BIODELIVERY SCIENCES INTERNATIONAL INC
Form S-3
March 12, 2008
Table of Contents

As filed with the Securities and Exchange Commission on March 12, 2008

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:

Douglas S. Ellenoff, Esq.

Lawrence A. Rosenbloom, Esq.

Ellenoff Grossman & Schole LLP

150 East 42nd Street, 11th Floor

New York, New York 10017

(212) 370-1300

Fax: (212) 370-7889

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	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 CDC Warrant	1,000,000 shares[1]	$3.80[2]	3,800,000	$149.34
TOTAL	1,000,000 shares	$3.80	3,800,000	$149.34

(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) Based on the exercise prince of the warrant pursuant to Rule 457(g)(i).

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.

Table of Contents

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 March 12, 2008**

1,000,000 Shares

Common Stock

This prospectus relates to the public offering of up to 1,000,000 shares of our common stock, par value $0.001 per share, for sale by CDC IV, LLC (which we refer to herein as CDC) for its own account. The shares to be sold by CDC are comprised of up to 1,000,000 shares of our common stock issuable upon the exercise of a common stock purchase warrant held by CDC (which we refer to as the CDC Warrant) issued by us to CDC on March 12, 2007.

To the extent CDC wishes to sell its shares of our common stock as provided for herein, CDC 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 CDC Warrant, but we will receive funds upon the exercise of such warrant. Any such proceeds, if any, will be used by us 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 common stock is quoted on both the Nasdaq Capital Market under the symbol BDSI . On March 11, 2008, the closing sales price for the common stock on the Nasdaq Capital Market was $2.58 per share.

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

An investment in the shares of our common stock being offered by this prospectus involves a high degree of risk. You should read the Risk Factors section beginning on page 4 before you decide to purchase any shares of our common stock.

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

The date of this prospectus is _____, 2008.

Table of Contents

TABLE OF CONTENTS

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.

Table of Contents

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

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

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed on March 7, 2008; and

2. The description of our common stock contained in our registration statement on Form 8-A filed on June 19, 2002, as amended June 20, 2002, and as it may be further amended from time to time.

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.

We will provide without charge to each person to whom a copy of this prospectus is delivered, upon the written or oral request of any such person, a copy of any document described above (other than exhibits). Requests for such copies should be directed to BioDelivery Sciences International, Inc., 324 South Hyde Park Avenue, Suite 350, Tampa FL 33606, 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.

Table of Contents

NOTE ON FORWARD LOOKING STATEMENTS

Certain statements contained 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 an 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 our lead product, 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 U.S. Food and Drug Administration and the timing, status and results of pre-clinical work and clinical studies;
- our ability to 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 interest in licensed patents, or our ability to enforce our rights under such licenses;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and formulations;
- the ability of our commercial partners to market and sell the products we license to them;
- our ability to retain members of our management team and our employees; and
- competition existing today or 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.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights selected information contained 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 its licensed, owned and proprietary 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 development strategy focuses on the utilization of the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration, which we refer to herein as the FDA.

Our drug delivery technologies include:

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

Utilizing our 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. We have completed the principal Phase III studies and submitted a New Drug Application, or NDA, to the FDA for our lead product, 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). The PDUFA date for this NDA (the date we expect a decision by the FDA on the approvability of BEMA Fentanyl) is August 31, 2008. Our next product utilizing the BEMA technology is BEMA Buprenorphine, a treatment for moderate to severe pain conditions, which is currently in Phase I.

Our lead Bioral® formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for systemic fungal infections. We refer to our Bioral® Amphotericin B as CAMB. We also believe our Bioral® technology has the potential to be applied to other types of pharmaceuticals and also to other therapeutics such as small interfering RNA, or siRNA.

Some of our products, such as BEMA Fentanyl 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 use.

Table of Contents

To date, we have not generated revenue from sales of our products or royalty revenue from such sales. In 2006 and 2007, we received initial up-front non-refundable licensing payments of $2.5 million and $30.0 million for, respectively, the rights to commercialize BEMA Fentanyl in Europe and the U.S., Canada and Mexico. We generated $2.5 million from the sale of a royalty stream asset in 2004 and have also historically generated nominal revenue from research collaborations and grants. Ultimately, if we secure approval from the FDA and other regulatory bodies throughout the world for our licensed and/or proprietary products, our goal will be to augment our sources of revenue with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators where they exist.

We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- applying our drug delivery technologies to existing therapeutics to create our own proprietary products, which we will then seek to obtain approval from the FDA and other worldwide regulatory approval for and, subsequently, commercialize;

- partnering with pharmaceutical companies to assist in the distribution of our products for which we will receive milestone and royalty payments,

- licensing and joint venture arrangements with third parties, including pharmaceutical companies whose own proprietary pharmaceutical products may benefit from our drug delivery technologies; and

- proceeds raised from public and private financings and strategic transactions.

Table of Contents

The Offering

Outstanding Common Stock	19,160,637 shares of common stock issued and 19,145,546 shares of common stock outstanding as of March 7, 2008.
Common Stock Offered	Up to 1,000,000 shares of common stock for sale by CDC. Such shares underlie the CDC Warrant.
Selling Stockholder	CDC is the selling stockholder. CDC has previously provided funding to us for our lead product, BEMA™ Fentanyl, and owns a material portion of our outstanding common stock. See Selling Stockholder .
Proceeds	We will not receive any proceeds from the sale by the selling stockholder of 1,000,000 shares of our common stock underlying the CDC Warrant.
	We would, however, receive proceeds upon the exercise of the CDC Warrant which, if all such warrant was exercised in full at the present exercise price, the proceeds would be approximately $3,800,000.
	CDC is under no obligation to exercise its warrant. Proceeds, if any, received from the exercise of the warrant and option 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

Table of Contents

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 or any supplement hereto, before deciding to buy or exercise our securities. If any of such 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 December 31, 2007, we have recorded accumulated losses totaling approximately $75 million. As of December 31, 2007, we had working capital of approximately $2.8 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 BEMA™ Fentanyl. 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, commercialize, 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 FDA 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.

Table of Contents

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 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 December 31, 2007, we had cash and cash equivalents of approximately $13.8 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 2008, assuming that we do not accelerate the development of other opportunities available to us, engage in an extraordinary transaction or otherwise face unexpected events or contingencies, any of which could effect our cash requirements.

We expect to receive an additional $30 million milestone payment from Meda in connection with FDA approval and commercial launch of BEMA™ Fentanyl. If BEMA™ Fentanyl 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 will need to raise additional capital to fund our anticipated operating expenses and future expansion. If BEMA™ Fentanyl 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 capital raising 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 business risks associated with our company. 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 formulations incorporating such technologies. We will require additional funds to conduct research and development, establish and conduct pre-clinical and clinical trials, secure commercial-scale manufacturing arrangements and provide for the marketing and distribution, especially if BEMA™ Fentanyl 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;

Table of Contents

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 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 and other professional 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 proposed 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 BEMA™ Fentanyl asset.

Under our agreements with CDC, if we do not meet certain conditions, CDC can assume control of the BEMA™ Fentanyl project and related intellectual property assets. For example, in the event that

Table of Contents

we do not diligently pursue the development and regulatory approval of BEMA™ Fentanyl or encounter certain specified negative circumstances regarding the development of BEMA™ Fentanyl, CDC has the right to require the assignment of our BEMA Fentanyl assets to CDC and to pursue development and commercialization of BEMA™ Fentanyl 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 BEMA™ Fentanyl 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 customer acceptance of our proposed pharmaceutical 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, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

Table of Contents

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 and governmental agencies for both strategic and financial resources. Key among these agreements is our U.S. and European commercialization agreements with Meda and our supply agreement with Aveva relating to BEMA™ Fentanyl. 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. In addition, under our collaborative agreements with Meda, we are responsible for paying the certain costs relating to BEMA™ Fentanyl. 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 we be sued, because we do not currently have product liability insurance above and beyond our general insurance coverage.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. Such claims may be asserted against us. In addition, the use in our clinical trials of pharmaceutical formulations and products that our potential collaborators may develop 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 liquidity 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 drug product 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 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 any of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;

Table of Contents

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, although we do not believe that our BEMA Fentanyl product is in conflict with or covered by external patents and do not believe that we require licenses under these patents for BEMA Fentanyl in the United States. Although there can be no assurance that a court of law in the United States might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our BEMA Fentanyl product. 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.

We have a been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by Lohmann Therapie Systeme to market the BEMA™ fentanyl product 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 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. 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.

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.

Table of Contents

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 protect such rights.

Our ability to license 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 patent, patent applications and licensed rights may not provide protection against competitive technologies or may be held invalid if challenged or 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 all 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 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 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.

Table of Contents

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 agreement with Aveva, 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, 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 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 no equipment or facilities 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 contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay 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

Table of Contents

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.

Table of Contents

We currently rely on the facilities of the University of Medicine and Dentistry of New Jersey for all of our research activities relating to our Bioral® 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® technology, as well as third party 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, other than through the Universities, 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.

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 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.

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, BEMA™ Fentanyl, on which we submitted an NDA in October 2007. Finally, although we have received a PDUFA date of August 31, 2008 for a decision by FDA on our BEMA™ Fentanyl NDA, it is possible that a decision by FDA could come after such date.

Table of Contents

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 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 commercialize such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

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 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

Table of Contents

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 drug, 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, QLT and Reckitt. 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. 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 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 BEMA™ Fentanyl and BEMA™ Buprenorphine, contain 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 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 mandatory reformulation of our products in order to make abuse more difficult. In addition, state health departments and boards of pharmacy have authorit