

BIODELIVERY SCIENCES INTERNATIONAL INC

Form S-8

August 23, 2013

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As filed with the Securities and Exchange Commission on August 23, 2013

Registration No. 333-

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM S-8**  
**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

**BioDelivery Sciences International, Inc.**

(Exact name of registrant as specified in charter)

Delaware  
(State or other jurisdiction of

35-2089858  
(I.R.S. Employer

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incorporation or organization)

Identification No.)

**801 Corporate Center Drive, Suite #210**

**Raleigh, NC**  
(Address of principal executive offices)

**27607**  
(Zip Code)

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

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

(Full title of plan)

**Mark A. Sirgo, Pharm.D.**

**801 Corporate Center Drive, Suite 210**

**Raleigh, North Carolina 27607**

**(919) 582-9050**

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

*Copies to:*

**Lawrence A. Rosenbloom, Esq.**

**Ellenoff Grossman & Schole LLP**

**150 East 42<sup>nd</sup> Street, 11<sup>th</sup> Floor**

**New York, New York 10017**

**(212) 370-1300**

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

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

### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Shares of common stock issuable under Amended 2011 Equity Incentive Plan	2,600,000	\$4.44	\$11,544,000	\$1,574.60
<b>Total</b>	<b>2,600,000</b>		<b>\$11,544,000</b>	<b>\$1,574.60</b>

- (1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended (the "Securities Act"), this Registration Statement shall also cover any additional shares of common stock, par value \$.001 per share (the "Common Stock"), of BioDelivery Sciences International, Inc. (the "Company") which become issuable under the employee benefit plans described herein by reason of stock dividends, stock splits, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of the outstanding shares of Common Stock.
- (2) This calculation is made solely for the purpose of determining the registration fee pursuant to Rule 457(c) under the Securities Act based on the 5 day average of the high and low prices of the registrant's common stock on the NASDAQ Capital Market ending on August 20, 2013.

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**Explanatory Note**

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

Register an additional 2,600,000 shares of our common stock, par value \$.001 per share, issuable pursuant to our 2011 Equity Incentive Plan (as amended and approved by our stockholders in July 2013, and which we refer to herein as the 2011 Plan), of which 63,853 shares underlying options or restricted stock units were granted to certain of our officers and directors under the 2011 Plan in August 2013. Shares of our common stock underlying options or restricted stock units granted pursuant to our Amended and Restated 2001 Incentive Plan (which we refer to as the 2001 Plan) and the 2011 Plan were previously registered on Form S-8 (No. 333-176476, filed on August 24, 2011, and which we refer to as the 2011 S-8); and

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

The reoffer prospectus contained herein has been prepared in accordance with the requirements of General Instruction C of Form S-8 and Part I of Form S-3. The 6,327,140 shares included in the reoffer prospectus are the number of shares of our common stock underlying options or restricted stock units that have been or may be acquired by the selling stockholders the 2001 Plan and the 2011 Plan.

Accordingly: (i) the reoffer prospectus included herein is a combined prospectus with the reoffer prospectus included as part of the 2011 S-8 pursuant to Rule 429(a) under the Securities Act, and (ii) this Registration Statement, which is a new registration statement, also constitutes a post-effective amendment to the 2011 S-8 pursuant to Rule 429(b) under the Securities Act.

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**PART I**

**INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS**

**Item 1. Plan Information.\***

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

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

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**Reoffer Prospectus**

**6,327,140 Shares**

**Common Stock**

This reoffer prospectus is a combined prospectus relating to shares of our common stock, par value \$.001 per share, that have been registered with the Securities and Exchange Commission, or SEC, under the Securities Act of 1933, as amended, or the Securities Act, and that have been or may be acquired by certain of our prior, current and future officers and directors (or any of their respective assigns) (who we refer to herein as the selling stockholders) pursuant to option awards under our Amended and Restated 2001 Incentive Plan (which we refer to as the 2001 Plan) and our 2011 Equity Incentive Plan, as amended (which we refer to as the 2011 Plan).

The selling stockholders listed herein (which include the executive officers and directors of our company) are offering and selling up to 6,327,140 shares that have been or may hereafter be acquired by such selling stockholders upon the exercise of options to purchase our common stock that were granted to such selling stockholders under the 2001 Plan and the 2011 Plan. We will not receive any proceeds from the sale of the shares hereunder. However, we will receive the proceeds, if any, from the exercise of the options granted under the 2001 Plan and the 2011 Plan.

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

Our common stock is quoted on the Nasdaq Capital Market under the symbol **BDSI** . On August 20, 2013, the closing sales price for the common stock on the Nasdaq Capital Market was \$4.53 per share.

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

**Investing in our common stock involves a high degree of risk. You should read the Risk Factors section beginning on page 4 and in the documents incorporated by reference herein before you decide to purchase any shares of our common stock.**

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

**The date of this reoffer prospectus is August 23, 2013.**

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You should rely only upon the information contained or incorporated by reference in this reoffer prospectus and the registration statement of which this reoffer prospectus is a part. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The selling stockholders are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume the information appearing in this reoffer prospectus is accurate only as of the date on the front cover of this reoffer prospectus. Our business, financial condition, results of operations and prospects may have changed since that date. This reoffer prospectus is based on information provided by us and other sources that we believe are reliable. We have summarized certain documents and other information in a manner we believe to be accurate, but we refer you to the actual documents for a more complete understanding of what we discuss in this reoffer prospectus. In making an investment decision, you must rely on your own examination of our business and the terms of the offering, including the merits and risks involved.

We obtained statistical data, market data and other industry data and forecasts described or incorporated by reference in this reoffer prospectus from market research, publicly available information and industry publications. Industry publications generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy and completeness of the information. Similarly, while we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information. We have not sought the consent of the sources to refer to their reports appearing or incorporated by reference in this reoffer prospectus.

This reoffer prospectus contains, or incorporates by reference, trademarks, tradenames, service marks and service names of BioDelivery Sciences International, Inc. and other companies.



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**CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS**

Certain statements contained in this reoffer prospectus, including the documents referred to or incorporated by reference in this reoffer prospectus or statements of our management referring to our summarizing the contents of this reoffer prospectus, include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and related releases issued by the U.S. Securities and Exchange Commission, or SEC, and within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). We have based these forward-looking statements on our current expectations and projections about future events. Our actual results may differ materially or perhaps significantly from those discussed herein, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, expect, anticipate, intend, estimate, plan, project and similar expressions. In addition, any statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements included in this reoffer prospectus or our other filings with the SEC include, but are not necessarily limited to, those relating to:

our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the BEMA<sup>®</sup> technology platform and any proposed products, product candidates or marketed products, including our sole marketed product, ONSOLIS<sup>®</sup>, our partnered product candidate, BEMA<sup>®</sup> Buprenorphine and our other lead product candidate, BUNAVAIL<sup>™</sup>, as well as Clonidine Topical Gel;

the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including (i) the timing, status and results of our filings with the U.S. Food and Drug Administration, (ii) the timing, status and results of non-clinical work and clinical studies and (iii) 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;

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

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

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

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

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the outcome of ongoing or potential future litigation or other claims or disputes relating to our business, technologies, products or processes;

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

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

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

competition existing today or that will likely arise in the future; and

regulatory oversight of our company by the SEC and the NASDAQ Stock Market.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see Risk Factors for additional risks which could adversely impact our business and financial performance.

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

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### PROSPECTUS SUMMARY

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

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

#### Overview

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of proven therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. We have developed and are continuing to develop pharmaceutical products aimed principally in the areas of pain management and addiction.

In formulating our products and product candidates, we utilize the novel, patent protected and proprietary BioErodible MucoAdhesive (known as BEMA<sup>®</sup>) drug delivery technology, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek). Our first U.S. Food and Drug Administration (which we refer to as the FDA) approved product, ONSOLIS<sup>®</sup> (fentanyl buccal soluble film), as well as two of our product candidates, utilize our BEMA<sup>®</sup> technology.

In addition to our FDA-approved product ONSOLIS<sup>®</sup>, our lead products in development are:

**BEMA<sup>®</sup> Buprenorphine**, a potential treatment for moderate to severe chronic pain, which is currently in Phase 3 trials and which is partnered on a worldwide basis to Endo Health Solutions, Inc. (which we refer to herein as Endo);

**BUNAVAIL<sup>™</sup> (formerly known as BEMA<sup>®</sup> Buprenorphine/Naloxone, or BNX)**, a high dose formulation of buprenorphine along with an abuse deterrent agent naloxone, which is a potential treatment for opioid dependence, for which we filed a New Drug Application (or NDA) with the FDA in late July 2013; and

**Clonidine Topical Gel**, a topical administration of the approved product clonidine for the potential treatment of painful diabetic neuropathy and other indications, for which we plan to prepare for a confirmatory Phase 2b study in the later portion of 2013 which could lead to data availability by the end of 2014.

ONSOLIS<sup>®</sup> and our product candidates such as BEMA<sup>®</sup> Buprenorphine, BUNAVAIL<sup>™</sup> and Clonidine Topical Gel may also have broader indications. When presented with viable commercial opportunities for broader indications of our products, we will consider developing the product for those uses. We also continue to explore the use of the BEMA<sup>®</sup> technology with additional pharmaceutical products that may fulfill an unmet medical need.

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we may seek to acquire or license additional drug delivery technologies or other development stage products in novel technologies such as Clonidine Topical Gel. Should we gain access to such

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technologies, we would seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through commercial partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace. We plan to follow the same strategy should we acquire or license other development stage products in novel technologies.

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

### **Additional Information**

Since inception and through June 30, 2013, we have recorded accumulated losses totaling approximately \$120.1 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for our product candidates, our goal will be to augment our current sources of revenue and, as applicable, deferred revenue (principally licensing fees), with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

We have based our estimates of development costs, market size estimates, peak annual sales projections and similar matters described or incorporated by reference in this reoffer prospectus on our market research, third party reports and publicly available information which we consider reliable. However, readers are advised that the projected dates for filing and approval of our Investigational New Drug Applications (INDs) or New Drug Applications (NDAs) with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding ONSOLIS<sup>®</sup>, BEMA<sup>®</sup> Buprenorphine, BUNAVAIL<sup>™</sup>, Clonidine Topical Gel or any other product candidates discussed elsewhere (or incorporated by reference) in this reoffer prospectus are merely estimates and subject to many factors, many of which may be beyond our control, which will likely cause us to revise such estimates. Readers are also advised that our projected sales figures do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our management's reasonable judgments given the information available and their previous experiences, although such estimates may not prove to be accurate.

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 801 Corporate Center Drive, suite 210, Raleigh, North Carolina, 27607, telephone number (919) 582-9050.

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**The Offering**

<b>Outstanding Common Stock</b>	38,121,230 shares of our common stock are outstanding as of August 20, 2013.
<b>Common Stock Offered</b>	Up to 6,327,140 shares of common stock for sale by the selling stockholders (which include our executive officers and directors) for their own account pursuant to the 2001 Plan and the 2011 Plan.
<b>Selling Stockholders</b>	The selling stockholders are set forth in the section entitled <b>Selling Stockholders</b> of this reoffer prospectus on page 5.
<b>Proceeds</b>	We will not receive any proceeds from the sale of our common stock by the selling stockholders. We would, however, receive proceeds upon the exercise of the stock options by those who receive options under the Plans and exercise such options for cash. Any cash proceeds will be used by us for general corporate purposes.
<b>Risk Factors</b>	The securities offered hereby involve a high degree of risk. See <b>Risk Factors</b> .
<b>Nasdaq Capital Market Symbol</b>	BDSI

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**RISK FACTORS**

We have included discussions of the risks, uncertainties and assumptions under the heading "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2012 (as updated in our subsequently filed Quarterly Reports on Form 10-Q), which risk factors are incorporated by reference into this reoffer prospectus. See "Where You Can Find More Information" for an explanation of how to get a copy of this report.

**Investing in our securities involves a high degree of risk.** Before deciding whether to invest in our securities, you should carefully consider the risk factors we describe herein and in any document incorporated herein by reference, including our Annual Report on Form 10-K for the year ended December 31, 2012, or any Annual Report on Form 10-K or Quarterly Report on Form 10-Q that is incorporated by reference into this reoffer prospectus after the date of this reoffer prospectus. Although we discuss key risks in those risk factor descriptions, additional risks not currently known to us or that we currently deem immaterial also may impair our business. Our subsequent filings with the SEC may contain amended and updated discussions of significant risks. We cannot predict future risks or estimate the extent to which they may affect our financial performance.

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

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

**USE OF PROCEEDS**

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

**SELLING STOCKHOLDERS**

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

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

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

<b>Name</b>	<b>Position, Office, or Other Material Relationship</b>	<b>Number of Shares Owned (1)</b>	<b>Number of Shares to be Offered for the Account of the Selling Stockholder (2)(3)</b>	<b>Number of Shares to be Owned After Offering</b>	<b>% Owned After Offering</b>
Andrew L. Finn	(4)(5)	770,653	399,105	770,653	2.02%
James A. McNulty	(6)(7)	49,399	316,586	49,399	*
Francis E. O'Donnell, Jr.	(8)(9)	141,261	255,000	141,261	*
William S. Poole	(10)(11)	18,690	257,500	18,690	*
John J. Shea	(12)(13)	16,305	142,500	16,305	*
Mark A. Sirgo	(14)(15)	871,842	1,050,075	871,842	2.29%
William B. Stone	(16)(17)	63,175	350,000	63,175	*
Thomas W. D'Alonzo	(18)(19)	25,625	65,000	25,625	*
Samuel P. Sears	(20)(21)	33,353	17,363	33,353	*

\* Less than 1%

- (1) Represents common stock owned.
- (2) Represents vested and unvested options.
- (3) These shares constitute control securities as such term is defined in General Instruction C to Form S-8.
- (4) Andrew L. Finn, Pharm.D., is our Executive Vice President of Product Development.
- (5) Includes options to purchase 373,212 shares of common stock, all of which are currently exercisable. Includes options to purchase 25,893 shares of common stock which are not currently exercisable. Of the total options, 349,812 and 49,293 have been granted under the 2001 Plan and 2011 Plan, respectively.





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- (6) James A. McNulty is our Secretary, Treasurer and Chief Financial Officer.
- (7) Includes options to purchase 289,223 shares of our common stock, all of which are currently exercisable. Includes options to purchase 27,363 shares of common stock which are not currently exercisable. Of the total options, 283,653 and 32,933 have been granted under the 2001 Plan and 2011 Plan, respectively.
- (8) Francis E. O'Donnell, Jr., M.D. is our Executive Chairman.
- (9) Includes options to purchase 255,000 shares of our common stock, all of which is currently exercisable. Of the total options, 212,500 and 42,500 have been granted under the 2001 Plan and 2011 Plan, respectively.
- (10) William S. Poole is a member of our Board of Directors.
- (11) Includes options to purchase 257,500 shares of our common stock, all of which are currently exercisable. Of the total options, 220,000 and 37,500 have been granted under the 2001 Plan and 2011 Plan, respectively.
- (12) John J. Shea is a member of our Board of Directors.
- (13) Includes options to purchase 142,500 shares of our common stock, all of which are currently exercisable. Of the total options, 105,000 and 37,500 have been granted under the 2001 Plan and 2011 Plan, respectively.
- (14) Mark A. Sirgo, Pharm.D., is our President and Chief Executive Officer and a member of our Board of Directors.
- (15) Includes options to purchase 1,012,337 shares of common stock, all of which are currently exercisable. Includes options to purchase 37,738 shares of common stock which are not currently exercisable. Of the total options, 946,628 and 103,447 have been granted under the 2001 Plan and 2011 Plan, respectively.
- (16) William B. Stone is a member of our Board of Directors and our Lead Director.
- (17) Includes options to purchase 350,000 shares of our common stock, all of which are currently exercisable. Of the total options, 290,000 and 60,000 have been granted under the 2001 Plan and 2011 Plan, respectively.
- (18) Thomas W. D'Alonzo is a member of our Board of Directors.
- (19) Includes options to purchase 65,000 shares of our common stock, all of which are currently exercisable. All options have been granted under the 2001 Plan.
- (20) Samuel P. Sears is a member of our Board of Directors.
- (21) Includes options to purchase 17,363 shares of our common stock, all of which are currently exercisable. All Options have been granted under the 2011 Plan.

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**PLAN OF DISTRIBUTION**

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

the persons identified in the table above as the selling stockholders; and

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

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

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

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

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

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

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

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

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

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

## **LEGAL MATTERS**

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

## **EXPERTS**

The financial statements and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Report on Internal Control over Financial Reporting) incorporated in this reoffer prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2012 have been so incorporated in reliance on the report of Cherry Bekaert LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## **WHERE YOU CAN FIND MORE INFORMATION**

We have filed a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered by this reoffer prospectus. This reoffer prospectus is part of that registration statement and does not contain all the information included in the registration statement. For further information with respect to our common stock and us, you should refer to the registration statement, its exhibits and the material incorporated by reference therein. Portions of the exhibits have been omitted as permitted by the rules and regulations of the Securities and Exchange Commission. Statements made in this reoffer prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete. In each instance, we refer you to the copy of the contracts or other documents filed as an exhibit to the registration statement, and these statements are hereby qualified in their entirety by reference to the contract or document. The registration statement may be inspected and copied at the public reference facilities maintained by the Securities and Exchange Commission at Room 1024, Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549 and the Regional Offices at the Commission located in the Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and at 233 Broadway, New York, New York 10279. Copies of those filings can be obtained from the Commission's Public Reference Section, Judiciary Plaza, 100 F Fifth Street, N.E., Washington, D.C. 20549 at prescribed rates and may also be obtained from the web site that the Securities and Exchange Commission maintains at <http://www.sec.gov>.

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You may also call the Commission at 1-800-SEC-0330 for more information. We file annual, quarterly and current reports and other information with the Securities and Exchange Commission. You may read and copy any reports, statements or other information on file at the Commission's public reference room in Washington, D.C. You can request copies of those documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission.

**DISCLOSURE OF COMMISSION POSITION ON**

**INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS**

Our certificate of incorporation, as amended, provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted under the Delaware General Corporation Law, provided that they acted in good faith and that they reasoned their conduct or action was in, or not opposed to, the best interest of our company. Our Amended and Restated Bylaws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the Delaware General Corporation Law. Further, we maintain officer and director liability insurance. However, insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

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

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, as filed with the SEC on March 18, 2013;

Our Current Report on Form 8-K, as filed with the SEC on January 22, 2013;

Our Current Report on Form 8-K, as filed with the SEC on February 28, 2013;