BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B1
August 04, 2006
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Filed Pursuant to Rule 424(b)(1)
Registration No. 333-135746

Prospectus

3,505,120 Shares of Common Stock

This prospectus relates to the public offering of up to 3,505,120 shares of our common stock, par value $0.001 per share, for sale by CDC IV, LLC, which we refer to herein as CDC or the selling stockholder, for its own account. These shares include: (i) 2,000,000 shares of our common stock issued to CDC on May 16, 2006, (ii) up to 601,120 shares of our common stock issuable upon the exercise of a warrant issued by us to CDC on February 15, 2006 and (iii) up to 904,000 shares of our common stock issuable upon the exercise of a warrant issued by us to CDC on May 16, 2006.

Our common stock and warrants are quoted on both the Nasdaq Capital Market and the Boston Stock Exchange under the symbols BDSI and BDSIW , respectively. On August 1, 2006, the closing sales price for the common stock on the Nasdaq Capital Market was $2.19 per share and the closing sales price for our warrants was $0.24 per share.

To the extent it 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 owned by CDC, but we will receive funds from the exercise of their warrants upon exercise. 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 principal executive offices are located at 2501 Aerial Center Parkway, Suite 205, Morrisville, North Carolina 27560. Our telephone number is (919) 653-5160.

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 5 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 August 3, 2006.

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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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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-KSB for the fiscal year ended December 31, 2005;

2. Our Current Report on Form 8-K, filed April 3, 2006;

3. Our Quarterly Report on Form 10-QSB for the quarterly period ended March 31, 2006;

4. Our Current Report on Form 8-K, filed May 22, 2006;

5. Our Definitive Proxy Statement on Schedule 14A, filed June 27, 2006; and

6. Our Current Report on Form 8-K, filed July 28, 2006.

Each document filed subsequent to the date of this prospectus pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering shall be deemed to be incorporated by reference in this prospectus and shall be part hereof from the date of filing of such document.

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.

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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, the financial statements and the notes to the financial statements. 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 biopharmaceutical company that is exploiting its licensed and 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 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 membrane) drug delivery technology, and
- the patented Bioral® nanocochleate 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 such as:

- pain,
- nausea and vomiting,
- insomnia, and
- fungal infections

We also believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals.

We currently generate revenue from licensing milestone payments and royalties, and have generated revenue from grants. Ultimately, if we secure approval from the FDA 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 pay royalties or other fees to our licensors and/or third-party collaborators.

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BEMA Technology and Products

Our BEMA drug delivery technology consists of a small, dissolvable polymer disc for application to mucosal (inner lining of cheek) membranes. BEMA discs deliver a rapid, reliable dose of drug across mucous membranes for time-critical conditions like breakthrough cancer pain (i.e., episodes of severe pain which break through the medication used to control the persistent pain), or trauma cases where intravenous lines or injections are unavailable or not practical. We license the BEMA drug delivery technology on a worldwide exclusive basis from Atrix Laboratories, Inc. (now a wholly-owned subsidiary of QLT Inc.), which we refer to herein as Atrix.

Our lead BEMA products are: BEMA Fentanyl, a treatment for breakthrough cancer pain; BEMA Long Acting Analgesic, which we refer to herein as BEMA LA, a BEMA formulation of an already approved product in the U.S. that will target a broader range of pain conditions including post operative and, potentially, chronic pain due to osteoarthritis, lower back disorders and rheumatoid arthritis; and BEMA Zolpidem, a BEMA formulation of the most widely prescribed drug for the treatment of insomnia.

Bioral® Technology and Products

Our Bioral® encochleation drug delivery technology encapsulates the selected drug in a nanocrystalline structure termed a cochleate cylinder. All of the components of the cochleate cylinder are naturally occurring substances. We believe that the cochleate cylinder provides an effective delivery mechanism without forming a chemical bond, or otherwise chemically altering, the selected drug. We believe this technology will allow us to take certain drugs that were only available by intravenous injection and convert them to formulations that can be taken orally. Our Bioral® drug delivery technology was developed in collaboration with The University of Medicine and Dentistry of New Jersey, which we refer to herein as UMDNJ, and the Albany Medical College, which we refer to herein, collectively with UMDNJ, as the Universities, each of which has granted us the exclusive worldwide licenses under applicable patents.

Our lead Bioral® formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for treating systemic fungal infections. A Bioral® formulation of Amphotericin B would have the potential for oral delivery of a drug that is currently only given by intravenous injection. Bioral® Amphotericin B is currently in the last stages of preclinical testing. A second formulation for intranasal administration of Amphotericin B to treat chronic rhinosinusitis, or CRS, is now in development. In April 2004, we licensed this second product to Accentia Biopharmaceuticals, Inc., an affiliate of ours which we refer to herein as Accentia, for the use in the treatment of CRS and asthma. Certain of our officers and directors are officers, directors and/or stockholders of Accentia or its subsidiaries. We have also explored other potential applications of our encochleation technology, including the creation of cochleate formulations of siRNA therapeutics, certain vaccines and important nutrients.

Emezine®

We are also developing Emezine®, a formulation of prochlorperazine, which we believe will be the first drug to be delivered transmucousally for treatment of nausea and vomiting. On February 28, 2006, we received a non-approvable letter from the FDA regarding our New Drug Application, or NDA, relating to Emezine®. The non-approvable letter stated that additional information would be required to address remaining questions. On May 17, 2006, we met with representatives of the FDA to discuss the issues outlined in their non-approvable letter and are presently working toward a plan with the FDA to address its remaining concerns. Once this plan has been solidified, we intend announce our intentions to progress Emezine®. This decision will be based on the costs of such a plan as well as the length of time

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to complete the plan and ultimately obtain FDA s approval of Emezine®. No assurances can be given, however, that we will be able to satisfy any FDA concerns regarding Emezine®, and we may be forced to abandon this project. Despite the fact Emezine® represents a relatively small portion of our potential future revenues, the failure to achieve FDA approval of Emezine® could have a material adverse effect on our business. We do not, however, expect that such failure would seriously impair our overall potential future revenue growth. We licensed Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

The CDC Transactions

On May 16, 2006, we consummated a transaction with CDC IV, LLC, or CDC, pursuant to which $7 million in funds previously committed by CDC to us in July 2005 to fund the clinical development of the our BEMA™ Fentanyl product were converted into shares of our common stock at a value equal to $3.50 per share. As a result of this transaction, CDC was issued 2 million shares of our common stock in return for accelerating the funding of the $4.2 million balance of $7 million of aggregate commitment under our July 2005 agreements with CDC and for eliminating the $7 million milestone payable to CDC upon the approval by the FDA of BEMA™ Fentanyl.

The 2 million shares of common stock granted to CDC in the transaction are equivalent to a price of $3.50 per share based on the total $7 million funded. In addition, CDC was issued a warrant to purchase an additional 904,000 shares of common stock at $3.00 per share. Until such time as the shares of common stock underlying the warrant are registered with the Securities and Exchange Commission, or SEC, CDC shall have the right to exercise the warrant on a cashless basis. In addition, until the date that is ninety (90) days subsequent to regulatory approval of BEMA™ Fentanyl, the exercise price of the warrant will be reduced to a price equal to the per share price of issuances of securities by us at less than the warrant exercise price.

We have agreed to register the shares of common stock issued to CDC in this transaction plus the shares of Common Stock underlying the warrant with the SEC, and the registration statement of which this prospectus forms a part is intended to satisfy this obligation. The shares of common stock and warrant were sold and issued to CDC pursuant to Section 4(2) of the Securities Act of 1933, as amended, in a transaction not involving any public offering.

On July 15, 2005, we entered into a clinical development and license agreement with CDC pursuant to which CDC was to provide up to $7 million in funding for the clinical development of BEMA Fentanyl. Following an up front payment of $2 million made in February 2006, we were receiving equal monthly payments in accordance with the expected timeline for the BEMA Fentanyl Phase III development program. Under the prior agreement, we were required to repay the $7 million to CDC within 60 days of approval by the FDA of BEMA Fentanyl. As such, the funding was accounted for on our balance sheet as a refundable deposit. Under the amended CDC transaction described above, the full $7 million commitment was immediately converted into shares of common stock and we received an immediate cash infusion of $4.2 million, the balance of the CDC committed funds. As under the original arrangement, CDC will receive royalties based on net sales of BEMA Fentanyl.

Pursuant to the CDC development agreement, and concurrently with the timing of CDC s initial $2.0 million payment to us in February 2006, we entered into a security agreement granting CDC a security interest in assets related to BEMA Fentanyl. Such security agreement remains in place, and, as in the original agreement, the security interest granted to CDC will terminate on FDA approval of BEMA Fentanyl. However, the clinical development and license agreement and security agreement were amended in the May 2006 transaction to eliminate our obligation to reimburse CDC $7 million prior to the release of CDC s security interest in BEMA Fentanyl.

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The Offering

Outstanding Common Stock	13,938,146 shares as of the date of this prospectus.
Common Stock Offered	Up to 3,505,120 shares of common stock for sale by CDC for its own account. These shares include: (i) 2,000,000 shares of our common stock issued to CDC on May 16, 2006, (ii) up to 601,120 shares of our common stock issuable upon the exercise of a warrant issued by us to CDC on February 15, 2006 and (iii) up to 904,000 shares of our common stock issuable upon the exercise of a warrant issued by us to CDC on May 16, 2006.
Proceeds	We will not receive any proceeds from the sale by CDC of the 2 million shares of our common stock issued to CDC in May 2006. We would, however, receive proceeds upon the exercise of the warrants held by CDC which, if all such warrants are exercised in full a their present exercise price, would be approximately $4,461,319. CDC is under no obligation to exercise its warrants. Proceeds, if any, received from the exercise of warrants 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 Symbols	BDSI, BDSIW

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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 Related to Our Technologies

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. On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. The non-approvable letter stated that additional information would be required to address remaining questions. On May 17, 2006, we met with representatives of the FDA to discuss the issues outlined in their non-approvable letter and are presently working toward a plan with the FDA to address its remaining concerns. Once this plan has been solidified, we intend announce our intentions to progress Emezine®. This decision will be based on the costs of such a plan as well as the length of time to complete the plan and ultimately obtain FDA s approval of Emezine®. No assurances can be given, however, that we will be able to satisfy any concerns the FDA may have regarding Emezine®. Therefore, we may be forced to abandon the Emezine® project and any revenues that we had hoped to generate from Emezine® would not be achieved. Thus, any failure to obtain regulatory approvals, including those for Emezine®, could materially and adversely effect our business, results of operations and viability.

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;

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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 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 (as well as a product, Emezine®) that we license from third parties such as the Universities, Atrix and Reckitt. The loss of these 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

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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.

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 March 31, 2006, we have recorded accumulated losses totaling approximately $29.251 million. As of March 31, 2006, we had negative working capital of $1,766,058. 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.

Although we have earned some licensing-related revenue to date, we have not generated any revenue from the commercial sale of our proposed formulations or products. Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel, although we have more recently begun to focus on commercialization activities as well with the acquisition of Arius. We have not generated revenues to date other than research grants, limited licensing or royalty revenues and a $2.5 million sale of a royalty revenue stream to Accentia. This limited 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.

We will 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. 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, and the proceeds from our October 2005 public offering and our agreements with CDC, that our current working capital and available financing will be sufficient to satisfy

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our contemplated cash requirements into approximately the second quarter of 2007, assuming that we do not accelerate the development of other opportunities available to us, have Laurus Master Fund, Ltd., which we refer to herein as Laurus, demand repayment of $2,500,000 of its loan to us, engage in an extraordinary transaction or otherwise face unexpected events or contingencies, any of which could effect our cash requirements. Thereafter, and given that our current cash on hand will not fully fund all development costs of our leading product formulations, we will likely need to raise additional capital to fund our anticipated operating expenses and future expansion. Among other things, external financing will be required to cover the further development of our product formulations and other operating costs. While we expect that we will be able to find the needed capital to progress our business plan, we cannot assure you that 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 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 revenue from grants and collaborative agreements may not be sufficient to meet our future capital requirements. We do not know when this will change. We have expended and will continue to expend substantial funds in the research, development and clinical and pre-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 clinical and pre-clinical trials, commercial-scale manufacturing arrangements and to provide for the marketing and distribution. While we expect that we will have access to financial resources so that we will be able to progress with our business plan, 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 expected to depend on many factors, including, among others:

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

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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 regards to our delivery technologies and our proposed formulations and products.

Additionally, investors are cautioned that the total projected development costs for BEMA Fentanyl may exceed the maximum amounts CDC is required to fund us. In such a case, we will require additional financial resources to complete the development of BEMA Fentanyl, which resources may not be available to us.

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

The additional financings which we have undertaken and which we will require have and may in the future 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.

Our agreements with CDC are subject to several contingencies.

Under our agreements with CDC, if we do not meet certain conditions, CDC can assume control of the BEMA Fentanyl project. For example, in the event that 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 pursue development and commercialization of BEMA Fentanyl pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of our BEMA Fentanyl assets to CDC. Our loss of the BEMA Fentanyl project would have a material adverse effect on our business.

If an event of default occurs under our convertible notes with Laurus Master Fund, Ltd., it could seriously harm our operations.

On February 22, 2005 and May 31, 2005, we issued two separate $2.5 million secured convertible term notes with Laurus. The notes and related agreements contain numerous events of default which include:

failure to pay interest, principal payments or other fees when due (pursuant to certain amendments to our notes, we will owe Laurus an aggregate of $1,742,434 in deferred principal payments on the first business day of July 2006; no assurances can be given that we will have the resources to make such payments);

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breach by us of any material covenant or term or condition of the notes or any agreements made in connection therewith;

breach by us of any material representation or warranty made in the notes or in any agreements made in connection therewith;

default on any indebtedness exceeding, in the aggregate, $100,000, to which we or our subsidiaries are a party;

assignment for the benefit of our creditors, or a receiver or trustee is appointed for us;

bankruptcy or insolvency proceeding instituted by or against us and not dismissed within 30 days;

money judgment entered or filed against us for more than $100,000 and remains unresolved for 30 days;

common stock suspension for 10 consecutive days or 10 days during any 30 consecutive days from a principal market, provided that we are unable to cure such suspension within 30 days or list our common stock on another principal market within 60 days; and

loss, damage or encumbrance upon collateral securing the Laurus debt which is valued at more than $100,000 and is not timely mitigated.

If we default on the notes and the holder demands all payments due and payable, the cash required to pay such amounts would most likely come out of working capital, which may not be sufficient to repay the amounts due. In addition, since we rely on our working capital for our day to day operations, such a default on the note could materially adversely affect our business, operating results or financial condition to such extent that we are forced to restructure, file for bankruptcy, sell assets or cease operations. Further, our obligations under the notes are secured by substantially all of our assets. Failure to fulfill our obligations under the notes and related agreements could lead to loss of these assets, which would be detrimental to our operations.

Certain restrictions on our activities contained in the Laurus financing documents could negatively impact our ability to obtain financing from other sources.

So long as 25% of the principal amount of either of the February and May Laurus notes are outstanding, the Laurus financing documents restrict us from obtaining additional debt financing without Laurus approval and subject to certain specified exceptions. To the extent that Laurus declined to approve a debt financing that does not otherwise qualify for an exception to the consent requirement, we would be unable to obtain such debt financing. In addition, subject to certain exceptions, we have granted to Laurus a right of first refusal to provide additional financing to us in the event that we propose to engage in additional debt financing or to sell any of our equity securities. Laurus right of first refusal could act as a deterrent to third parties which may be interested in providing us with debt financing or purchasing our equity securities. To the extent that such a financing is required for us to conduct our operations, these restrictions could materially adversely impact our ability to achieve our operational objectives.

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Low market prices for our common stock could result in greater dilution to our stockholders, and could negatively impact our ability to convert the Laurus debt into equity.

The market price of our common stock significantly impacts the extent to which the Laurus debt is convertible into shares of our common stock. The lower the market price of our common stock as of the respective times of conversion, the more shares we will need to issue to Laurus to convert the principal and interest payments then due. If the market price of our common stock falls below certain thresholds, we will be unable to convert any such repayments of principal and interest into equity, and we will be required to make such repayments in cash. Our operations could be materially adversely impacted if we are required to make repeated cash payments on the unrestricted portion of the Laurus debt.

The Laurus financing documents prohibit the payment of dividends by us. You should not invest in our securities on the expectation that you will receive dividends.

So long as 25% of the principal amount of either of the February or May Laurus notes are outstanding, we will be prohibited from paying dividends without the prior consent of Laurus. Moreover, we have not paid dividends on our common stock in the past, and we do not anticipate paying any such dividends for the foreseeable future. You should not invest in our securities on the expectation that you will receive dividends.

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 universities, governmental agencies, manufacturers, contract research organizations and corporate partners for both strategic and financial resources. Our inability to secure such relationships as needed, or the loss of or failure to perform by us or our partners under any applicable agreements or arrangements, may 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.

We have a license agreement with the Universities in which they grant us exclusive license to conduct research and development of the encochleation drug delivery technology. Our research facilities are currently located on the premises of the University of Medicine and Dentistry of New Jersey pursuant to a research agreement. In addition, our BEMA technology and Emezine® product are licensed from third parties.

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 the University of Medicine and Dentistry of New Jersey, or UMDNJ, and Albany Medical College (which we refer to collectively with UMDNJ as the Universities) for this purpose in relation to our Bioral® technology, as well as third party providers of testing and trial services.

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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 currently lease our research facility from UMDNJ. Although a new one year lease was signed with UMDNJ in December 2005 for this facility, no assurances can be given that we will be able to extend or renew the new lease beyond this one year extension, 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.

We may be unable to obtain, or elect not to pursue, extensions of our NIH grants and we may not be able to secure new NIH or similar grants in the future, which could deny us important funding.

In 2001, the NIH awarded us a Small Business Innovation Research Grant, or SBIR, which we utilized in our research and development efforts relating to our Bioral® Amphotericin B formulation. We have received all anticipated funding under this grant to date, and this grant expired in August 2004.

In 2002, the NIH awarded us a second SBIR grant which we have utilized in our research and development efforts relating to a proposed encochleated HIV subunit vaccine. This grant expired in December 2005 but was extended by the NIH in February 2006 until July 31, 2006, and we believe this will be the final extension for this grant. As a result of this extension, we expect to receive approximately $74,000 in additional funds from the NIH for this project. In 2005, we subcontracted the responsibilities under the NIH grant for this project to UMDNJ.

Also, in late July 2005, we received an indication from the NIAID, which is affiliated with the NIH, that the NIAID would, at its expense and following our achievement of certain milestones, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. No assurances can be given that NIAID will proceed with or actually pay for this testing.

Moreover, although we may seek additional NIH funding for either of these or other programs, we may choose not to seek such funding or such funding may be unavailable to us even should we desire it. The absence of additional funding from the NIH could impair our ability to further develop our Bioral® Amphotericin B formulation or other projects. Furthermore, as a result of these expirations, we incurred a decline in sponsored research revenue with associated NIH grant expenditures in 2005.

We are exposed to product liability, clinical and pre-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.

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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 with 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.

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 payors 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, payors 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.

We may be sued by third parties who claim that our drug formulations or products infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents.

We may be exposed to future litigation by third parties based on claims that our technologies, formulations, products or activities 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 medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether or not valid, could result in substantial costs,

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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. In addition, intellectual property litigation or claims could 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;
- 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.

Other parties could have patent rights which may block our products. We are aware of two issued United States patents dealing with lipid formulations of Amphotericin B products. The first of these patents, United States Patent No. 4,978,654, claims an Amphotericin B liposome product. We do not believe that our patent or technology are in conflict with this existing patent, although there can be no assurance that a court of law in the United States patent authorities might determine otherwise. Our belief is based upon the fact that our cochleate product does not contain liposomes, which is required by the issued claims of this patent. The second of these patents, United States Patent No. 5,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our Bioral® nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we require a license under this patent.

We are also aware of United States Patent No. 6,585,997, related to mucoadhesive erodible drug delivery devices. We do not believe that our BEMA Fentanyl product is in conflict with the existing patent, at least because there are limitations recited in the issued claims that are not met by our product. Accordingly, we do not believe that we require a license under this patent for BEMA Fentanyl. We have not, however, conducted any patent searches with respect to our other proposed BEMA -based products. We are further aware of U.S. Patents Nos. 5,948,430, 6,177,096 and 6,284,264, and European Patent No. 949 925, which are owned by LTS Lohmann and which also relate to mucoadhesive erodible drug delivery devices.

If a court were to determine that we infringe any of these or other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B and/or our 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 U.S. 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 protect such rights.

Our ability to obtain license to 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 to access the patents. Without these licenses, the technologies would be protected from our use and we would not be able to even conduct research without prior permission from the patent holder. Therefore, any disruption in access to the technologies could substantially delay the development of our technologies.

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 applications and any issued and licensed patents 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, and that all inventions arising out of the individual s relationship with us shall be our exclusive property. 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 our information and techniques, 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 the patents is a significant factor in the development and commercialization of our drug delivery technologies. Aside from the general body of scientific knowledge from other drug delivery processes and lipid technology, these patents, to the best of our knowledge and based upon our current scientific data, are 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 our rights for 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.

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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. For example, Aveva is our sole supplier of BEMA Fentanyl, and we currently purchase our lipid supplies only from Chemi, a subsidiary of Italfarmico, and from Lipoid GmbH. 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 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 timeframes, 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 once our drug formulations or products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost.

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, once our proposed formulations or products are approved for commercial sale, we will need to establish, most likely through third parties, the capability to commercially manufacture our formulations or products in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our formulations or products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our proposed formulations or products. We presently plan to rely on third party contractors to manufacture part or all of our proposed formulations or products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanic shut downs, employee strikes, or any other unforeseeable acts that may delay production.

Due to the fact that we must build our marketing, sales, managed care, and distribution infrastructure and channels, we may be unsuccessful in our efforts to sell our formulations or products.

Except for our non-exclusive distribution agreement with BioTech Specialty Partners, Inc., a development-stage company affiliated with Dr. Francis E. O Donnell, a member of our management and

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significant beneficial owner of our securities, and the agreement between us and TEAMM Pharmaceuticals, also an affiliate of Dr. O Donnell, relating to Emezine®, we have yet to establish marketing, sales or distribution capabilities for our proposed formulations or products. Even though our proposed formulations or products have not been approved by the regulatory authorities, we devote meaningful time and resources in this regard. At the appropriate time, we intend to enter into agreements with third parties to sell our proposed formulations or products, or we may (in the future, resources permitting) develop our own sales and marketing force. 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. Our experience in developing a fully integrated commercial organization is limited to previous experience of a single member of our management. If we choose to establish a fully integrated commercial organization, we may incur substantial additional 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.

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.

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.

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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.

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 payors, 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 payors 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