BIODELIVERY SCIENCES INTERNATIONAL INC
Form 424B4
September 30, 2005
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Filed pursuant to Rule 424(b)(4)
SEC File No. 333-127157

Prospectus

4,400,000 Shares

Common Stock

We are offering 4,400,000 shares of our common stock. Our common stock and warrants are quoted on the Nasdaq SmallCap Market under the symbols BDSI and BDSIW, respectively, and are also listed on the Boston Stock Exchange. On September 29, 2005, the closing sales price for the common stock on the Nasdaq SmallCap Market was $2.04 per share and the closing sales price for the warrants was $0.49 per warrant.

This prospectus contains important information that you should know before investing. Please read it before you invest and keep it for future reference.

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 8 before you decide to purchase any shares of our common stock.

	Per Share	Total [1]
Public offering price	$ 2.00	$ 8,800,000
Underwriting discount	$ 0.13	$ 572,000
Proceeds, before expenses, to us [2]	$ 1.87	$ 8,228,000

(1) We have granted the underwriters a 30-day option to purchase up to an additional 660,000 shares of our common stock (15% of the shares we are offering) at the public offering price, less the 6.5% underwriting discount. If this over-allotment option is exercised in full, the total public offering price will be $10,120,000, the total underwriting discount will be $657,800 and the total proceeds, before expenses, to us would be $9,462,200.

(2) We estimate that we will incur approximately $335,000 in offering expenses in connection with this offering. We have also agreed to pay the lead underwriter an advisory fee equal to 1.5% of the gross proceeds of this offering, all of which shall be paid at the closing of the offering.

This is a firm commitment underwriting. The underwriters expect to deliver the shares on or about October 5, 2005. The underwriters have the option to purchase up to 15% of the number of shares of common stock sold in this offering within 30 days from the date of this prospectus to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Ferris, Baker Watts

Incorporated

Maxim Group LLC **GunnAllen Financial, Inc.**

The date of this prospectus is September 29, 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, and the underwriters 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, and the underwriters 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 partially 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) conditions occurring in cancer and surgical patients such as:

- pain,
- anxiety,
- nausea and vomiting,

insomnia, and

fungal infections

We also believe that our drug delivery technologies may have the potential to be applied to other types of pharmaceuticals. 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 or other fees to our licensors and/or third-party collaborators.

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 certain drugs that were only available by intravenous injection and convert them to formulations that can be taken orally. Our Bioral® drug delivery technology was developed in collaboration with The University of Medicine and Dentistry of New Jersey, which we refer to herein as UMDNJ, and the Albany Medical College, which we refer to herein, collectively with UMDNJ, as the Universities. 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. In late July 2005, we received an indication from the National Institute of Allergy and Infectious Diseases, or NIAID, which is affiliated with the National Institutes of Health, or NIH, that the NIAID would, at its expense, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B.

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 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. On July 15, 2005, we entered into a clinical development and licensing agreement with Clinical Development Capital, LLC, which we refer to herein as CDC, which will provide up to $7 million towards the Phase III clinical development of BEMA Fentanyl beginning in February 2006. We expect these funds will represent a majority of the funds we will need for such Phase III program.

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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A third BEMA product we intend to begin to pursue with a small portion of the proceeds of this offering is BEMA Zolpidem. Zolpidem, sold under the Ambien® label, is the most widely prescribed drug for the treatment of insomnia. By creating a BEMA-formulated zolpidem, we believe that we can achieve a clinically significant improvement in the time of onset of the product versus the current method of delivery (i.e., a swallowed pill, with the onset of BEMA Zolpidem beginning in the range of 10-15 minutes versus 30-45 minutes for the pill). Moreover, by avoiding the digestive tract, we believe that BEMA Zolpidem may be able to provide the drug s effect on a more consistent basis than orally administered zolpidem. In addition, because the BEMA disc dissolves completely in the mouth, no water would be required, a feature which is important for many patients at bedtime. Our ability to dedicate any time or resources to beginning the development of BEMA Zolpidem at this time is due primarily to the funding provided for BEMA Fentanyl under the CDC transaction and the funding provided to us in this offering.

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. On July 11, 2005, we received written confirmation from the FDA that our Emezine® submission was accepted for review by the FDA. 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 partially 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.

In the near term, we intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through the proceeds from this offering and from our transaction, with CDC. In addition, as in the past, we will also seek to finance our operations through:

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

licensing and joint venture arrangements with pharmaceutical companies, whose own proprietary pharmaceutical products may benefit from our drug delivery technologies.

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Recent Events

CDC Transaction

On July 15, 2005, we entered into a clinical development and license agreement with CDC pursuant to which CDC will provide, beginning in February 2006 and subject to certain conditions, up to $7 million in funding (including a $2 million upfront payment and subsequent monthly payments) for the clinical development of our BEMA Fentanyl product. All funds made available to us under our transaction with CDC must be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and therefore will be accounted for by us as a refundable deposit.

Under the agreement, CDC is entitled to receive:

- as referenced above, a milestone fee equal to the lesser of $7 million or the actual amount provided by CDC for development of BEMA Fentanyl;
- royalties based on net sales of BEMA Fentanyl (including minimum royalties); and
- a portion of any licensing revenue received by us prior to FDA approval of BEMA Fentanyl.

In addition, we granted CDC a warrant exercisable for up to 500,000 shares of our common stock at an exercise price of $3.50 per share.

Upon execution of the CDC agreement, all data, information, and intellectual property rights concerning BEMA Fentanyl were exclusively licensed to CDC, subject to CDC s return grant of an exclusive license for us to utilize all such information and rights. Further, CDC shall own all data generated in the course of the product development supported by its funds, provided that we shall have an exclusive license to use such data for purposes of our development and commercialization of BEMA Fentanyl. Under our agreement with CDC, CDC s obligation to provide funding under the agreement is subject to several conditions, including the entry by us of BEMA Fentanyl in Phase III clinical trials.

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 Management, LLC, the manager of Laurus, a closing payment equal to $93,750 plus due diligence and legal expenses of $39,500. We agreed to register the shares of common stock underlying the February note and warrant issued to Laurus with the Securities and Exchange Commission, which we refer to herein as the SEC, which registration statement was declared effective on June 20, 2005.

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, 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).

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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 agreed to register the shares of common stock underlying the May note and warrant and the two June warrants issued to Laurus with the SEC, which registration statement was declared effective on July 11, 2005.

We may, in our sole discretion, use proceeds from this offering to repay all or a portion of our debt to Laurus under our February and May 2005 notes with Laurus. In addition, if this offering is consummated, Laurus shall have the right, for a period of 90 days following the closing of this offering, to demand payment of any or all of the outstanding principal amount of the May note outstanding at such time, together with accrued but unpaid interest thereon and any and all other sums due, accrued or payable under such note.

Ferris, Baker Watts Incorporated, or FBW, the lead underwriter of this offering, advised us on the Laurus transactions, for which it earned cash advisory fees of $350,000.

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

Common stock outstanding prior to this offering	7,269,196 shares
Common stock offered	4,400,000 shares
Common stock outstanding after this offering	11,669,196 shares
Use of proceeds	We intend to use the estimated net proceeds from this offering to fund the continued development of our principal product and formulation candidates and for general corporate purposes, including working capital.

We may, however, and in our sole discretion, use proceeds from this offering to repay all or a portion of our debt to Laurus under our February and May 2005 notes with Laurus. In addition, if this offering is consummated, Laurus shall have the right, for a period of 90 days following the closing of this offering, to demand payment of any or all of the outstanding principal amount of the May note outstanding at such time, together with accrued but unpaid interest thereon and any and all other sums due, accrued or payable under such note. This amount would be in excess of $2.5 million.

Nasdaq SmallCap Market symbols	BDSI , BDSIW
Risk factors	See Risk Factors for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The total number of outstanding shares of common stock above excludes the shares underlying the over-allotment option granted to the underwriters in connection with this offering and:

- 1,647,059 shares of common stock issuable upon full conversion of shares of our Series A Non-Voting Convertible Preferred Stock and 941,177 shares of common stock issuable upon full conversion of shares of our Series B Convertible Preferred Stock;
- 2,054,595 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $4.50 per share;
- 2,085,000 shares of common stock issuable upon exercise of our outstanding publicly-traded warrants at a weighted average exercise price of $6.30 per share;
- 292,000 shares of common stock issuable upon exercise of our non-public warrants at a weighted average exercise price of $5.02 per share and 500,000 shares potentially issuable under the warrant issued to CDC at an exercise price of $3.50 per share; and
- Up to a maximum potential of 2,945,037 shares of common stock issuable upon full conversion or exercise, as the case may be, of our February and May 2005 notes and warrants and our June 2005 warrants with Laurus.

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Summary Selected Consolidated Financial Data

We derived the following summary selected consolidated financial data from our audited consolidated financial statements for the periods ended December 31, 2004 and 2003 and from our unaudited consolidated financial statements for the six month periods ending June 30, 2005 and 2004. Historical results are not necessarily indicative of the results to be expected in the future. You should read the summary selected consolidated financial data presented below in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the notes to those financial statements appearing elsewhere in this prospectus.

	Six Months Ended June 30, (unaudited)		Year Ended December 31,	
	2005	2004	2004	2003
	(in thousands, except per share data)			
Consolidated Statements of Operations Data:				
Net revenue	$ 598	$ 519	$ 1,779	$ 2,913
Cost of sales				
Gross margin	598	519	1,779	2,913
Operating expenses:				
Research and development	2,876	1,526	3,180	2,336
Research and development, related party			808	298
General and administrative	2,116	1,341	3,011	2,637
Stock-based compensation	29	78	264	200
Total operating expenses	5,021	2,945	7,263	5,471
Operating income (loss)	(4,423)	(2,426)	(5,484)	(2,558)
Other income (expense):				
Interest (expense) income, net	(355)	(25)	(59)	69
Other income (expense)			2,717	
Net income (loss) before income taxes	(4,777)	(2,451)	(2,826)	(2,489)
Income tax benefit (expense)				
Net income (loss)	(4,777)	(2,451)	(2,826)	(2,489)
Preferred stock dividends	(32)		(22)	
Income (loss) attributable to common stockholders	$ (4,809)	(2,450)	$ (2,848)	$ (2,489)
Weighted average shares outstanding, basic and diluted	7,237	6,986	7,055	7,017
Net loss attributable to common stockholders	$ (0.66)	$ (0.35)	$ (0.40)	$ (0.35)

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RISK FACTORS

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

Risks Related to Our Technologies

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

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

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

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

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

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

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

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

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

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. See Business Competition.

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 June 30, 2005, we have recorded accumulated losses totaling $18,272,568. As of June 30, 2005, we had a working capital deficit of $1,226,950. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed formulations and products, obtain the required regulatory approvals and manufacture, market and sell our proposed formulations and products.

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Although we have earned some licensing-related revenue to date, we have not generated any revenue from the commercial sale of our proposed formulations or products. Since our inception, we have engaged primarily in research and development, licensing technology, seeking grants, raising capital and recruiting scientific and management personnel, although we have more recently begun to focus on commercialization activities as well with the acquisition of Arius. We have not generated revenues to date other than research grants, limited licensing or royalty revenues and a $2.5 million sale of a royalty revenue stream to Accentia. This limited history may not be adequate to enable you to fully assess our ability to develop and commercialize our technologies and proposed formulations or products, obtain FDA approval and achieve market acceptance of our proposed formulations or products and respond to competition. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and derive material revenues from our proposed formulations or products in development.

We will likely need to raise additional capital to continue our operations, and our failure to do so would impair our ability to fund our operations, develop our technologies or promote our formulations or products.

Our operations have relied almost entirely on external financing to fund our operations. Such financing has historically come primarily from the sale of common and preferred stock and convertible debt to third parties and to a lesser degree from grants, loans and revenue from license and royalty fees. We anticipate, based on our current proposed plans and assumptions relating to our operations (including the timetable of, and costs associated with, new product development) and financings we have undertaken prior to the date of this prospectus, and the proceeds from this offering and our agreement with CDC, that our current working capital will be sufficient to satisfy our contemplated cash requirements for approximately 12 months, assuming that we do not accelerate the development of other opportunities available to us, have Laurus demand repayment of $2,500,000 of its loan to us, engage in an extraordinary transaction or otherwise face unexpected events or contingencies, any of which could effect our cash requirements. Thereafter, and given that the use of proceeds from this offering will not fully fund all development costs of our leading product formulations, we will likely need to raise additional capital to fund our anticipated operating expenses and future expansion. Among other things, external financing will be required to cover the further development of our product formulations and other operating costs. 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.

We may have difficulty raising needed capital in the future as a result of, among other factors, our limited operating history and business risks associated with our company.

Our business currently does not generate any sales, and revenue from grants and collaborative agreements may not be sufficient to meet our future capital requirements. We do not know when this will change. We have expended and will continue to expend, including with the proceeds of this offering, substantial funds in the research, development and clinical and pre-clinical testing of our drug delivery technologies and product formulations incorporating such technologies. We will require additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials, commercial-scale manufacturing arrangements and to provide for the marketing and distribution. 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 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;

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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, including the proceeds from this offering, 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.

Our agreements with CDC are subject to several contingencies, and the funds provided for under such agreement may not be available to us if we fail to meet certain milestones.

Under our agreements with CDC, CDC s obligation to provide funding for the clinical development of BEMA Fentanyl is conditioned upon, among certain other conditions, our:

demonstration of certain technical criteria with respect to BEMA Fentanyl,

initiation of the Phase III clinical trial to be supported by CDC by a certain date, and

establishment of a contractual relationship providing for the supply of BEMA Fentanyl.

If we do not meet these or other similar or related requirements, we will not be eligible to receive funds from CDC, we will be required to use proceeds from this offering to fund the BEMA Fentanyl project and we will have less funds than anticipated to spend on the development of other projects described in this prospectus.

In addition, following the initiation of funding (which is expected to be in February 2006), if we are unable to meet additional milestones or requirements, CDC can terminate their funding obligations and assume control of the BEMA Fentanyl project. For example, in the event that we do not diligently pursue the development and regulatory approval of BEMA Fentanyl or encounter certain specified negative circumstances regarding the development of BEMA Fentanyl, CDC has the right to pursue development and commercialization of BEMA Fentanyl pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of our BEMA Fentanyl assets to CDC. Our loss of the BEMA Fentanyl project would have a material adverse effect on our business.

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The funds we may receive from CDC must be paid back upon FDA approval of BEMA Fentanyl, and we may not be able to meet this obligation when due, which could result in our loss of BEMA Fentanyl.

Under our agreement with CDC, we must repay to CDC, as a milestone fee and within 60 days of FDA approval of BEMA Fentanyl, all funding previously provided to us by CDC. Assuming that CDC fully satisfies its funding commitment to us, of which no assurances can be given, this amount could be up to $7 million dollars. No assurances can be made that we will have funds available to us to meet this obligation. Our failure to make this payment would result in our loss of, and CDC s assumption of, the rights to BEMA Fentanyl and the right to continue development thereof. Our loss of the BEMA Fentanyl project would have a material adverse effect on our business.

If an event of default occurs under our convertible notes with Laurus, 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 to fulfill our obligations under the notes and related agreements could lead to loss of these assets, which would be detrimental to our operations. See Description of Securities for a discussion of our financings with Laurus.

We may elect, or in some cases be required, to repay all or a portion of our debt with Laurus from the proceeds of this offering, which repayment would diminish the amount of funds we could use for our further development.

Upon the consummation of this offering, Laurus shall have the right, for a period of 90 days following the closing of this offering, to demand payment of any or all of the outstanding principal amount of the May note outstanding at such time, together with accrued but unpaid interest thereon and any and all other sums due, accrued or payable under such note. This amount would be in excess of $2.5 million. No assurances can be given as to when, if at all, Laurus may exercise this right. As a result, we will, for at least 90 days, need to reserve for such amount in the event that Laurus exercises its repayment right.

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Moreover, we have indicated in this prospectus that we may, in our sole discretion, use proceeds from this offering to repay all or a portion of our debt to Laurus, although no assurances can be given that we will elect to do so. Using proceeds from this offering to pay down our debt to Laurus would diminish the amount of proceeds from this offering which we could use to continue developing our technologies and pharmaceutical products and formulations.

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

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

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

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

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

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

We 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. See Business Description of our Drug Delivery Technologies and Proposed Products and Formulations Relationship with the University of Medicine and Dentistry of New Jersey and Historical Relationship with Albany Medical College.

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We currently lease our research facility from UMDNJ, which 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 currently rely, and will continue to rely, on numerous collaborative agreements with universities, governmental agencies, manufacturers, contract research organizations and corporate partners for both strategic and financial resources. Our inability to secure such relationships as needed, or the loss of or failure to perform by us or our partners under any applicable agreements or arrangements, may substantially disrupt or delay our research and development and commercialization activities, including our in-process and anticipated clinical trials. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We have a license agreement with the Universities in which they grant us exclusive license to conduct research and development of the encochleation drug delivery technology. Our research facilities are 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 expired, and we may be unable to obtain extensions thereof or obtain new NIH grants, which could deny us important funding.

In 2001, the NIH awarded us a Small Business Innovation Research Grant, or SBIR, which we utilized in our research and development efforts relating to our Bioral® Amphotericin B formulation. We have received all anticipated funding under this grant to date, and this grant expired in August 2004. In 2002, the NIH awarded us a second SBIR grant which we have utilized in our research and development efforts relating to a proposed encochleated HIV subunit vaccine. All anticipated funding under this second grant has been made available to us as of the date of this prospectus, and the grant expired on July 31, 2005 with approximately $234,000 left undrawn by us. We are currently seeking a potential extension of this second grant, but no assurances can be given that such extension will be granted. Also, in late July 2005, we received an indication from the NIAID, which is affiliated with the NIH, that the NIAID would, at its expense, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. However, no assurances can be given that NIAID will proceed with or actually pay for this testing. Moreover, although we may seek additional NIH funding for either of these or other programs, we may choose not to seek such funding or such funding may be unavailable to us even should we desire it. The absence of additional funding from the NIH could impair our ability to further develop our Bioral® Amphotericin B formulation or other projects. 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.

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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 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;

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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 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 licenses to access the patents. Without these licenses, the technologies would be

protected from our use and we would not be able to even conduct research without prior permission from the patent holder. Therefore, any disruption in access to the technologies could substantially delay the development of our technologies. Please see

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Business Description of our Drug Delivery Technologies and Proposed Products and Formulations for a description of our drug delivery technologies and related licenses.

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

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

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

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any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required timeframes, if at all, to meet our needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing; or cause us to lose sales, incur additional costs, delay new product introductions or harm our reputation. Furthermore, components from a new supplier may not be identical to those provided by the original supplier. Such differences if they exist could affect product formulations or the safety and effectiveness of our products that are being developed.

We have limited manufacturing experience, and once our drug formulations or products are approved, we may not be able to manufacture sufficient quantities at an acceptable cost.

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization. Accordingly, once our proposed formulations or products are approved for commercial sale, we will need to establish, most likely through third parties, the capability to commercially manufacture our formulations or products in accordance with FDA and other regulatory requirements. We have limited experience in establishing, supervising and conducting commercial manufacturing. If we fail to adequately establish, supervise and conduct all aspects of the manufacturing processes, we may not be able to commercialize our formulations or products. We do not presently own manufacturing facilities necessary to provide clinical or commercial quantities of our proposed formulations or products.

We presently plan to rely on third party contractors to manufacture part or all of our proposed formulations or products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanic shut downs, employee strikes, or any other unforeseeable acts that may delay production. See Business Manufacturing.

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. See Business Sales and Marketing.

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

fail to satisfy financial or contractual obligations to us;

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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.

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.

Risks Related to Our Industry

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

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

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

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

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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 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,

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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 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.

Additionally, we do not currently maintain key person life insurance on the lives of our Chairman of the Board, Dr. Frank O Donnell, our President and Chief Executive Officer, Dr. Mark Sirgo, or any of our other executive officers. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

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

Prior to this offering, our directors, executive officers and affiliated principal stockholders, together with their affiliates, beneficially own, in the aggregate, approximately 62.0% of our outstanding common stock. Following this offering, such persons and entities will beneficially own, in the aggregate, approximately 38.6% of our outstanding common stock. These figures do not reflect any conversion or exercise 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, or our convertible notes with Laurus. Additionally, these figures do not reflect any future potential exercise of our Class A warrants or other outstanding warrants (including those issued to Laurus and CDC) 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, even following this offering, these current officer and director stockholders would have the ability to exercise significant control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

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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. See Certain Relationships and Related Transactions.

Risks Related to the Offering

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.

You will suffer immediate and substantial dilution as a result of this offering.

The public offering price per share in this offering is expected to be substantially higher than the net tangible book value per share immediately after the offering. As a result, you will pay a price per share that substantially exceeds the book value of our assets after subtracting our liabilities. Based on the offering price of $2.00, you will incur immediate and substantial dilution of $1.24, or approximately 58.5%, in the net

tangible book value per share of the common stock from the price you paid. In addition, and depending on the conversion or exercise price of such securities, to the extent that certain of our securities are converted or exercised, including our convertible subordinated promissory notes and warrants with Laurus or securities we may issue in the future at prices less than the offering price in this offering, you will experience significant further dilution. See Dilution.

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. Also, on September 15, 2005,

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the Nasdaq Stock Market informed us of its view that we did not meet continuing listing requirements as a result of the non-independent status of Donald L. Ferguson, a director of our company. These issues have been resolved and we have been advised that we are currently in compliance with Nasdaq listing 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 and a majority of independent directors on our board of directors. 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.

We will have broad discretion over how we use the proceeds of this offering, and we may use them for corporate purposes that do not immediately enhance our profitability or market share.

Our management will have considerable discretion in the application of the net proceeds of this offering, and you will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. We may use the net proceeds from this offering for corporate purposes that do not immediately enhance our profitability or increase our market value.

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 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 5,000,000 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 for our common stock.

We presently have a significant number of convertible securities outstanding, including: (i) 1,647,059 shares of common stock issuable upon full conversion of shares of our Series A Non-Voting Convertible Preferred Stock and 941,177 shares of common stock issuable upon full conversion of shares of our Series B Convertible Preferred Stock, (ii) 2,054,595 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $4.50 per share, (iii) 2,085,000 shares of common stock issuable upon exercise of our outstanding publicly-traded warrants at a weighted average exercise price of $6.30 per share, (iv) 292,000 shares of common stock issuable upon

exercise of our non-public warrants at a weighted average exercise price of $5.02 per share and 500,000 shares potentially issuable under the warrant issued to CDC at an exercise price of $3.50 per share, and (v) up to a maximum potential of 2,945,037 shares of common stock issuable upon full conversion or exercise, as the case may be, of our February and May 2005 notes and warrants and our June 2005 warrants with

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Laurus. If and when these securities are converted or exercised into shares of our common stock, our shares outstanding will increase. Such increase in our outstanding securities, and any sales of such shares, could have a material adverse effect on the market for our common stock and the market price of our common stock.

In addition, from time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, 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, development and commercialization 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 availability to us of funding under our agreement with CDC to develop BEMA Fentanyl;
- 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 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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USE OF PROCEEDS

We estimate that we will receive approximately $7.76 million in net proceeds from the sale of our common stock in this offering, or approximately $9.08 million if the underwriters over-allotment option is exercised in full, based on the public offering price of $2.00 per share and after deducting the underwriting discounts, commissions and an advisory fee payable to Ferris, Baker Watts (the lead underwriter of this offering) and estimated offering expenses payable by us. We currently intend to use the estimated net proceeds from this offering primarily for funding the continued development of our leading proposed product formulations, and also for working capital.

The following table describes the approximate allocation of the net proceeds of the offering and the percentage of net proceeds per allocation, assuming, in each case, that the underwriters do not exercise their over-allotment option:

	Approximate Allocation of Net Proceeds[1]	Approximate Percentage of Net Proceeds[1]
Pre-clinical and clinical development costs associated with Bioral® Amphotercin B	$ 1.80 million	23%
Clinical development costs associated with BEMA LA	$ 3.14 million	40%
Clinical development costs associated with BEMA Zolpidem	$ 0.50 million	6%
Pre-clinical work associated with BEMA Fentanyl[2]	$ 2.00 million	25%
General corporate purposes, including working capital[3]	$ 0.43 million	6%
Total	$ 7.76 million	100%

(1) To the extent we have excess proceeds from this offering, or should the underwriters over-allotment be exercised, we will apply such proceeds to the continued development of our proposed product formulations listed above. However, investors are cautioned that no assurances are given that such excess proceeds will exist or that the underwriters over-allotment will be exercised. Moreover, investors are cautioned that these estimated uses will not cover all projected development costs associated with Bioral® Amphotercin B, BEMA LA and BEMA Zolpidem. See Management s Discussion and Analysis or Plan of Operation Major Research and Development Projects.

(2) Under our agreements with CDC, we expect to receive up to $7 million to be used towards the development of BEMA Fentanyl, although we anticipate, as described above, that up to approximately $2 million of proceeds from this offering will be used by us in connection with the BEMA Fentanyl program until February 2006, the time when, if we meet certain thresholds, funding under the CDC agreement is expected to begin. No assurances can be given that we will meet such thresholds or that such funding will commence. Moreover, if our agreement with CDC terminates or the funds under such agreement are no longer available to us due to our inability to meet milestones or otherwise, we would expect to use proceeds from this offering to further develop BEMA Fentanyl. In the event this occurs, our other proposed product formulations would be de-emphasized pending our raising of additional funds.

(3) We may also, in our sole discretion, use proceeds from this offering to repay all or a portion of our debt to Laurus under our February and May 2005 notes with Laurus. No assurances can be given that we will elect to take such action. In addition, upon the consummation of this offering, Laurus shall have the right, for a period of 90 days following the closing of this offering, to demand payment of any or all of the outstanding principal amount of the May note outstanding at such time, together with accrued but unpaid interest thereon and any and all other sums due, accrued or payable under such note. This amount would be in excess of $2.5 million. No assurances can be given as to when, if at all, Laurus may exercise this right.

Investors are cautioned that expenditures may vary substantially from these estimates. The amounts and timing of our actual expenditures will depend upon numerous factors, including the status of our product development efforts, the FDA approval process, our funding or lack thereof from CDC and the amount of cash generated by our operations. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

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Circumstances that may give rise to a change in the use of proceeds include:

- the existence of other opportunities or the need to take advantage of changes in timing of our existing research and development activities; and/or

- the need or desire on our part to accelerate, increase or eliminate existing initiatives due to, among other things, results of clinical trials or non-clinical studies and related factors, changing market conditions, competitive developments and changes in the costs associated with securing our intellectual property and patent protection.

From time to time, we evaluate these and other factors and we anticipate continuing to make such evaluations to determine if the existing allocation of resources, including the proceeds of this offering, is being optimized. Pending any of the proposed or potential uses of proceeds described above, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment grade securities.

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CAPITALIZATION

The following table describes our capitalization as of June 30, 2005: (i) on an actual basis and (ii) on an as adjusted basis to reflect our sale of 4,400,000 shares of common stock in this offering at a public offering price of $2.00 per share, after deducting the underwriters discount and commission and payment of the advisory fee to Ferris, Baker Watts and all other estimated offering-related expenses. You should read the following table in conjunction with our consolidated financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations contained elsewhere in this prospectus.

As of June 30, 2005

Unaudited

(in thousands)

	Actual[1]	As adjusted[2]
Cash and cash equivalents, restricted and unrestricted	$ 1,790	$ 9,551
Total Debt	4,658	4,658
Stockholders equity:		
Common stock, $.001 par value: 45,000,000 shares authorized, 7,304,687 shares issued and 7,269,197 shares outstanding, actual, 11,669,196 pro forma outstanding	7	11
Preferred stock, Series A, $.001 par value: 1,647,059 shares designated, 1,647,059 issued and outstanding, actual	3,706	3,706
Preferred stock, Series B, $.001 par value: 941,177 shares designated, 341,176 shares issued and outstanding, actual	1,450	1,450
Additional paid-in capital	17,712	25,469
Treasury stock, at cost, 35,490 shares	(108)	(108)
Accumulated deficit	(18,273)	(18,273)
Total stockholders equity	4,495	12,256
Total Capitalization	$ 9,152	$ 16,914

(1) The number of actual and as adjusted outstanding shares of common stock as of June 30, 2005 excludes: (i) 1,647,059 shares of common stock issuable upon full conversion of shares of our Series A Non-Voting Convertible Preferred Stock and 941,177 shares of common stock issuable upon full conversion of shares of our Series B Convertible Preferred Stock, (ii) 2,054,595 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $4.50 per share, (iii) 2,085,000 shares of common stock issuable upon exercise of our outstanding publicly-traded warrants at a weighted average exercise price of $6.30 per share, (iv) 292,000 shares of common stock issuable upon exercise of our non-public warrants at a weighted average exercise price of $5.02 per share and 500,000 shares potentially issuable under the warrant issued to CDC at an exercise price of $3.50 per share, (v) up to a maximum potential of 2,945,037 shares of common stock issuable upon full conversion or exercise, as the case may be, of our February and May 2005 notes and warrants and our June 2005 warrants with Laurus, and (vi) shares underlying the over-allotment option granted to the underwriters in connection with this offering.

(2) Assumes the completion of this offering.

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DILUTION

As of June 30, 2005, our net tangible book value was $1.2 million, or $.16 per share of common stock. Pro forma net tangible book value per share represents total tangible assets (which excludes goodwill, intangible assets and deferred loan costs), less total liabilities, divided by the pro forma number of shares of our outstanding common stock. After giving effect to the issuance and sale of 4,400,000 shares of our common stock in this offering and our receipt of approximately $7,761,000 in net proceeds from that sale, based on a public offering price of $2.00 per share and after deducting the underwriting discounts and commissions, an advisory fee paid to Ferris, Baker Watts and estimated offering-related expenses, our pro forma as adjusted net tangible book value, as of June 30, 2005, would have been $8.92 million, or $0.76 per pro forma share of common stock. This represents an immediate increase in pro forma net tangible book value of $0.60 per share to existing stockholders and an immediate dilution of $1.24, or approximately 58.5%, per share to new investors participating in this offering. The following table illustrates this per share dilution:

Public offering price per share	$ 2.00
Historical net tangible book value per share as of June 30, 2005	$ 0.16
Increase in pro forma net tangible book value per share attributable to this offering	$ 0.60
Pro forma as adjusted net tangible book value per share after this offering	$ 0.76
Dilution per share to new investors participating in this offering	$ (1.24)

The foregoing discussion and tables assume no exercise of any stock options or warrants and no issuance of shares reserved for future issuance under our equity plans. As of June 30, 2005, there were 7,269,196 shares of common stock outstanding, which excludes the shares underlying the over-allotment option granted to the underwriters in connection with this offering and also excludes:

- 1,647,059 shares of common stock issuable upon full conversion of shares of our Series A Non-Voting Convertible Preferred Stock and 941,177 shares of common stock issuable upon full conversion of shares of our Series B Convertible Preferred Stock;
- 2,054,595 shares of common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of $4.50 per share;
- 2,085,000 shares of common stock issuable upon exercise of our outstanding publicly-traded warrants at a weighted average exercise price of $6.30 per share;
- 292,000 shares of common stock issuable upon exercise of our non-public warrants at a weighted average exercise price of $5.02 per share and 500,000 shares potentially issuable under the warrant issued to CDC at an exercise price of $3.50 per share; and
- Up to a maximum potential of 2,945,037 shares of common stock issuable upon full conversion or exercise, as the case may be, of our February and May 2005 notes and warrants and our June 2005 warrants with Laurus.

We may, in our sole discretion, use proceeds from this offering to repay all or a portion of our debt to Laurus under our February and May 2005 notes with Laurus. However, no assurances can be given that we will elect to take such action. In addition, we may grant additional options or warrants or issue other equity securities in the future that may be dilutive to investors in this offering.

Assuming the exercise in full of the underwriters option to purchase 660,000 shares of common stock to cover over-allotments, our pro forma as adjusted net tangible book value as of June 30, 2005 would have been $10.24 million, or $0.83 per share. This represents an immediate increase in the pro forma net tangible book value of $0.07 per share to existing stockholders and immediate dilution of $1.17 per share to new investors participating in this offering.

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DIVIDEND POLICY

We have not paid any cash dividends since our inception and do not anticipate paying any cash dividends on our common stock in the foreseeable future, and our agreements with Laurus prohibit us from paying dividends on our common stock. The shares of our Series B Convertible Preferred Stock accrue annual dividends at a rate of 4.5%. We expect to retain our earnings, if any, to provide funds for the expansion of our business. Future dividend policy will be determined periodically by our board of directors based upon conditions then existing, including our earnings and financial condition, capital requirements and other relevant factors.

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SELECTED CONSOLIDATED FINANCIAL DATA

We derived the following selected consolidated financial data from our consolidated financial statements for the periods ended December 31, 2004 and 2003, which have been audited by Aidman, Piser & Company, P.A., our independent auditors, and from our unaudited consolidated financial statements as of June 30, 2005 and 2004. In the opinion of management, the unaudited financial data for the six month periods ended June 30, 2005 and 2004 includes all adjustments (consisting of any normal recurring adjustments) necessary to present the financial data for such periods. As adjusted data assumes the receipt of $7,761,000 in net proceeds from this offering. Historical results are not necessarily indicative of the results to be expected in the future. You should read the selected consolidated financial data presented below in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the notes to those financial statements appearing elsewhere in this prospectus.

	Six Months Ended June 30, (unaudited)		Year Ended December 31,	
	2005	2004	2004	2003
	(in thousands, except per share data)			
Consolidated Statements of Operations Data:				
Net revenue	$ 598	$ 519	$ 1,779	$ 2,913
Cost of sales				
Gross margin	598	519	1,779	2,913
Operating expenses:				
Research and development	2,876	1,526	3,180	2,336
Research and development, related party			808	298
General and administrative	2,116	1,341	3,011	2,637
Stock-based compensation	29	78	264	200
Total operating expenses	5,021	2,945	7,263	5,471
Operating income (loss)	(4,423)	(2,426)	(5,484)	(2,558)
Other income (expense):				
Interest (expense) income, net	(355)	(25)	(59)	69
Other income (expense)			2,717	
Net income (loss) before income taxes	(4,777)	(2,451)	(2,826)	(2,489)
Income tax benefit (expense)				
Net income (loss)	(4,777)	(2,451)	(2,826)	(2,489)
Preferred stock dividends	(32)		(22)	
Income (loss) attributable to common stockholders	$ (4,809)	(2,450)	$ (2,848)	$ (2,489)
Weighted average shares outstanding, basic and diluted	7,237	6,986	7,055	7,017
Net loss attributable to common stockholders	$ (0.66)	$ (0.35)	$ (0.40)	$ (0.35)

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	As of June 30, 2005 (unaudited) (in thousands)	
	Actual	As Adjusted[1]
Consolidated Balance Sheet Data:		
Cash and cash equivalents, restricted and unrestricted	$ 1,790	$ 9,551
Working capital (deficit)	(1,227)	6,534
Total assets	9,152	16,914
Notes Payable	1,098	1,098
Long-term liabilities	1,098	1,098
Total stockholders equity	$ 4,495	$ 12,256

(1) The as adjusted unaudited consolidated balance sheet data as of June 30, 2005 gives effect to the sale of the 4,400,000 shares of common stock we are offering pursuant to this prospectus, at a public offering price of $2.00 per share, after deducting the underwriting discounts and commissions, advisory fee payable to Ferris, Baker Watts and the estimated offering expenses payable by us. In addition, the as adjusted calculation does not reflect any potential exercise of the underwriters over-allotment option or the repayment of any of our debt to Laurus as described in Use of Proceeds.

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MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis of our financial condition and plan of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this prospectus. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those which are not within our control.

Limited Operating History; Background of Our Company

Until 2002, we were a development stage company. Our first license agreement was funded in 2003 in the amount of $2 million, and we had an additional license funded in 2004 for $1 million, as part of our acquisition of Arius. We expect to continue research and development of our drug delivery technologies, and while we are seeking additional license agreements, which may include up-front payments, we anticipate nominal royalty revenues from the sale or commercialization of our products under development (other than license fees) during 2005. The funding will come primarily from the sale of debt or equity securities (including securities in this offering), collaborative research agreements, including pharmaceutical companies, grants from public service entities and government entities, and the potential exercise of our warrants.

In 2001, the NIH awarded us a three-year $2.7 million SBIR grant, which was fully funded through 2004, and which was utilized in our research and development efforts. We have an additional grant of approximately $0.6 million which expired on July 31, 2005. We are currently seeking an extension of this second grant, and approximately $0.2 million will be available to us under this grant if the extension is granted.

We have a limited history of operations, and while we have received license revenues in 2003, 2004 and 2005 for licensing our technology, we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future. We believe period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies maturing in commercialization of their technologies, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. For the foreseeable future, we must, among other things, seek regulatory approval for and commercialize our proposed drugs, which may not occur. We may not be able to appropriately address these risks and difficulties. We may require additional funds to complete the development of our technology and to fund expected operations in the next several years.

For the Six Months Ended June 30, 2005 Compared to the Six Months Ended June 30, 2004

Sponsored Research Revenue. During the six-month period ended June 30, 2005, we reported $.2 million of sponsored research revenues from a grant from the NIH. In the prior year, revenue aggregating $0.5 million was derived from an SBIR grant, which was fully funded in August 2004.

License Fee Revenues. During the six-month period ended June 30, 2005, we reported $.4 million in licensing (milestone) revenue from a related party. There were no license or milestone revenues during the same period in 2004.

Royalty Revenues. During the six-month period ended June 30, 2005, we reported $0.03 million of royalty revenue from a related company. There were no such royalties in the prior year.

Research Fee Revenues. During the six-month period ended June 30, 2005, we reported $0.02 million of research fee revenue. There were no research fee revenues in 2004.

Research and Development. Research and development expenses of approximately $2.9 million and $1.5 million were incurred during the six-month periods ended June 30, 2005 and 2004, respectively. Our scientific

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staff continued to work toward increased development and application of our BEMA and Bioral® cochleate technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options in 2004 by directors, and funding of an equity line of credit from HCG. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA and Bioral® drug delivery technologies.

General and Administrative Expenses. General and administrative expenses of approximately $2.1 million and $1.3 million were incurred in the six-month periods ended June 30, 2005 and 2004, respectively. These expenses are principally comprised of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, and other business development costs. Furthermore, expenses include approximately $0.05 million and $0.1 million of expenses related to BND operating activities in the three months ended June 30, 2005 and 2004, respectively. BND is inactive at June 30, 2005. Stock-based compensation costs of $0.03 million in 2005 were associated with vested options during the period. Employees stock option grants were treated under APB 25 through December 31, 2004. We intend to adopt FAS 123 in 2005 for new options granted to employees. The increase in general and administrative expenses in 2005 is primarily due to increased staffing following the acquisition of Arius, and additional legal and patent costs, partially offset by reduced costs associated with BND.

Interest Income (Expense). Interest income (expense) for the periods ended June 30, 2005 and 2004 was principally comprised of interest expense on the line of credit, notes payable and capital leases payable, and costs attributable to the February and May financings, partially offset by nominal earnings from invested cash. Interest expense in 2005 also includes amortization of loan costs associated with warrants issued to our investment banker of $0.01 million and amortization of the Laurus discount of $0.1 million.

Income Taxes. While net operating losses were generated during the six month period ended June 30, 2005, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Other Comprehensive Gain. Other comprehensive gain in 2004 consists exclusively of unrealized gains on marketable equity securities held for sale. At June 2004, all marketable equity securities had been sold.

For the Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003

Sponsored Research Revenue. During the year ended December 31, 2004, we recognized sponsored research revenue of $0.8 million, compared to $0.9 million in the prior year. Except for $0.01 million in 2003 from collaborative research agreements, the sponsored research revenues were from the NIH which was completed in August 2004. We have a second NIH grant of $0.6 million, which was partially drawn ($0.01 million) in the year ended December 31, 2001, $0.01 million was funded in calendar 2004, and the balance will be drawn through August 2005.

License Fee Revenues. In 2004, and prior to its acquisition by us, Arius entered into a license agreement relating to Emezine® with TEAMM Pharmaceuticals, a subsidiary of Accentia, and earned a $1.0 million license fee. The revenues were recognized in full in the year ended December 31, 2004. During December 2002, we entered into a licensing agreement with a company (which is a stockholder), which included a non-refundable payment of $2 million. We recognized $ 2 million license income in 2003 over the period of the related research and development commitment.

Research and Development Expenses. During the years ended December 31, 2004 and 2003, research and development expenses totaled $4.0 million and $2.6 million, respectively. Our scientific staff continued to work

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toward increased development and application of our BEMA and Bioral® cochleate technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options by directors, and funding of an equity line of credit from HCG. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA and Bioral® drug delivery technologies. For more detail on expenditures related to our major projects currently under development, see Major Research and Development Projects below.

General and Administrative Expenses. During the years ended December 31, 2004 and 2003, general and administrative expenses totaled $3.0 million and $2.6 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, executive personnel costs, consulting fees, and business development costs. Furthermore, we incurred expenses in 2004 and 2003 of approximately $0.2 million and $0.5 million respectively, related to operating activities of our Bioral Nutrient Delivery, LLC subsidiary that commenced in 2003, approximately $0.2 million of which related to offering costs associated with a registration statement that was pending throughout the latter half of 2003 and most of 2004 until it was withdrawn in early 2005. The increase in general and administrative expenses in 2004 is primarily due to increased staffing following the acquisition of Arius, and additional patent costs, partially offset by reduced costs associated with BND.

Stock-Based Compensation Expense. Stock-based compensation expenses of $0.3 million and $0.2 million were incurred in 2004 and 2003, respectively for stock options granted for services rendered by the underwriter of our initial public offering and our legal counsel. Employees stock option grants are treated under APB 25 through December 31, 2004. We intend to adopt FAS 123 in 2005 for new options granted to employees.

Other income. We are parties to a License Agreement, dated April 12, 2004, with Accentia pursuant to which we licensed to Accentia a topical version of encochleated Amphotericin B. Accentia is currently a privately-held biopharmaceutical holding company partly-owned by HCG, which is partly-owned and controlled by our Chairman of the Board. In September 2004, we sold to Accentia a portion of the royalty revenue stream that is associated with the License Agreement in consideration of a cash payment of $2.5 million. The $2.5 million is included in other income in the financial statements for the year ended December 31, 2004.

Interest Income (Expense), Net. During the year ended December 31, 2004 we had net interest expense of $0.06 million, compared to net interest income of $0.07 million in 2003. The decrease in net interest income is primarily due to reduction of invested liquid funds which we used to fund our operations. We borrowed funds to purchase laboratory equipment and to make leasehold improvements in 2003. Our bank note terms with Gold Bank called for interest-only through October 2003 and amortization of principal over 48 months beginning in November 2003. Such note was paid in February 2005, as further discussed below.

Income Tax Benefit. We incurred net operating losses during both years presented, and we did not recognize any benefit associated with these losses. We had federal and state net operating loss carryforwards of $10.5 million at December 31, 2004. The federal net operating loss carryforwards expire beginning in 2020, if not utilized. We sold New Jersey state tax credits in 2004 totaling $3.3 million, which generated cash of $0.2 million. The state operating loss carryforwards expire beginning in 2008, if not utilized. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

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Major Research and Development Projects

In 2004, we dedicated most of our corporate resources to the development of Emezine®, BEMA Fentanyl, Bioral® Amphotericin B and BEMA LA. Under our June 2005 agreement with CDC, up to $7 million will made available to us for the development of BEMA Fentanyl. As a result, we intend to use a small portion of the proceeds from this offering to begin the development of BEMA Zolpidem. We believe that other projects which we have previously identified as being in our pipeline (Bioral® NSAID, Bioral® Paclitaxel, Bioral® siRNA therapeutics, Subunit HIV Vaccine and Autologous HIV Vaccine) represent promising opportunities. However, we are consistently evaluating such opportunities as to whether or not (or how) to actively pursue them. Presently, such opportunities are available for licensing by third parties. As a result, due to our limited corporate resources, we are presently focusing mainly on the five projects discussed below.

Investors in this offering and our stockholders generally 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 best judgments given their previous experiences, but no assurances can be given that such estimates will prove to be accurate.

Emezine®. We are the exclusive U.S. licensee of Emezine®, a transmucously delivered formulation of prochlorperazine, an anti-emetic product used for treating nausea and vomiting which occurs after surgeries and chemotherapy. Arius licensed Emezine® from Reckitt and we acquired this license with the Arius acquisition in August 2004. During 2004, we expended approximately $0.514 million on our efforts relating to Emezine®. In March 2005, we received notice from the FDA that it granted, under a small business exception, our request for a waiver of the FDA s human drug application fee in connection with our pending NDA for Emezine®. We believe this fee would have been approximately $672,000. This one-time exemption represents a considerable savings to our company.

Once the NDA for Emezine® is submitted, which occurred on April 29, 2005, the FDA has 60 days during which to accept the application for filing. On July 11, 2005, we received written confirmation from the FDA that our Emezine® submission was accepted for review by the FDA. In connection with the FDA review process, following Prescription Drug User Fee Act guidelines, the FDA will have up to 10 months from the date of the submission is accepted to review and render a decision on the application as to whether it is approvable or not. If they render it non approvable, it is likely we will have additional work to complete before resubmitting. If approved by the FDA, we anticipate an approximate 3 month period before our marketing partner, TEAMM Pharmaceuticals, a subsidiary of Accentia, will have the product in the various distribution channels for sale. This 3 month period is used to distribute product samples, provide sales training to sales staff and prepare final marketing and advertising materials based on the final labeling the FDA allows for the product. Reckitt will be responsible for manufacturing the product for distribution in the U.S.

Based on our market research, we believe that Emezine® may be able to achieve minimum peak sales of approximately $25 million annually, on which we will receive a royalty from TEAMM Pharmaceuticals, our commercialization partner (and on which we will pay a royalty to Reckitt), although no assurances can be given of this estimation. We do not expect to generate any revenue from Emezine®, if ever, until at least mid-2006.

The risks to our company associated with the Emezine® project include: (i) failure of the FDA to approve our NDA or a delay in the approval process because the FDA requires additional information; (ii) if Reckitt, our manufacturing partner, fails to fulfill its obligations under their licensing and supply agreement with us; (iii) if TEAMM, our commercial partner, fails to fulfill their contractual obligations to us (including funding obligations) and (iv) if the product fails to meet sales forecasts. However, given the relatively small outlays we are actually making on this project, and given that our size of market projections regarding Emezine® are relatively small, we do not presently believe that the failure of this project, though potentially damaging to our market reputation and our stock price, among other matters, would seriously impair our potential

future revenue growth.

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BEMA Fentanyl. We license the BEMA drug delivery technology on a worldwide exclusive basis from Atrix. We acquired this license when we acquired Arius in August 2004. Our lead BEMA product is a formulation of the narcotic analgesic medication fentanyl. We recently announced that we received confirmation from the FDA that we will be able to utilize the FDA s 505(b)(2) process for submission of the NDA for BEMA Fentanyl. As a result of this guidance, we anticipate entering BEMA Fentanyl into Phase III clinical studies in the second half of 2005. Due to the nature of treating patients with breakthrough cancer pain, our patient recruitment process for the BEMA Fentanyl clinical program may take anywhere from 6 to 18 months. When patient recruitment is complete, it will likely take an additional 3 to 6 months, approximately, to submit our NDA. If the FDA accepts the NDA for filing, they will have up to 10 months from the date of submission to render a decision on the approvability of our application. If their decision is positive and an approval letter is granted, we anticipate launching the product 3 months from the receipt of the approval letter.

During 2004, we expended approximately $0.26 million on our efforts relating to BEMA Fentanyl. We estimate that the clinical development costs of BEMA Fentanyl will be approximately $5.35 million. We believe that BEMA Fentanyl may have the potential to capture a significant share of the breakthrough cancer pain market in the U.S., which we estimate could result in annual peak sales of approximately $250 million, on which we will pay a royalty to Atrix and to CDC, although no assurances can be given of this estimation. We do not expect to generate any revenue from BEMA Fentanyl, if ever, until at least mid-2008.

The risks to our company associated with the BEMA Fentanyl project include: (i) failure to develop an adequate formulation; (ii) inability of our contract manufacturer to make clinical supplies; (iii) slow patient enrollment in clinical trials; (iv) lack of funding to progress the program; (v) failure to demonstrate efficacy in clinical trials; (vi) the development of safety issues with the product, (vii) the conclusion by the FDA that the risk benefit is inadequate; (viii) the conclusion by the FDA that our submission is inadequate and additional information is required; and (ix) failure to identify a manufacturer that can meet our commercial supply requirements. The failure of the BEMA Fentanyl project or a failure of the product to meet commercial forecasts would seriously impair our potential future revenues, as well as investor confidence and potentially our public stock price, as we believe it would be the first of our formulations with a significant market opportunity to reach market.

Bioral® Amphotericin B. We license the encochleation drug delivery technology which we use in our Amphotericin B formulation from the Universities. We estimate that the filing of our IND on this oral formulation of amphotericin, which we expect will be for the treatment of esophageal candidiasis, will be made in the first quarter of 2006. If the FDA accepts our IND, we intend to begin Phase I studies in normal volunteers immediately. These studies will assess the oral absorption of amphotericin from our cochleate formulation. Following completion of Phase I trials, we would then move into a Phase II study in patients sometime in the second half of 2006 and Phase III trials in late 2006 or 2007. A Phase III program would run approximately 18-24 months after which we would spend 3-6 months compiling and submitting the NDA. If the FDA accepts the NDA for filing, they will then have up to 10 months from the date the submission is accepted to decide whether the application is approvable. If we receive approval within this timeframe we would be prepared for a product launch within 3 months from this time. No assurances can be given that we will successfully complete any clinical phase of clinical trials.

Since 2001, we have expended approximately $2.53 million on our efforts relating to encochleated Amphotericin B (including approximately $0.75 million in 2004). We are responsible for all costs and expenses on our Bioral® Amphotericin B product. We estimate that the pre-clinical and clinical development costs of this formulation will be approximately $7.0 million. 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.

Our market research indicates that Bioral® Amphotericin B formulation may be able to achieve peak sales of approximately $400 million annually, on which we will pay a royalty to UMDNJ, although no assurances can be given of this estimation. We do not anticipate generating any revenue for Bioral® Amphotercin B, if ever, until at least late 2008.

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The risks to our company associated with the Bioral® Amphotericin B project include: (i) if the FDA fails to accept the IND upon first submission; (ii) the inability of a contract manufacturer to produce clinical supplies; (iii) Phase I studies do not show significant oral absorption of product; (iv) failure of clinical trials, including if the Phase II study shows drug is ineffective in treating the fungal infection in question; (v) if the product encounters safety issues; and (vi) lack of corporate funding to progress the program. Of the five major programs to which we are currently dedicating material resources, we believe this program has the highest risk because of the early-stage and more complex nature of the Bioral® technology (as opposed to BEMA). However, due to the large market for anti-fungal projects, we believe the upside potential of Bioral® Amphotericin B from a commercial perspective may be significant to us. The failure of this program or a failure of the product to meet commercial forecasts would have a serious impact on long term corporate revenue and could also negatively affect other encochleation projects and investor confidence in our company (and potentially our public stock price) generally, as Bioral® Amphotericin B is our lead Bioral® product and is likely viewed as a way to validate the broader encochleation concept.

BEMA Long Acting Analgesic. We license the BEMA drug delivery technology on a worldwide exclusive basis from Atrix. We acquired this license when we acquired Arius in August 2004. This formulation would be our second BEMA analgesic product after BEMA Fentanyl. We expect to submit an IND for BEMA LA in the second half of 2005. In the event that the FDA accepts this IND, we would proceed with a Phase I trial in normal volunteers whereby we would measure the blood concentrations of the product in these patients. If these concentrations meet our objectives, we would then move into our Phase III program, under which we would be treating patients who have moderate to severe pain. This pain condition may be either acute, requiring short term therapy (such as sprains and strains), or chronic (such as arthritis requiring chronic therapy). The BEMA LA Phase III program may take from 12-24 months, depending on the final indication patient population that we decide to evaluate and agreements with the FDA. After completing the Phase III program, it would likely take approximately 3 to 6 months to compile and submit our NDA to the FDA. After submission, the FDA will then have up to 10 months from the date the submission is accepted to render a decision on the approvability of our application. If the FDA approves the application we would anticipate launching the product within 3 months of that approval.

During 2004, we did not expend any resources on our efforts relating to BEMA LA. We estimate that the future clinical development costs of this formulation will be approximately $5.5 million.

Due to the ability of BEMA LA being able to participate in all four of the key pain markets (chronic pain, post-operative pain, breakthrough malignant pain, breakthrough non-malignant pain), we believe that BEMA LA has the potential to achieve a 1-2% share of the total worldwide pain market which is valued at approximately $24 billion. This would translate into an estimated $250-500 million in peak annual sales, on which we will pay a royalty to Atrix, although no assurances can be given of this estimation. We do not expect to generate any revenue from BEMA LA, if ever, until at least late 2008.

The risks to our company associated with the BEMA LA project include: (i) our inability to develop a final formulation; (ii) the inability of a contract manufacturer to produce clinical supplies; (iii) if the FDA fails to accept the IND upon first submission; (iv) slow patient enrollment in clinical trials; (v) lack of corporate funding to progress the program; (vi) failure of clinical trials, including if the Phase III study does not show efficacy; (vii) if the product encounters safety issues; (viii) if overall composite of data from clinical trials does not support NDA submission; and (ix) even if an NDA is submitted, the failure of the FDA to approve such NDA or a delay in the approval process because the FDA requires additional information. A failure of this product, or a failure of the product to meet commercial forecasts, would have a pronounced effect on our future revenue stream and could also negatively affect investor confidence in our company and potentially our public stock price.

BEMA Zolpidem. This formulation would be our third BEMA product after BEMA Fentanyl and BEMA LA. We anticipate filing an IND on this product during the first quarter of 2006, and this will be followed by our first Phase I trial in normal volunteers whereby we would measure the blood concentrations of the product in these patients. Based on the results of this first Phase I trial, one to two additional Phase I trials

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would be conducted. One of these studies would be conducted in a sleep laboratory. Based on the results of these studies, a final formulation would be chosen for initiating the Phase III program. The BEMA Zolpidem Phase III program may take from 12-24 months, depending on the final agreements with the FDA. After completing the Phase III program, it would likely take approximately 3 to 6 months to compile and submit our NDA to the FDA. After submission, the FDA will then have up to 10 months from the date the submission is accepted to render a decision on the approvability of our application. If the FDA approves the application we would anticipate launching the product within 3 months of that approval.

During 2004, we did not expend any resources on our efforts relating to BEMA Zolpidem. We estimate that the future development costs of this formulation will be approximately $8.3 million. If we do not consummate this offering, we may not be able to pursue further development of this opportunity.

Due to the potential ability of BEMA Zolpidem being able to induce sleep in 10-15 minutes versus the time for standard products (30-45 minutes), our market research indicates that BEMA Zolpidem has the potential to achieve a 5% share of the total worldwide insomnia market which has a projected 2010 value of $5 billion. This would translate into an estimated $250 million in peak annual sales, on which we will pay a royalty to Atrix, although no assurances can be given of this estimation. We do not expect to generate any revenue from BEMA Zolpidem, if ever, until at least mid-2009.

The risks to our company associated with the BEMA Zolpidem project include: (i) our inability to develop a final formulation; (ii) the inability of a contract manufacturer to produce clinical supplies; (iii) if the FDA fails to accept the IND upon first submission; (iv) slow patient enrollment in clinical trials; (v) lack of corporate funding to progress the program; (vi) failure of clinical trials, including if the Phase III study does not show efficacy; (vii) if the product encounters safety issues; (vii) if overall composite of data from clinical trials does not support NDA submission; and (ix) even if an NDA is submitted, the failure of the FDA to approve such NDA or a delay in the approval process because the FDA requires additional information. A failure of this product, or a failure of the product to meet commercial forecasts, would have a pronounced effect on our future revenue stream and could also negatively affect investor confidence in our company and potentially our public stock price.

Liquidity and Capital Resources

Since inception, we financed our operations primarily from the private sales of our convertible preferred stock, convertible debt and common stock, our initial public offering, exercise of options, various licensing agreements, NIH grants, bank financing, and through the sale of a royalty stream asset to Accentia. From inception through March 31, 2002, we raised approximately $1.8 million, net of issuance costs, through private placements or convertible preferred stock and common stock financings. On April 1, 2001, we issued 137,300 shares of common stock in consideration for payment in full of the approximate $500,000 payable to the UMDNJ due through March, 2001. Our June 2002 public offering, net of offering costs of $2.4 million, and including the exercise of the underwriter s over-allotment option raised approximately $8.6 million. At June 30, 2005, we had cash and cash equivalents of $1.8 million. The adequacy of cash for our operations in continued research is dependent on, among other things, licensing opportunities we are able to negotiate in the coming year, as well as the funding of our equity line of credit, further described below, which had a balance remaining of $2.6 million at June 30, 2005.

In 2001, the NIH awarded us a three-year SBIR grant of $2.7 million which was used through 2004 to fund research and development efforts. In addition, we have a second grant from NIH for a total of $0.6 million, which has a remaining balance of approximately $0.234 million at June 30, 2005. Both of these grants have expired, although we are currently seeking an extension of the second grant so that we might draw down the remaining funds.

We used $2.9 million of cash for operations in of the year ended December 31, 2004. This consisted of a net operating loss of $2.8 million, which was funded through liquidation of our investments of $2.0 million, and we acquired cash of $.06 million in our August 2004 acquisition of Arius. We purchased equipment of $0.1 million in calendar 2004. We do not anticipate any material capital expenditures in 2005.

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In the first quarter of 2003, we received a $1 million bank line of credit from Gold Bank, which was converted to a four year term loan, with a 75% loan to value ratio, at an interest rate of 7.5%, to be used in the purchase of laboratory and other equipment and facilities improvements in our Newark, New Jersey lab. The collateral consisted of all equipment owned by us in our Newark facility. We drew 100% of these funds during 2003, all of which was utilized for our Newark laboratory needs. During 2004, with a loan balance of approximately $0.8 million, we were out of covenant with the bank, and paid down principal of $0.4 million. The loan was paid in full in February 2005.

During the second quarter of 2003, we, as authorized by our board of directors, repurchased 100,000 shares of our common stock with a per share price between $2.80 and $3.20 for a total cost of $303,894.

In September 2004, we entered into an Equity Line of Credit Agreement with HCG, an affiliated entity which is controlled and partially-owned by our Chairman of the Board. Pursuant to the Equity Line Agreement, HCG will, as requested by us, invest up to $4.0 million in our company through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock. As of August 3, 2005, $1.45 million has been drawn under the Equity Line Agreement. The holders of the Series B Preferred are entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred is convertible into shares of our common stock at any time as of or after April 1, 2006, or earlier upon a change of control of our company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to our common stock and our Series A Preferred Stock and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. Additionally, we have the right, in our discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. Furthermore, the Certificate of Designations for the Series B Preferred provides for certain limitations on the conversion of the Series B Preferred into shares of Common Stock without the prior approval of the our stockholders. Finally, HCG has no rights to cause the redemption or buy-back by us of the Series B Preferred.

In January 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. 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. 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 BDSI common stock, up to an aggregate potential of $1.5 million worth of such shares. Such additional unregistered shares will be issued at the lesser of: (i) $4.25 and (ii) the average of the closing trade price of BDSI s common stock for the ten (10) trading days through and including the applicable payment date, with an absolute floor of $3.54 per share. 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.

On February 22, 2005, we closed a $2.5 million secured convertible debt financing from Laurus. Net proceeds from the financing will be used primarily to support our research, development and commercialization opportunities and for general working capital purposes. We also used approximately $300,000 to retire our secured equipment bank loan with Gold Bank in connection with the closing. Also, on May 31, 2005, we closed an additional $2.5 million secured convertible debt financing from Laurus. Net proceeds from this second Laurus financing will be used primarily to support our research, development and commercialization opportunities and for general working capital purposes.

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On July 15, 2005, we entered into a clinical development and license agreement with CDC pursuant to which CDC will provide, beginning in February 2006 and subject to certain conditions, up to $7 million in funding (including a $2 million upfront payment and subsequent monthly payments) for the clinical development of our BEMA Fentanyl product. All funds made available to us under our transaction with CDC must be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and therefore will be accounted for by us as a refundable deposit.

We have incurred significant net losses and negative cash flows from operations since our inception. The initial public offering allowed us to pay all of our outstanding debts, including all bank debt, and outstanding obligations resulting from a dispute with a former stockholder and officer. As of June 30, 2005, we had stockholders equity of $4.5 million, versus $0.77 million at June 30, 2004.

We anticipate that cash used in operations will increase significantly in the future as we research, develop, and, potentially, manufacture our technologies and proposed drug formulations. While we believe further application of our BEMA and Bioral® cochleate technologies to other drugs will result in license or other agreements with strategic third parties (which, in turn, we expect, will lead to the commercialization of, and sales generated from, our products and formulations), our principal plan of operations in the next 18 months is focused on our further development of the BEMA and Bioral® cochleate technologies and their use in a limited number of applications, and not on the marketing, production or sale of FDA approved products. In addition, we will, within 60 days of FDA approval of BEMA Fentanyl, be required to repay to CDC all amounts previously funded to us under our agreements with CDC.

We formed Bioral Nutrient Delivery, LLC (which we refer to herein as BND) as a majority-owned subsidiary in January 2003. We sub-license to BND, on an exclusive basis, our cochleate technology for use in the processed food and beverage and personal care product industries. The minority members are Class B founder shareholders with no cost basis and no obligation to fund deficits. Our business plan calls for BND to pay 8% royalties to BDSI, as BND transacts its business in the food and beverage industry. In February, 2003, we made an unsecured loan to BND in the amount of $0.5 million to cover organization expenses and initial working capital requirements. The loan accrues interest at a rate of 4.85% annually; with the principal to be paid back solely from 10% of any royalty revenue that may be received by BND, with payments first applied to interest, then to principal. We are under no obligation to make any capital contributions or any additional loan funds to BND beyond the initial $0.5 million. We also entered into a management services and administrative agreement with BND, which terminated at December 31, 2004. As a result of our decision to focus on other areas of our business in the near-term, we withdrew the pending registration statement relating to our proposed distribution to our stockholders of Class B interest in BND in February 2005 and did not renew the management services agreement. The processed food and beverage and personal care product application of our cochleate technology is not presently a high priority for us. All of the transactions between us and BND eliminate in consolidation.

Our existing cash and cash equivalents, together with the use of proceeds from this offering, our agreement with CDC, and other available financing, including the remaining balances of our existing equity line of credit and grant, and potential new license revenue, is considered by our management to be sufficient to finance our planned operations and capital expenditures for approximately 12 months, 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. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

- public equity markets;
- private equity financings;
- collaborative arrangements;

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grants and new license revenues;

bank loans;

public or private debt; and

redemption and/or exercise of existing public warrants.

There can be no assurance that additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. We believe that the following are some of the more critical judgment areas in the application of our accounting policies that affect our financial condition and results of operations. We have discussed the application of these critical accounting policies with our Board of Directors and its Audit Committee.

Revenue recognition:

Sponsored research amounts are recognized as revenue when the research underlying such payments has been performed or when the funds have otherwise been utilized, such as for the purchase of operating assets. Grant revenue is recognized to the extent provided for under the related grant or collaborative research agreement. Research and development expenses are charged to operations as incurred.

License fees are payments for the initial license of and access to the Company s technology. For nonrefundable license fees received at the initiation of license agreements for which the Company has an ongoing research and development commitment, the Company defers these fees and recognizes them ratably over the period of the related research and development. For nonrefundable license fees received under license agreements where the continued performance of future research and development services is not required, the Company recognizes revenues upon delivery of the technology.

In addition to license fees, the Company may also generate revenue from time to time in the form of milestone payments. Milestone payments are only received and recognized as revenues if the specified milestone is achieved and accepted by the customer and continued performance of future research and development services related to that milestone are not required. The Company, for arrangements where non-refundable upfront fees exist and there are further payments due upon achieving certain milestones, recognizes such revenue pursuant to Emerging Issues

Task Force 00-21, Revenue Arrangements with Multiple Deliverables, whereby multiple deliverables are evaluated to determine whether such deliverables should be considered a single unit of accounting.

Recent accounting pronouncements:

In March 2005, the FASB issued Interpretation No. 47, Accounting for Conditional Asset Retirement Obligations, an interpretation of FASB Statement No. 143 (FIN 47), which requires an entity to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability s fair value can be reasonably estimated. FIN 47 is effective for fiscal years ending after December 15, 2005. The Company is currently evaluating the effect that the adoption of FIN 47 will have on its consolidated resulted of operations and financial condition but does not expect it to have a material impact.

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In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections (SFAS 154), which replaces Accounting Principles Board Opinions No. 20 Accounting Changes and SFAS No. 3, Reporting Accounting Changes in Interim Financial Statements An Amendment of APB Opinion No. 28. SFAS 154 provides guidance on accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005 and is required to be adopted by the Company in the first quarter of fiscal 2006. The Company is currently evaluating the effect that the adoption of SFAS 154 will have on its consolidated results of operations and financial condition, but does not expect it to have a material impact.

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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) conditions occurring in cancer and surgical patients such as:

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

We also believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals. 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 or other fees to our licensors and/or third-party collaborators.

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 certain drugs that were only available by intravenous injection and convert them to formulations that can be taken orally. Our Bioral® drug delivery technology was developed in collaboration with the Universities, each of which has granted us the exclusive worldwide licenses under applicable patents. Our lead Bioral® formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for treating systemic fungal infections. A Bioral® formulation of Amphotericin B would have the potential for oral delivery of a drug that is currently only given by intravenous injection. 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

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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. We license the BEMA drug delivery technology on a worldwide exclusive basis from 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. Under our July 2005 agreement with CDC, CDC will provide up to $7 million towards the Phase III clinical development of BEMA Fentanyl beginning in February 2006. We expect these funds will represent a majority of the funds we will need for such Phase III program.

A second product under development, BEMA LA, 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.

A third product under development, BEMA Zolpidem, is a BEMA formulation of the most widely prescribed drug for the treatment of insomnia. We intend to submit an IND on BEMA Zolpidem during the first quarter of 2006.

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. On July 11, 2005, we received written confirmation from the FDA that our Emezine® submission was accepted for review by the FDA. 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 and (iii) in the near term, the proceeds of this offering and the CDC transaction.

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 $8,571,397. As of the fiscal year ended December 2004, we had exhausted substantially all of the proceeds from our public offering.

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

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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. In early 2005, Dr. Sirgo was named President of our company and in August 2005 was named our Chief Executive Officer. 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 of the Board. 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 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, 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.

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.

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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 agreed to register the shares of common stock underlying the May note and warrant and the June warrants with Laurus with the SEC, which registration statement was declared effective on July 11, 2005.

CDC Development and Licensing Agreement

On July 15, 2005, we entered into a clinical development and license agreement with CDC pursuant to which CDC will provide, beginning in February 2006 and subject to certain conditions, up to $7 million in funding (including a $2 million upfront payment and subsequent monthly payments over a year) for the clinical development of our BEMA Fentanyl product. All funds made available to us under our transaction with CDC must be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and therefore will be accounted for as a refundable deposit.

Under the agreement, CDC is entitled to receive:

- as reference above, a milestone fee equal to the lesser of $7 million or the actual amount provided by CDC for development of BEMA Fentanyl;
- royalties based on net sales of BEMA Fentanyl (including minimum royalties); and
- a portion of any licensing revenue received by us prior to FDA approval of BEMA Fentanyl.

In addition, we granted CDC a warrant exercisable for up to 500,000 shares of our common stock at an exercise price of $3.50 per share. Upon execution of the CDC agreement, all data, information, and intellectual property rights concerning BEMA Fentanyl were exclusively licensed to CDC, subject to CDC s return grant of an exclusive license for us to utilize all such information and rights. Further, CDC shall own all data generated in the course of the product development supported by its funds, provided that we shall have an exclusive license to use such data for purposes of our development and commercialization of BEMA Fentanyl.

CDC s obligation to provide funding for the clinical development of BEMA Fentanyl is conditioned upon, among certain other conditions, our

demonstration of certain technical criteria with respect to BEMA Fentanyl;

initiation of the Phase III clinical trial to be supported by CDC by a certain date; and

establishment of a contractual relationship providing for the supply of BEMA Fentanyl.

CDC shall provide development funding to us in the form of a significant upfront payment, to be made upon satisfaction of the aforementioned conditions, and monthly payments, for a period of twelve months, beginning

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February 10, 2006. The total of the upfront payment and monthly payments shall not exceed, in the aggregate, the lesser of: (i) $7,000,000 or (ii) the costs incurred in conducting the clinical development of BEMA Fentanyl, and such monthly amounts are subject to downward adjustment depending on the achievement by us of patient enrollment targets.

Royalties under the CDC agreement are subject to upward adjustments: (i) for delays in obtaining regulatory approval for BEMA Fentanyl, (ii) for the market entry of certain defined competing products in the United States prior to the first commercial sale of BEMA Fentanyl, or (iii) if the average selling price of BEMA Fentanyl is less than that of certain defined competing products. In the event we do not diligently pursue the development and regulatory approval of BEMA Fentanyl or if we encounter certain specified negative circumstances regarding the development of BEMA Fentanyl, CDC has the right to pursue development and commercialization of BEMA Fentanyl pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of our BEMA Fentanyl assets to CDC, provided that, under certain conditions, we may, despite such negative circumstances, retain our rights to BEMA Fentanyl and continue pursuing its development and/or commercialization itself subject to the reimbursement of all funding provided by CDC and payment of all royalties due, pro rated based on the amount of funding provided by CDC, under the development agreement.

The warrant issued to CDC is exercisable at $3.50 per share and contains certain antidilution provisions with respect to certain issuances of stock (or issuance of securities convertible into stock) at a price per share less than the exercise price stated in the warrant during the six months following its issuance. Also, the number of shares for which the warrant may be exercised are subject to adjustment based on the amount of funding provided by CDC, provided the warrant shall not, in any event, be exercisable for less than 100,000 shares of our common stock. Finally, such warrant expires after the earlier of: (i) 5:00 p.m. Eastern Time on the second anniversary of the approval by the FDA of the first NDA relating to BEMA Fentanyl, (ii) the closing of a sale of all or substantially all of our assets or the acquisition of BDSI by another entity by means of merger or other transaction as a result of which our stockholders immediately prior to such acquisition possess a minority of the voting power of the acquiring entity immediately following such acquisition, or (iii) any liquidation or winding up of BDSI.

Pursuant to the CDC development agreement, we also agreed that, concurrently with the timing of CDC s initial $2.0 million payment to us, we shall enter into a security agreement granting CDC a security interest in assets related to BEMA Fentanyl, which interest terminates upon our payment to CDC of the milestone payment (due within sixty (60) days of FDA approval of BEMA Fentanyl) equal to the lesser of $7 million or the actual amount provided by CDC for development of BEMA Fentanyl.

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 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

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indication of a pharmaceutical that has previously been approved by the FDA. This regulation enables us to partially 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.

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	Pre-clinical	In-house commercialization
Bioral® Amphotericin B	Fungal infections	Pre-clinical	In-house commercialization
BEMA Zolpidem	Insomnia	Pre-clinical	In-house commercialization

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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, and will dedicate proceeds from this offering, toward the development and commercialization of Emezine®, BEMA Fentanyl (which project is being mostly financed through our agreement with CDC), Bioral® Amphotericin B and BEMA LA. Following this offering, we intend to use a small portion of the proceeds from this offering to begin to fund the development of BEMA Zolpidem.

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, investors in this offering and our stockholders generally 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 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.

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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.

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