together or separately, up to $150,000,000 in the aggregate of:

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

rights to purchase our securities; or

units comprised of, or other combinations of, the foregoing securities.

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

Table of Contents

Common Stock

As of the date of this prospectus, there were 52,436,926 shares of common stock issued and 52,421,435 shares of common stock outstanding, held of record by approximately 115 stockholders. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Subject to preferential rights with respect to any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by our board of directors out of funds legally available therefore. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and satisfaction of preferential rights of any outstanding preferred stock.

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

Preferred Stock

Our certificate of incorporation, as amended, empowers our board of directors, without action by our shareholders, to issue up to 5,000,000 shares of preferred stock from time to time in one or more series, which preferred stock may be offered by this prospectus and supplements thereto. As of the date of this prospectus, we had 2,709,300 shares of preferred stock designated as Series A Preferred Stock and had 2,093,155 shares of Series A Preferred Stock issued and outstanding. Our board may fix the rights, preferences, privileges and restrictions of our authorized but undesignated preferred shares, including:

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

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

the title of the series and the number of shares in the series;

the price at which the preferred stock will be offered;

the dividend rate or rates or method of calculating the rates, the dates on which the dividends will be payable, whether or not dividends will be cumulative or noncumulative and, if cumulative, the dates from which dividends on the preferred stock being offered will cumulate;

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

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

Table of Contents

the liquidation preference per share;

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

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

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

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

any preemptive rights;

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

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

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

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

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

Series A Preferred Stock

In connection with our registered financing which closed on December 3, 2012, our board of directors designated 2,709,300 of the 5,000,000 authorized shares of preferred stock as our Series A Non-Voting Convertible Preferred Stock, par value $.001 per share.

Rank

The Series A Preferred Stock will rank:

senior to our common stock;

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

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

Table of Contents

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

Conversion

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

Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series A Preferred Stock will receive a payment equal to $.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of our common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock and holders of Series A Preferred Stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

Voting Rights

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

Dividends

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

Redemption

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

Listing

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

Fundamental Transactions

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

Table of Contents

Warrants

We may issue warrants for the purchase of our common stock, preferred stock or debt securities or any combination thereof. Warrants may be issued independently or together with our common stock, preferred stock or debt securities and may be attached to or separate from any offered securities. To the extent warrants that we issue are to be publicly-traded, each series of such warrants will be issued under a separate warrant agreement to be entered into between us and a bank or trust company, as warrant agent. The warrant agent will act solely as our agent in connection with such warrants. The warrant agent will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. This summary of certain provisions of the warrants is not complete. For the terms of a particular series of warrants, you should refer to the prospectus supplement for that series of warrants and the warrant agreement for that particular series.

Debt Securities

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

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

General

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

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

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

Prospectus Supplement

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

the title of debt securities and whether they are subordinated, senior subordinated or senior debt securities;

Table of Contents

any limit on the aggregate principal amount of debt securities of such series;

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

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

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

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

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

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

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

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

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

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

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

the rate or rates of amortization of the debt securities;

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

what subordination provisions will apply to the debt securities;

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

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

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

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

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

based on or related to foreign currencies;

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

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

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

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

Table of Contents

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

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

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

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

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

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

Rights

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

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

- the date of determining the security holders entitled to the rights distribution;

Table of Contents

the aggregate number of rights issued and the aggregate amount of securities purchasable upon exercise of the rights;

the exercise price;

the conditions to completion of the rights offering;

the date on which the right to exercise the rights will commence and the date on which the rights will expire; and

any applicable federal income tax considerations.

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

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

Transfer Agent and Registrar

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

Listing

Our common stock is listed on The NASDAQ Capital Market under the trading symbol BDSI.

Table of Contents

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, direct sales to the public, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

A prospectus supplement or supplements will describe the terms of the offering of the securities, including, to the extent applicable:

- the terms of the offering;
- the name or names of the underwriters, if any;
- the purchase price of the securities or other consideration therefor, and the proceeds, if any, we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents or underwriters compensation;
- any public offering price;
- any discounts or concessions allowed or re-allowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters or agents named in the prospectus supplement will be underwriters of or agents for the securities offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities, and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

Table of Contents

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

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

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

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

We may provide agents and underwriters with indemnification against civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Any underwriters or agents that are qualified market makers on The NASDAQ Capital Market may engage in passive market making transactions in the common stock on The NASDAQ Capital Market in accordance with Regulation M under the Exchange Act, during the business day prior to the pricing of the offering, before the commencement of offers or sales of our common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the

passive market maker s bid, however, the passive market maker s bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Table of Contents

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered by this prospectus, and any supplement thereto, will be passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York. The legality of the securities for any underwriters, dealers or agents will be passed upon by counsel as may be specified in the applicable prospectus supplement.

EXPERTS

The financial statements and management s assessment of the effectiveness of internal control over financial reporting (which is included in Management s Report on Internal Control over Financial Reporting) incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2014 have been so incorporated in reliance on the report of Cherry Bekaert LLP, an independent registered public accounting firm, given on the authority of said firm 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 with respect to the shares of our common stock offered by this prospectus. This prospectus is part of that registration statement and does not contain all the information included in the registration statement.

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

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

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

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

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

Table of Contents

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 and June 4, 2015;

Our Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 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.

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

BioDelivery Sciences International, Inc.

4131 ParkLake Avenue, Suite # 225

Raleigh, North Carolina 27612

Telephone: (919) 582-9050

Attention: Ernest R. De Paolantonio

Table of Contents

5,000 Shares

BioDelivery Sciences International, Inc.

Series B Non-Voting Convertible Preferred Stock

Prospectus Supplement

May 17, 2018

Placement Agent

William Blair