

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 424B5

April 10, 2019

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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-228292

The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and is effective. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated April 10, 2019

Preliminary Prospectus Supplement

(To Prospectus dated January 18, 2019)

Shares

Common Stock

We are offering _____ shares of our common stock.

Our common stock trades on The Nasdaq Capital Market under the trading symbol **BDSI** . On April 9, 2019, the last reported sale price of our common stock on The Nasdaq Capital Market was \$5.04 per share.

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See Underwriting for additional information regarding underwriting compensation.

The selling stockholder has granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to an additional _____ shares of our common stock at the public offering price, less the estimated underwriting discounts and commissions. We will not receive any of the proceeds from the sale of shares of common stock by the selling stockholder.

We estimate the expenses of this offering, excluding underwriting discounts and commissions, will be approximately \$.

Investing in our common stock involves risks. See Risk Factors beginning on page S-10 of this prospectus supplement.

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 supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about April , 2019.

Cantor

SunTrust Robinson Humphrey

The date of this prospectus supplement is April , 2019

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document consists of two parts. The first part is this prospectus supplement, which describes the specific terms of this common stock offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in this prospectus supplement and the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

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.

We have not and the selling stockholder has not authorized anyone to provide any information other than that contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction to or from any person to whom or from whom it is unlawful to make such offer or solicitation of an offer in such jurisdiction. The information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled *Where You Can Find More Information* and *Incorporation of Certain Information by Reference* in this prospectus supplement and in the accompanying prospectus.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless the context otherwise indicates, references in this prospectus to the company, we, us and our refer to BioDelivery Sciences International, Inc. and our subsidiaries. We own various trademark registrations and

applications, and unregistered trademarks, including BioDelivery Sciences International, Inc., BEMA, BELBUCA, BUNAVAIL, ONSOLIS and our corporate logo. This prospectus contains trade names, trademarks and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or TM symbols.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical facts, that we include in this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus may be deemed forward-looking statements for purposes of the Securities Act and the Exchange Act. We use words such as believe, expect, anticipate, may, could, intend, will, plan, target, estimate, project, will, would and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements appear throughout this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus and are statements regarding our current intent, belief or expectation, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding the following:

our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA (as defined below) 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, or the FDA, 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 or licensors, to actually develop, commercialize, secure raw materials or active pharmaceutical ingredients in sufficient quantities, manufacture or distribute our products and product candidates, including for BELBUCA, Symproic and BUNAVAIL;

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 in patents or other intellectual property that we license, of our or our partners' or licensors' 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;

the ability of our licensors or 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.

We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and, accordingly, you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those expressed or implied by these forward-looking statements, including those discussed under "Risk factors" and elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus.

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Any forward-looking statement speaks only as of the date on which it is made, and we disclaim any obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere in this prospectus supplement and the accompanying prospectus and in the documents we incorporate by reference. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering carefully, including the Risk Factors section contained in this prospectus supplement and the accompanying prospectus and our consolidated financial statements and the related notes and the other documents incorporated by reference herein.

Overview

We are a rapidly growing commercial-stage specialty pharmaceutical company dedicated to helping patients living with chronic pain and associated conditions. At our core is a shared passion to make every day a little bit easier for patients and help improve the lives of people living with chronic conditions so they can experience life to the fullest. We have built a portfolio of products that includes utilizing our novel and proprietary BioErodible MucoAdhesive, or BEMA, drug-delivery technology to develop and commercialize new applications of proven therapies aimed at addressing important unmet medical needs. We commercialize in the United States using our own sales force while working in partnership with third parties to commercialize our products outside the United States. We have made it a point to deeply understand the patients' journeys and are driven by recognizing the full impact of their condition so we can deliver life-altering solutions.

BELBUCA

BELBUCA (*buprenorphine buccal film*) is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative options are inadequate. BELBUCA is differentiated from other opioids and has the potential to address some of the most critical issues facing healthcare providers treating chronic pain with prescription opioids—abuse, misuse, addiction and the risk of overdose. As a Schedule III opioid, buprenorphine has less abuse and addiction potential compared to Schedule II opioids such as oxycodone, hydrocodone and morphine. Compared to currently marketed products and products under development, we believe that BELBUCA is differentiated based on the following features:

strong and durable efficacy in both opioid naïve and opioid experienced patients;

Schedule III designation by DEA, which indicates less abuse and addiction potential compared to Schedule II opioids, which include oxycodone, hydrocodone and morphine;

in published studies, investigators observed that respiratory depression from buprenorphine administration reached a plateau, and we believe this ceiling effect may result in a lower risk of overdose related respiratory depression;

favorable tolerability with a low incidence of constipation and low discontinuation rate;

flexible dosing options with seven available strengths; and

buccal administration to optimize buprenorphine delivery.

Because of the safety, tolerability and efficacy benefits associated with buprenorphine, we believe that BELBUCA is a clear choice as a first-line long-acting opioid for patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatments, such as non-opioids or immediate release opioids, are inadequate.

We believe that there are long-term growth opportunities for BELBUCA and we focus our commercial efforts primarily on BELBUCA. Our sales force is focused on current BELBUCA prescribers and clinicians we believe have the greatest opportunity to be adopters of BELBUCA, such as high prescribers of long-acting opioids, BuTrans (a transdermal formulation of buprenorphine) and/or healthcare providers who prescribe short acting opioids around-the-clock for patients with chronic pain. In parallel, we are heavily focused on increasing market access for BELBUCA. As of January 2019, BELBUCA had formulary coverage for more than 88% of commercial lives. Approval rates within the commercial channel remained favorable throughout 2018 at about 80%. In 2018, BELBUCA attained preferred access for over 7.5 million Medicare lives within the Humana network. BELBUCA continues to have favorable approval rates within other Medicare plans, as we pursue improved access to BELBUCA for the senior population suffering with chronic pain.

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In 2018, we also made significant improvements in patient access for BELBUCA, resulting in over 100 million commercial lives having preferred access to BELBUCA. According to Symphony Health, in 2018, BELBUCA prescriptions totaled over 160,000, an increase of 91% over 2017. In addition to a steady increase in BELBUCA prescription volume throughout 2018, there was also an increase in the use of higher doses of BELBUCA as healthcare providers continued to gain comfort titrating patients to higher optimal doses. In 2018, 36% of BELBUCA prescriptions were for doses of 450 mcg or greater, compared to 33% in 2017. Therefore, the weighted average price per prescription continued to increase in 2018.

According to data from Symphony Health, monthly prescriptions for BELBUCA totaled 20,681 and 20,664 for January 2019 and February 2019, respectively, and are projected to have been approximately 22,512 for March 2019. Further, according to IQVIA NPA Market Dynamics, new-to-brand prescriptions for BELBUCA totaled 4,263 and 4,588 for January 2019 and February 2019, respectively. Also according to Symphony Health, in January 2019 and February 2019, there were 4,228 and 4,350 unique prescribers of BELBUCA and 424 and 375 new prescribers of BELBUCA, respectively. As of April 2019, more than 50% of commercial covered lives and more than 20% of Medicare covered lives, respectively, had access to BELBUCA as a preferred medication.

SYMPROIC

On April 4, 2010, we entered into an exclusive license agreement, or the license agreement, with Shionogi Inc., or Shionogi, to commercialize Symproic (*naldemedine tosylate*) 0.2 mg tablets in the United States, including Puerto Rico, effective immediately. See Recent Developments.

Symproic is a peripherally acting mu-opioid receptor antagonist, or PAMORA, and was approved by the FDA on March 23, 2017 for the treatment of opioid-induced constipation, or OIC, in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. OIC occurs primarily via activation of enteric mu-receptors in the small intestine and proximal colon, which results in harder stool and less frequent and less effective defecation. Because OIC results from the specific effects of opioids, it differs mechanistically from other forms of constipation, and deserves dedicated medical management. Compared to currently marketed products and products under development for OIC, we believe that Symproic is differentiated based on the following features:

strong and durable efficacy observed in randomized, double-blind, placebo controlled clinical trials of 12 week and 52 week duration in OIC patients;

OIC relief that was more frequent, more complete, with less straining than patients taking placebo

recommended by the American Gastroenterological Association for patients with laxative refractory OIC;

adverse event profile comparable to placebo, with low rates of abdominal pain observed across the phase III program; and

the only prescription OIC medication with the convenience of once daily dosing, with only a tablet strength, and that can be taken with or without food and with or without laxatives.

Because of the durable efficacy, tolerability and convenience benefits, we believe that Symproic is a best-in-class PAMORA that reliably provides durable relief of OIC, which frees both the patient and the healthcare provider to focus on treating the patient's chronic pain.

We believe that there are long-term growth opportunities for Symproic. In 2018, according to data from Symphony Health, the market for PAMORAs included over 550,000 prescriptions dispensed. This represents a 1% growth in prescription volume from 2017. The growth rate of the PAMORAs has slowed since 2017, driven by a decline in opioid prescription rates.

BUNAVAIL

In June 2014, BUNAVAIL (*buprenorphine and naloxone buccal film*) was approved by the FDA for the maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support. In May 2017, we announced that the FDA had approved a Supplemental New Drug

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Application, or sNDA, for BUNAVAIL revising the BUNAVAIL indication to include induction, or the initial process undertaken when a patient is transitioned from the abused opioid responsible for their addiction. BUNAVAIL contains the partial opioid agonist buprenorphine, which binds to the same receptors as opiate drugs but has a higher affinity, and naloxone, an opioid antagonist and an abuse deterrent.

BUNAVAIL provides an alternative treatment utilizing the advanced BEMA drug delivery technology. BUNAVAIL has approximately twice the bioavailability of sublingual buprenorphine-containing products for opioid dependence, allowing for effective treatment with half the dose when compared to Suboxone film. Additionally, BUNAVAIL offers convenient and discrete buccal administration and avoids the need for patients to avoid talking and swallowing during administration. BUNAVAIL has demonstrated an excellent tolerability profile, with a 68% reduction in the incidence of constipation at the end of 12 weeks in a Phase 3 trial in patients converted from Suboxone sublingual tablets or film to BUNAVAIL.

Our BUNAVAIL efforts are focused on current BUNAVAIL prescribers and on increasing prescriptions related to current, upcoming and future managed care contracts where BUNAVAIL is placed in a favorable formulary position.

ONSOLIS

In July 2009, ONSOLIS (*fentanyl buccal soluble film*) was approved for the management of pain that breaks through the effects of other medications being used to control persistent pain, or breakthrough pain, in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. We refer to breakthrough pain in opioid tolerant patients with cancer as BTCP. ONSOLIS provides significant reduction in pain for patients suffering from BTCP in a convenient formulation with a range of doses to allow patients to titrate to an adequate level of pain control.

We are assessing options for U.S. commercialization of ONSOLIS, including the use of our current sales force, or potentially out-licensing the product. Regulatory documentation to qualify an alternate manufacturer of ONSOLIS was submitted to the FDA in June 2018, and in October 2018, we received notification of the FDA's approval of Tapemark as the new ONSOLIS manufacturer.

BEMA Drug Delivery Technology

Our BEMA drug delivery technology consists of a small, bi-layered erodible polymer film for application to the buccal mucosa (the lining inside the cheek). BEMA films have the capability to deliver a rapid, reliable dose of drug across the buccal mucosa for time-critical conditions such as breakthrough cancer pain or in situations where gastrointestinal absorption of an oral drug is not practical or reliable, or in facilitating the administration of drugs with poor oral bioavailability.

We believe that the BEMA technology permits control of two critical factors allowing for better dose-to-dose reproducibility: (i) the contact area for mucosal drug delivery, and (ii) the time the drug is in contact with that area, known as residence time. In contrast to competing transmucosal delivery systems such as lozenges, buccal tablets and matrix-based delivery systems placed under the tongue or sprayed in the oral cavity, BEMA products are designed to:

adhere to buccal mucosa in seconds and dissolve in minutes;

permit absorption without patients being required to move the product around in the mouth for absorption, thus avoiding patient intervariability;

allow for unidirectional drug flow into the mucosa as a result of a backing layer on the side of the BEMA film facing into the patient's mouth;

provide a reproducible delivery rate, not susceptible to varying or intermittent contact with oral membranes; and

dissolve completely, leaving no residual product or waste and avoiding patient removal, and the possibility for diversion or disposal of partially used product.

We currently own the BEMA drug delivery technology.

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Our Strategy

Our strategy is evolving with the establishment of our commercial footprint in the management of chronic conditions. We seek to build a well-balanced, diversified, high-growth specialty pharmaceutical company. Through our industry-leading commercialization infrastructure, we are executing the commercialization of our existing products. As part of our corporate growth strategy, we have licensed, and will continue to explore opportunities to acquire or license additional products that meet the needs of patients living with debilitating chronic conditions and treated primarily by therapeutic specialists. As we gain access to these drugs and technologies, we intend to employ our commercialization experience to bring them to the marketplace. With a strong commitment to patient access and a focused business-development approach for transformative acquisitions or licensing opportunities, we intend to leverage our experience and apply it to developing new partnerships that enable us to commercialize novel products that can change the lives of people suffering from debilitating chronic conditions.

We intend to pursue additional therapeutic products as well as new formulations of previously approved, active therapeutics through the FDA's 505(b)(2) approval process. Our historical clinical and regulatory development strategy has focused primarily on our ability to use the 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, with less regulatory approval risk than other FDA-approval approaches.

Recent Developments

License Agreement with Shionogi Inc.

On April 10, 2019, we announced that we had entered into the license agreement with Shionogi to commercialize Symproic (*naldemedine tosylate*) 0.2 mg tablets in the United States, including Puerto Rico, effective immediately.

Pursuant to the terms of the license agreement, we have agreed to pay Shionogi a \$30 million up-front payment, payable in two installments (i.e., \$20 million on the effective date of the license agreement and \$10 million on the six-month anniversary of the effective date of the license agreement (or earlier if the license agreement is assigned or transferred)), and quarterly, tiered royalty payments on potential sales of Symproic in the United States, including Puerto Rico, or the Territory. The quarterly royalty payments range from 8.5% to 17.5% (plus an additional 1% of net sales on a pass-through basis to a third-party licensor of Shionogi) of net sales of Symproic based on volume of net sales and whether Symproic is being sold as an authorized generic.

We and Shionogi have also entered into a customary supply agreement under which Shionogi will supply Symproic to us at cost plus an agreed upon markup for an initial term of up to two years. In the event we elect to source Symproic from a third party supplier, Shionogi would continue to supply us with naldemedine tosylate for use in Symproic at cost plus such agreed upon markup for the duration of the license agreement. We and Shionogi also entered into a customary transition services and distribution agreement under which Shionogi will continue to perform certain sales, distribution and related activities and commercialization and administrative services on our behalf until June 30, 2019, or such later date as may be agreed by the parties pursuant to the transition services and distribution agreement, or the Transition Date, (during which time, in lieu of paying royalties and cost-plus supply, distribution and transitional services during this period, Shionogi will retain 35% of the net sales of Symproic in the Territory and remit the remaining 65% of net sales to us) and certain other customary transitional services (if so requested by us), initially at no cost and thereafter, at a specified hourly rate for a term not to exceed three months from the Transition Date or the term of the agreement.

Estimated Financial and Balance Sheet Data as of March 31, 2019

We estimate that for the three-month period ended March 31, 2019, we generated between \$17.5 million and \$18.5 million of net sales of BELBUCA and between \$18.5 million and \$19.5 million of total company net revenue. In addition, we estimate that, as of March 31, 2019, we had approximately \$41.0 to \$41.5 million of cash and cash equivalents.

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The information above is based on preliminary unaudited information and management estimates for the three months ended March 31, 2019, is not a comprehensive statement of our financial results, and is subject to completion of our financial closing procedures. Our independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these preliminary estimates. Our net revenues are net of estimated allowances for rebates, price adjustments, returns, chargebacks and prompt payment discounts. A significant majority of our gross to net adjustments to gross product revenues are the result of accruals for our voucher program and rebates related to Medicare Part D, the Part D Coverage Gap, Medicaid, and commercial contracts with most of those programs having an accrual to payment cycle of anywhere from one to three months. During our financial closing process our estimates can differ materially from our initial estimates presented herein based on our receipt of updated information.

Company Information

We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002. Our executive offices are located at 4131 ParkLake Avenue, Suite 225, Raleigh, North Carolina, and our telephone number is (919) 582-9050. Our website address is www.bdsi.com. We do not incorporate the information on or accessible through our website into this prospectus. We have included our website address in this prospectus supplement as an inactive textual reference only.

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2,166,102 shares of common stock reserved for issuance upon settlement of restricted stock units as of December 31, 2018;

2,136,020 shares of common stock issuable upon the exercise of warrants to purchase common stock outstanding as of December 31, 2018 at an exercise price of \$2.60 per share;

an aggregate of 1,874,086 additional shares of common stock reserved for future issuance under our 2011 equity incentive plan, and our 2001 stock incentive plan as of December 31, 2018;

2,093,155 shares of common stock issuable upon conversion of the Series A Non-Voting Convertible Preferred Stock; and

17,222,223 shares of common stock issuable upon conversion of the Series B Non-Voting Convertible Preferred Stock.

Except as otherwise noted, we have presented the information in this prospectus supplement assuming:

no exercise by the underwriters of their option to purchase up to an additional shares of our common stock in this offering; and

no exercise of outstanding stock options and warrants described above, no issuance of common stock upon settlement of restricted stock units and no conversion of outstanding shares of Series B Non-Voting Convertible Preferred Stock.

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RISK FACTORS

Investing in our common stock involves significant risks. In deciding whether to invest, you should carefully consider the following risk factors, as well as the other information contained in this prospectus supplement, the accompanying prospectus and in our filings with the Securities and Exchange Commission, or the SEC, that we have incorporated by reference in this prospectus supplement and the accompanying prospectus. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.

Risks Related to our Business

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

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

delays associated with development and non-clinical and clinical trials due to an inability to timely obtain a single or limited source component;

inability to timely obtain an sufficient quantities of API and an adequate supply of required components; and

reduced control over pricing, quality and timely delivery.

Our relationships with our manufacturers and suppliers are particularly important to us and any loss of or material diminution of their capabilities due to factors such as regulatory issues, accidents, acts of God or any other factor would have a material adverse effect on our company. Any loss of or interruption in the supply of components from our suppliers or other third-party suppliers would require us to seek alternative sources of supply or require us to manufacture these components internally, which we are currently not able to do.

If the supply of any components is lost or interrupted, API, product or components from alternative suppliers may not be available in sufficient quality or in volumes within required time frames, if at all, to meet our or our partners' needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing or cause us to lose sales, force us into breach of other agreements, incur additional costs, delay new product introductions or harm our reputation. Furthermore, product or components from a new supplier may not be identical to those provided by the original supplier. Such differences could have material effects on our overall business plan and timing, could fall outside of regulatory requirements, affect product formulations or the safety and effectiveness of our products that are being developed.

If our competitors are successful in obtaining approval for Abbreviated New Drug Applications for products that have the same active ingredients as BELBUCA, Symproic or BUNAVAIL, sales of BELBUCA, Symproic or BUNAVAIL may be adversely affected.

Our competitors may submit for approval certain Abbreviated New Drug Applications, or ANDAs, which provide for the marketing of a drug product that has the same active ingredients in the same strengths and dosage form as a drug product already listed with the FDA, and which has been shown to be bioequivalent to such FDA-listed drug. Drugs approved in this way are commonly referred to as generic versions of a listed drug and can often be substituted by pharmacists under prescriptions written for an original listed drug. Any applicant filing an ANDA is required to make patent certifications to the FDA, such as certification to the FDA that the new product subject to the ANDA will not infringe an already approved product's listed patents or that such patents are invalid (otherwise known as a Paragraph IV Certification).

In February 2016, we announced that a generic competitor, Teva Pharmaceutical Industries Ltd., or Teva, had filed a Paragraph IV Certification challenging certain of our BUNAVAIL-related patents and we received notices regarding Paragraph IV certifications from Teva in November and December 2016, seeking to find invalid two Orange Book listed patents relating specifically to BELBUCA. The filing of this certification required us to initiate costly litigation against Teva. In addition, a number of our competitor companies have filed Paragraph IV Certifications challenging the patent for Suboxone[®] film, the market leader in the field in which we are seeking to generate sales of BUNAVAIL. To the extent that any company is successful in challenging the validity of certain patents covering BUNAVAIL or Suboxone[®] film under a Paragraph IV Certification, it could result in FDA approval of a drug that is lower in price to BUNAVAIL or Suboxone[®] film. Such a new drug could make it more difficult for BUNAVAIL to gain any significant market share in an increasingly generic marketplace, which would have a material adverse effect on our results of operations, cash flow, reputation and stock price.

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In October 2017, we announced that we had entered into a settlement agreement with Teva that resolved our BUNAVAIL patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the Settlement Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BUNAVAIL in the U.S. on July 23, 2028 or earlier under certain circumstances. Other terms of the agreement are confidential.

In February 2018, we announced that we had entered into a Settlement Agreement with Teva that resolves our previously reported BELBUCA, patent litigation against Teva pending in the United States District Court for the District of Delaware. As part of the settlement agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BELBUCA in the U.S. on January 23, 2027 or earlier under certain circumstances. Other terms of the agreement are confidential.

As such, we have been and may continue to be subject to ANDA-related litigation, which is costly and distracting and has the potential to impair the long-term value of our products.

We are presently a party to lawsuits by third parties who claim that our products, methods of manufacture or methods of use infringe on their intellectual property rights, and we may be exposed to these types of claims in the future.

We are presently, and may continue to be, exposed to litigation by third parties based on claims that our technologies, processes, formulations, methods, or products infringe the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in pharmaceutical patents is, in most instances, uncertain and highly complex. Any litigation or claims against us, whether or not valid, would result in substantial costs, could place a significant strain on our financial and human resources and could harm our reputation. Such a situation may force us to do one or more of the following:

incur significant costs in legal expenses for defending against an intellectual property infringement suit;

delay the launch of, or cease selling, making, importing, incorporating or using one or more or all of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;

obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or

redesign our formulations or products, which would be costly and time-consuming.

With respect to our BEMA delivery technology, the thin film drug delivery technology space is highly competitive. There is a risk that a court of law in the United States or elsewhere could determine that one or more of our BEMA based products conflicts with or covered by external patents. This risk presently exists in our litigation with Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC, or Aquestive) relating to our BUNAVAIL product which was filed in September 2014 and in our litigation with

Aquestive relating to our BELBUCA product which was filed in January 2017. If the courts in these cases were to rule against us and our partner in these cases, we could be forced to license technology from Aquestive or be prevented from marketing BUNAVAIL or BELBUCA, or otherwise incur liability for damages, which could have a material adverse effect on our ability for us or our partners to market and sell BUNAVAIL or BELBUCA.

We have been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market BELBUCA and ONSOLIS within the countries of the European Union. We are required to pay a low single digit royalty on sales of products that are covered by this patent in the European Union. We have not conducted freedom to operate searches and analyses for our other proposed products. Moreover, the possibility exists that a patent could issue that would cover one or more of our products, requiring us to defend a patent infringement suit or necessitating a patent validity challenge that would be costly, time consuming and possibly unsuccessful.

Our lawsuits with Aquestive and RB Pharmaceuticals have caused us to incur significant legal costs to defend ourselves, and we would be subject to similar costs if we are a party to similar lawsuits in the future. Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our BEMA products. We may be unable to obtain such licenses from the patent holders, which could materially and adversely impact our business.

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Risks Related to this Offering and Our Common Stock

Investors in this offering will pay a much higher price than the book value of our common stock.

If you purchase common stock in this offering, you will incur an immediate and substantial dilution of \$ _____ per share after giving effect to the sale by us of _____ shares of common stock offered in this offering at the public offering price of \$ _____ per share, and after deducting estimated underwriting discounts and commissions for shares sold in the public offering and estimated offering expenses payable by us. See Dilution. In the past, we have issued options and warrants to acquire common stock at prices significantly below this offering price. To the extent these outstanding options or warrants are ultimately exercised, you will incur additional dilution. Furthermore, if the underwriters exercise their option to purchase additional shares, you will also incur additional dilution.

Our management will have broad discretion over the use of the net proceeds from this offering, and you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. Accordingly, you may be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for us.

If our stock price fluctuates, purchasers of our common stock could incur substantial losses.

The market price of our common stock has fluctuated significantly and may continue to fluctuate significantly in response to factors that are beyond our control. The stock market in general has from time to time experienced extreme price and volume fluctuations, and the biotechnology sector in particular has experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the clinical development progress or operating performance of these companies, including as a result of adverse development events. These broad market and sector fluctuations have resulted and could in the future result in extreme fluctuations in the price of our common stock, which could cause purchasers of our common stock to incur substantial losses.

Sales of additional shares of our common stock, including by us or our directors and officers following expiration or early release of the 60-day lock-up, could cause the price of our common stock to decline.

Sales of substantial amounts of our common stock in the public market, or the availability of such shares for sale, by us or others, including the issuance of common stock upon exercise of outstanding options or warrants, could adversely affect the price of our common stock. In connection with this offering, we, the selling stockholder and our directors and officers have entered into lock-up agreements for a period of 60 days following this offering. We, the selling stockholder and our directors and officers may be released from lock-up prior to the expiration of the lock-up period at the discretion of Cantor Fitzgerald & Co. See Underwriting. Upon expiration or earlier release of the lock-up, we, the selling stockholder and our directors, officers may sell shares into the market, which could adversely affect the market price of shares of our common stock. In addition, during the lock-up period and thereafter, sales of shares held by our directors and officers are permitted under trading plans, as in effect as of the date of the applicable lock-up agreement, established pursuant to Rule 10b5-1 of the Exchange Act. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of _____ shares of our common stock in this offering will be approximately \$ _____ million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any of the proceeds from the sale of shares by the selling stockholder, although we will bear the costs, other than the underwriting discounts and commissions, associated with those sales.

We expect to use the net proceeds of this offering, in addition to our existing cash resources, for working capital and other corporate purposes.

We have not determined the amounts we plan to spend on any of the areas identified above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering. We may temporarily invest the net proceeds in investment-grade, interest-bearing securities until they are used for their stated purpose.

Table of Contents**SELLING STOCKHOLDER**

The following table sets forth the number of shares owned by the selling stockholder prior to this offering, the number of shares to be offered by the selling stockholder in this offering, the number of shares to be owned by the selling stockholder after the completion of this offering and the percentage of common stock to be owned by the selling stockholder after giving effect to the completion of this offering. We have prepared the table based on the information given to us, by or on behalf of, the selling stockholder. The beneficial ownership of our common stock by the selling stockholder set forth in the table is determined as of March 14, 2019.

Name of Selling Stockholder ⁽¹⁾	Shares Beneficially Owned before Offering	Percentage Exercised	Shares Number Beneficially of Owned Additional		
			Number of Shares to be Offered if Underwriter's Option is not Exercised	Number of Shares to be Offered if Underwriter's Option is Exercised	Percentage of Shares to be Offered if Underwriter's Option is Exercised
Broadfin Healthcare Master Fund, Ltd. ⁽²⁾	16,597,289	23.38% ⁽³⁾	0	0	% ⁽³⁾

(1) The business address of the selling stockholder is 300 Park Avenue, 25th Floor, New York, New York 10022.

(2) Broadfin Capital, LLC, the investment manager of Broadfin Healthcare Master Fund, Ltd., or Broadfin, may be deemed to beneficially own the shares owned by Broadfin Healthcare Master Fund, Ltd. Kevin Kotler, the managing member of Broadfin Capital, LLC, may be deemed to beneficially own the shares owned by Broadfin Healthcare Master Fund, Ltd.

(3) Broadfin Healthcare Master Fund, Ltd. beneficially owns 4,375,066 shares of common stock and 12,222,223 shares of common stock issuable upon conversion of the Series B Preferred Stock. The Series B Preferred Stock owned by Broadfin is subject to a beneficial ownership limitation that prohibits Broadfin from converting its shares of Series B Preferred Stock into shares of common stock to the extent that, as a result of such conversion, Broadfin and its affiliates would beneficially own more than 9.98% of the total number of shares of common stock then issued and outstanding.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to our term loan agreement, dated February 21, 2017, as amended September 1, 2017 and April 4, 2019, with CRG Servicing LLC and certain lenders named therein, we are prohibited from paying any cash dividends. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Table of Contents**DILUTION**

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

Our net tangible book value at December 31, 2018 was \$(9.7) million, or \$(0.14) per share, based on 70,778,234 shares of our common stock then outstanding. After giving effect to the sale by us of _____ shares of common stock in this offering at a public offering price of \$ _____ per share, less the underwriting discounts and commissions for shares sold in the public offering and estimated offering expenses payable by us, our net tangible book value at December 31, 2018 would have been approximately \$ _____ million, or \$ _____ per share. This represents an immediate increase in net tangible book value of \$ _____ per share to existing stockholders and an immediate dilution of \$ _____ per share to investors in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share	\$
Net tangible book value per share as of December 31, 2018	\$ (0.14)
Increase per share attributable to new investors purchasing shares in this offering	
As adjusted net tangible book value per share after this offering	\$ (0.14)
Dilution per share to new investors purchasing our common stock in this offering	\$ 0.14

The number of shares of our common stock to be outstanding after this offering is based on 70,778,234 shares outstanding as of December 31, 2018, and excludes:

4,406,004 shares of common stock issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$3.19 per share as of December 31, 2018;

2,166,102 shares of common stock reserved for issuance upon settlement of restricted stock units as of December 31, 2018;

2,136,020 shares of common stock issuable upon the exercise of warrants to purchase common stock outstanding as of December 31, 2018 at an exercise price of \$2.60 per share;

an aggregate of 1,874,086 additional shares of common stock reserved for future issuance under our 2011 equity incentive plan, and our 2001 stock incentive plan as of December 31, 2018;

2,093,155 shares of common stock issuable upon conversion of the Series A Non-Voting Convertible Preferred Stock; and

17,222,223 shares of common stock issuable upon conversion of the Series B Non-Voting Convertible Preferred Stock.

Except as otherwise noted, we have presented the information in this prospectus supplement assuming:

no exercise by the underwriters of their option to purchase up to an additional _____ shares of our common stock in this offering; and

no exercise of outstanding stock options and warrants described above, no issuance of common stock upon settlement of restricted stock units and no conversion of outstanding shares of Series B Non-Voting Convertible Preferred Stock.

To the extent that any of these outstanding options or warrants are exercised, there will be further dilution to new investors. In addition, in the discussion and table above, we assume no exercise by the underwriters of their option to purchase additional shares. If the underwriters exercise their option to purchase additional shares and the selling stockholder converts shares of our Series B Non-Voting Preferred Stock into shares of our common stock to sell to the underwriters, there will be further dilution to new investors.

Table of Contents**UNDERWRITING**

Subject to the terms and conditions set forth in the underwriting agreement, dated April , 2019, among us, Broadfin Healthcare Master Fund, Ltd., as selling shareholder (the Selling Shareholder), and Cantor Fitzgerald & Co., 499 Park Avenue, New York, New York 10022, and SunTrust Robinson Humphrey, Inc., 3333 Peachtree Road NE, 9th Floor, Atlanta, GA 30326, as representatives of the underwriters named below (the Representatives), we and the Selling Shareholder have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us and the Selling Shareholder, as applicable, the shares of common stock shown opposite its name below:

Underwriter	Number of Shares
Cantor Fitzgerald & Co.	
SunTrust Robinson Humphrey, Inc.	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Option to Purchase Additional Shares

The Selling Shareholder has granted to the underwriters an option, exercisable 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of _____ shares from the Selling Shareholder at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions. If the underwriters exercise this option, the underwriters will be obligated, subject to certain conditions, to purchase a number of additional shares approximately proportionate to that underwriter's initial purchase commitment as indicated in the table above.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ _____ per share of common stock. After the initial offering, the Representative may change the offering price and other selling terms.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown

assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$
Proceeds to Selling Shareholder, before expenses	\$	\$	\$	\$

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We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$. We have also agreed to reimburse the underwriters for up to \$.

Listing

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

No Sales of Similar Securities

We, our officers and our directors and the Selling Shareholder have agreed, subject to certain specified exceptions, not to directly or indirectly, for a period of 60 days after the date of the underwriting agreement:

sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open put equivalent position within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise dispose of, any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially,

enter into any swap, hedge or other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock, or

publicly announce an intention to do any of the foregoing for a period of 60 days after the date of this prospectus supplement without the prior written consent of Cantor Fitzgerald & Co.

In addition, we, our officers and our directors and the Selling Shareholder agree that, without the prior written consent of Cantor Fitzgerald & Co., we, our officers and our directors and the Selling Shareholder will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The above-referenced restrictions do not apply to our officers, our directors and the Selling Shareholder in certain circumstances, including:

transfers as a *bona fide* gift or gifts;

transfers to any trust for the direct or indirect benefit of such persons or the immediate family of such persons;

transfers pursuant to a qualified domestic order or in connection with a divorce settlement;

transfers by will or intestate succession to the legal representative, heir, beneficiary or immediate family member of such persons upon the death of such persons;

transfers pursuant to existing 10b5-1 plans and certain proposed amendments thereto;

shares issued pursuant to option exercises granted under our equity incentive plans; provided that such issued shares remain subject to the 60-day period;

the establishment of a written trading plan designed to comply with Rule 10b5-1(c) of the Exchange Act, provided that no public filing or announcement is made in connection with the establishment of such plan and no sales occur under such plan during the 60-day period; or

sales of common stock acquired in the open market following the offering; provided no public filing reporting a reduction in beneficial ownership is required other than a Form 5 following the expiration of the 60-day period.

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The above-referenced restrictions do not apply to issuances by us of shares of our common stock or options to purchase our common stock:

upon exercises of options to purchase our common outstanding as of the date hereof;

pursuant to any stock option, stock bonus or other stock plan or arrangement in place as of the date hereof;
or

upon exercise or conversion of outstanding preferred stock or warrants.

Cantor Fitzgerald & Co. may, in its sole discretion and at any time or from time to time before the termination of the 60-day period release all or any portion of the securities subject to lock-up agreements. Any such release could allow the securities that are subject to lock-up agreements to then be sold privately or into the market, subject to, and in accordance with, applicable federal and state securities laws.

Market Making, Stabilization and Other Transactions

The underwriters may make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in its sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, and certain persons participating in the offering, may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either covered short sales or naked short sales.

Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

Naked short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of

shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, may end any of these activities at any time.

Passive Market Making

The underwriters may also engage in passive market making transactions in our common stock on the NASDAQ in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and, if commenced, may end passive market making activities at any time.

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Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters, selling group members (if any) or their affiliates. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' respective websites and any information contained in any other website maintained by any of the underwriters is not part of this prospectus supplement, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in a wide range of activities for their own accounts and the accounts of customers, which may include, among other things, corporate finance, mergers and acquisitions, merchant banking, equity and fixed income sales, trading and research, derivatives, foreign exchange, futures, asset management, custody, clearance and securities lending. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of its business, the underwriters and their respective affiliates may, directly or indirectly, hold long or short positions, trade and otherwise conduct such activities in or with respect to debt or equity securities and/or bank debt of, and/or derivative products. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Stamp Taxes

If you purchase shares of common stock offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

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NOTICE TO INVESTORS

Canada

This prospectus supplement constitutes an exempt offering document as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the common stock. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this prospectus supplement or on the merits of the common stock and any representation to the contrary is an offence.

Canadian investors are advised that this prospectus supplement has been prepared in reliance on section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105). Pursuant to section 3A.3 of NI 33-105, this prospectus supplement is exempt from the requirement that the Company and the underwriter(s) provide investors with certain conflicts of interest disclosure pertaining to connected issuer and/or related issuer relationships that may exist between the Company and the underwriter(s) as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the common stock in Canada is being made on a private placement basis only and is exempt from the requirement that the Company prepares and files a prospectus under applicable Canadian securities laws. Any resale of the common stock acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, pursuant to a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the common stock outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the common stock will be deemed to have represented to the Company and the underwriter(s) that the investor (i) is purchasing the common stock as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an accredited investor as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* (NI 45-106) or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a permitted client as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this prospectus supplement does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the common stock and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the common stock or with respect to the eligibility of the common stock for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum (such as this prospectus supplement), including where the distribution involves an eligible foreign security as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a misrepresentation as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur Canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

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Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

a sophisticated investor under section 708(8)(a) or (b) of the Corporations Act;

a sophisticated investor under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or

a professional investor within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each referred to herein as a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, referred to herein as the Relevant Implementation Date, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

to any legal entity which is a qualified investor as defined in the Prospectus Directive;

to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

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Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a prospectus as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;

where no consideration is given for the transfer; or

where the transfer is by operation of law.

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Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and qualified individuals, each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors (as defined in the Prospectus Directive) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated. Each such person is referred to herein as a Relevant Person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

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LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Goodwin Procter LLP. The underwriters are being represented in connection with this offering by Latham & Watkins LLP.

EXPERTS

The consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Annual Report on Internal Control over Financial Reporting) incorporated in this prospectus supplement by reference to the Annual Report on Form 10-K for the year ended December 31, 2018 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 file reports, proxy statements and other information with the SEC as required by the Exchange Act. You can review our electronically filed reports, proxy and information statements on the SEC's website at www.sec.gov or on our website at www.bdsi.com. Information included on our website is not a part of this prospectus supplement or the accompanying prospectus.

This prospectus supplement is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus supplement and the accompanying prospectus regarding us and the securities, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC or from the SEC's website.

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INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate into this prospectus supplement information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. The information incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus. Information that we file with the SEC in the future and incorporate by reference in this prospectus supplement and the accompanying prospectus automatically updates and supersedes previously filed information as applicable. The following documents filed with the SEC pursuant to the Exchange Act are incorporated herein by reference (other than, in each case, documents or information deemed to have been furnished and not filed in accordance with SEC rules):

our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 14, 2019;

our Current Reports on Form 8-K filed with the SEC on January 29, 2019, March 4, 2019, March 6, 2019, March 14, 2019 and April 10, 2019; and

the description of our Common Stock contained in our registration statement on Form 8-A, filed with the SEC on June 19, 2002 and any amendment or report filed with the SEC for the purpose of updating the description.

In addition, this prospectus supplement incorporates by reference all documents and reports that we file pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and prior to the completion or termination of this offering of common stock even though they are not specifically identified in this prospectus supplement, 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 Exchange Act.

You may request, orally or in writing, a copy of the documents which are incorporated by reference, which will be provided to you at no cost by contacting: BioDelivery Sciences International, Inc., 4131 ParkLake Avenue, Suite 225, Attention: Michelle Brown, Raleigh, North Carolina; telephone: (919) 582-9050.

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PROSPECTUS

\$75,000,000

Common Stock

Preferred Stock

Debt Securities

Warrants

Units

and

12,222,223 Shares of

Common Stock

Offered by the Selling Stockholder

By this prospectus, we may offer and sell from time to time, in one or more series or classes, up to \$75,000,000 in aggregate principal amount of our common stock, preferred stock, debt securities, warrants and/or units. We may also offer securities as may be issuable upon conversion, redemption, repurchase, exchange or exercise of any securities registered hereunder, including any applicable anti-dilution provisions.

In addition, the selling stockholder may, from time to time in one or more offerings, offer and sell up to 12,222,223 shares of our common stock issuable upon conversion of our Series B Preferred Stock held by the selling stockholder. In the prospectus supplement relating to any sales by the selling stockholder, we will, among other things, identify the number of shares of our common stock that the selling stockholder will be selling.

This prospectus provides a general description of the securities we may offer. Each time we offer securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement, as well as any documents incorporated by reference, before you invest in any of the securities being offered.

Our common stock is listed on The Nasdaq Capital Market under the symbol BDSI. On January 17, 2019, the closing price for our common stock, as reported on The Nasdaq Capital Market, was \$4.28 per share. We or the selling stockholder may offer and sell these securities directly to investors, through agents designated from time to time or to

or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled **Plan of Distribution** in this prospectus. If any agents or underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such agents or underwriters and any applicable fees, commissions, discounts or over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement. We will not receive any proceeds from the sale of securities by the selling stockholder.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties referenced under the heading Risk Factors contained in this prospectus beginning on page 6 and any applicable prospectus supplement, and under similar headings in the other documents that are incorporated by reference into this prospectus.

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

The date of this prospectus is January 18, 2019.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this shelf registration process, we may from time to time sell any combination of the securities described in this prospectus in one or more offerings for an aggregate offering price of up to \$75,000,000, and the selling stockholder may sell up to an aggregate amount of 12,222,223 shares of our common stock issuable upon conversion of our Series B Preferred Stock held by the selling stockholder in one or more offerings.

This prospectus provides you with a general description of the securities we and the selling stockholder may offer. Each time we and/or the selling stockholder sell securities, we will provide one or more prospectus supplements that will contain specific information about the terms of the offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and the accompanying prospectus supplement together with the additional information described under the heading **Where You Can Find More Information** beginning on page 34 of this prospectus.

You should rely only on the information contained in or incorporated by reference in this prospectus, any accompanying prospectus supplement or in any related free writing prospectus filed by us with the SEC. We have not authorized anyone to provide you with different information. This prospectus and the accompanying prospectus supplement do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in the accompanying prospectus supplement or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, any prospectus supplement, the documents incorporated by reference and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

Unless the context otherwise indicates, references in this prospectus to the company, we, us and our refer to BioDelivery Sciences International, Inc.

This prospectus contains trade names, trademarks and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or TM symbols.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as may, will, could, should, expects, intends, plans, anticipates, believes, estimates, predicts, and similar expressions, or the negative of these terms, or similar expressions. Accordingly, these statements involve estimates, assumptions, risks and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors referenced in the section Risk Factors.

This prospectus contains forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. These statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA (as defined below) 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;

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

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

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

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

These forward-looking statements are neither promises nor guarantees of future performance due to a variety of risks and uncertainties and other factors more fully discussed in the Risk Factors section in this prospectus, the section of any accompanying prospectus supplement entitled Risk Factors and the risk factors and cautionary statements described in other documents that we file from time to time with the SEC. Given these uncertainties, readers should not place undue reliance on our forward-looking statements. These forward-looking statements speak only as of the date on which the statements were made and are not guarantees of future performance. Except as may be required by applicable law, we do not undertake to update any forward-looking statements after the date of this prospectus or the respective dates of documents incorporated by reference herein or therein that include forward-looking statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this prospectus, even if new information becomes available in the future.

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PROSPECTUS SUMMARY

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.

BELBUCA (buprenorphine) buccal film incorporates buprenorphine in our BEMA technology and was approved by the U.S. Food and Drug Administration, or the 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, or the DEA, as a Schedule III product, meaning it has 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. (or Collegium).

Company Information

We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002. Our executive offices are located at 4131 ParkLake Avenue, Suite 225, Raleigh, North Carolina, and our telephone number is (919) 582-9050. Our website address is www.bdsi.com. We do not incorporate the information on or accessible through our website into this prospectus.

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described under the heading "Risk Factors" contained in the applicable prospectus supplement, and under similar headings in the other documents that are incorporated by reference into this prospectus, before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. Our business, financial condition or results of operations could be materially adversely affected by the materialization of any of these risks. The trading price of our securities could decline due to the materialization of any of these risks, and you may lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations.

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USE OF PROCEEDS

We intend to use the net proceeds from the sale of any securities offered under this prospectus for general corporate purposes unless otherwise indicated in the applicable prospectus supplement. General corporate purposes may include costs to commercialize our products, research and development and clinical development costs to support the advancement of our product candidates and the expansion of our product candidate pipeline; funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. We may temporarily invest the net proceeds in a variety of capital preservation instruments, including investment grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government, or may hold such proceeds as cash, until they are used for their stated purpose. 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 net proceeds.

We will not receive any proceeds from the sale by the selling stockholder of up to 12,222,223 shares of common stock issuable upon conversion of our Series B Preferred Stock held by the selling stockholder and covered by this prospectus.

Table of Contents**SELLING STOCKHOLDER**

This prospectus also related to the possible resale by one of our stockholders, who we refer to in this prospectus as the selling stockholder, of up to 12,222,223 shares of our common stock issuable upon conversion of our Series B Preferred Stock held by the selling stockholder. In May 2018, we entered into a securities purchase agreement with the selling stockholder and certain other investors, or the Securities Purchase Agreement, pursuant to which we agreed to issue and sell an aggregate of 5,000 shares of Series B Preferred Stock. Each share of Series B Preferred Stock is convertible, from time to time at the option of the holder thereof, 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 certain adjustments for stock splits and stock dividends).

In connection with the Securities Purchase Agreement, we entered into a registration rights agreement, or the Registration Agreement, with the selling stockholder pursuant to which we granted the selling stockholder certain registration rights for the sale of shares of common stock issuable upon the conversion of the Series B Preferred Stock.

The following table provides information regarding the selling stockholder and the number of shares the selling stockholder is offering under this prospectus. We have prepared this table based on information furnished to us by or on behalf of the selling stockholder. Under the rules of the SEC, beneficial ownership includes shares over which the indicated beneficial owner exercises voting or investment power. Beneficial ownership is determined under Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and generally includes voting or investment power with respect to securities, including any securities that grant a selling stockholder the right to acquire common stock within 60 days of December 31, 2018. Unless otherwise indicated in the footnotes below, we believe that the selling stockholder has sole voting and investment power with respect to all shares beneficially owned. The percentage ownership data is based on 70,810,339 shares of our common stock issued and outstanding as of January 18, 2019 and does not reflect the applicable beneficial ownership limitation described below. Therefore, the beneficial ownership of the selling stockholder is calculated and presented (for purposes of disclosure in this prospectus only) on a fully as converted basis. The number of shares of common stock beneficially owned by the selling stockholder is based on information provided by the selling stockholder as of January 18, 2019.

The shares may be sold by the selling stockholder, by those persons or entities to whom it transfers, donates, devises, pledges or distributes its shares or by other successors in interest. The information regarding shares beneficially owned after this offering assumes the sale of all shares offered by the selling stockholder. The selling stockholder may sell less than all of the shares listed in the table. In addition, the shares listed below may be sold pursuant to this prospectus or in privately negotiated transactions. Accordingly, we cannot estimate the number of shares the selling stockholder will sell under this prospectus.

Name of Selling Stockholder ⁽¹⁾	Common Stock Beneficially Owned			
	Shares Beneficially Owned before Offering		Maximum Number of Shares that may be Offered Pursuant to this Prospectus	Shares Beneficially Owned After Offering ⁽²⁾
	Number	Percentage	Number	Percentage (%)
Broadfin Healthcare Master Fund, Ltd. ⁽³⁾	12,222,223	17.26% ⁽⁴⁾	12,222,223	

- (1) The business address of the selling stockholder is 300 Park Avenue, 25th Floor, New York, New York 10022. Additional information concerning the named selling stockholder or pledgees, donees, transferees or other successors-in-interest of the selling stockholder may be set forth in a prospectus supplement to this prospectus.

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- (2) We do not know when or in what amounts the selling stockholder may offer shares for sale. The selling stockholder may not sell any or all of the shares offered by this prospectus. Because the selling stockholder may offer all or some of the shares pursuant to this offering and because there are currently no agreements, arrangements or undertakings with respect to the sale of any of the shares, we cannot estimate the number of shares that will be held by the selling stockholder after completion of this offering. However, for purposes of this table, we have assumed that, after completion of this offering, none of the shares covered by this prospectus will be held by the selling stockholder.
- (3) Broadfin Capital, LLC, the investment manager of Broadfin Healthcare Master Fund, Ltd., or Broadfin, may be deemed to beneficially own the shares owned by Broadfin Healthcare Master Fund, Ltd. Kevin Kotler, the managing member of Broadfin Capital, LLC, may be deemed to beneficially own the shares owned by Broadfin Healthcare Master Fund, Ltd.
- (4) The Series B Preferred Stock owned by Broadfin is subject to a beneficial ownership limitation that prohibits Broadfin from converting its shares of Series B Preferred Stock into shares of common stock to the extent that, as a result of such conversion, Broadfin and its affiliates would beneficially own more than 9.98% of the total number of shares of common stock then issued and outstanding.

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SECURITIES WE MAY OFFER

This prospectus contains summary descriptions of the securities we may offer from time to time. In addition, the selling stockholder may sell up to an aggregate of 12,222,223 shares of our common stock issuable upon conversion of our Series B Preferred Stock held by the selling stockholder. This prospectus provides you with a general description of the securities we and the selling stockholder may offer. These summary descriptions are not meant to be complete descriptions of each security. The particular terms of any security will be described in the applicable prospectus supplement.

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DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. In addition, the selling stockholder may sell up to an aggregate of 12,222,223 shares of our common stock issuable upon conversion of our Series B Preferred Stock held by the selling stockholder. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our amended and restated certificate of incorporation and amended and restated bylaws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. The terms of our common stock and preferred stock may also be affected by Delaware law.

General

Our authorized capital stock consists of 125,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of the date of this prospectus, our capital stock consists of 70,810,339 shares of issued and outstanding common stock, \$0.001 par value, 2,093,155 shares of outstanding Series A Preferred Stock, par value \$0.001 per share and 3,100 shares of outstanding Series B Preferred Stock, par value \$0.001 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 outstanding options underlying shares of our common stock related to our Amended and Restated 2001 Incentive Plan or (iii) pursuant to outstanding options and restricted stock units underlying shares of our common stock related 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 \$75,000,000 in the aggregate of:

common stock;

preferred stock;

secured or unsecured debt securities consisting of notes, debentures or other evidences of indebtedness which may be senior debt securities, senior subordinated debt securities or subordinated debt securities, each of which may be convertible into equity securities;

warrants to purchase our securities;

rights to purchase our securities; or

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

We may issue the debt securities as exchangeable for or convertible into shares of common stock, preferred stock or other securities. The preferred stock may also be exchangeable for and/or convertible into shares of common stock, another series of preferred stock or other securities. The debt securities, the preferred stock, the common stock and the

warrants are collectively referred to in this prospectus as the securities. When a particular series of securities is offered, a supplement to this prospectus will be delivered with this prospectus, which will set forth the terms of the offering and sale of the offered securities.

Common Stock

As of the date of this prospectus, there were 70,810,339 shares of common stock issued and 70,794,848 shares of common stock outstanding, held of record by approximately 122 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.

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

Preferred Stock

Our certificate of incorporation, as amended, empowers our board of directors, without action by our shareholders, to issue up to 5,000,000 shares of preferred stock from time to time in one or more series, which preferred stock may be offered by this prospectus and supplements thereto. As of the date of this prospectus, we had 2,709,300 shares of preferred stock designated as Series A Non-Voting Convertible Preferred Stock, par value \$0.001 per share (the Series A Preferred Stock), and had 2,093,155 shares of Series A Preferred Stock issued and outstanding and 5,000 shares of preferred stock designated as Series B Non-Voting Convertible Preferred Stock, par value \$0.001 per share (the Series B Preferred Stock), and had 3,100 shares of Series B 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;

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;

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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 Non-Voting Convertible 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 rank:

senior to our common stock;

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

junior to any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock,
in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion

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

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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 and in parity with our Series B Preferred 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, holders of Series A Preferred Stock (and holders of the Series B 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.

Series B Preferred Stock

Our board of directors has designated 5,000 of the 5,000,000 authorized shares of preferred stock as our Series B Preferred Stock.

Rank

The Series B Preferred Stock rank:

par with our outstanding Series A 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;

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on parity with any class or securities of our capital stock hereafter created specifically ranking by its terms on parity with the Series B Preferred Stock; and

junior to any class or series of capital stock hereafter created specifically ranking by its terms senior 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 is convertible, from time to time at the option of the holder thereof, 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 certain adjustments for stock splits and stock dividends), 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 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 the Company.

Pursuant to written notice, we may also cause each holder of Series B Preferred Stock to convert all or part of such holder's Series B Preferred Stock into common stock, except that a holder will not be forced to convert shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder would beneficially own more than 9% of the total number of shares of common stock then issued and outstanding immediately after giving effect to the issuance of shares of common stock, pursuant to such written notice. We shall not deliver a forced conversion notice to holders of Series B Preferred Stock more than one time in a ninety (90) day period.

Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series B Preferred Stock will receive a payment equal to \$0.001 per share of Series B Preferred Stock before any proceeds are distributed to the holders of our common stock and in parity with our outstanding Series A Preferred 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 (and the holders of the Series A Preferred Stock), holders of Series B Preferred Stock (and the holders of the 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 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 designation 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 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 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.

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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 A 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 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.

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.

Anti-Takeover Effects of Delaware Law and our Certificate of Incorporation and Bylaws

Certain provisions of the Delaware General Corporation Law and of our certificate of incorporation and bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Provisions of our Certificate of Incorporation and Second Amended and Restated Bylaws

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies. Until the election of directors at the annual meeting scheduled to be held in 2020, our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Starting with the annual meeting held in 2018, directors elected by stockholders will be elected to one-year terms. Beginning at the 2020 annual meeting of our stockholders, the board of directors will be completely declassified and all directors will be subject to annual election for one-year terms.

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Until the election of directors at the annual meeting scheduled to be held in 2021, our certificate of incorporation provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds of the shares of the capital stock then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum or by a sole remaining director. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

Meetings of stockholders. Our bylaws provide that a special meeting of stockholders may be called exclusively by: (i) the Chairman of the Board of Directors or the Chief Executive Officer, President or other executive officer of the Company, (ii) an action of the Board of Directors or (iii) request in writing of the stockholders of record owning not less than sixty-six and two-thirds percent (66 2/3%) of the entire capital stock of the Company issued and outstanding and entitled to vote. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements. Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and by-laws. Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the outstanding shares entitled to vote on the amendment.

Undesignated preferred stock. Our certificate of incorporation provides for 5,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Transfer Agent and Registrar

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

Listing

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

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DESCRIPTION OF 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;

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;

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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;

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;

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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);

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.

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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.

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement or free writing prospectus the terms on which a series of debt securities may be convertible into or exchangeable for our common stock, our preferred stock or other securities (including securities of a third-party). We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock, our preferred stock or other securities (including securities of a third-party) that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement or free writing prospectus applicable to a particular series of debt securities, the indentures will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of all or substantially all of our assets. However, any successor to or acquirer of such assets must assume all of our obligations under the indentures or the debt securities, as appropriate. If the debt securities are convertible into or exchangeable for other securities of ours or securities of other entities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities that the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

Events of Default Under the Indenture

Unless we provide otherwise in the prospectus supplement or free writing prospectus applicable to a particular series of debt securities, the following are events of default under the indentures with respect to any series of debt securities that we may issue:

if we fail to pay interest when due and payable and our failure continues for 90 days and the time for payment has not been extended;

if we fail to pay the principal, premium or sinking fund payment, if any, when due and payable at maturity, upon redemption or repurchase or otherwise, and the time for payment has not been extended;

if we fail to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive notice from the trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and

if specified events of bankruptcy, insolvency or reorganization occur.

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We will describe in each applicable prospectus supplement or free writing prospectus any additional events of default relating to the relevant series of debt securities.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the trustee if notice is given by such holders, may declare the unpaid principal, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the unpaid principal, premium, if any, and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the trustee reasonable indemnity or security satisfactory to it against any loss, liability or expense. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series, provided that:

the direction so given by the holder is not in conflict with any law or the applicable indenture; and

subject to its duties under the Trust Indenture Act, the trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

the holder has given written notice to the trustee of a continuing event of default with respect to that series;

the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the trustee or security satisfactory to it against any loss, liability or expense or to be incurred in compliance with instituting the proceeding as trustee; and

the trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities, or other defaults that may be specified in the applicable prospectus supplement or free writing prospectus.

We will periodically file statements with the trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

Subject to the terms of the indenture for any series of debt securities that we may issue, we and the trustee may change an indenture without the consent of any holders with respect to the following specific matters:

to fix any ambiguity, defect or inconsistency in the indenture;

to comply with the provisions described above under Consolidation, Merger or Sale;

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to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act;

to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;

to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided under Description of Debt Securities General, to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;

to evidence and provide for the acceptance of appointment hereunder by a successor trustee;

to provide for uncertificated debt securities and to make all appropriate changes for such purpose;

to add to our covenants such new covenants, restrictions, conditions or provisions for the benefit of the holders, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default or to surrender any right or power conferred to us in the indenture; or

to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, subject to the terms of the indenture for any series of debt securities that we may issue or as otherwise provided in the prospectus supplement or free writing prospectus applicable to a particular series of debt securities, we and the trustee may make the following changes only with the consent of each holder of any outstanding debt securities affected:

extending the stated maturity of the series of debt securities;

reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption or repurchase of any debt securities; or

reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that, subject to the terms of the indenture and any limitation otherwise provided in the prospectus supplement or free writing prospectus applicable to a particular series of debt securities, we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

register the transfer or exchange of debt securities of the series;

replace stolen, lost or mutilated debt securities of the series;

maintain paying agencies;

hold monies for payment in trust;

recover excess money held by the trustee;

compensate and indemnify the trustee; and

appoint any successor trustee.

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In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, any premium and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement or free writing prospectus, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company or another depository named by us and identified in a prospectus supplement or free writing prospectus with respect to that series.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement or free writing prospectus, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement or free writing prospectus, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement or free writing prospectus the security registrar, and any transfer agent in addition to the security registrar that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series. If we elect to redeem the debt securities of any series, we will not be required to:

issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or

register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Trustee

The trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs.

Subject to this provision, the trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement or free writing prospectus, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

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We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement or free writing prospectus, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement or free writing prospectus, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement or free writing prospectus any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

Ranking of Debt Securities

The subordinated debt securities will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement or free writing prospectus. The subordinated indenture does not limit the amount of subordinated debt securities that we may issue. It also does not limit us from issuing any other secured or unsecured debt.

The senior debt securities will rank equally in right of payment to all our other senior unsecured debt. The senior indenture does not limit the amount of senior debt securities that we may issue. It also does not limit us from issuing any other secured or unsecured debt.

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DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement, which includes this prospectus.

General

We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we will issue under a separate warrant agreement. We will enter into the warrant agreement with a warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

the offering price and aggregate number of warrants offered;

the currency for which the warrants may be purchased;

if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;

in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

the terms of any rights to redeem or call the warrants;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the periods during which, and places at which, the warrants are exercisable;

the manner of exercise;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreement and warrants may be modified;

federal income tax consequences of holding or exercising the warrants;

the terms of the securities issuable upon exercise of the warrants; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

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DESCRIPTION OF UNITS

We may issue units comprised of shares of common stock, shares of preferred stock, debt securities and/or warrants in any combination. We may issue units in such amounts and in as many distinct series as we wish. This section outlines certain provisions of the units that we may issue. If we issue units, they will be issued under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. The information described in this section may not be complete in all respects and is qualified entirely by reference to the unit agreement with respect to the units of any particular series. The specific terms of any series of units offered will be described in the applicable prospectus supplement. If so described in a particular supplement, the specific terms of any series of units may differ from the general description of terms presented below. We urge you to read any prospectus supplement related to any series of units we may offer, as well as the complete unit agreement and unit certificate that contain the terms of the units. If we issue units, forms of unit agreements and unit certificates relating to such units will be incorporated by reference as exhibits to the registration statement, which includes this prospectus.

Each unit that we may issue 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. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. The applicable prospectus supplement may describe:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any provisions of the governing unit agreement;

the price or prices at which such units will be issued;

the applicable United States federal income tax considerations relating to the units;

any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and

any other terms of the units and of the securities comprising the units.

The provisions described in this section, as well as those described under [Description of Capital Stock](#), [Description of Debt Securities](#) and [Description of Warrants](#) will apply to the securities included in each unit, to the extent relevant and as may be updated in any prospectus supplements.

Issuance in Series

We may issue units in such amounts and in as many distinct series as we wish. This section summarizes terms of the units that apply generally to all series. Most of the financial and other specific terms of a particular series of units will

be described in the applicable prospectus supplement.

Unit Agreements

We will issue the units under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. We may add, replace or terminate unit agents from time to time. We will identify the unit agreement under which each series of units will be issued and the unit agent under that agreement in the applicable prospectus supplement.

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The following provisions will generally apply to all unit agreements unless otherwise stated in the applicable prospectus supplement:

Modification without Consent

We and the applicable unit agent may amend any unit or unit agreement without the consent of any holder:

to cure any ambiguity; any provisions of the governing unit agreement that differ from those described below;

to correct or supplement any defective or inconsistent provision; or

to make any other change that we believe is necessary or desirable and will not adversely affect the interests of the affected holders in any material respect.

We do not need any approval to make changes that affect only units to be issued after the changes take effect. We may also make changes that do not adversely affect a particular unit in any material respect, even if they adversely affect other units in a material respect. In those cases, we do not need to obtain the approval of the holder of the unaffected unit; we need only obtain any required approvals from the holders of the affected units.

Modification with Consent

We may not amend any particular unit or a unit agreement with respect to any particular unit unless we obtain the consent of the holder of that unit, if the amendment would:

impair any right of the holder to exercise or enforce any right under a security included in the unit if the terms of that security require the consent of the holder to any changes that would impair the exercise or enforcement of that right; or

reduce the percentage of outstanding units or any series or class the consent of whose holders is required to amend that series or class, or the applicable unit agreement with respect to that series or class, as described below.

Any other change to a particular unit agreement and the units issued under that agreement would require the following approval:

If the change affects only the units of a particular series issued under that agreement, the change must be approved by the holders of a majority of the outstanding units of that series; or

If the change affects the units of more than one series issued under that agreement, it must be approved by the holders of a majority of all outstanding units of all series affected by the change, with the units of all the affected series voting together as one class for this purpose.

These provisions regarding changes with majority approval also apply to changes affecting any securities issued under a unit agreement, as the governing document.

In each case, the required approval must be given by written consent.

Unit Agreements Will Not Be Qualified under Trust Indenture Act

No unit agreement will be qualified as an indenture, and no unit agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of units issued under unit agreements will not have the protections of the Trust Indenture Act with respect to their units.

Mergers and Similar Transactions Permitted; No Restrictive Covenants or Events of Default

The unit agreements will not restrict our ability to merge or consolidate with, or sell our assets to, another corporation or other entity or to engage in any other transactions. If at any time we merge or consolidate with, or sell our assets substantially as an entirety to, another corporation or other entity, the successor entity will succeed to and assume our obligations under the unit agreements. We will then be relieved of any further obligation under these agreements.

The unit agreements will not include any restrictions on our ability to put liens on our assets, nor will they restrict our ability to sell our assets. The unit agreements also will not provide for any events of default or remedies upon the occurrence of any events of default.

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Governing Law

The unit agreements and the units will be governed by Delaware law.

Form, Exchange and Transfer

We will issue each unit in global i.e., book-entry form only. Units in book-entry form will be represented by a global security registered in the name of a depository, which will be the holder of all the units represented by the global security. Those who own beneficial interests in a unit will do so through participants in the depository's system, and the rights of these indirect owners will be governed solely by the applicable procedures of the depository and its participants. We will describe book-entry securities, and other terms regarding the issuance and registration of the units in the applicable prospectus supplement.

Each unit and all securities comprising the unit will be issued in the same form.

If we issue any units in registered, non-global form, the following will apply to them.

The units will be issued in the denominations stated in the applicable prospectus supplement. Holders may exchange their units for units of smaller denominations or combined into fewer units of larger denominations, as long as the total amount is not changed.

Holdings may exchange or transfer their units at the office of the unit agent. Holdings may also replace lost, stolen, destroyed or mutilated units at that office. We may appoint another entity to perform these functions or perform them ourselves.

Holdings will not be required to pay a service charge to transfer or exchange their units, but they may be required to pay for any tax or other governmental charge associated with the transfer or exchange. The transfer or exchange, and any replacement, will be made only if our transfer agent is satisfied with the holder's proof of legal ownership. The transfer agent may also require an indemnity before replacing any units.

If we have the right to redeem, accelerate or settle any units before their maturity, and we exercise our right as to less than all those units or other securities, we may block the exchange or transfer of those units during the period beginning 15 days before the day we mail the notice of exercise and ending on the day of that mailing, in order to freeze the list of holders to prepare the mailing. We may also refuse to register transfers of or exchange any unit selected for early settlement, except that we will continue to permit transfers and exchanges of the unsettled portion of any unit being partially settled. We may also block the transfer or exchange of any unit in this manner if the unit includes securities that are or may be selected for early settlement.

Only the depository will be entitled to transfer or exchange a unit in global form, since it will be the sole holder of the unit.

Payments and Notices

In making payments and giving notices with respect to our units, we will follow the procedures as described in the applicable prospectus supplement.

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PLAN OF DISTRIBUTION

We and/or the selling stockholder may sell securities:

through underwriters;

through dealers;

through agents;

directly to purchasers; or

through a combination of any of these methods or any other method permitted by law.

In addition, we may issue the securities as a dividend or distribution or in a subscription rights offering to our existing security holders.

We may directly solicit offers to purchase securities, or agents may be designated to solicit such offers. In the prospectus supplement relating to such offering, we and/or the selling stockholder will name any agent that could be viewed as an underwriter under the Securities Act and describe any commissions that we must pay to any such agent. Any such agent will be acting on a best efforts basis for the period of its appointment or, if indicated in the applicable prospectus supplement, on a firm commitment basis. This prospectus may be used in connection with any offering of our securities through any of these methods or other methods described in the applicable prospectus supplement.

The distribution of the securities may be effected from time to time in one or more transactions:

at a fixed price, or prices, which may be changed from time to time;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

Each prospectus supplement will describe the method of distribution of the securities and any applicable restrictions.

The prospectus supplement with respect to the securities of a particular series will describe the terms of the offering of the securities, including the following:

the name of the agent or any underwriters;

the public offering or purchase price;

any discounts and commissions to be allowed or paid to the agent or underwriters;

all other items constituting underwriting compensation;

any discounts and commissions to be allowed or paid to dealers; and

any exchanges on which the securities will be listed.

If any underwriters or agents are used in the sale of the securities in respect of which this prospectus is delivered, we and/or the selling stockholder will enter into an underwriting agreement, sales agreement or other agreement with them at the time of sale to them, and we will set forth in the prospectus supplement relating to such offering the names of the underwriters or agents and the terms of the related agreement with them.

In connection with the offering of securities, we and/or the selling stockholder may grant to the underwriters an option to purchase additional securities with an additional underwriting commission, as may be set forth in the accompanying prospectus supplement. If we grant any such option, the terms of such option will be set forth in the prospectus supplement for such securities.

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If a dealer is used in the sale of the securities in respect of which the prospectus is delivered, we and/or the selling stockholder will sell such securities to the dealer, as principal. The dealer, who may be deemed to be an underwriter as that term is defined in the Securities Act, may then resell such securities to the public at varying prices to be determined by such dealer at the time of resale.

If we and/or the selling stockholder offer securities in a subscription rights offering to our existing security holders, we may enter into a standby underwriting agreement with dealers, acting as standby underwriters. We may pay the standby underwriters a commitment fee for the securities they commit to purchase on a standby basis. If we do not enter into a standby underwriting arrangement, we may retain a dealer-manager to manage a subscription rights offering for us.

Agents, underwriters, dealers and other persons may be entitled under agreements which they may enter into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

If so indicated in the applicable prospectus supplement, we and/or the selling stockholder will authorize underwriters or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in the prospectus supplement. Each contract will be for an amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in the prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will not be subject to any conditions except that:

the purchase by an institution of the securities covered under that contract shall not at the time of delivery be prohibited under the laws of the jurisdiction to which that institution is subject; and

if the securities are also being sold to underwriters acting as principals for their own account, the underwriters shall have purchased such securities not sold for delayed delivery. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of delayed delivery contracts.

Offered securities may also be offered and sold, if so indicated in the prospectus supplement, in connection with a remarketing upon their purchase, in accordance with a redemption or repayment pursuant to their terms, or otherwise, by one or more remarketing firms, acting as principals for their own accounts or as agents for us. Any remarketing firm will be identified and the terms of its agreement, if any, with us and its compensation will be described in the applicable prospectus supplement. Remarketing firms may be deemed to be underwriters in connection with their remarketing of offered securities.

Certain agents, underwriters and dealers, and their associates and affiliates, may be customers of, have borrowing relationships with, engage in other transactions with, or perform services, including investment banking services, for us or one or more of our respective affiliates in the ordinary course of business.

In order to facilitate the offering of the securities, any underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the securities or any other securities the prices of which may be used to determine payments on such securities. Specifically, any underwriters may over allot in connection with the offering, creating a

short position for their own accounts. In addition, to cover overallocments or to stabilize the price of the securities or of any such other securities, the underwriters may bid for, and purchase, the securities or any such other securities in the open market. Finally, in any offering of the securities through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the securities above independent market levels. Any such underwriters are not required to engage in these activities and may end any of these activities at any time.

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We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in two business days, unless the parties to any such trade expressly agree otherwise. The applicable prospectus supplement may provide that the original issue date for your securities may be more than two scheduled business days after the trade date for your securities. Accordingly, in such a case, if you wish to trade securities on any date prior to the second business day before the original issue date for your securities, you will be required, by virtue of the fact that your securities initially are expected to settle in more than two scheduled business days after the trade date for your securities, to make alternative settlement arrangements to prevent a failed settlement.

The securities may be new issues of securities and may have no established trading market. The securities may or may not be listed on a national securities exchange. We can make no assurance as to the liquidity of or the existence of trading markets for any of the securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

The anticipated date of delivery of offered securities will be set forth in the applicable prospectus supplement relating to each offer.

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LEGAL MATTERS

Certain legal matters in connection with this offering will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Any underwriters will also be advised about the validity of the securities and other legal matters by their own counsel, which will be named in the prospectus supplement.

EXPERTS

The consolidated financial statements incorporated in this Prospectus by reference from BioDelivery Sciences International, Inc.'s Annual Report on Form 10-K have been audited by Cherry Bekaert LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement that we have filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules of the SEC. For further information, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Statements contained in this prospectus or incorporated by reference concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed or incorporated by reference as an exhibit to the registration statement, we refer you to the copy of the contract or document that has been filed. Each statement in this prospectus or incorporated by reference relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains a web site (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC.

We are subject to the reporting and information requirements of the Exchange Act and, as a result, we file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference room and the web site of the SEC referred to above.

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INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference the information and reports we file with it, which means that we can disclose important information to you by referring you to these documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede the information already incorporated by reference. We are incorporating by reference the documents listed below, which we have already filed with the SEC, and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including all filings made after the date of the filing of this registration statement and prior to the effectiveness of this registration statement, except as to any portion of any future report or document that is not deemed filed under such provisions, after the date of this prospectus and prior to the termination of this offering:

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

The information specifically incorporated by reference in our Annual Report on Form 10-K for the year ended December 31, 2017, from our Definitive Proxy Statement on Schedule 14(a), as filed with the SEC on July 2, 2018;

Quarterly Reports on Form 10-Q filed with the SEC for the quarters ended September 30, 2018, March 31, 2018 and June 30, 2018, as filed with the SEC on November 8, 2018, May 10, 2018 and August 9, 2018, respectively;

Current Reports on Form 8-K filed with the SEC on January 17, 2019, November 8, 2018, October 29, 2018, September 14, 2018, August 9, 2018, August 6, 2018, May 22, 2018, May 21, 2018, May 17, 2018, May 11, 2018, May 8, 2018, May 3, 2018, March 16, 2018, March 7, 2018, February 6, 2018, January 30, 2018 and January 18, 2018; and

The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on June 19, 2006, including any amendments or reports filed for the purposes of updating this description.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to BioDelivery Sciences International, Inc., 4131 ParkLake Avenue, Suite 225, Attention: Michelle Brown, Raleigh, North Carolina; telephone: (919) 582-9050.

You also may access these filings on our website at www.bdsi.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

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Shares

Common Stock

Prospectus Supplement

April , 2019

Cantor

SunTrust Robinson Humphrey