BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B3
July 12, 2005
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Prospectus **Filed Pursuant to Rule 424(b)(3)**

Registration No. 333-126336

1,554,454 Shares of Common Stock

This prospectus relates to the public offering of up to 1,554,454 shares of our common stock, par value $0.001 per share, for sale by Laurus Master Fund, Ltd., which we refer to herein as Laurus or the selling stockholder, for its own account. These shares include up to 806,452 shares of common stock issuable upon conversion of a convertible note, up to 483,871 shares of common stock issuable upon the exercise of warrants, up to 234,131 shares of common stock issuable upon conversion of obligations underlying the convertible note issued to the selling stockholder and up to an aggregate of 30,000 shares of common stock issuable upon exercise of two additional warrants issued by us to Laurus on June 29, 2005. We will pay the expenses of registering these shares.

Our common stock and warrants are quoted on both the Nasdaq SmallCap Market and the Boston Stock Exchange under the symbols BDSI and BDSIW , respectively. On July 8, 2005, the closing sales price for the common stock on the Nasdaq SmallCap Market was $2.89 per share and the closing sales price for our warrants was $0.43 per warrant.

To the extent it wishes to sell its shares of our common stock as provided for herein, Laurus 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 Laurus, 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 Available 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 6 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 July 12, 2005.

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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 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 in this prospectus.

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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 our consolidated subsidiaries, including Arius Pharmaceuticals, Inc. Unless otherwise indicated, all information in this prospectus assumes that the underwriters will not exercise their option to purchase shares to cover over-allotments.

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. We are seeking to develop these formulations and bring them to market on an expedited basis by utilizing the Food and Drug Administration s, or FDA, 505(b)(2) regulatory approval process, which permits a company to rely on the clinical and non-clinical testing results of previously approved pharmaceuticals in connection with the filing by such companies of New Drug Applications, or NDAs, with the FDA.

Our formulations are targeted at segments of the pharmaceutical market which are growing and which we believe can be expanded by applying our drug delivery technologies to selected drugs. Our licensed drug delivery technologies include:

- the patented Bioral® nanocochleate drug delivery technology, designed for a potentially broad base of applications, and
- the patented BEMA drug delivery disc technology (which is applied to the inner cheek membrane), which we acquired in August 2004 with our acquisition of Arius Pharmaceuticals, Inc., which we refer to herein as Arius.

Utilizing our licensed delivery technologies, we are currently developing formulations of pharmaceuticals aimed principally at acute (i.e., short term) treatment opportunities in the areas of:

- pain,
- anxiety,
- nausea and vomiting,

insomnia, and

fungal infections

As a general matter, we are focused on treatments for cancer patients and patients who have recently undergone surgical procedures, although we believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals as well.

In addition to our Bioral® and BEMA platforms, we are also the exclusive U.S. licensee for Emezine®, a rapid-onset treatment of nausea and vomiting, on which we submitted an NDA to the FDA in late April 2005.

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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 to our licensors.

Bioral® Technology and Formulations

Our Bioral® 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 drugs that were only available by intravenous injection and convert them to formulations that can be taken via the mouth, thus potentially improving the amount of drug that is absorbed by the gastrointestinal tract for drugs that are poorly absorbed when given 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. The Universities have each granted us the exclusive worldwide licenses under applicable patents to the cochleate technology.

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. We believe this would represent the first orally available anti-fungicidal agent in the world to treat systemic fungal infections. A second formulation for intranasal administration Amphotericin B to treat chronic rhinosinusitis, or CRS, is now in development. In April 2004, we licensed this second product to Accentia Biopharmaceuticals, Inc., or Accentia, a related party, for the use in treatment of CRS and asthma.

BEMA Technology and Formulations

Our BEMA drug delivery technology consists of a dissolvable, dime-sized 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 product under development is BEMA Fentanyl, a treatment for breakthrough cancer pain. This product is projected to enter into Phase III trials for breakthrough cancer pain in the second half 2005.

A second product to treat pain, BEMA Long Acting Analgesic, or BEMA LA, is also under development. This is 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 chronic pain due to osteoarthritis, lower back disorders and rheumatoid arthritis. We intend to submit an Investigational New Drug Application, or IND, and enter BEMA Long Acting Analgesic into clinical trials in the second half of 2005.

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Emezine®

We are also developing Emezine®, a formulation of prochlorperazine, which we believe will be the first drug to be delivered transmucousally for rapid treatment of nausea and vomiting. Emezine® is not a BEMA™ formulation, but rather a formulation administered by placing a tablet between the bridge of the upper front teeth and gum where it dissolves, enabling the active ingredient to be absorbed through the lining of the cheek. In February 2005, we announced that we completed the clinical studies required for our pending NDA on Emezine® and, on April 29, 2005, we submitted such NDA to the FDA. As of the date of this prospectus, we have received verbal confirmation from the FDA that our Emezine® submission was accepted for review by the FDA, and we expect written confirmation in the near future. We license Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

Our Business Strategy

Our strategy is to utilize our licensed, patented and/or proprietary drug delivery technologies to create products and formulations that are targeted to significant market opportunities. Presently, these opportunities will be primarily centered on our Bioral® and BEMA™ technologies, although our licensed Emezine® product has been submitted to the FDA for approval, the first of our products to be so submitted.

An important element to the achievement of our business objectives is our utilization of the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved therapeutics. The 505(b)(2) process enables a company to rely on the findings of third parties which the FDA has published on approved pharmaceuticals, including clinical and non-clinical testing, thereby reducing, though not eliminating, the need to engage in these costly and time consuming activities. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, it is significantly less extensive and lengthy and, as a result, we believe, more cost efficient than attempting to gain approval of a new drug. By utilizing this regulatory process and focusing on creating new formulations of established pharmaceuticals that could potentially benefit from association with our delivery technologies, we believe that we will more quickly and efficiently navigate the FDA approval process, and, if such approval is obtained, of which no assurances can be given, move our formulations to market.

We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through: (i) applying our licensed technologies to existing therapeutics to create our own proprietary formulations, which we will then seek to obtain FDA approval for and subsequently commercialize and (ii) licensing and joint venture arrangements with pharmaceutical companies, whose own proprietary pharmaceutical products may benefit from our drug delivery technologies. We also have and may continue to raise additional funding from other sources, including debt financing and equity financing. While there can be no assurance that such sources will provide adequate funding for our operations, management believes such sources will be available to us.

February and May 2005 Laurus Financings

On February 22, 2005, we consummated a $2.5 million secured convertible debt financing with Laurus Master Fund, Ltd., or Laurus, in a private offering. Net proceeds from the financing were used primarily to retire our then existing secured equipment loan with Gold Bank (on which approximately $300,000 was owed), and are being used to support our research, development and commercialization opportunities and for general working capital purposes. As part of the financing, we paid Laurus Capital

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Management, LLC, the manager of Laurus, a closing payment equal to $93,750 plus due diligence and legal expenses of $39,500.

On May 31, 2005, we closed an additional $2.5 million secured convertible debt financing from Laurus in a private offering. Net proceeds from the May financing are also being used to support our research, development and commercialization opportunities and for general working capital purposes. As part of this financing, we paid Laurus Capital Management a closing payment equal to $93,750 plus due diligence and legal expenses of $15,000. Investment bankers Ferris, Baker Watts Incorporated, or FBW, advised us on both Laurus transactions.

In addition, on June 29, 2005, we entered into two separate amendments to our February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by us of principal under the February and May 2005 Laurus notes until December 1, 2005. In consideration of Laurus agreement, we issued to Laurus two warrants, one to purchase 22,500 shares of our common stock (in connection with the February amendment) and a second to purchase 7,500 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of our common stock at an exercise price of $.001 per share and expire on June 29, 2012. Except for the exercise price of the warrants, the warrants issued to Laurus in connection with the foregoing amendments are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005.

We have agreed to register the shares of common stock underlying the May 2005 note and warrant and the two June 2005 warrants with the Securities and Exchange Commission, which we are doing pursuant to the registration statement of which this prospectus is a part.

Corporate Information

Our predecessor was founded in 1995, and we reincorporated in Delaware in 2002 in connection with our June 2002 initial public offering. Our principal executive office is located at 2501 Aerial Center Parkway, Suite 205, Morrisville, North Carolina 27560 and our phone number there is (919) 653-5160. Our principal research facility is in Newark, New Jersey. We also have an administrative office in Tampa, Florida. Our website can be found at www.bdsinternational.com. Our website and its contents shall not be deemed a part of this prospectus.

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The Offering

We have agreed, pursuant to registration rights agreements, to register the shares of common stock underlying the May Laurus note and the warrant and the two warrants issued in connection with the June amendments to the Laurus agreements, and are fulfilling our agreement by filing the registration statement of which this prospectus is a part with the Securities and Exchange Commission, which we refer to herein as the SEC.

Outstanding Common Stock	7,269,196 shares as of the date of this prospectus.
Common Stock Offered	Up to 1,554,454 shares of common stock, including up to 806,452 shares of common stock issuable upon conversion of the Laurus note, up to 483,871 shares of common stock issuable upon the exercise of warrants, which warrants have an exercise price of $3.88 per share, up to 234,131 shares of common stock issuable upon conversion of obligations underlying the convertible note issued to the selling stockholder and up to an aggregate of 30,000 shares of common stock issuable upon exercise of two additional warrants issued by us to Laurus on June 29, 2005. We will pay the expenses of registering these shares.
Proceeds	We will not receive any proceeds from the sale of the common stock issuable upon conversion of the Laurus note that may be sold pursuant to this prospectus. We will, however, receive proceeds upon the exercise of the May warrant and the two June warrants which, if all such warrants are exercised in full, would be $1,877,449. Laurus 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 Small Cap and Boston Stock Exchange 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

The failure to complete development of our drug delivery technologies, obtain government approvals, including required FDA approvals, or to comply with ongoing governmental regulations 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, clinical trials and regulatory approval can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources.

In order to be commercially viable, we must successfully 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 successfully 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 time-frame necessary to achieve these developmental milestones may be long and uncertain, and we may not successfully complete these milestones for any of our proposed formulations or products in development.

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.

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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 product may be prohibitive.

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 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 or mucosal adhesive 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, 2005, we have recorded accumulated losses totaling $15,585,426. As of March 31, 2005, we had a working capital deficit of $344,337. Our

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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 may need to raise additional capital to continue our operations, and our failure to do so might preclude our ability to fund our operations, promote our formulations or products or develop our technologies.

Our operations have relied almost entirely on external financing to fund our operations. Such financing has historically primarily come 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, that our current working capital will be sufficient to satisfy our contemplated cash requirements until approximately October 31, 2005, 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. Thereafter, we may need to raise additional capital to fund our anticipated operating expenses and future expansion. Among other things, external financing may be required to cover our operating costs. We cannot assure you that financing whether from external sources or related parties will be available if needed or on favorable terms. 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.

If and when required, we may have difficulty raising needed capital in the future because of 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 may 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. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from any available source, we may have to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs or

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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:

- number of potential formulations 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 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 or our drug formulations or products;
- costs for recruiting and retaining employees and consultants; and
- costs for training physicians.

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.

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 or will effectively dilute 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.

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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 Universities 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 currently lease our research facility from UMDNJ, which lease expires on December 31, 2005. We plan to enter into discussions with UMDNJ during 2005 regarding a possible extension or renewal of this lease. No assurances can be given that we will be able to 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.

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 rely upon numerous collaborative agreements with universities, governmental agencies, manufacturers, contract research organizations and corporate partners. The loss of or failure to perform under any of these arrangements, by any of these entities, may substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials. This loss may also 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 also located on the premises of the UMDNJ pursuant to a research agreement. In addition, our BEMA™ technology and Emezine® product are licensed from third parties.

Our two National Institutes of Health grants have either expired or are set to expire, which could deny us important funding.

In 2001, the National Institutes of Health, which we refer to herein as 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. We have received anticipated funding under this second grant to date, and the grant is set to expire on July 31, 2005. Although we may seek additional NIH funding for either of these

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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. Also, as a result of these expirations, we have experienced 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.

Since we do not currently have any FDA-approved products or formulations, we do not currently have any product liability insurance, and we maintain liability insurance relating only to clinical trials on Emezine®. 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 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

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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, 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, using, 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 patents and that these 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

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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.

As of the date of this prospectus, and except as discussed above, we have not engaged in discussions, received any communications, nor do we have any well-founded reason to believe that any third party is challenging or has the right proper legal authority to challenge our intellectual property rights or those of the actual patent holders.

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 a license to access the patents. Without this license, 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.

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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 do not believe that we are violating any other patents in developing our technologies.

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.

Key components of our cochleate 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, we currently purchase our lipid supplies from Chemi, a subsidiary of Italfarmico. The reliance on a sole or limited number of suppliers could result in:

- potential delays associated with research and development and clinical and pre-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.

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

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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 our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our formulations or products, enter into relationships with third parties or develop a direct sales organization.

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 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. Until such time as our proposed formulations or products are further along in the regulatory process, we will not devote any 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 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. We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force 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, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

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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 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.

If an event of default occurs under our convertible notes with Laurus, 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 to Laurus. The note and related agreements contain numerous events of default which include:

failure to pay interest, principal payments or other fees when due;

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

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to fulfill our obligations under the notes and related agreements could lead to loss of these assets, which would be detrimental to our operations.

If we do not obtain stockholder approval of certain potential common stock issuances under our notes and warrants with Laurus by August 31, 2005, the May 2005 note with Laurus will be due September 1, 2005, and we may not have the resources to repay such note.

Our May 2005 note with Laurus is structured such that if our stockholders do not approve by August 31, 2005, in accordance with applicable Nasdaq Stock Market rules, potential common stock issuances under our February and May 2005 notes and warrants with Laurus and our June 2005 amendments thereto in excess of 19.99% of our outstanding common stock as of February 22, 2005, the May note will become due and owing on September 1, 2005. We have included such approval as a proposal for our 2005 Annual Meeting of Stockholders, which we expect will be held in late July 2005. No assurances can be given that we will obtain such stockholder approval. If we fail to obtain such stockholder approval by August 31, 2005, Laurus may require us, on or after September 1, 2005, to satisfy all of our obligations under the May note, including the payment in full of all principal and interest, and may pursue other legal or equitable remedies against us. Our ability to make such cash payments will depend on available cash resources at that time, and there can be no assurance that we will have the cash necessary to make such payments. The early payment of the May Laurus note would thus have a significantly adverse affect on our liquidity and financial condition.

The 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.

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

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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 and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

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

The testing, manufacture, marketing and sale of our proposed drug formulations involve an inherent risk that product liability claims will be asserted against us. We currently have a general liability policy with an annual aggregate limit of $2 million with a $1 million limit per occurrence which does not provide coverage for product liability. All of our pre-clinical trials have been and all of our proposed

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clinical and pre-clinical trials are anticipated to be conducted by collaborators and third party contractors. We currently have insurance relating to product liability or insurance related to clinical or pre-clinical trials only with respect to our Emezine® formulation, for which we have a clinical trial liability policy providing for a $2 million aggregate limit. We intend to seek additional insurance against such risks before our product sales are commenced, although there can be no assurance that such insurance can be obtained at such time, or even if it is available, that the cost will be affordable. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs. The cost and availability of such insurance are unknown. Product liability claims or other claims related to our proposed formulations and products, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our drug delivery technology. A product liability claim could also significantly harm our reputation and delay market acceptance of our proposed formulations and products.

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

In connection with our research and development activities and our manufacture of materials and drugs, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development may in the future involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. The current hazardous chemicals that we currently use, which may change as our research progresses, are chloroform and methanol. We are authorized to use these and other hazardous chemicals in our facilities through our affiliation with the UMDNJ. UMDNJ also disposes these chemicals from our premises as part of our agreement to use the facilities and carries general liability insurance in this regard.

Although we believe that our safety procedures for storing, handling and disposing of such materials will comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Our Management and Key Employees

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

Our success will depend to a significant degree upon the continued services of key management, technical, and scientific personnel, including Drs. Francis O Donnell, Mark Sirgo, Andrew Finn, Raphael Mannino and Mr. James McNulty. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, our success will depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified

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personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all.

We have key man life insurance policy for Dr. Raphael Mannino in the amount of $2.0 million. This insurance may not adequately compensate us for the loss of Dr. Mannino s services. Additionally, neither our Chairman and CEO, Dr. Frank O Donnell, our President and Chief Operating Officer, Dr. Mark Sirgo, nor any of our other executives currently has this coverage. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

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

As of the date of this prospectus, our directors, executive officers and principal stockholders, together with their affiliates, will beneficially own, in the aggregate, approximately 65.0% of our outstanding common stock. These figures do not reflect any conversion of our outstanding shares of Series A Preferred, the vast majority of which is held by Drs. Sirgo and Finn, our outstanding shares of Series B Preferred, all of which is held by HCG, an affiliate of Dr. O Donnell and our convertible notes and warrants with Laurus. Additionally, these figures do not reflect any future potential exercise of our Class A warrants or other outstanding warrants into shares of common stock or the increased percentages that our officers and directors may have in the event that they exercise any of the options granted to them under our Amended and Restated 2001 Stock Option Plan or if they otherwise acquire additional shares of common stock generally. The interests of our current officer and director stockholders may differ from the interests of other stockholders. As a result, these current officer and director stockholders would have the ability to exercise control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

election of directors;

adoption of or amendments to stock option plans;

amendment of charter documents;

issuance of blank check preferred stock; or

approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets.

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

Dr. O Donnell, who is an executive officer, on our board of directors and also is a substantial beneficial owner of our securities, including all of our outstanding shares of Series B Preferred, has a financial interest in a number of other companies which have business relationships with us. These companies include Accentia, RetinaPharma Technologies, Inc., Biotechnology Specialty Partners, Inc, and American Prescription Providers, Inc. We have entered into license agreements with Accentia and RetinaPharma International, Inc. with regard to proposed products incorporating our Bioral® technology. We have entered into a non-exclusive distribution with Biotechnology Specialty Partners, Inc. Each of these business arrangements was approved (with Dr. O Donnell abstaining) by our Board of Directors and our predecessor s board of directors.

These agreements or any future agreements may involve conflicting interests between our interests, the interests of the other entities and Dr. O Donnell.

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Risks Related to Our Publicly-Traded Securities

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

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

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.

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

In 2004, according to rules of the Nasdaq SmallCap Market, our shares of common stock were subject to potential delisting from such market because we did not meet certain requirements. Although, as of the date of this prospectus, our shares are still listed on the Nasdaq SmallCap Market, in the future, we may not be able to meet the listing maintenance requirements of the Nasdaq SmallCap Market and Nasdaq rules, which require, among other things, minimum stockholders equity of $2.5 million. If we are unable to satisfy the Nasdaq criteria for maintaining listing, our securities could again be subject to delisting. Trading, if any, of our securities would thereafter be conducted in the over-the-counter market, in the so-called pink sheets or on the National Association of Securities Dealers, Inc. s electronic bulletin board. As a consequence of any such delisting, an event of default may be called under our Laurus note and, regardless of whether such an event of default is called, a stockholder would likely find it more difficult to dispose of, or to obtain accurate quotations as to the prices of our securities.

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

We are authorized to issue 45 million shares of our common stock. As of the date of this prospectus, there are 7,304,686 shares of common stock issued and 7,269,196 shares outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options or warrants. To the extent such options or warrants are exercised, the holders of our common stock may experience further dilution. In addition, as in the case of

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our February and May 2005 financings with Laurus, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors may experience additional dilution. This same principal applies to potential conversions of shares our Series A and Series B convertible preferred stock.

In addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5 million shares of authorized preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one year holding period may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by our stockholders that are non-affiliates that have satisfied a two year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that preserve our current management.

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

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

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

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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, or the Exchange Act. The words believe, expect, anticipate, intend, estimate, plan and 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 and development relating to Emezine® or the Bioral and BEMA technology platforms and any proposed formulations or products relating thereto;
- the domestic and international regulatory process relating to our technologies and proposed products and formulations, including the timing and status of our filings with the FDA;
- our ability to generate commercial viability and acceptance of our Bioral and BEMA technology platforms and our proposed formulations and products;
- the protection and control afforded by our interest in licensed patents, or our ability to enforce our rights under such licenses;
- the ability of our sublicense partners to commercially exploit our drug delivery platforms;
- our ability to enter into sublicenses and to receive royalty and other payments from Accentia and other parties to whom we have sublicensed our technologies;
- our estimates and projections regarding the timing and costs associated with our projects in development;
- our estimates of the size of market opportunities relating to our proposed products and formulations and our estimates of our potential market share relating to such opportunities;
- our ability to retain members of our management team and our employees;
- our ability to receive federal, state, government or private grants and/or attract capital; and
- the competition that may arise in the future.

The foregoing does not represent an exhaustive list of risks. Other sections of this prospectus include additional risks which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. 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

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forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this prospectus.

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BUSINESS

Overview

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 FDA s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved therapeutics which incorporate our licensed drug delivery technologies. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and less time consuming than other FDA approval methods.

Our drug delivery technologies include:

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

Utilizing our licensed delivery technologies, we are currently developing formulations of pharmaceuticals aimed principally at acute (i.e., short term) treatment opportunities in the areas of:

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

As a general matter, we are focused on treatments for cancer patients and patients who have recently undergone surgical procedures, although we believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals as well.

In addition to our Bioral® and BEMA platforms, we are also the exclusive U.S. licensee for Emezine®, a rapid-onset treatment of nausea and vomiting, on which we submitted an NDA to the FDA in late April 2005.

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 to our licensors.

Our Bioral® 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 drug. We believe this technology will allow us to take drugs that were only available by intravenous injection and convert them to formulations that can be taken via the mouth, thus potentially improving the amount of drug that is absorbed by the gastrointestinal tract for drugs that are poorly absorbed when given orally. Our Bioral® drug delivery technology was developed in collaboration with 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®

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formulation of Amphotericin B would have the potential for oral delivery of a drug that is currently only given by intravenous injection. A second formulation for intranasal administration Amphotericin B to treat chronic rhinosinusitis is now in development. In April 2004, we licensed this second product to Accentia for the use in the treatment of CRS and asthma. We have also explored the creation of cochleate formulations of important nutrients, which we have prepared in kilogram quantities using standard manufacturing processes. We believe these preparations may stabilize the encochleated micronutrients during food processing and may enhance the shelf life of the end product.

Our BEMA drug delivery technology consists of a dissolvable, dime-sized 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, or trauma cases where intravenous lines or injections are unavailable or not practical. Our lead BEMA product under development is BEMA Fentanyl, a treatment for breakthrough cancer pain. This product is projected to enter into Phase III trials for breakthrough cancer pain in the second half 2005. A follow on product, BEMA LA, is also under development. This is 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 chronic pain due to osteoarthritis, lower back disorders and rheumatoid arthritis. We intend to submit an IND and enter BEMA LA into clinical trials in the second half of 2005. We license the BEMA drug delivery technology on a worldwide exclusive basis from Atrix.

We are also developing Emezine®, a formulation of prochlorperazine, which we believe will be the first drug to be delivered transmucousally for rapid treatment of nausea and vomiting. In February 2005, we announced that we completed the clinical studies required for our pending NDA on Emezine® and, on April 29, 2005, we submitted such NDA. As of the date of this prospectus, we have received verbal confirmation from the FDA that our Emezine® submission was accepted for review by the FDA, and we expect written confirmation in the near future. We license Emezine® from Reckitt.

We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through: (i) applying our licensed technologies to existing therapeutics to create our own proprietary formulations, which we will then seek to obtain FDA approval for and subsequently commercialize and (ii) licensing and joint venture arrangements with pharmaceutical companies, whose own proprietary pharmaceutical products may benefit from our drug delivery technologies. We also have and may continue to raise additional funding from other sources, including debt financing and equity financing. While there can be no assurance that such sources will provide adequate funding for our operations, management believes such sources will be available to us.

Historical and Recent Events

Public Offering and Financing

On June 24, 2002, the SEC declared our Registration Statement on Form SB-2, Registration No. 333-72877, effective. Commencing on June 25, 2002, and pursuant to such Registration Statement, we conducted an offering consisting of 2 million units, which we refer to herein as Units, with each Unit consisting of: (i) one share of common stock, par value $.001 per share, and (ii) one Class A common stock purchase warrant, or Warrants. Each Warrant entitles the owner to purchase one share of our common stock at a price of $6.30 through June 24, 2007. The net offering proceeds we received was $8,226,758. As of the fiscal year ended December 2004, we had exhausted substantially all of the proceeds from our public offering.

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Acquisition of Arius Pharmaceuticals, Inc.

On August 24, 2004, we consummated the acquisition of Arius. As a result of this acquisition, Arius was reorganized with and into a newly formed, wholly-owned subsidiary, which we renamed Arius Pharmaceuticals, Inc. following the closing. Arius is a specialty drug delivery company developing products for the acute treatment opportunities such as pain, anxiety, nausea and vomiting, targeted primarily to surgical and oncology patients. In 2004, Arius acquired an exclusive worldwide license to the BEMA delivery technology developed by Atrix, and also acquired the U.S. rights to a transmucousally delivered tablet formulation of Emezine®, an anti-nausea and vomiting medication. We license Emezine® from Reckitt.

Simultaneously with the closing of the Arius acquisition, Mark A. Sirgo, Pharm.D., a founder and the President and CEO of Arius, entered into an employment agreement with us and was named Senior Vice President of Commercialization and Corporate Development. Andrew L. Finn, Pharm.D., also a founder and the Chief Operating Officer of Arius, also entered into an employment agreement with us and was named Senior Vice President of Product Development at BDSI. Subsequent to the Arius closing, Dr. Sirgo was promoted to the position of Executive Vice President and Chief Operating Officer of our company and, in early 2005, was named President of our company. Dr. Finn was, subsequent to the Arius closing, promoted to the position of Executive Vice President of Clinical Development and Regulatory Affairs.

Hopkins Capital Group Equity Line of Credit

On September 3, 2004, we entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC, which we refer to herein as HCG, a principal stockholder of our company which is controlled and partially-owned by Dr. Francis E. O Donnell, Jr., our Chairman and CEO. Pursuant to the Equity Line Agreement, HCG will, at our request, invest up to $4.0 million in our company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock, or Series B Preferred. As of June 30, 2005, $1.45 million has been drawn under the Equity Line Agreement.

Sigma-Tau License and Stock Purchase Transaction

On January 20, 2005, we signed a definitive licensing agreement with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., or Sigma-Tau Pharma, for the application of our Bioral® nanocochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Sigma-Tau Pharma is an affiliate of The Sigma-Tau Group, one of Italy s leading pharmaceutical companies.

Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of US$250,000 from, Sigma-Tau Finanziaria S.p.A., or Sigma-Tau, a holding company of The Sigma-Tau Group. This upfront payment was applied towards the purchase by Sigma Tau of unregistered shares of our common stock priced at $4.25 a share.

The stock purchase agreement with Sigma-Tau provides for the purchase by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of our common stock, up to an aggregate potential of $1.5 million worth of such shares. These milestones lead up to and include the submission of product INDs by Sigma-Tau Pharma for one or more of the four subject encochleated compounds. Sigma-Tau, through other holding entities, is currently a stockholder of our company. In addition to the milestone payments, we will receive a royalty on future sales of each of the four products which may arise from the encochleated compounds.

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Laurus Financings

On February 22, 2005, we consummated a $2.5 million secured convertible debt financing from Laurus. Net proceeds from the financing were used primarily to retire our secured equipment loan with Gold Bank (on which approximately $300,000 was owed and was paid at the closing of the Laurus transaction) and will be used to support our research and development opportunities and for general working capital purposes.

The February Laurus investment takes the form of a convertible note secured by certain of our assets. The note has a 3-year term and bears interest at a rate equal to prime plus 2% per annum. The note is convertible, under certain conditions, into shares of our common stock at a price equal to $3.10 per share. In connection with the financing, we also issued Laurus a common stock purchase warrant to purchase up to 350,000 shares of our common stock at a price equal to $3.88 per share. A registration statement we filed with the SEC to register the shares of common stock underlying the February Laurus note and the warrant was declared effective on June 20, 2005.

On May 31, 2005, we closed an additional $2.5 million secured convertible debt financing from Laurus. As with the February 2005 Laurus financing, this financing takes the form of a secured convertible note and a warrant to purchase 483,871 shares of our common stock. The financing is in addition to the similar $2.5 million financing we received from Laurus in February 2005. Net proceeds from the May Laurus financing are to be used to support our research, development and commercialization opportunities and for general working capital purposes. As part of the May financing, we paid Laurus Capital Management, LLC, the manager of Laurus, a closing payment equal to $93,750 plus due diligence and legal expenses of $15,000.

In addition, on June 29, 2005, we entered into two separate amendments to our February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by us of principal under the February and May 2005 Laurus notes until December 1, 2005. In consideration of Laurus agreement, we issued to Laurus two warrants, one to purchase 22,500 shares of our common stock (in connection with the February amendment) and a second to purchase 7,500 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of our common stock at an exercise price of $.001 per share and expire on June 29, 2012. Except for the exercise price of the warrants, the warrants issued to Laurus in connection with the foregoing amendments are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005.

We have agreed to register the shares of common stock underlying the May note and warrant and the June warrants with Laurus with the SEC, which we are doing pursuant to the registration statement of which this prospectus is a part.

Overview of Specialty Pharmaceuticals and the 505(b)(2) Regulatory Pathway

Since our inception, we have focused primarily on research and development of our licensed Bioral® encochleation technology and the application of such technology to specific drugs. The drug delivery industry develops technologies for the improved administration of certain drugs. These technologies, including our own, have focused primarily on safety, efficacy, ease of patient use and patient compliance.

In 2004, however, and in particular as a result of our acquisition of Arius, we have begun to shift our corporate focus to what we call the area of specialty pharmaceuticals : applying our licensed technologies to existing therapeutics to create our own proprietary formulations, for which we then seek to obtain FDA approval and subsequently commercialize. We believe that focusing our drug delivery

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technologies for use with existing FDA approved drugs to be less risky than attempting to discover new drugs, sometimes called new chemical entities, or NCEs.

An important part of our strategy is to attempt to capitalize on the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of our formulations of previously approved therapeutics. Under the 505(b)(2) approval process, we are able to seek FDA approval of a new dosage form, dosage regimen or new indication of a pharmaceutical that has previously been approved by the FDA. This regulation enables us to rely on the findings of third parties which the FDA has published on approved pharmaceuticals, including clinical and non-clinical testing, thereby reducing, though not eliminating, the need to engage in these costly and time consuming activities. A typical development program for a 505(b)(2) submission will include:

- a single genotoxicity study with the drug substance,
- a 14 or 28-day multiple dose toxicity study in a single species,
- limited pharmacokinetic evaluation of the new dosage form in humans,
- two placebo controlled studies in humans,
- stability of drug substance,
- full description of drug product manufacturing process,
- 1 year stability data on 3 batches at commercial scale, and
- special studies specific to the formulation.

This approval program is significantly less extensive and lengthy and, as a result, we believe, more cost efficient than attempting to gain approval of an NCE. By utilizing this regulatory process and focusing on creating new formulations of established pharmaceuticals that could potentially benefit from association with our delivery technologies, we believe that we will more quickly and efficiently navigate the FDA approval process, and, if such approval is obtained, of which no assurances can be given, move our formulations to market.

As part of our strategy, however, we will also continue to seek partners, such as Sigma Tau, to whom we can license our delivery technologies so that they may be applied to the proprietary products of such partners. Drug delivery technologies can provide pharmaceutical and biotechnology companies with an avenue for developing new drugs, as well as extending existing drug patent protections. Drug delivery companies can also apply their technologies to drugs no longer patent protected. Pharmaceutical and biotechnology companies view new and improved delivery technology as a way to gain competitive advantage through enhanced safety, efficacy, convenience and patient compliance of their drugs, and we will continue to attempt to leverage this desire in the pharmaceutical industry for improved delivery systems.

We have and intend to continue to primarily target drugs that have large established markets for which there is an established medical need. As a result, doctors are familiar with the drug compounds and are accustomed to prescribing them. As with BEMA Fentanyl and Emezine®, we anticipate that many of the drug candidates we target will have been through the regulatory process and therefore the safety and efficacy of the drug has been previously established. Consequently, we believe that our clinical trials would primarily need to show that our Bioral® or BEMA technologies deliver the drug without harming the patient or changing the clinical attributes of the drug. Focusing on drug delivery compared to drug discovery should allow us to potentially form a number of collaborations to deliver a wide variety of medicines without limiting rights to utilize our proprietary technology with additional drug opportunities.

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Pipeline of Proposed Formulations and Products

The following table summarizes the status of our currently proposed formulations and products:

Formulation/Product	Indication	Development Status	Commercial Status
Emezine®	Nausea/Vomiting	Pre-registration	Partnered
BEMA Fentanyl	Breakthrough pain	Clinical Trials	In-house commercialization
BEMA Long Acting Analgesic	Pain	Preclinical	In-house commercialization
Bioral® Amphotericin B	Fungal infections	Preclinical	In-house commercialization

Although we have investigated other projects in the past, including certain of those discussed under Licensing Opportunities and Other Projects below, we are presently dedicating most of our corporate resources toward the development and commercialization of Emezine®, BEMA Fentanyl, Bioral® Amphotericin B and BEMA LA.

Description of Our Drug Delivery Technologies and Proposed Formulations and Products

We have based our estimates of development costs and related matters described below on our market research, third party reports and publicly available information which we consider reliable. However, readers should be aware that the projected dates for filing INDs or NDAs, our estimates of developments costs and our projected sales associated with each of our formulations discussed below and elsewhere in this prospectus are merely estimates and subject to many factors, many of which may be beyond our control, which could cause delays and or cost overruns or otherwise cause us to revise such estimates. These estimates are based upon our management s reasonable judgments given the information available and their previous experiences, but no assurances can be given that such estimates will prove to be accurate.

Encochleation Technology Overview

Our licensed Bioral® drug delivery technology is based upon encapsulating (or encochleating) drugs to potentially deliver the drug safely and effectively. Over the years, biochemists and biophysicists have studied artificial membrane systems to understand their properties and potential applications, as well as to gain insight into the workings of more complex biological membrane systems. In the late 1960 s, scientists began investigating the interactions of divalent cations with negatively charged lipid bilayers. They reported that the addition of calcium ions to small phosphatidylserine vesicles induced their collapse into discs which fused into large sheets of lipid. In order to minimize their interaction with water, these lipid sheets rolled up into nanocrystalline structures, termed cochleates, after the Greek name for a snail with a spiral shell.

Our licensed Bioral® cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our Bioral® cochleate technology are phosphatidylserine, or PS, and calcium. Phosphatidylserine is a natural component of essentially all biological membranes, and is most concentrated in the brain. Clinical studies by other investigators (more than 30 have been published that we

are aware of) to evaluate the potential of phosphatidylserine as a nutrient supplement indicate that PS is safe and may play a role in the support of mental functions in the

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aging brain. As an indication of its nontoxic nature, today phosphatidylserine isolated from soybeans is sold in health food stores as a nutritional supplement.

Research and development of cochleates has been conducted at the Universities for a number of years. Our scientists, some of whom were former researchers and others who still hold teaching positions with these Universities, supervised their cochleate research programs. As a result of the relationship between our scientists and the Universities, we became the exclusive worldwide licensee to develop this cochleate technology and in some cases co-own the patents with them.

Potential Advantages

We believe that our licensed Bioral® drug delivery technology represents a potentially important new delivery mechanism. While the characteristics and benefits of this technology will ultimately be established through FDA clinical trials, our research, based upon pre-clinical studies indicates that our Bioral® technology may have the following characteristics:

All-natural ingredients. Our Bioral® drug delivery technology uses phosphatidylserine, which can be sourced from soy beans, and calcium. Phosphatidylserine from soybeans is available commercially as a nutritional supplement with FDA-allowed health promotion claims.

Encapsulation. Our Bioral® drug delivery encapsulates, or entraps within a crystal matrix, the subject drug, rather than chemically bonding with the drug.

Enhanced Availability. Our Bioral® drug delivery technology is being developed to enable oral availability of a broad spectrum of compounds, such as those with poor water solubility, and protein and peptide biopharmaceuticals, which have been difficult to administer. Our Bioral® drug delivery technology also has the potential to be applied to substances which are not currently deliverable by traditional means so that they may be delivered via injection or orally.

Minimizing Side Effects. Our Bioral® drug delivery technology may reduce toxicity, stomach irritation and other side effects of the encapsulated drug.

Cellular Delivery. Our Bioral® drug delivery technology is being developed as membrane fusion intermediates. We believe that, when drugs encapsulated in our Bioral® drug delivery technology come into close approximation to a target membrane, a fusion event between the outer layer of the cochleate cylinder and the cell membrane may occur. This fusion may result in the delivery of a small amount of the encochleated material into the cytoplasm of the target cell. Further, we believe that drugs encapsulated in our Bioral® drug delivery technology may slowly fuse or break free of the cell and be available for another fusion event, either with this or another cell.

Stability. Our Bioral® drug delivery technology employs cochleates which consist of multi-layered structures of large, continuous, solid, lipid bilayer sheets, either stacked or rolled up in a spiral, with little or no internal aqueous space. We believe that our cochleate preparations can be stored in cation-containing buffer, or dried, by freezing in a high vacuum environment, to a powder, which is then stored at room temperature and reconstituted with liquid prior to administration. Our cochleate preparations have been shown to be stable for more than two years in cation-containing buffer, and at least one year as a powder at room temperature.

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Resistance to Environmental Attack. Our Bioral® drug delivery technology is being developed to provide protection from degradation of the encochleated drug. Traditionally, many drugs can be damaged from exposure to adverse environmental conditions such as sunlight, oxygen, water and temperature. Since the multilayered structure consists of a series of solid layers, we believe that components within the interior of the cochleate structure remain intact, even though the outer layers of the cochleate may be exposed to these conditions.

Patient Compliance. We believe that a potential benefit of our cochleate cylinders may include reducing unpleasant taste, unpleasant intestinal irritation, and in some cases providing oral availability.

Release Characteristics. Our cochleate technology may offer the potential to be tailored to control the release of the drug depending on desired application.

Initial Bioral® Products in Development

We plan a diverse pipeline of products to be developed by applying our Bioral® drug delivery technology to a potentially broad array of established and promising pharmaceuticals. Each intended Bioral® product (i.e., drug encapsulated with our drug delivery technology) will, upon completion of development, require separate FDA regulatory approval, and accordingly, will be subject to the uncertainty, time and expense generally associated with the FDA regulatory process. Even though we are targeting FDA approved, market- accepted drugs for encapsulation, each of the products currently in development face development hurdles, regulatory requirements and uncertainty before market introduction. Due to our current availability of corporate resources, in connection with our Bioral® portfolio, we are currently focusing primarily on our Bioral® Amphotericin B formulation, as described below.

Bioral® Amphotericin B

Systemic fungal infections continue to be a major domestic and international health care problem. Amphotericin B, which is delivered intravenously, is an established, commonly used drug to treat these infections. We are currently developing a Bioral® formulation of Amphotericin B for treatment of fungal infections which we expect will be for the treatment of esophageal candidiasis. We plan to submit an IND to the FDA and proceed into clinical trials in late 2005. In the last year, we have successfully sourced phosphatidylserine, or PS, from lecithin derived from soybeans rather than synthetic PS, thereby reducing the costs of goods for our delivery system. In addition, we have simplified our manufacturing approach to Bioral® Amphotericin B, thereby facilitating commercial scale-up. Also, we have changed the ratio of PS to active molecules, thus improving the efficacy while moderating costs. We are currently investigating the pharmacology and toxicology in animals. Accordingly, we estimate that the submission of our IND will be made in the fourth quarter of 2005. We estimate that the total development costs of this formulation will be approximately $9.3 million.

Amphotericin B is often used to treat diseases that frequently strikes patients with compromised immune systems. The use of the conventional injectable Amphotericin B to treat these infections is often limited by its propensity to cause kidney damage which we believe our Bioral® products may minimize. Bioral® Amphotericin B may have uses in other diseases such as Leishmaniasis and Chagas disease.

The primary advantage which we are seeking for our proposed Amphotericin B product is an oral formulation of the drug. Additional potential advantages include improved safety, extended shelf life, improved cellular uptake and reduced dosage. Assuming that we complete development of our proposed

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Bioral® Amphotericin B formulation and that we obtain FDA approval, we believe that Bioral® Amphotericin B may provide an effective orally administered version of Amphotericin B which may be more effective and less toxic.

According to market research firm Visiongain, the global antifungal market was approximately $6 billion in 2003 and is projected to grow to as much as $8 billion by 2009. Accordingly to our market research, annually, there are an estimated 500,000 severe fungal infections globally for which we believe Bioral® Amphotericin B may be an appropriate treatment. Our market research indicates that Bioral® Amphotericin B may be able to achieve peak sales of approximately $400 million annually, although no assurances can be given of this estimation.

In the development of this drug, we have collaborated with the NIH, the Public Health Research Institute of New York and the University of Kentucky. Further, we have been awarded and received all funds under a grant totaling approximately $2.7 million from the NIH to support the further development of this drug formulation.

Separately, on April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from Mayo Foundation for Medical Education and Research, or the Mayo Foundation, for the treatment of CRS and asthma on a worldwide basis. The technology consists of using low-dose topical antifungals to control the debilitating symptoms of CRS and asthma. Presently, Accentia is developing the encochleated Amphotericin B formulation (which is called BioNasal®) for potential use in a pump spray for the treatment of CRS. Accentia has not determined yet if the application of Amphotericin B to the asthma field is feasible. Accentia will not submit an IND regarding the asthma application of intrapulmonary Amphotericin B, either encochleated or unencochleated, until and if the proof of principle is completed by the Mayo Foundation pursuant to the terms of the Accentia license with the Mayo Foundation.

Our license agreement with Accentia was amended effective June 1, 2004, then modified in September 2004 by the asset purchase agreement with Accentia describe below, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. According to the terms of the license as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales of covered products in the designated field. Accentia estimates that annual prescription cost for its CRS product will be approximately $1,000 per patient. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

On September 8, 2004, we entered into a definitive Asset Purchase Agreement with Accentia pursuant to which we sold to Accentia an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of $2.5 million. The royalty revenue stream sold was a fifty percent (50%) interest in the future royalties earnable by us on sales by Accentia for products utilizing our topical formulation of our encochleated Amphotericin B for the treatment of CRS, thus effectively reducing our royalty on the sales of such CRS products by 50%. We agreed with Accentia, however, that the future royalty stream sold shall not include royalty payments that are payable by Accentia based on the sale of encochleated products exclusively intended to treat asthma, and the rights to such royalty payments, as originally set forth in the license agreement, shall remain with us.

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BEMA™ Technology Overview

Licensed to us from a third party, BEMA™ stands for bioerodible mucoadhesive. BEMA™ discs are the size of a dime and are composed of an adhesive layer and a non-adhesive backing layer made of polymers, with both layers capable of holding the desired drug. Upon application, the disc adheres to the mucosal surface (inner lining of the cheek) and delivers the dose of medication rapidly and efficiently, making it an excellent delivery system for time-critical conditions such as nausea, vomiting and breakthrough cancer pain, or trauma cases where intravenous lines or injections are unavailable or not practical. The BEMA™ system permits control of two critical factors allowing for better dose to dose reproducibility: (i) the contact area for mucosal drug delivery, and (ii) the time the drug is in contact with that area, known as residence time.

In contrast to competing transmucosal delivery systems like lozenges and matrix-based delivery systems placed under the tongue or sprayed in the oral cavity, BEMA™ products:

- Adhere to mucosa in seconds and dissolve in minutes;
- Permit absorption to be determined by the product, with patients not being required to swish or move the product around in the mouth for absorption;
- Have a narrow, reproducible delivery rate, not susceptible to varying or intermittent contact with mucus membranes;
- Dissolve completely, leaving no residual product or waste unlike certain other systems; and
- Cost of goods are relatively inexpensive unlike certain other systems.

Emezine® and Current BEMA™ Formulations In Development

Emezine®

We have licensed the U.S. rights to a transmucously delivered formulation of prochlorperazine called Emezine®, an anti-nausea and vomiting medication used for treating nausea and vomiting which occurs after surgeries, chemotherapy and for nausea and vomiting associated with flu and migraines. This is not a BEMA™ formulation, but rather a formulation administered by placing a tablet between the bridge of the upper front teeth and gum where it dissolves, enabling the active ingredient to be absorbed through the lining of the cheek. We license Emezine® from Reckitt.

Anti-nausea, also known as anti-emetic, products are provided as injectable, oral and rectal formulations. Injectable products require that the patient be in a medical facility and have an intravenous injection line in place. Oral products have limitations because delayed gastric emptying that is associated with nausea and vomiting impedes the absorption of the product and actual product ingestion can be nauseating. Rectal suppositories are inconvenient as well as slow and unpredictable in onset. We believe, therefore, that an alternative delivery system is necessary for anti-emetic products, the market for which we estimate to be approximately $2 billion dollars in the United States.

We believe that our licensed Emezine® tablet:

- Will be the first transmucousally delivered anti-emetic in U.S. market place;

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May offer predictability and speed of onset similar to intravenous injections; and