BIODELIVERY SCIENCES INTERNATIONAL INC
Form S-3
February 09, 2009
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As filed with the Securities and Exchange Commission on February 6, 2009

Registration No. 333-_____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or jurisdiction of incorporation or organization)

35-2089858

(I.R.S. Employer Identification No.)

801 Corporate Center Drive, Suite 210

Raleigh, NC 27607

(919) 582-9050

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Mark A. Sirgo, Pharm.D.

801 Corporate Center Drive, Suite 210

Raleigh, NC 27607

(919) 582-9050

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

Copies to:

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Approximate date of proposed sale to the public: As soon as practicable, after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registrations statement number of the earlier effective registration statement for the same offering. ¨ _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Dollar Amount to be registered	Proposed maximum offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee
common stock, par value $0.001 per share, underlying warrant with an exercise price of $5.55	475,000 shares[1]	$5.55	$2,636,250	$103.60
common stock, par value $0.001 per share	1,594,826 shares	$3.19[2]	$5,087,495	$199.94
TOTAL	2,069,826 shares			$303.54

(1) Also registered hereby are such additional and indeterminable number of shares as may be issuable due to adjustments for changes resulting from stock dividends, stock splits and similar changes as well as anti-dilution provisions applicable to the warrants.

(2) Estimated pursuant to Rule 457(c) solely for the purpose of calculating the registration fee, based upon the average of the high and low prices for such shares of the registrant s common stock on February 4, 2009, as reported on the Nasdaq Capital Market.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Preliminary Prospectus **Subject To Completion, dated February 6, 2009**

2,069,826 Shares

Common Stock

This prospectus relates to the public offering of up to 2,069,826 shares of our common stock, par value $0.001 per share, for sale by the selling stockholders named herein, which include Hopkins Capital Group II, LLC, which we refer to herein as HCG II, a principal stockholder of our company, and certain executive officers of our company, for their own accounts. The shares to be sold by the selling stockholders include: (i) up to 475,000 shares of our common stock, issuable upon the exercise of a warrant which we refer to as the HCG Warrant, issued by us to HCG II on September 5, 2007; (ii) up to an aggregate of 1,594,826 shares of our common stock previously issued by us to the other selling stockholders.

Our common stock is quoted on the Nasdaq Capital Market under the symbol BDSI . On February 4, 2009, the closing sales price for our common stock on the Nasdaq Capital Market was $3.20 per share.

To the extent the selling stockholders wish to sell their shares of our common stock as provided for herein, they may offer and sell such shares on a continuous or delayed basis in the future. These sales may be conducted in the open market or in privately negotiated transactions and at market prices, fixed prices or negotiated prices. We will not receive any of the proceeds from the sale of the shares of common stock underlying the HCG Warrant, but we will receive funds upon the exercise of such warrant. Such proceeds, if any, will be used for working capital and general corporate purposes. Prospective investors should read this prospectus and any amendment or supplement hereto together with additional information described under the heading Where You Can Find More Information.

Our principal executive offices are located at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina 27607. Our telephone number is (919) 582-9050.

Investing in our common stock involves a high degree of risk. See the section entitled Risk Factors beginning on page 4 and in the documents incorporated by reference herein before you decide to buy our common stock.

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 , 2009

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You should rely only upon the information contained in this prospectus and the registration statement of which this 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. We 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 prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date. This 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 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 used throughout, or incorporated by reference in, this 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 prospectus.

This 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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NOTE ON FORWARD LOOKING STATEMENTS

Certain statements contained or incorporated by reference in this prospectus constitute forward-looking statements as that term is defined under the Private Securities Litigation Reform Act of 1995 and releases issued by the 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). The words believe, expect, anticipate, intend, estimate, plan, project and other expressions which are predictions of or indicate future events and trends and which do not relate to historical matters identify forward-looking statements. Reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance or achievements to differ materially from anticipated future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to:

- our plans regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the BEMA and Bioral technology platforms and any proposed formulations or products relating thereto (including, without limitation, ONSOLIS , formerly known as BEMA Fentanyl);
- the domestic and international regulatory process relating to our technologies and proposed products and formulations, including the timing, status and results of our filings with the FDA and other similar international regulatory agencies, and the timing, status and results of pre-clinical work and clinical studies;
- our ability to manufacture and generate commercial viability and acceptance of our BEMA and Bioral technology platforms and our proposed formulations and products;
- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing partnerships;
- the protection and control afforded by our patents, or our interest in licensed patents, or our ability to enforce our rights under such patents or licenses;
- our ability to enter into and/or perform under strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and formulations;
- the ability of our sublicensed partners to commercially exploit our drug delivery platforms and our ability to enter into sublicenses and to receive royalty and other payments from parties to whom we have sublicensed our technologies;
- our ability to retain members of our management team and our employees;
- our ability to receive federal, state, government or private grants; and
- the competition that may arise in the future.

The foregoing does not represent an exhaustive list of risks. Please see Risk Factors for additional risks which could adversely impact our business and financial performance. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this prospectus are based on

information available to us on the date of this prospectus. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this prospectus.

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PROSPECTUS SUMMARY

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

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

Our Company

We are a specialty pharmaceutical company that is utilizing licensed and owned proprietary patented drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, clinically-significant new formulations of proven therapeutics.

Our drug delivery technologies include:

- the patented BEMA (transmucosal, or applied to the inner cheek membrane) drug delivery technology, and
- the patented Bioral cochleate drug delivery technology, designed for a potentially broad base of applications.

Utilizing our patented and licensed delivery technologies, we are currently developing formulations of pharmaceuticals aimed principally at acute (i.e., short term) conditions occurring in cancer and surgical patients, mostly notably in the areas of pain and fungal infections.

Our lead product candidate is ONSOLIS (formerly known as BEMA Fentanyl), a treatment for breakthrough cancer pain (i.e., episodes of severe pain which break through the medication used to control the persistent pain) in opioid tolerant patients. In December 2008, we resubmitted our New Drug Application, or NDA, for ONSOLIS to the U.S. Food and Drug Administration, or FDA, following our receipt of a complete response letter from FDA in August 2008. The only NDA deficiency that FDA noted in their complete response letter was the need for a Risk Evaluation and Mitigation Strategy (REMS) which the FDA had not required prior to the submission of our ONSOLIS NDA in October 2007. We anticipate that final FDA approval of ONSOLIS will occur in the second quarter of 2009. We have granted commercialization and distribution rights for ONSOLIS on a worldwide basis (except in South Korea and Taiwan) to Meda AB, a leading international specialty pharmaceutical company based in Sweden. ONSOLIS will be marketed as BREAKYL in Europe. In this prospectus, we refer to ONSOLIS and BREAKYL collectively as ONSOLIS .

Our follow on product to ONSOLIS is BEMA Buprenorphine, a treatment for moderate to severe pain conditions which is currently in Phase I trials.

Our lead Bioral formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for treating systemic fungal infections. This product is also currently in Phase I human testing. We also believe this drug delivery technology has the potential to be applied to other types of pharmaceuticals and also to other therapeutics such as small interfering RNA, or siRNA.

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Some of our products, such as ONSOLIS and BEMA Buprenorphine, may also have broader indications that would allow for chronic use. When such products present a viable commercial opportunity, we will also consider developing the product for chronic uses.

We currently generate revenue from licensing milestone payments and royalties, and have generated revenue from grants. Ultimately, if we secure approval from the FDA and other regulatory bodies throughout the world for our licensed and/or proprietary products and formulations, our goal will be to augment these revenues from sales of such products and formulations, on which we will also pay royalties or other fees to our licensors and/or third-party collaborators where they exist.

Our development strategy focuses on, but is not limited to, the utilization of the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved therapeutics which incorporate our licensed 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 less time consuming than other approval methods of the FDA.

Our principal executive offices are located at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina 27607. Our telephone number is (919) 582-9050.

The Offering

Outstanding Common Stock	19,179,029 shares of common stock issued and 19,163,538 outstanding as of February 4, 2009.
Common Stock Offered	Up to 2,069,826 shares of common stock for sale by the selling stockholders for their own account. These shares include: (i) up to 475,000 shares of our common stock issuable upon the exercise HCG Warrant; and (ii) up to 1,594,826 shares of our common stock held by the selling stockholders.
Selling Stockholders	Dr. Frank E. O Donnell, Jr., the Chairman of our Board of Directors, is the manager of HCG II. The 475,000 shares of common stock beneficially owned by HCG II which are the subject of this prospectus underlie a warrant held by HCG II which was issued to HCG II on September 5, 2007. The other selling stockholders are Dr. Mark A. Sirgo, our President, Chief Executive Officer and a director, and Dr. Andrew L. Finn, our Executive Vice President of Product Development. The 1,594,826 shares of common stock held collectively by Messrs. Sirgo and Finn (797,413 shares each) were acquired upon conversion of our Series C Preferred Stock that they received in connection with our acquisition of their company, Arius Pharmaceuticals, in 2004.

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Proceeds	We will not receive any proceeds from the sale of our common stock by the selling stockholders. We would, however, receive proceeds upon the exercise of the HCG Warrant which, if such warrant was exercised in full at the present exercise price, would be approximately $2,636,250. HCG II is under no obligation to exercise the HCG Warrant. Proceeds, received, if any, from the exercise of the HCG Warrant will be used for general corporate purposes.
Risk Factors	The securities offered hereby involve a high degree of risk. See Risk Factors.
Nasdaq Capital Market Symbol	BDSI

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RISK FACTORS

An investment in our company is extremely risky. You should carefully consider the following risks, in addition to the other information presented in this prospectus before deciding to buy or exercise our securities. If any of the following risks actually materialize, our business and prospects could be seriously harmed, the price and value of our securities could decline and you could lose all or part of your investment.

Risks Relating to Our Business

Since we have a limited operating history and have not generated any revenues from the sale of products to date, you cannot rely upon our limited historical performance to make an investment decision.

Since our inception in January 1997 and through September 30, 2008, we have recorded accumulated losses totaling approximately $75.0 million. As of September 30, 2008, we had a working capital deficit of approximately $30.0 million. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed formulations and products, obtain the required regulatory approvals and manufacture, market and sell our proposed formulations and products. No assurances can be given that we will be able to achieve these goals.

Although we have generated some licensing-related and other revenue to date, we have not generated any revenue from the commercial sale of products. Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel. Since 2005, we have also focused on commercialization activities, mostly relating to ONSOLIS . This limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize our technologies and proposed formulations or products, obtain FDA approval and achieve market acceptance of our proposed formulations or products and respond to competition. No assurances can be given as to exactly when, if at all, we will be able to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive material revenues from our proposed formulations or products in development.

As a result of our current lack of financial liquidity and negative stockholders equity, our auditors have expressed substantial doubt regarding our ability to continue as a going concern.

As a result of our current lack of financial liquidity, continued losses and negative stockholders equity, our auditors report for our 2007 financial statements, which are included in our 2007 Annual Report on Form 10-K, contains a statement concerning our ability to continue as a going concern. Our lack of sufficient liquidity could make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and may materially and adversely affect the terms of any financing that we may obtain and our public stock price generally.

Our continuation as a going concern is dependent upon, among other things, achieving positive cash flow from operations and, if necessary, augmenting such cash flow using external resources to satisfy our cash needs. Our plans to achieve positive cash flow include negotiating up-front (and ultimately recognizing revenues from) milestone payments on pipeline products under development, and royalties from sales of our products which secure regulatory approval and any milestone payments associated with such approved products. These cash sources could, potentially, be supplemented by financing or other strategic agreements. No assurances can be given, however, that we will be able to achieve these goals or that we will be able to continue as a going concern.

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We may need to raise additional capital to continue our operations, and our failure to do so would impair our ability to fund our operations, develop our technologies, attract development or commercial partners or promote our formulations or products.

Our operations have relied almost entirely on external financing to fund our operations. Such financing has historically come primarily from the sale of common and preferred stock and convertible debt to third parties and to a lesser degree from grants, loans and revenue from license and royalty fees. At September 30, 2008, we had cash of approximately $2.0 million. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) and financings we have undertaken prior to the date of this prospectus, that our current working capital and committed financing will be sufficient to satisfy our contemplated cash requirements into approximately the third quarter of 2009, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events, costs or contingencies, any of which could effect our cash requirements.

We expect to receive an additional aggregate $26.9 million in milestone payments from Meda in connection with FDA approval and commercial launch of ONSOLIS . If ONSOLIS is not approved and we do not receive such payment, and given that our current cash on hand will not fully fund all development costs of our leading product formulations, we may need to raise additional capital to fund our anticipated operating expenses and progress our business plans. If ONSOLIS is not approved, we may be unable to find the needed capital to progress our business plan, and we cannot assure you that any financing, whether from external sources or related parties, will be available. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on our operations may make the raising of capital more difficult and may also result in a lower price for our securities.

We may have difficulty raising any needed additional capital.

We may have difficulty raising needed capital in the future as a result of, among other factors, our limited operating history and the inherent business risks associated with our company, as well as present and future market conditions. Our business currently does not generate any sales, and current sources of revenue are limited and may not be sufficient to meet our present and future capital requirements. We have expended and plan to continue to expend substantial funds in the research, development and pre-clinical and clinical testing of our drug delivery technologies and product candidates. We will require additional funds to conduct research and development, establish and conduct pre-clinical and clinical trials, secure clinical and commercial-scale manufacturing arrangements and provide for the marketing and distribution, especially if ONSOLIS is not approved by the FDA and we therefore do not receive expected additional milestone payments from Meda. If adequate funds are unavailable, we may have to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs or product launches or marketing efforts which may materially harm our business, financial condition and results of operations.

Our long term capital requirements are subject to numerous risks.

Our long term capital requirements are expected to depend on many factors, including, among others:

- the number of potential formulations, products and technologies in development;

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continued progress and cost of our research and development programs;

progress with pre-clinical studies and clinical trials;

time and costs involved in obtaining regulatory (including FDA) clearance;

costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;

costs of developing sales, marketing and distribution channels and our ability to sell our drug formulations or products;

costs involved in establishing manufacturing capabilities for commercial quantities of our drug formulations or products;

competing technological and market developments;

market acceptance of our drug formulations or products;

costs for recruiting and retaining employees and consultants;

costs for training physicians; and

legal, accounting, insurance and other professional and business related costs.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through the exercising of our public warrants, equity or debt financings, collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. If adequate funds are not available, we may be required to significantly reduce or refocus our development and commercialization efforts with regard to our delivery technologies and our current and proposed future formulations and products.

Our additional financing requirements could result in dilution to existing stockholders.

The additional financings which we have undertaken and which we will in the future require, have and may be obtained through one or more transactions which have diluted or will dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 45 million shares of common stock and 5 million shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

If we breach our agreements with CDC, CDC has rights to gain control of our ONSOLIS asset.

Under our agreements with CDC IV, LLC (who we refer to herein as CDC), if we do not meet certain conditions, CDC can assume control of the ONSOLIS product and related intellectual property assets. For example, in the event that we do not diligently pursue the development and regulatory approval of ONSOLIS or encounter certain

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specified negative circumstances regarding the development of ONSOLIS , CDC has the right to require the assignment of our ONSOLIS assets to CDC and to pursue development and commercialization of ONSOLIS pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense. CDC has made claims against us in the past under our agreements with them. Our loss of ONSOLIS to CDC would have a material adverse effect on our business.

CDC s right of first refusal on future financings of ours could impede our ability to raise capital.

Under our May 2006 Securities Purchase Agreement with CDC, as amended, until such time as our public share price reaches $9 for certain time periods, in the event that we seek to raise money through the offer and sale of debt or equity securities, we must first offer CDC an opportunity to provide financing to us. If CDC elects to exercise its right to such opportunity, we must negotiate exclusively with CDC the terms of a financing for 30 days which must match the terms of the financing we present to them. If no terms are agreed to, we may pursue a financing with a third party for 60 days, but only on terms and conditions no less favorable to us than the terms and conditions presented to CDC. CDC has exercised similar rights to our detriment in the past. No assurances can be given that CDC will not seek to exercise the right again in the future. The existence or alleged existence of CDC s right of first refusal, or CDC s exercise thereof or claims related thereto, has and may in the future deter potential investors from providing us needed financing, which would have a material adverse effect on our operations and viability as a company.

Acceptance of our formulations or products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Our future financial performance will depend, at least in part, upon the introduction and physician and patient acceptance of our proposed formulations or products. Even if approved for marketing by the necessary regulatory authorities, our formulations or products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- receipt of regulatory clearance of marketing claims for the uses that we are developing;
- establishment and demonstration of the advantages, safety and efficacy of our formulations, products and technologies;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our proposed formulations or products; and
- our ability to market our formulations or products.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our proposed formulations or products. If we are unable to obtain regulatory approval, or are unable to manufacture, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

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We are dependent on our collaborative agreements for the development of our drug delivery technologies and business development which exposes us to the risk of reliance on the viability of third parties.

In conducting our research and development activities, we currently rely, and will continue to rely, on numerous collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements is our U.S. and European commercialization agreements with Meda and our development and supply agreement with Aveva Drug Delivery Systems, Inc., or Aveva, and LTS Lohmann Therapie-Systeme AG, or LTS, relating to ONSOLIS . The loss of, or failure to perform by us or our partners under, any applicable agreements or arrangements, or our failure to secure additional agreements for other products in development, would substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation. This is particularly true with regard to our relationship with Meda, who is our commercialization partner for our lead product ONSOLIS .

In addition, under our collaborative agreements with Meda, we are responsible for paying the certain costs relating to ONSOLIS . Our inability to adequately project or control such costs would have a material adverse effect on our potential profits from such agreements.

We are exposed to product liability, pre-clinical and clinical liability risks which could place a substantial financial burden upon us, should law suits be filed against us, because of the low level of general liability and clinical trial insurance we carry.

Our business exposes us to likely product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims are likely to be asserted against us at some point. In addition, the use in our clinical trials of pharmaceutical formulations and products and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

Since we do not currently have any FDA-approved products or formulations, we do not currently have any product liability insurance covering commercialized products, and we maintain liability insurance relating only to clinical trials on our products in development. We cannot assure you that we will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us could have a material adverse effect on our business, financial condition and results of operations.

We may be sued by third parties who claim that our products and formulations infringe on their intellectual property rights.

We may be exposed to future litigation by third parties based on claims that our technologies, 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

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breadth of claims covered in pharmaceutical patents are complex. Any litigation or claims against us, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. Most of our license agreements require that we pay the costs associated with defending this type of litigation. Such a situation may force us to do one or more of the following:

- 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.

We are currently aware United States patent 5,616,334 dealing with lipid formulations of Amphotericin B products. We do not believe that our Bioral™ products are covered by or in conflict with this patent, although there can be no assurance that a court of law in the United States might determine otherwise. Accordingly, we do not believe that we require a license under this patent. Although, if a court were to determine that we were infringing this or other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our Bioral™ formulation of Amphotericin B. However, there can be no assurance that we would be able to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

The mucoadhesive erodible drug delivery device technology space is congested. No assurances can be given that a court of law in the United States or elsewhere would not determine that ONSOLIS or another of our BEMA™ based products is in conflict with or covered by external patents. We have a been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market ONSOLIS within the countries of the European Union. Freedom to operate searches and analyses is currently ongoing, but has not been completed for other proposed BEMA™ based products.

If a lawsuit were to be filed against us for patent infringement, we would incur significant attorney costs to defend ourselves. 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 Bioral™ and/or BEMA™ products (including, without limitation, ONSOLIS). There can be no assurance that we would be able to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, we might be precluded from developing or commercializing these products, which would likely have a material adverse effect on our results of operations and business plans.

In addition, most of the inventions claimed in our Bioral™ patents were made with the United States government support. Therefore, the United States government has certain rights in the technology, and we have certain obligations to the United States government, which could be inconsistent with our plans for commercial development of products and/or processes. We believe to the extent the United States government would have rights in our licensed Bioral ™ technology due to their funding, we have to either obtain a waiver from the United States government relating to the United States government s rights in the technology, or have agreements with the United States government which would grant us exclusive rights.

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If we are unable to adequately protect or enforce our rights to intellectual property or secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to, enforce, maintain or protect such rights.

Our ability to license, enforce and maitain patents, maintain trade secret protection and operate without infringing the proprietary rights of others will be important to our commercializing any formulations or products under development. The current and future development of our drug delivery technologies is contingent upon whether we are able to maintain licenses and access patented technologies. Without these licenses, the use of technologies would be limited and the sales of our products could be prohibited. Therefore, any disruption in access to the technologies could substantially delay the development and sale of our products.

The patent positions of biotechnology and pharmaceutical companies, including ours which involves licensing agreements, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patents, patent applications and licensed rights may not provide protection against competitive technologies or may be held invalid if challenged or could be circumvented. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements provide that materials and confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology.

Although our trade secrets and technical know-how are important, our continued access to patented technology is a significant factor in the development and commercialization of our drug delivery products. Aside from the general body of scientific knowledge from other drug delivery processes and lipid technology, access to patented technologies, to the best of our knowledge and based upon our current scientific data, is the only intellectual property necessary to develop and apply our Bioral™ and BEMA™ drug delivery systems to the drugs to which we are attempting to apply them.

We may have to resort to costly and time consuming litigation to protect or enforce our rights under certain intellectual property, or to determine their scope, validity or enforceability. Enforcing or defending our rights is expensive, could cause significant diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technologies to develop or sell competing products.

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

Key components of our drug delivery technologies 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 research and development activities, such as lipids, 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:

- potential delays associated with research and development and pre-clinical and clinical trials due to an inability to timely obtain a single or limited source component;
- potential inability to timely obtain an adequate supply of required components; and
- potential for reduced control over pricing, quality and timely delivery.

Except for our agreements with Aveva and LTS, we do not have long-term agreements with any of our suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. Any interruption in the supply of components from Aveva or other third party suppliers could cause us to seek alternative sources of supply or manufacture these components internally. If the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required time frames, if at all, to meet our 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, components from a new supplier may not be identical to those provided by the original supplier. Such differences, if they exist, could fall outside of regulatory requirements, affect product formulations or the safety and effectiveness of our products that are being developed.

We have limited manufacturing experience and therefore depend on third parties to formulate and manufacture our products. We may not be able to secure or maintain the manufacture of sufficient quantities or at an acceptable cost necessary to successfully commercialize our products.

Our expertise is primarily in the research and development and pre-clinical and clinical trial phases of product development. We have more limited experience or expertise in the formulation and manufacturing of our products and have limited equipment and no facilities of our own from which these activities could be performed. Therefore, we are dependent on third parties for our formulation development and manufacturing of our products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to successfully launch and maintain the marketing of our products. Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to commercialize our products.

There are risks associated with our reliance on third parties for marketing, sales, managed care and distribution infrastructure and channels.

We expect that we will be required to enter into agreements with commercial partners (such as our agreements with Meda) to engage in sales, marketing and distribution efforts around our products in

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development. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors. If we do not enter into relationships with third parties for the sales and marketing of our proposed formulations or products, we will need to develop our own sales and marketing capabilities.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our formulations or products;
- cease operations with little or no notice to us; or
- offer, design, manufacture or promote competing formulations or products.

If we fail to develop sales, managed care, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

We will be subject to risks if we seek to develop our own sales force.

If we choose at some point to develop our own sales and marketing capability, our experience in developing a fully integrated commercial organization is limited. If we choose to establish a fully integrated commercial organization, we will likely incur substantial expenses in developing, training and managing such an organization. We may be unable to build a fully integrated commercial organization on a cost effective basis, or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

If we are unable to convince physicians as to the benefits of our proposed formulations or products, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our proposed formulations and products and related drug delivery technologies may require physicians to be informed regarding our proposed pharmaceutical formulations or products and the intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our proposed formulations or products. We may be unable to timely educate physicians regarding our intended pharmaceutical formulations or products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our formulations or products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our formulations or products is created, if at all.

We currently rely on the facilities of the University of Medicine and Dentistry of New Jersey (UMDNJ) for a significant portion of our research activities relating to our Bioral ^{TM} technology, which activities could be materially delayed should we lose access to those facilities.

We have no research and development facilities of our own. As of the date of this prospectus, we are entirely dependent on third parties to use their facilities to conduct research and development. To date, we have relied on UMDNJ for this purpose in relation to our Bioral^{TM} technology, as well as third party

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providers of testing and trial services. Additionally, the Universities own certain of the patents to our encochleation drug delivery technology. Our inability to conduct research and development, or our inability to find suitable third party providers of research and development services on an outsourcing basis, may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technologies, formulations and products.

We leased our research facility from UMDNJ, which expired December 31, 2005. We are currently leasing the space on a month to month basis. No assurances can be given that we will be able to enter into, extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations. Should the lease expire or if we are otherwise are required to relocate on short notice, we do not currently have an alternate facility where we could relocate. The cost and time to establish or locate an alternative research and development facility to develop our technologies, or to find suitable third party providers of research and development services on an outsourcing basis, could be substantial and might delay gaining FDA approval and commercializing our formulations and products, assuming that we have not defaulted on the terms of our intellectual property licenses and can continue with our approval process.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there can be no assurance that the assumptions made in preparing the projections, or the projections themselves, will prove accurate. There will be differences between actual and projected results, and actual results may be materially greater or less than those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

Risks Related to Our Products in Development and Regulation

Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our technologies and proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.

Our research and development activities and the manufacture and marketing of our proposed formulations and products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA or foreign regulatory clearance to market our proposed formulations and products, we will have to demonstrate that our formulations and products are safe and effective on the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, regulatory approvals can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources.

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Moreover, we may never receive regulatory approval of our proposed products and formulations, and we have received one non-approvable letter from the FDA in the past regarding our Emezine® NDA. No assurances can be given that we will be able to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and viability. This is especially true with respect to our lead product, ONSOLIS , on which we submitted an NDA in October 2007. Although we expect a final decision by FDA on our ONSOLIS NDA by the second quarter of 2009, it is possible that a decision by FDA could come after that time and any such delay would have a material adverse effect on our company.

Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair the viability of our company.

In order to be commercially viable, we must research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute formulations or products incorporating our technologies. For each drug that we formulate with our drug delivery technologies, we must meet a number of critical developmental milestones, including:

- demonstrate benefit from delivery of each specific drug through our drug delivery technologies;
- demonstrate through pre-clinical and clinical trials that our drug delivery technologies are safe and effective; and
- establish a viable Good Manufacturing Process capable of potential scale-up.

The required capital and time-frame necessary to achieve these developmental milestones is uncertain, and we may not be able to achieve these milestones for any of our proposed formulations or products in development. Our failure to meet these or other critical milestones would adversely affect the viability of our company.

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do not follow the FDA s requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell any drug or medical device for human consumption without FDA approval.

Moreover, it is our stated intention to attempt to avail ourselves of the FDA s 505(b)(2) approval procedure, which we believe is less costly and time consuming. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

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Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

Data already obtained, or in the future obtained, from pre-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data is susceptible to multiple and varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry, including those involved in competing drug delivery technologies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the potential product, resulting in delays to commercialization, and could materially harm our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

We depend on technology licensed to us by third parties, and the loss of access to this technology would terminate or delay the further development of our products, injure our reputation or force us to pay higher royalties.

We rely, in large part, on drug delivery technologies that we license from third parties such as the Universities and QLT. Although we have entered into agreements to purchase the BEMA™ technology from QLT, we may be unable to fulfill our obligations under such agreement. The loss of our key licenses would seriously impair our business and future viability. After the expiration of these licenses, this technology may not continue to be available on commercially reasonable terms, if at all, and may be difficult to replace. The loss of any of these technology licenses could result in delays in developing, introducing or maintaining our products and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the technology we may license in the future could prevent the implementation or impair the functionality of our products or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

Competitors in the drug development or specialty pharmaceutical industries may develop competing technology.

Drug companies and/or other technology companies may seek to develop and market nanoencapsulation, mucosal adhesive or other technologies which may compete with our technologies. While we believe that our technologies have certain advantages over potential competitors, competitors may develop similar or different technologies which may become more accepted by the marketplace or which may supplant our technology entirely. In addition, these competitors may be larger and better financed than we are, thus giving them a significant advantage over us.

Our lead product candidates contain tightly controlled narcotic ingredients. The development, manufacturing and sale of such products are subject strict regulation, including the necessity of risk management programs, which may prove difficult or expensive to comply with.

Our lead product candidates, most notably ONSOLIS and BEMA™ Buprenorphine, contain tightly controlled and highly regulated narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. The FDA or the U.S. Drug Enforcement Administration, or DEA, currently impose and may impose additional regulations concerning the development, manufacture, transportation and sale of prescription narcotics. Such regulations include labeling requirements, the development and implementation of risk management programs, restrictions on prescription and sale of these products and

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mandatory reformulation of our products in order to make abuse more difficult. This is particularly true with respect to the Risk Evaluation and Mitigation Strategy (REMS) that FDA has required for ONSOLIS . In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such current or new regulations may be difficult and expensive for us and our manufacturing and commercial partners to comply with, may delay the introduction of our products, may adversely affect our net sales, if any, and may have a material adverse effect on our results of operations.

The DEA limits the availability of the active ingredients used in our products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in our lead products in development, including fentanyl and buprenorphine, are listed by the DEA as Schedule II and III substances, respectively, under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled.

Furthermore, the DEA limits the availability of the active ingredients used in our products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to complete clinical trials or meet commercial demand. We must annually apply to the DEA for procurement quota in order to obtain these substances. The DEA may not establish procurement quota following FDA approval of an NDA for a controlled substance until after DEA reviews and provides public comment on the labeling, promotion, risk management plan and other documents associated with such product. No assurance can be given that the DEA review of such materials may not result in delays in obtaining procurement quota for controlled substances, a reduction in the quota issued to us or an elimination of our quota entirely. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials or product launches which could have a material adverse effect on our business and results of operations.

Risks Related to Our Industry

The market for our proposed formulations and products is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and proposed formulations or products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors financial, marketing, manufacturing and other resources.

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We are engaged in the development of drug delivery technologies. As a result, our resources are limited and we may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our technology. Our competitors may develop drug delivery technologies and drugs that are safer, more effective or less costly than our proposed formulations or products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or products, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies, formulations and products to receive widespread acceptance if commercialized.

If users of our proposed formulations or products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed formulations or products may be limited and we may not achieve revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our proposed formulations or products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

We could be exposed to significant drug product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. We currently have a general liability policy with an annual aggregate limit of $2 million with a $2 million limit per occurrence which does not exclude coverage for product liability for commercial products, but only would cover up to the foregoing amounts. All of our pre-clinical trials have been and all of our proposed pre-clinical and clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have insurance relating to product liability or insurance related to pre-clinical or clinical trials only with respect to our

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developmental product portfolio, for which we have a clinical trial liability policy providing for a $2 million aggregate limit. Should we decide to seek additional insurance against such risks before our product sales commence, no assurance can be given that such insurance will be available, or if it can be obtained at such time at an affordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs. Product liability claims or other claims related to our proposed formulations and products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our drug delivery technology. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products. In addition, although third party partners like Meda are required to provide insurance in connection with specific programs like ONSOLIS , such partners may face similar insurance related risks.

Our business involves environmental risks related to handling regulated substances which could severely affect our ability to conduct research and development of our drug delivery technology.

In connection with our research and development activities and our manufacture of materials and drugs, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development may in the future involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. The hazardous chemicals that we currently use, which may change as our research progresses, are chloroform and methanol. We are authorized to use these and other hazardous chemicals in our facilities through our affiliation with the UMDNJ. UMDNJ also disposes these chemicals from our premises as part of our agreement to use the facilities and carries general liability insurance in this regard. Although we believe that our safety procedures for storing, handling and disposing of such materials will comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Our Management and Key Employees

We depend upon key personnel who may terminate their employment with us at any time, and we will need to hire additional qualified personnel.

Our success will depend to a significant degree upon the continued services of key management, technical and scientific personnel. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, our success will depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

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Additionally, we do not currently maintain key person life insurance on the lives of our Chairman of the Board, Dr. Frank O Donnell, or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Executive officers, directors and entities affiliated with them have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders.

As of the date of this prospectus, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 40.78% of our outstanding common stock. These figures do not reflect any future potential exercise of common stock purchase warrants (including those issued to Laurus Master Fund, Ltd., CDC and others) into shares of common stock.

The interests of our current officer, director and affiliated stockholders may differ from the interests of other stockholders. As a result, these current officer, director and affiliated stockholders could have the ability to exercise significant control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

- approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets and material financing transactions;
- election of directors;
- adoption of or amendments to stock option plans;
- amendment of charter documents; or
- issuance of blank check preferred stock.

Certain of our management team have relationships which may potentially result in conflicts of interests.

Dr. O Donnell, who is the Chairman of our board of directors and also is a substantial beneficial owner of our securities through HCG II, has a financial interest in a number of other companies which have business relationships with us. These companies include Accentia, RetinaPharma Technologies, Inc. and Biotechnology Specialty Partners, Inc. We have entered into license agreements with Accentia and RetinaPharma International, Inc. with regard to proposed products incorporating our Bioral™ technology. We have entered into a non-exclusive distribution agreement with Biotechnology Specialty Partners, Inc. Each of these business arrangements was approved (with Dr. O Donnell abstaining) by our board of directors and our predecessor s board of directors. In addition, William Poole, a director of our company, is also a director of Accentia, Dr. Mannino is a member of the board of directors of Biovest International, Inc. (OTC:BVTIE.OB), a subsidiary of Accentia, and Mr. McNulty is employed by Accentia. These relationships and agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and such members of our management.

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Risks Related to Our Common Stock

Our stock price is subject to market factors, and your investment in our securities could decline in value.

Since our initial public offering in June 2002, there has only been a limited public market for our securities and there can be no assurance that an active trading market in our securities will be maintained. In addition, the overall market for securities in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies. In particular, the market prices of securities of biotechnology and pharmaceutical companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our securities, which could cause a decline in the value of your securities. These fluctuations, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

If we cannot meet the Nasdaq Capital Market s continuing listing requirements and Nasdaq rules, Nasdaq may delist our securities, which could negatively affect our company, the price of our securities and your ability to sell our securities.

As of the date of this prospectus, our shares are listed on the Nasdaq Capital Market. In the future, however, we may not be able to meet the listing maintenance requirements of the Nasdaq Capital Market and Nasdaq rules, which require, among other things, minimum stockholders equity of $2.5 million or a minimum market capitalization of $35 million and a majority of independent directors on our board of directors. We have been subject to delisting proceedings and comments by Nasdaq in the past. If we are unable to satisfy the Nasdaq criteria for maintaining listing, our securities could again be subject to delisting. Trading, if any, of our securities would thereafter be conducted in the over-the-counter market, in the so-called pink sheets or on the OTC Bulletin Board. As a consequence of any such delisting, our stockholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the prices of our securities.

Additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market for our common stock.

We are authorized to issue 45 million shares of our common stock. As of February 4, 2009, there were 19,179,029 shares of common stock issued and 19,163,538 shares of common stock outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. We will likely, subject to the approval of our stockholders, increase the size of our option plan at our next annual meeting of stockholders. To the extent such options (including options under our larger, amended option plan) or warrants are exercised, the holders of our common stock may experience further dilution.

In addition, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution. Moreover, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 764,705 authorized but undesignated shares of preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

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Shares eligible for future sale may adversely affect the market for our common stock.

We have a material number of shares of common stock underlying securities of our company, the future sale of which could depress the price of our publicly-traded stock. As of the date of this prospectus, 3,503,467 shares of common stock are issuable upon exercise of outstanding stock options at a weighted average exercise price of $3.55 per share, and (ii) 5,848,765 shares of common stock issuable upon exercise of our outstanding warrants at a weighted average exercise price of $3.69 per share. If and when these securities are exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

In addition, from time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, which we refer to herein as the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated stockholder (or stockholders whose shares are aggregated) may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated stockholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one year holding period without any limitation or restriction. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

Our certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing the issuance of blank check preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could allow our board of directors to affect your rights as a stockholder since our board of directors can make it more difficult for common stockholders to replace members of the board. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team.

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USE OF PROCEEDS

We will not receive any of the proceeds from the sale of common stock registered hereunder. If and when all of the shares underlying the warrant held by HCG II are exercised, we will receive the proceeds from the exercise of that warrant. HCG II is under no obligation to exercise such warrant. If the HCG Warrant is exercised in full, we will receive up to approximately $2,636,250. We expect to use such proceeds, if any, for the continued development of our products and for working capital and general corporate purposes.

SELLING STOCKHOLDERS

Up to 2,069,826 shares of common stock are being offered by this prospectus for sale by the selling stockholders for their own account. These shares include: (i) up to 475,000 shares of our common stock issuable upon the exercise of the HCG Warrant issued by us to HCG II on September 5, 2007; and (ii) an aggregate of 1,594,826 shares of our common stock held by Drs. Sirgo and Finn, our President and Chief Executive Officer and a director, and our Executive Vice President of Product Development, respectively.

As used in this prospectus, the term selling stockholders includes the selling stockholders and their respective transferees, assignees, pledgees, donees or other successors.

All proceeds of this offering will be received by the selling stockholders for their own accounts. We may receive proceeds in connection with the exercise of the HCG Warrant and the underlying shares associated with which may, in turn, be sold by HCG II.

The following table sets forth, to our knowledge, information as of the date of this prospectus, regarding beneficial ownership of our common stock by the selling stockholders, both before and immediately after the offering. Actual common stock ownership by HCG II is subject to the exercises of the HCG warrant, among other factors.

Beneficial ownership is determined in accordance with Rule 13d-3 promulgated by the SEC, and generally includes voting or investment power with respect to securities. In computing the number of shares beneficially owned by the holder and the percentage ownership of the holder, shares of common stock issuable upon conversion of the notes and upon exercise of the warrant held by the holder that are currently convertible or are exercisable or convertible or exercisable within 60 days after the date of the table are deemed outstanding.

To our knowledge, HCG II has sole voting and investment power with respect to all of the shares of common stock beneficially owned by it, except that our Chairman, Dr. Frank E. O Donnell is the manager of HCG II. The address for HCG II is 865 Longboat Club Road, Longboat Key, FL 34228. To our knowledge, Drs. Sirgo and Finn have respective sole voting and investment power with respect to all of the shares of common stock beneficially owned by them. The address for Dr. Sirgo is 1203 Clematis Street, Knightdale, NC 27545. The address for Dr. Finn is 3104 Raymond Street, Raleigh, NC 27607.

The percent of beneficial ownership for the selling stockholders is based on shares of common stock outstanding as of the date of this prospectus. Shares of common stock subject to warrants, options and other convertible securities that are currently exercisable or exercisable within 60 days of the date of this prospectus are considered outstanding and beneficially owned by a selling stockholder who holds those warrants, options or other convertible securities for the purpose of computing the percentage ownership of that selling stockholder but are not treated as outstanding for the purpose of computing the percentage ownership of any other stockholder.

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The shares of common stock being offered under this prospectus may be offered for sale from time to time during the period the registration statement of which this prospectus is a part remains effective, by or for the respective accounts of the selling stockholders. After the date of effectiveness of the registration statement of which this prospectus is a part, the selling stockholders may have sold or transferred, in transactions covered by this prospectus or in transactions exempt from the registration requirements of the Securities Act, some or all of its common stock. Information about the selling stockholders may change over time.

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

Name	Position, Office or Other Material Relationship	Total Number of Shares of common stock Beneficially Owned	Number of Shares to be Offered for the Account of the Selling Stockholder	Number of Shares to be Owned after this Offering	Percentage to be Beneficially Owned after this Offering[3]
Hopkins Capital Group II, LLC	Affiliate	3,940,490	475,000	3,465,490	18.08%
Mark A. Sirgo	Officer and Director	1,209,779[1]	797,413	412,336	2.15%
Andrew Finn	Officer	954,528 [2]	797,413	157,115	0.82%

(1) Includes 351,604 vested options to purchase common stock.
(2) Includes 152,115 vested options to purchase common stock.
(3) Based on 19,163,538 shares outstanding as of February 4, 2009.

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PLAN OF DISTRIBUTION

The selling stockholders and any of their pledges, assignees, donees selling shares received from such selling stockholder as a gift, and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales and therefore they will be subject to the prospectus delivery requirements of the Securities Act. In such event, any commissions received by such brokers-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. To our knowledge and based upon information we received from the selling stockholders: (i) the selling stockholders do not have any agreement or understanding, directly or indirectly, with any person to distribute the shares of common stock and (ii) the selling stockholders have not received any of the securities registered hereby as underwriting compensation. We are also not aware of any underwriting plan or agreement, underwriters or dealers compensation, or passive market making or stabilizing transactions involving the purchase or distribution of these securities.

We are required to pay all fees and expenses incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. To the extent required, we will amend or supplement this prospectus to disclose material arrangements regarding the plan of distribution. To comply with the securities laws of certain jurisdictions, registered or licensed brokers or dealers may need to offer or sell

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the shares offered by this prospectus. The applicable rules and regulations under the Exchange Act may limit any person engaged in a distribution of the shares of common stock covered by this prospectus in its ability to engage in market activities with respect to such shares. The selling stockholder, for example, will be subject to applicable provisions of the Exchange Act and the rules and regulations under it, which provisions may limit the timing of purchases and sales of any shares of common stock by the selling stockholder.

LEGAL MATTERS

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

EXPERTS

The consolidated financial statements as of and for each of the two years in the period ended December 31, 2007, incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2007, have been audited by Cherry, Bekaert & Holland, L.L.P. as successor by merger to Aidman, Piser & Company, P.A., our former independent registered public accounting firm, as stated in their report incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

All documents filed by the registrant after the date of filing the initial registration statement on Form S-3 of which this prospectus forms a part and prior to the effectiveness of such registration statement pursuant to Section 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 shall be deemed to be incorporated by reference into this prospectus and to be part hereof from the date of filing of such documents. In addition, the documents we are incorporating by reference as of the date hereof are as follows:

our Annual Report on Form 10-K for fiscal year ended December 31, 2007, as filed with the SEC on March 7, 2008, and as amended on March 17, 2008;

our Quarterly Report on Form 10-Q for fiscal quarter ended March 31, 2008 (as filed with the SEC on May 15, 2008);

our Quarterly Report on Form 10-Q for fiscal quarter ended June 30, 2008 (as filed with the SEC on August 14, 2008);

our Quarterly Report on Form 10-Q for fiscal quarter ended September 30, 2008 (as filed with the SEC on November 19, 2008);

our Current Reports on Form 8-K as filed with the SEC on May 8, 2008, May 30, 2008, June 6, 2008 (as amended June 11, 2008), July 28, 3008, August 28, 2008, October 9, 2008, November 7, 2008, November 21, 2008, December 16, 2008, January 6, 2009 and January 23, 2009;

our Annual Proxy Statement (Schedule 14A) for our Annual Shareholders Meeting , filed with the SEC on June 18, 2008,

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

all documents that we file with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this registration statement and prior to the filing of a post-effective amendment to this registration statement that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this registration statement by reference and to be a part hereof from the date of filing of such documents.

Any statement contained in a document we incorporate by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus (or in any other document that is subsequently filed with the Securities and Exchange Commission and incorporated by reference) modifies or is contrary to that previous statement. Any statement so modified or superseded will not be deemed a part of this prospectus except as so modified or superseded.

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

BioDelivery Sciences International, Inc.

324 South Hyde Park Avenue, Suite 350

Tampa FL 33606

Telephone: (813) 864-2562

Attention: James A. McNulty

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front page of those documents.

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

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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 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 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.

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You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

BioDelivery Sciences International, Inc.

2,069,826 shares

common stock

PROSPECTUS

, 2009

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth estimated expenses expected to be incurred in connection with the issuance and distribution of the securities being registered. All such expenses will be paid by us. The amounts listed below are estimates subject to future contingencies.

Securities and Exchange Commission Registration Fee	$ 299.18
Legal Fees and Expenses	$ 35,000.00
Accounting Fees and Expenses	$ 5,000.00
TOTAL	$ 40,299.18

Item 15. Indemnification of Directors and Officers.

Our certificate of incorporation 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 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.

Item 16. Exhibits

The following exhibits are filed with this Registration statement.

Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated August 10, 2004, by and among the Company, Arius Acquisition Corp., Arius Pharmaceuticals, Inc. Dr. Mark Sirgo and Dr. Andrew Finn (2)
3.4	Articles of Incorporation of the Company after reincorporation merger into Delaware (1)
4.6	Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 20, 2004 (2)
4.7	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 25, 2004. (3)
4.8	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated September 2, 2004 (4)
4.21	Certificate of Designations, Preferences and Rights, of the Series C Non-Voting Convertible Preferred Stock of the Company, dated February 22, 2007 (5)
5.1	Opinion of Ellenoff Grossman & Schole LLP (*)
10.41	Registration Rights Agreement, dated August 24, 2004, by and among the Company and the former stockholders of Arius Pharmaceuticals, Inc. (3)
10.128	Common Stock Purchase warrant (475,000 shares), dated September 5, 2007, by the Company in favor of HCG II (6)

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10.129 Registration Rights Agreement, dated September 5, 2007, by and among the Company and HCG II (6)

23.1 Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.1) (*)

23.2 Consent of Cherry, Bekaert & Holland, L.L.P (*)

* Filed herewith
(1) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(2) Previously filed with Form 8-K, August 12, 2004.
(3) Previously filed with Form 8-K, August 26, 2004.
(4) Previously filed with Form 8-K, September 8, 2004.
(5) Previously filed with Form 8-K, February 22, 2007.
(6) Previously filed with Form 8-K, September 10, 2007.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement

(i) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.

(5) That every prospectus (i) that is filed pursuant to paragraph (4) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act of 1933 and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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(7) To respond to requests for information that is incorporated by reference into the joint proxy statement/prospectus pursuant to Item 4, 10(b), 11 or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

(8) To supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Raleigh, State of North Carolina, on February 6, 2009.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer

BioDelivery Sciences International, Inc. and each of the undersigned do hereby appoint Mark A. Sirgo and James A. McNulty and each of them severally, its or his true and lawful attorney to execute on behalf of BioDelivery Sciences International, Inc. and the undersigned any and all amendments to this Registration Statement on Form S-3 and to file the same with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission; each of such persons shall have the power to act hereunder with or without the other.

In accordance with the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates stated.

Person	Capacity	Date
/s/ Francis E. O Donnell, Jr. Francis E. O Donnell, Jr.	Chairman of the Board and Director	February 6, 2009
/s/ Mark A. Sirgo Mark A. Sirgo	President and Chief Executive Officer (Principal Executive Officer)	February 6, 2009
	Chief Financial Officer, Secretary and Treasurer	
/s/ James A. McNulty James A. McNulty	(Principal Accounting Officer)	February 6, 2009
/s/ William B. Stone William B. Stone	Director	February 6, 2009
/s/ John J. Shea John J. Shea	Director	February 6, 2009
/s/ William S. Poole William S. Poole	Director	February 6, 2009