BIODELIVERY SCIENCES INTERNATIONAL INC
Form SB-2/A
September 23, 2005
Table of Contents

As filed with the Securities and Exchange Commission on September 23, 2005

Registration No. 333-127157

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 3 to

FORM SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BioDelivery Sciences International, Inc.

(Name of small business issuer in its charter)

Delaware	**2834**	**35-2089858**
(State or jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

2501 Aerial Center Parkway, Suite 205

Morrisville, North Carolina 27560

(919) 653-5160

(Address and telephone number of principal executive offices)

Mark A. Sirgo, Pharm. D.

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Morrisville, North Carolina 27560

(919) 653-5160

(Name, address and telephone number of agent for service)

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price [1][2]	Amount of registration fee
common stock, par value $0.001 per share	$ 12,650,000	$ 1,488.91[3]

(1) Includes shares of common stock that the underwriters have an option to purchase solely to cover over-allotments, if any.
(2) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act.
(3) $2,707.10 previously paid.

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

Table of Contents

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

Preliminary Prospectus **Subject To Completion Dated September 23, 2005**

5,000,000 Shares

Common Stock

We are offering 5,000,000 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 22, 2005, the closing sales price for the common stock on the Nasdaq SmallCap Market was $2.25 per share and the closing sales price for the warrants was $0.25 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	$	$
Underwriting discount	$	$
Proceeds, before expenses, to us [2]	$	$

(1) We have granted the underwriters a 30-day option to purchase up to an additional 750,000 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 $, the total underwriting discount will be $ and the total proceeds, before expenses, to us would be $.

(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 , 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 , 2005.

Table of Contents

TABLE OF CONTENTS

You should rely only upon the information contained in this prospectus and the registration statement of which this prospectus is a part. We have not, 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.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights selected information contained in this prospectus. This summary does not contain all of the information you should consider before investing in the securities. Before making an investment decision, you should read the entire prospectus carefully, including the risk factors section, 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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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).

Table of Contents

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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Table of Contents

The Offering

Common stock outstanding prior to this offering	7,269,196 shares
Common stock offered	5,000,000 shares
Common stock outstanding after this offering	12,269,196 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.

Table of Contents

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)

Table of Contents

RISK FACTORS

An investment in our company is extremely risky. You should carefully consider the following risks, in addition to the other information presented in this prospectus 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.

Table of Contents

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.

Table of Contents

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;

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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;

Table of Contents

obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or

redesign our formulations or products, which would be costly and time-consuming.

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

Table of Contents

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

Table of Contents

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;

Table of Contents

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.

Table of Contents

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,

Table of Contents

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, will 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 36.7% 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:

Table of Contents

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. Assuming an offering price of $2.20, you will incur immediate and substantial dilution of $1.31, or approximately 60%, 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,

Table of Contents

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 no 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

Table of Contents

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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Table of Contents

NOTE ON FORWARD LOOKING STATEMENTS

Certain statements contained in this prospectus constitute forward-looking statements as that term is defined under the Private Securities Litigation Reform Act of 1995 and releases issued by the SEC and within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, 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.

Table of Contents

USE OF PROCEEDS

We estimate that we will receive approximately $9.78 million in net proceeds from the sale of our common stock in this offering, or approximately $11.3 million if the underwriters over-allotment option is exercised in full, based on an assumed public offering price of $2.20 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	18%
Clinical development costs associated with BEMA LA	$ 3.14 million	32%
Clinical development costs associated with BEMA Zolpidem	$ 0.50 million	5%
Pre-clinical work associated with BEMA Fentanyl[2]	$ 2.00 million	20%
General corporate purposes, including working capital[3]	$ 2.45 million	25%
Total	$ 9.78 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.

Table of Contents

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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Table of Contents

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 5,000,000 shares of common stock in this offering at an assumed public offering price of $2.20 per share, after deducting the underwriters discount and commission and payment of the advisory fee to Ferris, Baker Watts, but excluding 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	$ 11,570
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, 12,269,196 pro forma outstanding	7	12
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	27,487
Treasury stock, at cost, 35,490 shares	(108)	(108)
Accumulated deficit	(18,273)	(18,273)
Total stockholders equity	4,495	14,275
Total Capitalization	$ 9,152	$ 18,933

(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.

Table of Contents

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 assumed issuance and sale of 5,000,000 shares of our common stock in this offering and our receipt of approximately $9,785,000 in net proceeds from that sale, based on an assumed public offering price of $2.20 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 $10.9 million, or $0.89 per pro forma share of common stock. This represents an immediate increase in pro forma net tangible book value of $0.73 per share to existing stockholders and an immediate dilution of $1.31, or approximately 60%, per share to new investors participating in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share	$ 2.20
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	$ 0.73
Pro forma as adjusted net tangible book value per share after this offering	$ 0.89
Dilution per share to new investors participating in this offering	$ (1.31)

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 750,000 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 $12.7 million, or $0.97 per share. This represents an immediate increase in the pro forma net tangible book value of $0.08 per share to existing stockholders and immediate dilution of $1.23 per share to new investors participating in this offering.

Table of Contents

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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Table of Contents

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 $9,785,000 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)

31

Table of Contents

	As of June 30, 2005 (unaudited) (in thousands)	
	Actual	**As Adjusted[1]**
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 1,790	$ 11,575
Working capital (deficit)	(1,227)	8,558
Total assets	9,152	18,937
Notes Payable	1,098	1,098
Long-term liabilities	1,098	1,098
Total stockholders equity	$ 4,495	$ 14,280

(1) The as adjusted unaudited consolidated balance sheet data as of June 30, 2005 gives effect to the sale of the 5,000,000 shares of common stock we are offering pursuant to this prospectus, at an assumed public offering price of $2.20 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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Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

38

Table of Contents

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.

Table of Contents

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.

Table of Contents

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;

41

Table of Contents

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.

Table of Contents

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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Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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

48

Table of Contents

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

Table of Contents

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.

Table of Contents

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® Amphotericin B

Systemic fungal infections continue to be a major domestic and international health care problem. Amphotericin B, which is delivered intravenously, is an established, commonly used drug to treat these infections. We are currently developing a Bioral® formulation of Amphotericin B for treatment of fungal infections which we expect will be for the treatment of esophageal candidiasis. We plan to submit an IND to the

Table of Contents

FDA and proceed into clinical trials in 2006. In late July 2005, we received an indication from the NIAID that such institution would, at its expense, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. We believe these studies, if they occur, represent an important third-party validation of our encochleation technology. We also believe these studies will result in cost savings for us as they are being funded by NIAID.

In the last year, we have successfully sourced phosphatidylserine, or PS, from lecithin derived from soybeans rather than synthetic PS, thereby reducing the costs of goods for our delivery system. In addition, we have simplified our manufacturing approach to Bioral® Amphotericin B, thereby facilitating commercial scale-up. Also, we have changed the ratio of PS to active molecules, thus improving the efficacy while moderating costs. We are currently investigating the pharmacology and toxicology in animals. We estimate that the total development costs of this formulation will be approximately $9.3 million.

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

The primary advantage which we are seeking for our proposed Amphotericin B product is an oral formulation of the drug. Additional potential advantages include improved safety, extended shelf life, improved cellular uptake and reduced dosage. Assuming that we complete development of our proposed Bioral® Amphotericin B formulation and that we obtain FDA approval, we believe that Bioral® Amphotericin B may provide an effective orally administered version of Amphotericin B which may be more effective and less toxic.

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

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

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

Our license agreement with Accentia was amended effective June 1, 2004, then modified in September 2004 by the asset purchase agreement with Accentia describe below, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. According to the terms of the license as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales of covered products in the designated field. Accentia estimates that annual prescription cost for its CRS product will be approximately $1,000 per patient. Accentia is responsible for all expenses related to the development of an

52

Table of Contents

encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

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

BEMA Technology Overview

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

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

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

Emezine® and Current BEMA Formulations In Development

Emezine®

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

Anti-nausea, also known as anti-emetic, products are provided as injectable, oral and rectal formulations. Injectable products require that the patient be in a medical facility and have an intravenous injection line in place. Oral products have limitations because delayed gastric emptying that is associated with nausea and vomiting impedes the absorption of the product and actual product ingestion can be nauseating. Rectal suppositories are

Table of Contents

inconvenient as well as slow and unpredictable in onset. We believe, therefore, that an alternative delivery system is necessary for anti-emetic products, the market for which we estimate to be approximately $2 billion dollars in the United States.

We believe that our licensed Emezine® tablet:

- Will be the first transmucousally delivered anti-emetic in U.S. market place;
- May offer predictability and speed of onset similar to intravenous injections; and
- Will avoid the discomfort of injections and the inconvenience of suppositories.

Postoperative nausea and vomiting, or PONV, occurs in approximately 30% of patients undergoing operative procedures. Many factors influence the risk and severity of PONV. These include patient specific factors (age, gender), operative procedure (type and duration of procedure) anesthetic related factors (type and duration) and postoperative factors (presence of pain, oral intake). Although significant progress has been made in the prevention of symptoms, patients continue to have difficulty with PONV. Vomiting can result in dehydration, electrolyte imbalances, prolonged recovery room stay, hospital admissions and loss of work.

Anti-emetic agents are most effective when given prior to the surgical procedure or at cessation of anesthesia and frequently must be continued for several hours after the operative procedure. Products commonly employed for prevention and treatment of PONV are limited to dopamine receptor antagonists (droperidol, prochlorperazine) and serotonin receptor antagonists (ondansetron, granisetron, dolasetron, palonosetron). Dopamine receptor antagonists were the first agents used for PONV and remain the most effective agents.

Chemotherapy induced nausea and vomiting, or CINV, occurs in 70% to 80% of patients receiving different regimes of chemotherapy. CINV is classified five (5) different ways:

- *Anticipatory*: nausea and vomiting occurring as a conditional response from previous chemotherapy;
- *Acute*: acutely within the first 24 hours of the patient receiving their chemotherapy regimen;
- *Delayed*: nausea and vomiting occurring 24 hours after chemotherapy administration (may begin as early as 16 hours after chemotherapy);
- *Breakthrough*: nausea and vomiting occurring despite preventative therapy; and
- *Refractory*: nausea and vomiting occurring during subsequent cycles of chemotherapy when anti-emetic prophylaxis or rescue therapy (or both) has failed in earlier cycles.

Various classes of drugs have efficacy against acute emetogenic chemotherapy and radiotherapy. These include dopamine receptor antagonists, cannabinoids, corticosteroids and the serotonin (5-HT3) receptor antagonists. Emezine® s active ingredient has activity against Acute, Delayed and Breakthrough CINV. Nausea and vomiting also occur in relation to other conditions such as migraine, vertigo, viral illness and the use of opiod analgesics. Dopamine receptor antagonists are utilized to treat nausea and vomiting caused by many of these conditions.

Based on our market research, we believe that Emezine® may be able to participate in the CINV, PONV and the general nausea and vomiting markets. Such research indicates that Emezine® may be able to achieve peak sales of approximately $25 million annually, although no assurances can be given of this estimation.

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. In addition, 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.

Table of Contents

BEMA Fentanyl

The global market for pain medication generates annual sales of over $24 billion. Between $2 billion and $4 billion is spent to treat breakthrough pain. The leading product for breakthrough cancer pain is the U.S. market is Actiq, which had reported sales of $345 million in 2004 and is projected to exceed sales of $400 million in 2005. We believe there is a clear need and growing market for additional narcotic agents in alternative dosage forms to provide rapid pain relief. Fentanyl belongs to the group of medicines called narcotic analgesics. Narcotic analgesics are used to relieve pain. The transmucosal form of fentanyl is a powerful narcotic used to treat breakthrough cancer pain. Fentanyl applied with our licensed BEMA technology has the potential to meet the need for new narcotics and, we believe, will be ideal for breakthrough pain in opioid-tolerant patients.

After receiving approval for the initial indication of break-through cancer pain, we may pursue additional indications for BEMA Fentanyl in:

Post-operative patients following step-down from intravenous narcotics;

Hospitalized patients or outpatients without intravenous access; and

Emergency room patients where available intravenous lines are limited or impractical.

In March 2005, we announced that we received confirmation from the U.S. Food and Drug Administration that we will be able to utilize the FDA s 505(b)(2) process for regulatory approval consideration of our licensed BEMA Fentanyl formulation. As a result of this guidance, we plan to enter BEMA Fentanyl into Phase III clinical studies in the second half of 2005. We estimate that the total development costs of this formulation will exceed $7 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, although no assurances can be given of this estimation. 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.

BEMA Long Acting Analgesic

In addition to our lead BEMA product, BEMA Fentanyl, we are also developing a second analgesic product with a longer duration of action suited for a broad range of pain conditions. The pain market is well established with many pharmaceutical companies marketing innovative products as well as generic versions of older, non patent protected products. The market recognized 2004 sales of $21 billion and is estimated to grow to $29.8 billion by 2008. BEMA LA is formulated with a marketed opioid analgesic which has equal potency to morphine but with a lower propensity for adverse reactions and addiction. The lower potential for addiction places BEMA LA as a Schedule III controlled substance versus the majority of the other potent opioids, such as morphine and oxycodone, which are Schedule II. This may help create a broader market opportunity for BEMA LA as doctors are able to call Schedule III prescriptions into the pharmacy whereas the prescription for a Schedule II controlled substance must be obtained by the patient from the doctor s office which the patient then must take to the pharmacy for filling.

The FDA-approved compound which forms the basis of BEMA LA has been shown to produce comparable pain relief to morphine, with an improved safety profile and extended duration of action, but poor oral bioavailability. The BEMA delivery system may enable us to provide this

product in a form suitable for ambulatory care and, because of the safety advantage associated with this product, we believe that BEMA LA will be an ideal next step product for patients with incomplete pain relief on non-narcotic analgesics.

Our proposed BEMA formulation of this long acting analgesic is intended to meet the need for a new narcotic and will be ideally used for:

Table of Contents

Post-operative pain;

Chronic pain, including lower back, osteoarthritis and rheumatoid arthritis; and

breakthrough pain.

Compared to the competition under development and the currently marketed products, we believe that BEMA LA will be differentiated based on the following features:

efficacy equivalent to morphine but unlike morphine is a Schedule III narcotic making it more convenient for physicians to prescribe, pharmacists to dispense, and patients to obtain,

broad applicability across a wide spectrum of patients with varying types of moderate to severe pain either used in combination with less potent analgesics such as Nonsteroidal anti-inflammatory drugs, or NSAIDS, or used as sole therapy,

a longer half life which allows for less frequent dosing than Tramadol®, many of the NSAIDs and the other potent opioids increasing patient compliance,

an established safety profile compared to the agents in development, and

potential for improved safety including a lower propensity for addiction over other opioid analgesics.

We expect to submit an IND for BEMA LA in the second half of 2005. Entrance into clinical trials will follow immediately thereafter. We estimate that the total development costs of this formulation will be approximately $8.3 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, although no assurances can be given of this estimation.

BEMA Zolpidem

In addition to our two BEMA analgesic products, we are also commencing development of a BEMA formulation of Zolpidem, an FDA-approved compound that has been shown to effectively treat transient and chronic insomnia with few next day residual effects. The standard form of Zolpidem, a swallowed pill, has a typical onset of action 30-45 minutes after taking an oral dose, although this could vary depending on, among other things, the content of the stomach at the time of ingestion. The BEMA delivery system may enable us to provide an onset of action which is in the 10-15 minute range and, since the digestive tract is avoided, potentially provide drug absorption on a more consistent basis. Our proposed BEMA formulation of Zolpidem is intended to meet the need for a product to treat insomnia that has a rapid onset and will be ideally used as a short term treatment for patients with insomnia.

The insomnia market is well established with many pharmaceutical companies marketing innovative products as well as generic versions of older, non patent protected products. The market recognized 2004 sales of $2.3 billion is estimated to grow to $3 billion by 2007 and to $5 billion in 2010. BEMA Zolpidem will compete in this market with an indication for the short term treatment of insomnia. Zolpidem is the active ingredient in Ambien®. Ambien® is the world s best selling product for insomnia with 2004 sales of $1.4 billion.

Compared to the competition under development and the currently marketed products, we believe that BEMA Zolpidem is differentiated based on the following features:

- onset of effect in 10-15 minutes versus 30-45 minutes with orally dosed products,
- no water necessary for administration, reducing the need for elderly patients to urinate during the night, and
- absorption not effected by delayed stomach emptying or first pass metabolism therefore provides for a predictable response every time it is used.

Table of Contents

Due to these advantages, we believe that BEMA Zolpidem will effectively compete against current and future insomnia products.

We expect to finalize a formulation for BEMA Zolpidem and file an IND by the end of the first quarter of 2006. This will allow us to enter Phase I clinical trials during mid-2006. Based on the outcome of several Phase I studies to determine the ideal strength and formulation of BEMA Zolpidem, we would anticipate entering into Phase III clinical trials. We estimate that the total development costs of this formulation will be approximately $8.3 million.

Due to the rapid onset characteristics of BEMA Zolpidem, our market research indicates that BEMA Zolpidem has the potential to achieve a 5% share of the total worldwide insomnia market which has a 2010 projected value of approximately $5 billion. This would translate into an estimated $250 million in peak annual sales, although no assurances can be given of this estimation.

Licensing Opportunities and Other Projects

In addition to the foregoing, we have in the past dedicated resources to other projects. Given our limited resources, we decided during 2004 and 2005 to either focus exclusively on seeking licensing or similar collaborative opportunities for these projects and/or significantly scale back, outsource or place these projects on hold. If there are additional funds remaining from the use of proceeds of this offering, we may apply such funds to such products or formulations, which include:

Bioral® siRNA. Small interfering RNA, or siRNA, is a new class of oligonucleotides that may offer the ability to identify therapeutics directly based on genomic information of the host or pathogens. Like other oligonucleotide candidates such as antisense, siRNA is very susceptible to degradation by plasma enzymes. In early 2005, we established a collaborative research agreement with a major pharmaceutical company to explore the use of our cochleate delivery technology for systemic and oral delivery of siRNA, and we will likely continue to search for collaborators and strategic partners in this area.

Bioral® NSAIDS. We have targeted inflammation disorders, such as arthritis, for development of Bioral® products, based upon accepted, unpatented, over-the-counter and prescription anti-inflammatory drugs such as generic aspirin or ibuprofen. Various types of over-the-counter anti-inflammatory compounds are currently available. NSAIDs significantly decrease inflammation at higher dosages. We believe that Bioral® cochleates may be used to effectively deliver anti-inflammatory drugs with reduced side effects. The primary advantages which we are seeking for our proposed Bioral® anti-inflammatory products include reduced gastrointestinal side effects, reduced required dosage and improved cellular uptake. Anti-inflammatories formulated within cochleates are inside a multi-layered solid particle which we believe may enhance the safety and efficacy profiles and could potentially transform the compounds into an entirely new class of improved anti-inflammatory drugs.

In early 2005, we announced that, in laboratory testing, we applied our licensed Bioral® nanocochleate drug delivery technology to aspirin and traditional NSAIDS that are not selective COX-2 inhibitors. We contracted with an independent testing laboratory to test Bioral® formulations of aspirin and other NSAIDs in a well-established animal model of inflammation. These proof-of-principle animal studies have demonstrated that encochleated NSAIDS enabled a statistically significant reduction in gastro-intestinal toxicity (e.g., ulceration) compared to standard formulations at clinically-relevant high doses of these NSAIDs and aspirin while providing comparable anti-inflammatory effects.

Bioral® Paclitaxel. Paclitaxel is one of the most commonly prescribed chemotherapies for solid tumors such as breast cancer. Paclitaxel is very insoluble in water and is currently available in either a cremophor formulation, which often has significant vehicle-related toxicities, or in a

formulation composed as paclitaxel bound to albumin. Both are available as injections. We are working on an oral form of paclitaxel, making therapy for patients more convenient and reducing the risks associated with intravenous therapies.

Table of Contents

Autologous HIV Therapy. We have developed and are investigating our patented autologous (patient-specific) HIV therapy for AIDS which uses a cochleate related (proteoliposome) delivery vehicle. Currently, we are investigating the potential cost for the research and administrative efforts that would be necessary to obtain an FDA approved IND necessary to continue this program. If these costs turn out to be prohibitively high, we may elect to not pursue this program or seek a development and commercial partner.

Subunit HIV Vaccine. We are also developing a subunit HIV vaccine formulation with our cochleate technology that may have the ability to work following oral administration. This program is currently funded via an NIH grant which expires during 2005. We plan on evaluating a potential extension of this grant in 2005.

Bioral Nutrient Delivery, LLC. In January 2003, we formed Bioral Nutrient Delivery, LLC to investigate the potential application of our proprietary encochleation technology for use in processed food and beverages and personal care products. While our preliminary findings suggest that, by using our encochleation technology, a variety of nutrients, which are substances with potentially beneficial properties, might be protected from degradation during the manufacturing process and delivered with substantially all of the characteristics of the nutrient intact, the BND opportunity is not presently a high priority for us.

Relationship with The University of Medicine and Dentistry of New Jersey and Historical Relationship with Albany Medical College

We have had and continue to have critical relationships with UMDNJ and Albany Medical College. Some of our scientists were former researchers and educators at these Universities researching cochleate technology. All of our current research and development is done using facilities provided to us on the campus of UMDNJ, pursuant to a lease, or at the facilities of our contractors or collaborators. Both of these Universities are stockholders in our company and have a substantial financial interest in our business.

In September 1995, we entered into a license agreement with the Universities to be the exclusive worldwide developer and sub-licensor of the cochleate technology. Under the license agreement, we and the Universities have also jointly patented certain aspects of the cochleate technology and co-own such patents with them. Pursuant to the license agreement, we agreed that each University would be issued an equity interest in our capital stock, originally equal to 2% of our outstanding capital stock. These arrangements were subsequently revised in December, 2002. On December 16, 2002, we amended our license agreement with the Universities to provide for a decrease in the royalty payments to be paid to the Universities on sublicenses in consideration of an increase in the royalty on product sales and the issuance to the Universities of options to purchase shares of our common stock. As of June 30, 2005, UMDNJ owns 139,522 shares (including shares issued under a research agreement) and warrants to purchase 9,951 shares of our common stock at $3.06 and 75,000 options to purchase our common stock at a price per share of $2.37. As of June 30, 2005, Albany Medical College owns 2,222 shares of our common stock and warrants to purchase 9,951 shares of our common stock at $3.06 and 75,000 options to purchase our common stock at a price per share of $2.37. There are no further requirements to provide either University any additional equity interests in our company.

The license agreement, as amended, grants us an exclusive license to the cochleate technology owned by these Universities and obligates us to pay a royalty fee structure as follows:

(a) For commercial sales made by us or our affiliates, we shall pay to the Universities a royalty equal to 5% of net sales of cochleate products; and

(b) For commercial sales of cochleate products made by any of our sublicensees, we shall pay to the Universities royalties up to 5% of our revenues received from the sublicensee from the sale of such products.

Our royalty payments to the Universities will be divided equally among them pursuant to the license. In 2004, we accrued a $125,000 royalty payment to the Universities in connection with our $2.5 million asset sale to Accentia.

In April 2001, we entered into a research agreement with UMDNJ whereby we agreed with UMDNJ to share the rights to new research and development that jointly takes place at UMDNJ s facilities until

Table of Contents

December 31, 2005. We also agreed to provide UMDNJ with progress and data updates and allow its researchers to publish certain projects. We lease our research facilities totaling approximately 8,000 square feet located on their campus pursuant a lease agreement ending December 31, 2005. The monthly rent was $3,340 for 2001, $3,840 for 2002, $4,340 for 2003, $4,840 for 2004 and $5,340 for 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.

In addition to our rent payments, we have also agreed to pay for certain other services provided by UNDNJ. These include two employees from UNDNJ for a total of $209,811.45, a budget to purchase supplies and chemicals (adjusted to exact cost), and an indirect cost factor constituting 8% for 2001 (12% in 2002, 16% in 2003, 20% for 2004 and 24% for 2005) of the direct costs of the employee costs and chemicals.

Collaborative and Supply Relationships

We are a party to collaborative agreements with universities, government agencies, corporate partners, and contractors. Research collaboration may result in new inventions which are generally considered joint intellectual property. Our collaboration arrangements are intended to provide us with access to greater resources and scientific expertise in addition to our in-house capabilities. We also have supply arrangements with a few of the key component producers of our delivery technology. In addition to our relationship with CDC, our collaborative and supply relationships include:

Atrix Laboratories, Inc. On May 27, 2004, prior to its acquisition by us, Arius entered into a worldwide, exclusive royalty-bearing license agreement with Atrix to develop, market, and sell products incorporating Atrix s BEMA technology, including its BEMA Fentanyl product, and to use the BEMA trademark in conjunction therewith. The BEMA delivery technology consists of an easy to use, dissolvable, dime-sized polymer disc that is applied to the mucus membrane of the mouth. All research and development related to the BEMA technology, including three existing INDs, have been transferred to Arius in accordance with the Atrix license agreement.

Under the terms of the Atrix license agreement, we are required to pay Atrix: (i) an upfront licensing fee of $1 million, which was paid in August 2004, (ii) additional cash payments upon achievement of certain developmental and regulatory milestones, (iii) for reimbursement for research and development support, and (iv) royalties on commercial sales of all BEMA products. A joint development management committee comprised of representatives of our company and Atrix oversees product development. We are responsible for the research and development of the products, including costs and expenses, and for their sale, marketing, manufacture and distribution. Atrix retains certain co-promotion rights to the BEMA Fentanyl product.

Reckitt Benckiser Healthcare (UK) Limited. Effective January 6, 2004, Arius entered into an exclusive royalty-bearing license with Reckitt Benckiser Healthcare (UK) Limited to develop, market, and sell Reckitt s Emezine® (buccal prochlorperazine maleate) product for the treatment of nausea and vomiting in the United States, and to use the Emezine® trademark in conjunction therewith. Under the terms of the license agreement, we are required to pay Reckitt: (i) an upfront licensing fee, which has been previously paid in accordance with the Reckitt agreement, (ii) an additional cash payment upon achievement of a certain developmental and regulatory milestone, and (iii) royalties on commercial sales of the licensed product. We are responsible for the development of the product, including costs and expenses, and for its sale, marketing, and distribution in the United States. In addition, we shall be required to obtain from Reckitt, and Reckitt shall be required to supply to us, at our expense, all product to be sold under the license.

Sigma-Tau. In January 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. 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. This upfront payment was made in

59

Table of Contents

consideration of unregistered shares of our common stock priced at $4.25 a share. The stock purchase agreement with Sigma-Tau provides for the acquisition 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.

Pharmaceutical Product Development, Inc. On December 31, 2002, we entered into an agreement with Pharmaceutical Product Development, Inc. (NASDAQ:PPDI), which we refer to herein as PPDI, pursuant to which PPDI was granted a license to apply our Bioral® nano-delivery technology to two therapeutic products. In connection therewith, we received a $2 million up-front royalty payment. In addition, the terms of the license require additional royalty payments based on regulatory milestones and a running royalty rate based on worldwide sales.

Potential siRNA Partner. In early 2005, we entered into a pre-evaluation agreement with a major pharmaceutical company focusing on siRNA targets. The goal of the agreement is to generate proof of concept of the ability of our nanochocleates to successfully formulate the siRNA targets. After proof of concept is achieved, the agreement has an option to progress these targets to therapeutics at which time royalties will be discussed.

National Institutes of Health. To investigate the properties of new antifungal cochleate formulations. Grants totaling approximately $2.7 million have been awarded to us by NIH for the development of our proposed Amphotericin B product. Additionally, we are conducting anti-fungal studies using our Bioral® drug delivery technology through NIH selected and paid contractors. The NIH has reserved broad and subjective authority over future disbursements under the grant. While no objective or specific milestones for future disbursements have been established by the NIH, we must generally demonstrate to the satisfaction of the NIH that our research and use of proceeds are consistent with the goal of developing a formulation for the oral delivery of Amphotericin B. Furthermore, we are required to submit to the NIH an annual report of activities under the grant. To date we have received all expected disbursements under the NIH grant and anticipate that no future disbursements will be made by the NIH under the terms of the grant.

Additionally, 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.

Public Health Research Institute of New York. To investigate our proposed Amphotericin B product and other anti-fungal applications of our drug delivery technology. This relationship may involve shared expense reimbursement and shared intellectual property with regard to joint inventions.

We also have agreements with entities that are affiliated with and partially-owned by key members of our board of directors and management to conduct research and license certain proposed drugs. See Certain Relationships and Related Transactions for affiliations with our management.

As of December 31, 2001, our board of directors appointed an audit committee consisting of independent directors to review all agreements and transactions which have been entered into with related parties, as well as all future related party transactions. At the meeting the independent board members, with Dr. O Donnell abstaining, and after seeking and reviewing advice from an independent valuation firm and inquiring about the details of the various transactions, ratified all prior related party transactions. Subsequent to this meeting, the audit committee independently ratified these agreements. During 2004, after compliance with our internal policies and procedures, we also entered into several new related party contracts. The following are the related-party agreements entered into prior to our initial public offering and subsequently:

Accentia Biopharmaceuticals, Inc. We have several business relationships with Accentia Biopharmaceuticals, Inc. and its affiliates. HCG, which is controlled by Dr. Frank O Donnell, our Chairman of the Board and which owns a significant percentage of our common stock as of the date of

60

Table of Contents

this prospectus, as well as all of our Series B Convertible Preferred Stock, is a significant stockholder of Accentia. In addition, Dr. O Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, is the Treasurer and Corporate Secretary of Accentia.

Amphotericin B License. On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from the Mayo Foundation for the treatment of CRS and asthma on a worldwide basis. The technology consists of using low-dose topical antifungals to control the debilitating symptoms of CRS and asthma. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indications of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

Arius/TEAMM Distribution Agreement. On March 17, 2004, Arius granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc., or TEAMM, with respect to Arius licensed Emezine® product for the treatment of nausea and vomiting. TEAMM is a specialty pharmaceutical company and wholly-owned subsidiary of Accentia. As part of this agreement, TEAMM has agreed to pay for the development costs of Emezine®. We received development cost reimbursements of $1.0 million in 2004 from Accentia in connection with this agreement.

Analytica International Market Studies. During 2004, Analytica International, a provider of research, commercialization, and communications services to the pharmaceutical and biotechnology industries and a subsidiary of Accentia, performed two market studies for us. We paid Analytica $47,800 for these reports, some of which we paid in 2005.

RetinaPharma Technologies, Inc. We previously entered into a license agreement with this development-stage biotechnology company to use our delivery technology in connection with their proposed nutraceutical product with potential application for macular degeneration and retinitus pigmentosa, a disease affecting the retina, and through an agreement with Tatton Technologies, LLC (which subsequently merged into RetinaPharma), certain apoptotic drugs and apoptotic naturally occurring substances to treat certain neuro-degenerative diseases. This exclusive worldwide right to use our Bioral® drug delivery technology in conjunction with their effort to develop, commercialize and manufacture their proposed products, or to sublicense to a third party, is only for the purpose of treating antiapoptotic pharmaceutical and nutraceutical treatment of retinal disease and glaucoma. These licenses shall remain in effect as long as RetinaPharma remains in compliance with the terms of the agreements. HCG, one of our significant stockholders, and Dr. Francis E. O Donnell, Jr., our Chairman of the Board, are affiliated as stockholders and a director of RetinaPharma.

Biotech Specialty Partners, LLC. We have entered into a non-exclusive distribution agreement with Biotech Specialty Partners, LLC, or BSP, a development-stage distribution company, to market and distribute our proposed products once we have completed the commercialization of our products. Our financial arrangement with BSP requires us to sell to BSP all of our proposed products, as and when purchased by with BSP at a cost which is the lesser of:

(i) ten percent (10%) below the lowest wholesale acquisition cost, inclusive of rebates, quantity discounts, etc.; and

(ii) the lowest cost at which we are then selling the product(s) to any other purchaser. The term of the agreement shall be for a term of five years once a product becomes available for distribution. BSP is a start-up enterprise, which to date has not distributed any pharmaceutical products.

These agreements generally provide that, except for on-going development costs related to our cochleate drug delivery technology, we are not required to share in the costs of the development of the pharmaceutical product or technologies of these companies. In connection with our acquisition of Arius, BSP waived its rights

61

Table of Contents

under its distribution agreement with us with respect to all of Arius products. HCG, which is affiliated with Dr. Francis E. O Donnell, Jr., our Chairman of the Board, are affiliated as stockholders, and a member of the management, of Accentia.

We are entitled to receive the following royalty and other payments:

Accentia Biopharmaceuticals, Inc. Under our license agreement with Accentia as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales in the U.S. of its CRS products and other products in the designated field. On September 8, 2004, we entered into a definitive Asset Purchase Agreement with Accentia pursuant to which we sold to Accentia an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of $2.5 million. The royalty revenue stream sold was a fifty percent (50%) interest in the future royalties earnable by us on sales by Accentia for products utilizing our topical formulation of our encochleated Amphotericin B for the treatment of CRS, thus effectively reducing our royalty on the sales of such CRS products by 50%. We agreed with Accentia, however, that the future royalty stream sold shall not include royalty payments that are payable by Accentia based on the sale of encochleated products exclusively intended to treat asthma, and the rights to such royalty payments, as originally set forth in the license agreement, shall remain with us.

TEAMM Pharmaceuticals, Inc. Under the distribution agreement with TEAMM, TEAMM: (i) has previously paid to Arius an upfront fee, (ii) has previously paid to Arius an initial milestone payment and shall in the future pay to us certain additional milestone payments upon achievement of certain developmental and regulatory milestones, (iii) shall support our clinical development costs with respect to such product, and (iv) shall pay royalties to us based on the sales of such product. In addition, we shall be obligated to supply TEAMM, at TEAMM s expense, with such products for sale and promotional use. We received development cost reimbursements of $1.0 million in 2004 from Accentia in connection with this agreement.

RetinaPharma Technologies, Inc. We are entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into the proposed products with potential application to various neuro-degenerative diseases. The planned RetinaPharma products are in early stage development and no sales of such products or royalty revenue therefrom is anticipated in the foreseeable future. We are also entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into RetinaPharma s proposed product with potential application to various neuro-degenerative diseases. This latter product (which was transferred to RetinaPharma in its merger with Tatton Technologies, LLC) is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future.

In pursuing potential commercial opportunities, we intend to seek and rely upon additional collaborative relationships with corporate partners. Such relationships may include initial funding, milestone payments, licensing payments, royalties, access to proprietary drugs or potential applications of our drug delivery technologies or other relationships. Our agreements with PPDI, Accentia and Sigma-Tau are examples of these types of relationships, and we will continue to seek other similar arrangements.

Licenses, Patents and Proprietary Information

Our interest in the intellectual property is subject to and burdened by various royalty payment obligations and by other material contractual or license obligations.

In general, the patent position of biotechnology and pharmaceutical firms is frequently considered to be uncertain and involve complex legal and technical issues. There is considerable uncertainty regarding the breadth of claims allowed in such cases and the degree of protection afforded under such patents. While we believe that our intellectual property position is sound and that we can develop our drug delivery technologies, we

cannot provide any assurances that our patent applications will be successful or that our current or future intellectual

Table of Contents

property will afford us the desired protection against competitors. It is possible that our intellectual property will be successfully challenged or that patents issued to others may preclude us from commercializing our drugs.

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, there may be a material adverse effect upon our business plan to commercialize these products.

Most of the inventions claimed in our cochleate 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.

We rely on trade secrets and confidentiality agreements with collaborators, advisors, employees, consultants, vendors and other service providers. We cannot assure you that these agreements will not be breached or that our trade secrets will not otherwise become known or be independently discovered by competitors. Our business would be adversely affected if our competitors were able to learn our secrets or if we were unable to protect our intellectual property.

Cochleate Technology

With respect to our Bioral® cochleate technology and also the liposome technology related to the autologous HIV therapy we have explored, we are the owner and/or the exclusive licensee of nine issued United States patents and six foreign issued patents owned by the parties listed in the chart below. We believe that our licenses to this intellectual property will enable us to develop this new drug delivery technology based upon cochleate and cochleate related technology. Our intellectual property strategy is intended to maximize our potential patent portfolio, license agreements, proprietary rights and any future licensing opportunities we might pursue. With regard to our Bioral® cochleate technology, we intend to seek patent protection for not only our delivery technology, but also potentially for the combination of our delivery technology with

various drugs no longer under patent protection. Below is a table summarizing patents we believe are currently important to our business and technology position.

Table of Contents

Patent Number	Issued	Expires	Title	Owner
EUR0722338	07/25/2001	09/30/2014	Protein- and peptide cochleate vaccines methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,165,502	12/26/2000	09/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,153,217	11/28/2000	01/22/2019	Nanocochleate formulations, process of preparation and method delivery of pharmaceutical agents	BioDelivery Sciences International, Inc., The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,592,894	07/15/2003	01/22/2019	Nanocochleate formulations, process of preparation and method delivery of pharmaceutical agents	BioDelivery Sciences International, Inc., The University of Medicine and Dentistry of New Jersey and Albany Medical College
AUS722647	11/23/2000	09/02/2017	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,994,318	11/30/1999	11/24/2015	Cochleate delivery vehicles	The University of Medicine and Dentistry of New Jersey and Albany Medical College
EUR 812209	05/06/2004	02/22/2016	Cochleate delivery vehicles for biologically relevant molecules	The University of Medicine and Dentistry of New Jersey and Albany Medical College
CA 2,246,754	10/22/2002	02/21/2017	Cochleate delivery vehicles	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,840,707	11/24/1998	11/24/2015	Stabilizing and delivery means of biological molecules	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,834,015	11/10/1998	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
AUS753008	01/23/03	2/22/2016	Cochleate delivery vehicles for biologically relevant molecules	The University of Medicine and Dentistry of New Jersey and Albany Medical College
AUS689505	02/02/1998	09/30/2014	Protein- or peptide-cochleate immunotherapeutics and methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,643,574	07/01/1997	07/01/2014	Protein- or peptide-cochleate immunotherapeutics methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US04,871,488	10/03/1989	10/03/2006	Reconstituting viral glycoproteins into large phospholipid vesicles	Albany Medical College
US04,663,161	05/05/1987	04/22/2005	Liposome methods and compositions	Albany Medical College

Table of Contents

BEMA Technology

We license from Atrix the following U.S. and foreign patents and patent applications relating to the BEMA technology:

Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
08/734,519	US	10/18/1996	5,800,832	09/01/1998	10/18/2016	Bioerodable Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
09/144,827	US	09/01/1998	6,159,498	12/12/2000	10/18/2016	(same as above)
09/069,703	US	04/29/1998	Pending			Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
09/684,682	US	10/04/2000	Pending			(same as above)
10/962,833	US	10/12/2004	Pending			(same as above)
11/069,089	US	03/01/05	Pending			(same as above)
10/763,063	US	01/22/2004	Pending			Bioerodible Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
60/425,508	US	11/12/02	N/A	N/A	N/A	Adhesive Bioerodible Ocular Drug Delivery System
10/706,603	US	11/12/2003	Pending			Adhesive Bioerodible Ocular Drug Delivery System
60/495,356	US	08/15/2003	N/A	N/A	N/A	Adhesive Bioerodible Transmucosal Drug Delivery System
US97/18605	PCT	10/16/1997	N/A	N/A	N/A	Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
4757497	Australia	10/16/1997	729516	05/17/2001	10/16/2017	(same as above)
2,268,187	Canada	10/16/1997	Pending		10/16/2017	(same as above)
2001508037	Japan	10/16/1997	Pending		10/16/2017	(same as above)
9791047	EP*	10/16/1997	0973497	12/11/02	10/16/2017	(same as above)
US99/09378	PCT	04/29/1999	N/A	N/A	N/A	(same as above)
3967899	Australia	04/29/1999	746339		04/29/2019	(same as above)
2,329,128	Canada	04/29/1999	Pending		04/29/2019	(same as above)
2002512950	Japan	04/29/1999	Pending		04/29/2019	(same as above)
99922753	EP	04/29/1999	1079813	02/09/05	04/29/2019	(same as above)
10/121,430	US	04/11/2002	Pending			Process for Loading a Drug Delivery Device
US03/11313	PCT	04/11/2003	N/A	N/A	N/A	(same as above)

* Validated in the following European countries: Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Greece, Ireland, Italy, Netherlands, Sweden.

65

Table of Contents

Emezine®

With respect to Emezine®, we license from Reckitt U.S. Patent No. 4,717,723, issued January 5, 1988, entitled Pharmaceutical Compositions.

Competition

The biopharmaceutical industry in general is competitive and subject to rapid and substantial technological change. Developments by others may render our proposed Bioral® or BEMA technologies and proposed drug formulations (including Emezine®) under development noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Below are some examples of companies seeking to develop potentially competitive technologies. Many of these entities have significantly greater research and development capabilities than do we, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors research, financial, marketing, manufacturing and other resources. Such potential competitive technologies may ultimately prove to be safer, more effective or less costly than any drugs which we are currently developing or may be able to develop. Additionally, our competitive position may be materially affected by our ability to develop or successfully commercialize our drugs and technologies before any such competitor.

Cochleate Technology

While many development activities are private, and therefore we cannot know what research or progress has actually been made, we are not aware of any other drug delivery technology using a naturally occurring drug delivery vehicle or carrier that can be used to simultaneously address two important clinical goals: oral delivery of drugs that normally require injection and targeted cell delivery once the drug is in the body.

Included among the companies which we believe are developing potentially competitive technologies are Emisphere Technologies, Inc. (NASDAQ:EMIS) and Novavax, Inc. (NASDAQ:NVAX), each a publicly-traded company, and CyDex, Inc and NOBEX Corporation, each a privately-held company. We believe that these potential competitors are seeking to develop and commercialize technologies for the oral delivery of drugs which may require customization for various therapeutics or groups of therapeutics. While our information concerning these competitors and their development strategy is limited, we believe our technology can be differentiated because our cochleate technology is seeking to deliver a potential broad base of water soluble and water insoluble (fat or lipid soluble) compounds with limited customization for each specific drug.

We believe that our technology may have cell-targeted delivery attributes as well. Additional companies which are developing potentially competitive technologies in this area may include Valentis Inc. (NASDAQ:VLTS) and Enzon Pharmaceuticals Inc. (NASDAQ:ENZN), both publicly-traded companies, and Flamel Technologies and Inex Pharmaceuticals Corporation, both of which are privately-held companies, which we believe may be seeking to develop technologies for cell-targeted delivery of drugs. American Pharmaceutical Partners (NASDAQ:APPX) has recently received approval for Abraxane, which is a formulation of paclitaxel, which is bound to albumin. This provides for cellular delivery via the gp60 receptor. While we have limited information regarding these potential competitors and their development status and strategy, we believe that our technology may be differentiated because unlike these potential competitors, we seek to use our cochleate to encapsulate the therapeutic to achieve drug delivery into the interior of the cells such as inflammatory cells.

Although the competitors mentioned above are developing drug delivery techniques conceptually similar to ours with respect to encapsulation, or more specifically nano-encapsulation, we believe that our approach is different, proprietary and protected under our licensed and patented technology. One primary way we can be differentiated from our competitors is in our approach of using naturally occurring substances to form a cochleate which encapsulates the drug in a scroll-like multilayered delivery vehicle.

Table of Contents

BEMA Formulations

Included among the companies which we believe are developing potentially competitive technologies to BEMA are Hollis Eden (NASDAQ:HEPH), a publicly-traded company, and TransOral Pharmaceuticals, a privately-held company. We believe that these potential competitors are seeking to develop and commercialize technologies for the buccal delivery for various therapeutics or groups of therapeutics. While our information concerning these competitors and their development strategy is limited, we believe our technology can be differentiated because the BEMA technology provides for a consistent dose based on how the BEMA technology adheres to the buccal membrane and dissolves over a predetermined rate. We are aware that Access Pharmaceuticals is developing a technology which is similar to BEMA. We are exploring options in defense of our patent position in regard to this technology.

For BEMA Fentanyl, in the breakthrough cancer pain area, we believe the most advanced competitors are Cephalon, Inc. (NASDAQ:CEPH) and Endo Pharmaceutical Holdings (NASDAQ:ENDP) both publicly-traded companies. Cephalon s lead product for this indication is Actiq which generated $345 million in sales in 2004. Cephalon will license this product to Barr Laboratories upon approval of OraVescent Fentanyl. This product utilizes an effervescent tablet which is administered buccally. Endo has licensed, from Orexo Pharmaceuticals AB, Rapinyl, which is a polymer formulated sublingual fentanyl tablet indicated for breakthrough cancer pain. This product is administered sublingually. Generex Biotechnology and Arakis, Ltd. are developing sublingual spray formulations of opioids for breakthrough pain. LAB International, Inc. and Delex Therapeutics, Inc are developing inhaled formulations of fentanyl for administration either nasally or across the alveoli in the lungs. While we have limited information regarding these potential competitors and their development status and strategy, we believe that our technology may be differentiated because unlike these potential competitors, BEMA Fentanyl has a predefined residence time on the buccal membrane providing for consistent drug delivery from dose to dose. We believe that all of the competitive formulations of fentanyl will have intra-dose variability.

BEMA LA will be positioned primarily as a first line therapy for post surgical patients. This would include hospital or outpatient surgeries. Market competitors for this indication include but are not limited to: non-steroidal anti-inflammatory (NSAIDs, e.g. ibuprofen), COX-2 inhibitors (Celebrex® from Pfizer), Tramadol (Ultracet® from Ortho McNeil), and potent opioids (hydrocodone combination products from various companies, Oxycontin® from Purdue, Kadian® from Alpharma, Avinza® from Ligand and Duragesic® from Johnson & Johnson).

A secondary focus will be to position BEMA LA as a step up from an NSAID instead of Schedule II narcotics. Indications for such combination use with NSAIDs include pain associated with severe arthritis and lower back conditions. Marketed competitors for these indications include Tramadol and the potent opioids such as morphine and Oxycontin®.

Other competition includes multiple new chemical entities with different mechanisms of action. These include a glutamate antagonist from Neurocrine, a mixed delta/mu antagonist from Enhance Biotech/Alza and multiple COX-2 products from GSK, Sanofi-Aventis, Novartis and Sankyo.

Finally, there are also products under development in special delivery technologies including Tramadol flash dose from Biovail, Tramadol extended release from Labopharm, and sufentanil transdermal patch from Durect/Endo.

BEMA Zolpidem will compete in the insomnia market with an indication for the short term treatment of insomnia. Zolpidem is the active ingredient in Ambien®. Ambien® is the world s best selling product for insomnia with 2004 sales of $1.4 billion. BEMA Zolpidem will be positioned primarily as a first line therapy for insomnia patients. This would include hospital and primary care applications. Market competitors for this indication include but are not limited to: Ambien® (Sanofi-Aventis), Lunesta® (Sepracor) and Sonata® (King Pharmaceuticals).

67

Table of Contents

Other competition includes multiple new chemical entities. These include indiplon (Neurocrine/Pfizer), gaboxadol (Lundbeck/Merck and remelteon (Takeda).

Finally, there are also approved products development in special delivery technologies including zolpidem Flashdose® from Biovail, Ambien® CR, an extended release from Sanofi-Aventis, and Sonata® ER from King Pharmaceuticals.

Emezine®

The nausea and vomiting market is well established with many established pharmaceutical companies marketing products as well as generic versions of older, non patent protected products. The primary classes are the 5HT3 antagonists, the dopamine antagonists, the substance P antagonists, and the antihistamines. The 5HT3 antagonists account for the largest share of the market with GlaxoSmithKline s (NSYE:GSK) Zofran (tablets, injection and solution), which presently accounts for the largest share of the market. MGI Pharma s (NASDAQ:MOGN) Aloxi injection is the newest entry into the market and has gained significant share in a short period of time in the CINV market. Merck s (NYSE:MRK) Emend tablet has the highest revenue of the non 5HT3 drugs. Emend is available by tablet. The rest of the market is covered by the phenothiazines (dopamine antagonists) and antihistamines. These are generically available by injection, tablet or suppository. Emezine will be differentiated in this market due to the buccal route of administration.

Manufacturing

During drug development and the regulatory approval process, we plan to rely on third-party manufacturers to produce our compounds for research purposes and for pre-clinical and clinical trials. Except as provided for under our license agreement with Reckitt for Emezine®, we do not presently have manufacturing arrangements with respect to our intended product. Emezine® will be manufactured by Reckitt in Hall, England. This facility has been inspected by the FDA and is currently used for the manufacture of other products sold in the U.S. The formulation for BEMA Fentanyl development, and initial clinical trial material for the manufacturer, will be done by Dow Pharmaceutical Sciences and Aveva Drug Delivery Systems, Inc., respectively. We are in the process of finalizing an agreement for the manufacture of large scale clinical trial suppliers and a NDA stability batch with a commercial scale manufacturer that currently produces products for the U.S. market on identical equipment to that planned for BEMA manufacture. As our intended products near market introduction, we intend to outsource manufacturing to third party manufacturers, which comply with the FDA s applicable Good Manufacturing Practices. While we are currently seeking manufacturing partners for certain of our products and formulations and believe that such commercial manufacturing arrangements may be available to us in general, no such relationships have been established to date.

We have and intend to purchase component raw materials from various suppliers. As our intended products near market introduction, we intend to seek multiple suppliers of all required components although there may not actually be more than one at that time.

Sales and Marketing

Our marketing strategy, assuming completion of our drug delivery technologies, product and formulation development and regulatory approval, is to market and sell our approved formulations and products under the Bioral®, BEMA or other brand names which we either own or license from third parties. Our commercial efforts will be primarily focused on hospitals, oncologists and pain centers to maintain cost efficiency. We plan to initiate the sales organization around the launch of BEMA Fentanyl with 75-100 representatives focused on physicians, hospitals and

groups who treat cancer patients. For sales and marketing into primary care and geographies outside of the United States, we will explore a wide range of potential arrangements, such as licensing, direct sales, co-marketing, joint venture and other arrangements. Such arrangements may be with large or small pharmaceutical companies, general or specialty distributors, biotechnology companies, physicians or clinics, or otherwise. We have licensed the commercial rights to Emezine® to TEAMM Pharmaceuticals, a subsidiary of Accentia. TEAMM is

Table of Contents

responsible for the sales and marketing of Emezine®. We have a non-exclusive distribution arrangement with Biotech Specialty Partners, LLC, an early-stage alliance of specialty pharmaceutical and biotechnology companies, although BSP has waived its rights with respect to Arius products.

Government Regulation

The manufacturing and marketing of any drug which we formulate with our licensed Bioral® or BEMA technologies and Emezine®, as well as our related research and development activities, are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. We anticipate that these regulations will apply separately to each drug formulation with our drug delivery technologies. We believe that complying with these regulations will involve a considerable level of time, expense and uncertainty.

In the United States, drugs are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our drugs. Drug development and approval within this regulatory framework is difficult to predict and will take a number of years and involve the expenditure of substantial resources.

The steps required before a pharmaceutical agent may be marketed in the United States include:

1. Laboratory and clinical tests for safety and small scale manufacturing of the agent;

2. The submission to the FDA of an IND which must become effective before human clinical trials can commence;

3. Clinical trials to characterize the product and establish its safety and efficacy in the intended patient population;

4. The submission of a NDA or Biologic License Application to the FDA; and

5. FDA approval of the NDA or Biologic License Application prior to any commercial sale or shipment of the product.

In addition to obtaining FDA approval for each product, each product-manufacturing establishment must be registered with, and approved by, the FDA. Manufacturing establishments are subject to biennial inspections by the FDA and must comply with the FDA s Good Manufacturing Practices for products, drugs and devices.

Pre-clinical Trials

Pre-clinical testing includes laboratory evaluation of chemistry and formulation, as well as tissue culture and animal studies to assess the safety and potential efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices. No assurance can be given as to the ultimate outcome of such pre-clinical testing. The results of pre-clinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of clinical trials. Unless the FDA objects to an IND, clinical studies may begin thirty (30) days after the IND is submitted.

We intend to largely rely upon contractors to perform pre-clinical trials.

Clinical Trials

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor

Table of Contents

safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA prior to its conduct. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution where the study will be conducted. The institutional review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The drug product used in clinical trials must be manufactured according to Good Manufacturing Practices.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the product into healthy human subjects, the drug is tested for safety (adverse side effects), absorption, dosage tolerance, metabolism, bio-distribution, excretion and pharmacodynamics (clinical pharmacology). Phase II is the proof of principal stage and involves studies in a limited patient population in order to:

Asses the potential efficacy of the product for specific, targeted indications;

Identify the range of doses likely to be effective for the indicator; and

Identify possible adverse side effects and safety risks.

When there is evidence that the product may be effective and has an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to establish the clinical efficacy and the safety profile of the product within a larger population at geographically dispersed clinical study sites. Phase III frequently involves randomized controlled trials and, whenever possible, studies are conducted in a manner so that neither the patient nor the investigator knows what treatment is being administered. We, or the FDA, may suspend clinical trials at any time if it is believed that the individuals participating in such trials are being exposed to unacceptable health risks.

We intend to rely upon third party contractors to advise and assist us in the preparation of our INDs and clinical trials that will be conducted under the INDs. Two (2) studies were conducted in 2004 under the Emezine® IND. Multiple studies will be conducted in 2005 under the INDs for BEMA Fentanyl, Bioral® Amphotericin B and BEMA LA.

New Drug Application and FDA Approval Process

The results of the manufacturing process development work, pre-clinical studies and clinical studies are submitted to the FDA in the form of a New Drug Application for approval to market and sale of the product. The testing and approval process is likely to require substantial time and effort. In addition to the results of pre-clinical and clinical testing, the NDA applicant must submit detailed information about chemistry, manufacturing and controls that will describe how the product is made. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Consequently, there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may deny a New Drug Application if applicable regulatory criteria are not satisfied, require additional testing or information or require post-marketing testing (Phase IV) and surveillance to monitor the safety of a company s product if it does not believe the NDA contains adequate evidence of the safety and efficacy of the drug. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Post approval studies may be conducted to explore further intervention, new indications or new product uses.

Among the conditions for NDA approval is the requirement that any prospective manufacturer s quality control and manufacturing procedures conform to Good Manufacturing Practices and the specifications approved in the NDA. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of drug and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by other federal, state or local agencies. Additionally, in the event of non-compliance, FDA may issue warning letters and seek criminal and civil penalties, enjoin manufacture, seize product or revoke approval.

Table of Contents

International Approval

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country at this time has its own procedures and requirements.

Other Regulation

In addition to regulations enforced by the FDA, we are also subject to regulation under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Our research and development may involve the controlled use of hazardous materials, chemicals, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of any accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Employees

As of September 22, 2005, we had 19 full-time employees, of which 7 are laboratory scientists and 12 are involved in our operations, administration, accounting and IT. Four of our employees have Ph.D. degrees. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors to support our engineering and support and administrative functions. We consider relations with our employees to be good. Each of our current scientific personnel has entered into confidentiality and non-competition agreements with us.

Description of Property

In early 2005, we relocated our principal executive offices to Arius offices in Morrisville, North Carolina. The lease for this approximately 2000 square foot space terminates in September 2007. Rental payment due on this space are: (i) from February 1, 2005 through September 30, 2005, $2,733.50 per month; (ii) From October 1, 2005 through September 30, 2006, $2,816.33 per month; and (ii) from October 1, 2006 through September 30, 2007, $2,900.82 per month. The landlord for this space is Pizzagalli Properties, LLC. We believe this space is presently adequate for use as our principal executive office.

We conduct our research operations a single site located on the campus of UMDNJ. Pursuant to a five year lease agreement with UMDNJ ending December 31, 2005, we occupy a total of approximately 8,000 square feet. The monthly rent was $3,340 in 2001, $3,840 in 2002, $4,340 in 2003, $4,840 in 2004 and is $5,340 in 2005 plus agreed payments for graduate student assistants, two BDSI executives and supplies used by us. The payments to UMDNJ for certain executive salaries totaled $211,747 for 2004. Historically, the payments for rent and supplies have averaged approximately $75,000 annually. The terms of the lease allows us flexibility of terminating the lease arrangement and relocating to a new space better suited for our long-term space requirements. Our ability to terminate is without a penalty provided that we give prior written

notice. 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.

Table of Contents

Legal Proceedings

On or about April 19, 2004, we were named as the defendant in an action commenced by MAS Capital Inc. in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks monetary damages from us in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for us through an initial public offering. We have provided MAS Capital s counsel with copies of documents executed by either MAS Capital or its affiliates that we allege fully release the Company. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that fully release us, we have filed an Amended Answer asserting a claim for our attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. We filed a motion for summary judgment on June 9, 2005, with a ruling thereon expected in the fourth quarter of 2005. We believe that the plaintiff s claims are without merit and we intend to continue to vigorously defend the lawsuit.

We may, from time to time, be involved in other actual or potential legal proceedings that we consider to be in the normal course of our business. We do not believe that any of these proceedings will have a material adverse effect on our business.

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Table of Contents

DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

Our directors are elected at our annual meeting of stockholders and hold office until their successors are elected and qualified. Subject to applicable employment agreements, our officers are appointed annually by the board of directors and serve at the pleasure of the board. There are no family relationships among any directors, executive officers or significant employees, or among persons nominated or chosen to become a director or executive officer.

Our directors and executive officers and their ages as of September 16, 2005 are as follows:

Name	Age	Position
Francis E. O Donnell, Jr., M.D.	55	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	51	President, Chief Executive Officer and Director
Raphael J. Mannino, Ph.D.	58	Executive Vice President, Chief Scientific Officer and Director
Andrew L. Finn, Pharm.D.	56	Executive Vice President of Clinical Development and Regulatory Affairs
James A. McNulty	55	Chief Financial Officer, Secretary and Treasurer
L.M. Stephenson, Ph.D.	63	Director (*)(**)(***)
William B. Stone	62	Director (*)(***)
John J. Shea	78	Director (*)(**)
William S. Poole	58	Director (**)(***)

(*) Member of Audit Committee
(**) Member of Nominating and Corporate Governance Committee
(***) Member of Compensation Committee

Francis E. O Donnell, Jr., M.D., age 55, has been our Chairman of the Board and a Director on a full time basis since March 29, 2002 when Dr. O Donnell executed an employment agreement to become our full-time interim President and Chief Executive Officer. In January 2005, his employment agreement was amended to reduce his salary to $1 per year and he relinquished the title of President. In August 2005, he relinquished the title of Chief Executive Officer. As a result, since January 2005, he is no longer considered a full time employee of our company. As Chairman of the Board, Dr. O Donnell acts as a liaison between our executive management team and our board of directors and also has general oversight responsibilities. For more than the last six years, Dr. O Donnell has served as managing director of The Hopkins Capital Group, an affiliation of limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare. He is a co-founder and chairman of RetinaPharma Technologies, Inc. which now includes Tatton Technologies, LLC, and a co-founder of Biotech Specialty Partners, LLC, an alliance of specialty pharmaceutical and biotechnology companies. He serves as Chairman and CEO of Accentia Biopharmaceuticals, Inc., a holding company with commercialization assets representing a vertically-integrated platform for specialty pharmaceuticals and biologics. Dr. O Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital. Dr. O Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. Dr. O Donnell holds 34 U.S. Patents. Dr. O Donnell is the 2000 Recipient of the Jules Stein Vision Award sponsored by Retinitis Pigmentosa International. He is a trustee of the Health Careers Foundation and of St Louis University.

Mark A. Sirgo, Pharm.D., age 51, has been our President and Chief Executive Officer and a Director since August 2005 and was our Chief Operating Officer from January to August 2005. He joined the company in August 2004 upon our acquisition of Arius, of which he was a co-founder, in the capacity of Senior Vice President of Commercialization and Corporate Development, and, prior to being named our President, was promoted to Executive Vice President, Corporate and Commercial Development and Chief Operating Officer. As Chief Executive Officer, Dr. Sirgo has direct management responsibility over all of our operations. Dr. Sirgo has more than 20 years of experience in the pharmaceutical industry, including 16 years in clinical drug development

73

Table of Contents

and 7 years in marketing, sales, and business development. Prior to his involvement with Arius from 2003 to 2004, he spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc., a leading contract service provider to the pharmaceutical industry. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

Raphael J. Mannino, Ph.D., age 58, has been our Executive Vice President and Chief Scientific Officer since October 2000, and a Director since October 2001. Dr. Mannino has served as President, CEO, Chief Scientific Officer, and a member of the Board of Directors of BioDelivery Science, Inc. since its incorporation in 1995. Dr. Mannino s previous experience includes positions as Associate Professor, at the University of Medicine and Dentistry of New Jersey (1990 to present), Assistant, then Associate Professor, Albany Medical College (1980 to 1990), and Instructor then Assistant Professor, Rutgers Medical School (1977 to 1980). His postdoctoral training was from 1973 to 1976 at the Biocenter in Basel, Switzerland. Dr. Mannino received his Ph.D. in Biological Chemistry in 1973 from the Johns Hopkins University, School of Medicine.

Andrew L. Finn, Pharm.D., age 56, has been our Executive Vice President of Clinical Development and Regulatory Affairs since September 2004. He joined the company in August 2004 upon our acquisition of Arius, of which he was a co-founder, in the capacity of Senior Vice President of Product Development and was subsequently promoted to his current position. Dr. Finn has more than 20 years experience in pharmaceutical product development. Prior to his involvement with Arius, he was, from 2000 to 2003, Executive Vice President of Product Development at POZEN Inc. with responsibilities for formulation development, non-clinical development, clinical research and regulatory affairs. He participated in the activities leading up to the initial public offering and submitted marketing applications in Europe and the U.S. for 2 migraine products. From 1996 to 1999, Dr. Finn was Co-Founder and Chief Executive Officer of enVision Sciences, a regulatory and clinical service company. From 1991 to 1996, he was Vice President of U.S. Clinical Research for Solvay Pharmaceuticals, where he oversaw NDA submissions in the areas of inflammatory bowel disease, osteoporosis prevention and treatment of obsessive-compulsive disorder. Prior to this he spent 10 years in positions of increasing responsibility at Glaxo Inc., where he oversaw a number of NDA submissions, including Zofran for chemotherapy induced nausea and vomiting. Dr. Finn received his BS in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

James A. McNulty, age 55, has served as our Secretary, Treasurer and Chief Financial Officer on a part time basis (estimated to constitute approximately 50% of his time) since October 2000. Mr. McNulty has, since May 2000, also served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture activities. Hopkins Capital Group is owned and controlled by Dr. Francis E. O Donnell, Jr. Mr. McNulty also serves as the Treasurer and Corporate Secretary of Accentia Biopharmaceuticals, Inc., a holding company with commercialization assets representing a vertically-integrated platform for specialty pharmaceuticals and biologics. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded Pender McNulty & Newkirk, which became one of Florida s largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He served as CFO of Star Scientific, Inc. from October 1998 to May 2000. From June 2000 through January 2002 he served as CFO/COO of American Prescription Providers, Inc. He is a principal in Pinnacle Group Holdings, a Tampa real estate development company. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, and is a member of the American and Florida Institutes of CPA s.

Table of Contents

L.M. Stephenson, Ph.D., age 63, is a member of our board of directors. Dr. Stephenson is currently Vice Provost for Research at Drexel University. He was associated with the University of Medicine and Dentistry of New Jersey from 1995 until 2003, serving as the Vice President for Research with responsibility over developing the research capability, research funding and intellectual property of New Jersey s medical science campuses, including three medical schools, dental, nursing and public health schools and a graduate school of biomedical sciences. He also served as the Acting Associate Dean for Research of the New Jersey Medical School, and served as the Director of Patents and Licensing of the University of Medicine and Dentistry of New Jersey where he was responsible for management of the Intellectual Property Assets, including marketing of patents and establishment of new ventures. His new responsibilities at Drexel are closely similar to UMDNJ. Dr. Stephenson is a graduate of the University of North Carolina where he earned a BS in chemistry and was awarded the Venable Medal for outstanding senior in chemistry. Dr. Stephenson earned his Ph.D. in chemistry from the California Institute of Technology where he earned the Kodak Prize for outstanding chemistry graduate student and was an NSF Predoctoral Fellow. Additionally, Dr. Stephenson was a Research Fellow at Harvard University. Dr. Stephenson also serves on the board of directors of the following institutions: University City Science Center (Non-Profit), and Crescent Genomics.

William B. Stone, age 61, is a member of our board of directors. For thirty years, until his retirement in October 2000, Mr. Stone was employed with Mallinckrodt Inc. For the last twenty years of his career, he held positions of Vice President and Corporate Controller and Vice President and Chief Information Officer for 16 years and 4 years, respectively. Mr. Stone is a graduate of the University of Missouri-Columbia where he earned BS and MA degrees in accounting, and is a Certified Public Accountant.

John J. Shea, age 78, is a member of our board of directors. He is currently the head of his own firm of John J. Shea & Associates and has also been a Quality Systems Adviser with Quintiles, a private consulting firm. Mr. Shea has been employed at John J. Shea Associates since 1989. Mr. Shea has also served in the capacity of Director of Quality Assurance and was responsible for the implementation of quality assurance procedures in a number of public companies. From 1987-1989, he served as Director of Quality Assurance at NeoRx Corporation. Mr. Shea was also the Director of Corporate Quality Assurance at Hexcel Corporation from 1980-1987. Mr. Shea has also served as the quality assurance person for other companies including, Teledyne Relays, Ortho Diagnostics, Inc. and Bio Reagents & Diagnostics, Inc. Mr. Shea earned a B.S. in Chemistry at Bethany College.

William S. Poole, age 58, was appointed to our board of directors on April 28, 2005. He was formerly a member of Arius Commercial Advisory Board. Mr. Poole has extensive experience in the bio-pharmaceutical and medical device industries for over thirty years. From 1972 to early 1996, Mr. Poole worked for Lederle Laboratories, a Division of American Cyanamid Company. During his 24-year career at Cyanamid, Mr. Poole held positions of increasing responsibility and held the position of World-Wide Division President of the Medical Device Division when Wyeth acquired Cyanamid in 1995. After a brief stint as President of Fisons Pharmaceuticals, which was acquired by Rhone Poulenc-Rorer, Mr. Poole went on to become President, North American Pharmaceuticals, of Novo Nordisk Pharmaceuticals, where he served from 1997 to 2000. From 2001 to 2003, he served as President of Biovail Pharmaceuticals. In both of these companies, Mr. Poole was instrumental in aggressively growing revenue, building a solid management team and dramatically improving profitability. As President of these firms, Mr. Poole had total P&L responsibility and directly oversaw vice presidents in charge of manufacturing, research & development, sales, legal, marketing, finance, regulatory and human resources functions. Since his departure from Biovail, Mr. Poole has acted as an independent consultant to the pharmaceutical industry. Mr. Poole graduated from Boston University in 1972 with a B.A. in Psychology.

Director Independence

We believe that William B. Stone, L.M. Stephenson, John J. Shea and William S. Poole qualify as independent directors for Nasdaq Stock Market purposes. This means that our board of directors is comprised of a majority of independent directors as required by NASD rules.

Table of Contents

On September 15, 2005, we received a written deficiency notification from the staff of the Nasdaq Stock Market indicating the staff s view that Donald L. Ferguson was not independent under NASD Rule 4200(a)(15) and that, therefore, our board of directors was not comprised of a majority of independent directors as required by NASD Rule 4350(c)(1). Accordingly, the NASD staff indicated its position that we did not meet the independent director requirement for continued listing on the Nasdaq Stock Market.

As a result of the NASD staff s determination, Mr. Ferguson and Alan Pearce, a director of the Company who was not independent, resigned from our board of directors effective September 15, 2005. We notified the NASD staff of this action and, as a result, the staff provided us with a written notification that we had regained compliance with NASD rules and that this matter is closed.

Scientific Advisory Board

We have established our Scientific Advisory Board as an additional scientific and technical resource for our management team to confer with on an as needed basis. There are no formal or regularly scheduled meetings of the Scientific Advisory Board. Members of our historical advisory board have entered into consulting agreements that provide for expense reimbursements, 10,000 non-qualified stock options and cash compensation of $1,500 for attendance at each formal board meeting.

When we acquired Arius, we added their Scientific Advisory Board members to our Scientific Advisory Board. Simultaneously with such merger, the options held by the Arius Scientific Advisory Board members to purchase shares of Arius common stock were accelerated and converted into shares of Arius common stock. As a result, in the merger, each Scientific Advisory Board member received a small amount of Series A Preferred shares. Such Arius Scientific Advisory Board members have not been granted options to purchase shares of our common stock.

The following is a short discussion of the backgrounds of our Scientific Advisory Board members:

Stephane E. Allard, M.D. is formerly the Vice President of Medical Affairs with Sanofi-Synthelabo, a six billion dollar global pharmaceutical company manufacturing and marketing products such as Plavix, Ambien, Avapro, Hyalgan and Primacor and was responsible for a staff of 120 people. Dr. Allard has served as President of Synthelabo, Inc. and Director of Research and Development at Lorex Pharmaceuticals. At Synthelabo, Dr. Allard was responsible for the start up of Synthelabo, Inc. (USA). He was also key in establishing Phase I through IV clinical activities for products such as Ambien, Kerlone and Alfuzosin, and managed and led the liaison with the FDA and other government agencies. Dr. Allard staffed and led the group s 11 person New Jersey operation and the 40 person (Clinical, Biostatistics, and Data Management) Chicago office. Dr. Allard served as European Clinical Director of Clinical Research from 1990 to 1993 for six divisions in Synthelabo (Paris), France, Director of Clinical Development from 1987 to 1990, and as Associate Director of Clinical Development from 1985 to 1987. From 1978 to 1985, Dr. Allard was Associate Medical Director and Medical Advisor at Wyeth, a division of American Home Products. Dr. Allard received his medical doctorate from Rouen Medical College and has been awarded a Diplomate of CESAM (Certificate of Statistical Studies Applied to Medicine) Ph.D, as well as a Diplomate of Clinical Pharmacology and Pharmacokinetics (Pitie-Salpetriere Hosp.); Paris, France.

Ralph Arlinghaus, Ph.D. is Professor and Chairman of the Department of Molecular Pathology at M. D. Anderson Cancer Center since 1986. Dr. Arlinghaus has an extensive research background and experience in several fields, including small RNA viruses (picornaviruses), retroviruses, including HIV, molecular mechanisms involved in signal transduction, and molecular aspects of leukemia research both at the level of diagnostics and developing novel strategies to treat leukemia. From 1983-1986 Dr. Arlinghaus was Director of Vaccine Development at the Johnson & Johnson Biotechnology Center in La Jolla, CA.

Susan G. Bonitz, Ph.D., has served as a pharmaceutical business development consultant to numerous early-stage biotechnology companies. Until August 2005, Dr. Bonitz served as Director, Business Development for BDSI. She has an extensive research background in molecular biology, including DNA cloning, RNA characterization, and PCR analysis. She has conducted research at Genentech, Exxon Research and Engineering,

Schering-Plough, and Cold Spring Harbor Laboratory. Because of her evaluations of a wide range of

biotechnology companies, she has interacted with both the scientific and business pharmaceutical community. Dr. Bonitz has done extensive editing for two widely used technique publications-Current Protocols in Molecular Biology and Current Protocols in Immunology. She received her Ph.D. from Columbia University in mitochondrial research and has published articles in the field in peer-reviewed journals.

Floyd H. Chilton, Ph.D., is Founder, Director, President, Chief Executive Officer and Chief Scientific Officer of Pilot Therapeutics. Prior to joining Pilot Therapeutics as CEO and CSO in December 2000, Dr. Chilton was Director of Molecular Medicine, Professor of Physiology and Pharmacology, Professor of Internal Medicine (Section on Pulmonary and Critical Care Medicine) and Professor of Biochemistry at the Wake Forest University School of Medicine. Dr. Chilton is widely recognized in academia and industry for his leading work on the role of arachidonic acid metabolism in human diseases.

Jeff Katz, MD is an associate professor of anesthesiology at Northwestern University Medical School. He also serves as director of the Pain Clinic at the Veterans Healthcare Service Lakeside Division as well as associate director of the Section of Pain Medicine at Northwestern Hospital. Dr. Katz has published numerous chapters and papers on the subjects of acute and chronic pain as well as in the area of anesthesiology, and he continues to be active in clinical practice as well as teaching and research. Dr. Katz is on the Arius Scientific Advisory Board.

Celeste Lindley, Pharm. D, MS. FCCP, FASHP, BCPS, BCOP is an associate professor of Pharmacotherapy and Experimental Therapeutics in the School of Pharmacy and clinical associate professor of medical oncology in the School of Medicine at the University of North Carolina at Chapel Hill. Her professional service includes serving as Chair of the ASHP Commission on Therapeutics and Section of Clinical Specialists, Vice Chair of the BPS Oncology Advisory Board and member of advisory committees for the USP and American Society of Clinical Oncology. Her research interests include pharmacokinetics and drug metabolism, as well as clinical research in the management of pain, nausea and vomiting. She has over 150 publications including original research, reviews and book chapters. Dr. Lindley is on the Arius Scientific Advisory Board.

Arthur G. Lipman, Pharm. D, FASHP is a Professor of Pharmacotherapy in the College of Pharmacy, Adjunct Professor of Anesthesiology in the School of Medicine, and Director of Clinical Pharmacology at the University of Utah Hospitals and Clinics Pain Management Center. Dr. Lipman served on both the Acute Pain Management and Cancer Pain Management Guidelines Panel of the U.S. Public Health Service Agency for Health Care Policy and Research. His professional service includes being co-chair of the Arthritis Pain Management Clinical Guidelines Panel of the American Pain Society, the American Cancer Society National Advisory Group on Cancer Pain Relief, the American Pain Society Analgesic Regulatory Affairs Committee and the joint Ethics Task Force of the American Pain Society and American Academy of Pain Medicine. Lipman has over 100 publications and is the founding editor of the Journal of Pain and Palliative Care Pharmacotherapy. Dr. Lipman is on the Arius Scientific Advisory Board.

Gerald Lee Mandell, M.D., MACP is the Owen R. Cheatham Professor of the Sciences and Professor of Medicine at the University of Virginia. He is the founding editor of the world s leading reference source, Principles and Practices of Infectious Diseases and the journal Current Infectious Diseases. He is a past-President of the Infectious Diseases Society of America and was holder of an NIH MERIT Award for his research focused on neutrophils and infection and neutrophil interactions with antibiotics. He is a member of the Institute of Medicine.

Bill McCarberg MD is Founder of the Chronic Pain Management Program for Kaiser Permanente in San Diego, California. He was on the board of directors of the American Pain Society. He is co-president of the Western Pain Society and Assistant Clinical Professor (voluntary) at the University of California at San Diego School Medicine. Dr McCarberg is a member of the American Academy of Family Physicians, the American Academy of Pain Medicine, the American Pain Society, and the International Association for the Study of Pain. He is the recipient of several awards, including the Shilling Compassionate Care Award, and in 1998 was named the Highest Rated Physician by Member Appraisal of Physician Services at Kaiser Permanente. He also received the Elizabeth Narcessian award for leader in the field of pain education from the American Pain Society. He has

77

given more than 30 presentations on pain management issues and is the author or co-author of several publications. He is board certified by the American College of Pain Medicine, the American Board of Family Practice and additionally certified in Geriatrics. Dr McCarberg received his MD degree from Northwestern University Medical School in Chicago, Illinois. He completed a medical internship and a residency in family practice at Highland Hospital in Rochester, New York. Dr. McCarberg is on the Arius Scientific Advisory Board.

James M. Oleske, M.D., MPH is François-Xavier Bagnoud Professor of Pediatrics and Director, Division of Pulmonary, Allergy, Immunology and Infectious Diseases Department of Pediatrics UMD-New Jersey Medical School. Dr. Oleske is an internationally recognized expert in the management of children with HIV/AIDS. His earlier interest in immune based therapy for infants and children with primary immunodeficiency has been extended to children with HIV infection. His multiple medical Board certifications (Allergy/Immunology, Infectious Disease, Laboratory Immunology and Palliative/Hospice Care and Pain) reflect his lifelong commitment of advocacy for children.

David S. Perlin, Ph.D., is Scientific Director of the Public Health Research Institute, a 63 year old biomedical research organization that specializes in infectious diseases research. His laboratory studies the molecular basis for clinical resistance to antifungal drugs and helps develop rapid diagnostic approaches for fungal pathogens, agents of bioterrorism, and new disease agents like the SARS coronavirus. As Scientific Director, Dr. Perlin has helped PHRI emerge as one of the foremost tuberculosis research organizations in the world. He also provided leadership for the development of the International Center for Public Health, a specialized center for infectious diseases research in Newark, NJ. Dr. Perlin was a consultant to the US Senate for their investigation of the Fall 2001 anthrax outbreak and he is an Executive Committee member of the Northeast Biodefense Center. He regularly serves on NIH review panels, is on the editorial board of a number of biomedical research journals, is a member of Senator Jon Corzine s New Jersey Healthcare Taskforce, and serves on the New York City Department of Health advisory panel on bioterrorism and emerging pathogens.

Leo A. Whiteside, M.D., is founder and President of Missouri Bone and Joint Center, Missouri Bone and Joint Research Laboratory, and Whiteside Biomechanics Inc. Dr. Whiteside is an internationally recognized arthritis surgeon and innovator, specializing in total replacement of the hip and knee. He has been the surgeon-inventor for three major hip replacement and two major knee replacement systems, and his company is involved with developing and marketing orthopedic surgical instruments and implantable devices. He is past president of the Hip Society. He is recipient of the Charnley award for excellence for research involving hip replacement surgery, the Volvo Award for innovative research involving the spine and the Ranawat Award for excellence in research involving knee replacement surgery. He is currently on the editorial board of The Journal of Arthroplasty and Clinical Orthopedics and Related Research.

Arius Commercial Advisory Board

Arius has also established a Commercial Advisory Board as an additional sales and marketing resource for our management team. When we merged with Arius, we kept their Commercial Advisory Board in place. At the merger, the options of the Arius Commercial Advisory Board in the predecessor Arius were accelerated. As a result, each such member received shares of our Series A Preferred upon the consummation of the merger. Such Arius Commercial Advisory Board members have not been granted options to purchase shares of our common stock. On April 28, 2005, William S. Poole, a Commercial Advisory Board member, was appointed to our Board of Directors. Therefore, as of such date, our Commercial Advisory Board has one member, whose biography follows:

William O. Baicy has nearly 30 years of sales, marketing and general management experience in the pharmaceutical industry. Most recently Bill held the position of Executive Vice President of Commercial Development for Andrx Pharmaceutcials. Prior to holding this position Bill Baicy held several senior commercial management positions at Glaxo, Glaxo Wellcome and GlaxoSmithKline including Vice President of Marketing Cerenex Division; Vice President and General Manager of Care Management Division; Vice President of New Product Market Planning and Vice President of Business Development. Bill was also the President of

78

Table of Contents

HealthMatics, a joint venture between Glaxo Wellcome and Physicians Computer Newtwork, Inc. a developer and distributor of practice management systems to 100,000 physicians. Mr. Baicy began his career in the pharmaceutical industry as a Sales Representative for Syntex Laboratories.

Board Committees

Our board of directors has established three standing committees Audit, Compensation, and Nominating and Corporate Governance. The Audit and Nominating and Corporate Governance Committees each operate under a charter that has been approved by the board.

As compensation for their duties, directors receive $1,000 for appearing in person at a board of directors meeting. Compensation also includes 20,000 options to purchase common stock for each year served as a director. Additionally, each director is granted 10,000 options to purchase common stock per year for serving as a chairman of a committee of the board of directors and 5,000 options to purchase common stock per year for serving on a committee of the board of directors.

Audit Committee

Our board of directors has an Audit Committee, comprised of William B. Stone, L.M. Stephenson and John J. Shea, all of whom are independent directors as defined by the rules of the National Association of Securities Dealers, or NASD. Mr. Stone serves as chairman of the committee. The board of directors has determined that Mr. Stone is an audit committee financial expert as defined in Item 401(e) of Regulation S-B.

The Audit Committee met eight times during 2004. Each member of the Audit Committee was present at all of the Audit Committee meetings held during such director s tenure as a member of the Audit Committee. The Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the independence and performance of, and assesses the qualifications of, our independent auditors, and engages such independent auditors. The Audit Committee approves the plan and fees for the annual audit, review of quarterly reports, tax and other audit-related services, and approves in advance any non-audit service to be provided by the independent auditors. The Audit Committee monitors the rotation of partners of the independent auditors on our engagement team as required by law. The Audit Committee reviews the financial statements to be included in our Annual Report on Form 10-KSB and reviews with management and the independent auditors the results of the annual audit and our quarterly financial statements. In addition, the Audit Committee oversees all aspects our systems of internal accounting control and corporate governance functions on behalf of the board. The Audit Committee provides oversight assistance in connection with legal and ethical compliance programs established by management and the board, including Sarbanes-Oxley implementation, and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our board of directors has a Nominating and Corporate Governance Committee comprised of William S. Poole, L.M. Stephenson and John J. Shea. Mr. Shea serves as the chairman of the committee. Mr. Shea was named chairman of this committee on August 22, 2005. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The Nominating and Corporate Governance Committee was formed in May of 2004 and did not formally meet during 2004, although this committee has been active in 2005. The Nominating and Corporate

Governance Committee has a charter. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the NASD. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders. To recommend a nominee please write to the Nominating and Corporate Governance Committee c/o the Company, Attn: James A McNulty. There are no minimum qualifications for consideration for nomination to be a director of the Company. The nominating committee will assess all director nominees using

Table of Contents

the same criteria. All of the current nominees to serve as directors on our board of directors have previously served in such capacity. During 2004, we did not pay any fees to any third parties to assist in the identification of nominees. During 2004, we did not receive any director nominee suggestions from stockholders.

Compensation and Investment Committees

Our board of directors also has a compensation committee, which, either alone or in conjunction with the full board, as the case may be, reviews or recommends the compensation arrangements for our management. The members of the compensation committee are William S. Poole, who was named chairman of this committee effective August 22, 2005 (replacing Dr. O Donnell), L.M. Stephenson and William B. Stone. The compensation committee as such did not meet during 2004.

Our board of directors also has an investment committee, which either alone or in conjunction with the full board, as the case may be, reviews and recommends the investment arrangements for our company. The members of the investment committee are Dr. Francis E. O Donnell, William Stone and L.M. Stephenson. The investment committee as such did not meet during 2004.

There are no other board of directors committees at this time.

Code of Ethics

On March 24, 2003, our board of directors adopted a code of ethics that applies to our principal executive and financial officers. We intend to file amendments, changes or waivers to the code of ethics as required by SEC rules.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the reporting persons) file with the SEC various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in 2004, not all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons. We believe there are some delinquent filings in 2005.

Securities Authorized for Issuance under Equity Compensation Plans

For information regarding securities authorized for issuance under Equity Compensation Plans, and the equity compensation plan information table see Market for Common Equity and Related Stockholder Matters.

80

Table of Contents

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN BENEFICIAL OWNERS

The following table sets forth information regarding the beneficial ownership of our common stock as of September 22, 2005, and as adjusted to reflect the sale of 5,000,000 shares of our common stock offered by this prospectus (assuming no purchase of common stock in this offering), by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock;
- each of our executive officers and directors; and
- all our officers and directors as a group.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by them.

Name of Beneficial Owner	Number of Shares of Common Stock Owned	Percentage of Class Before the Offering[1]	Percentage of Class After the Offering[1]
Hopkins Capital Group II, LLC [2]	3,111,580	42.8%	25.4%
Francis E. O Donnell, Jr., M.D.[3]	3,517,113	48.4%	28.7%
The Francis E. O Donnell, Jr. Irrevocable Trust #1 [4]	3,279,080	45.1%	26.7%
Pharmaceutical Product Development, Inc. [5]	690,000	9.5%	5.6%
Jonnie R. Williams, Sr. [6]	3,203,114	44.1%	26.1%
MOAB Investments, LP [7]	3,157,347	43.4%	25.7%
Laurus Master Fund, Ltd. [8]	362,733	4.99%	4.99%
Donald L. Ferguson [9]	386,133	5.3%	3.1%
Mark A. Sirgo, Pharm.D. [10]	28,300	*	*
Andrew L. Finn, Pharm.D. [11]		*	*
Raphael J. Mannino, Ph.D. [12]	397,508	5.5%	3.2%
James A. McNulty [13]	86,782	1.2%	*
L.M. Stephenson, Ph.D [14]	150,000	2.1%	1.2%
William B. Stone [15]	185,000	2.5%	1.5%
John J. Shea [16]	105,000	1.4%	*
William S. Poole [17]	35,000	*	*
All Directors and Officers as a group (9 persons)	4,504,703	62.0%	36.7%

* Less than 1%

(1) Based on 7,269,196 shares of common stock outstanding as of September 22, 2005 and 12,269,196 shares of common stock assumed to be outstanding following this offering. The number of shares of common stock assumed to be outstanding following this offering does not include: (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 Laurus.

(2) Hopkins Capital Group II, LLC is owned one third by each of: (i) various trusts of the O Donnell family (see Note 4); (ii) John R. Williams, Sr. and his family trusts (see Note 6); and (iii) MOAB Investments, LP, which is beneficially owned by Dr. Dennis Ryll and members of his family (see Note 7). Hopkins Capital Group II, LLC also owns 341,176 shares of our Series B Convertible Preferred Stock, of which none are presently convertible into shares of our common stock.

Table of Contents

(3) Dr. O Donnell is our Chairman of the Board and a Director. Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2) and 45,767 shares of common stock, owned by his wife, as to which Dr. O Donnell disclaims beneficial interest of. Includes 167,500 shares owned by The Francis E. O Donnell, Jr. Irrevocable Trust #1, of which Dr. O Donnell s sister, Kathleen O Donnell, is trustee, and as to which Dr. O Donnell disclaims beneficial interest (see Note 4). The remaining 4,577 shares of common stock are owned by Dr. O Donnell s sister. In addition, this number includes options to purchase 130,000 shares of our common stock, all of which is currently exercisable. Dr. O Donnell s address is 709 The Hamptons Lane, Chesterfield MO 63017.

(4) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2), of which The Francis E. O Donnell, Jr. Irrevocable Trust #1 owns approximately 27%. The remaining 167,500 shares of common stock are held directly by this trust.

(5) PPDI s address is 3151 South Seventeenth Street, Wilmington, NC 28412.

(6) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2). Also includes 45,766 shares of common stock that are personally owned by Mr. Williams and an additional 45,767 shares owned by Mr. Williams s wife. Mr. Williams s address is 1 Starwood Lane, Manakin-Sabot, VA 23103.

(7) Includes the shares owned by Hopkins Capital Group II, LLC (see Note 2). MOAB Investments, LP is beneficially owned by Dr. Dennis Ryll and members of his family. The remaining 45,767 shares of common stock are personally owned by Dr. Ryll. The address for MOAB and Dr. Ryll is 2595 Red Springs Drive, Las Vegas, NV 89135.

(8) Up to a maximum potential of 2,945,037 shares of common stock are 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. However, the terms of the convertible notes and warrants issued by us to Laurus provide that Laurus is not entitled to receive shares upon exercise of the warrants, upon payment of principal and interest on the notes, or upon conversion of the notes if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% of the outstanding shares of our common stock on the date of issuance of such shares (such provision may be waived by Laurus upon 75 days prior written notice to us or without notice upon an event of default). Laurus address is 825 Third Avenue, 14th Floor, New York, NY 10022.

(9) Mr. Ferguson is a former officer and director of our company. Includes 91,533 shares of our common stock owned through a holding entity and options to purchase 294,600 shares of our common stock, all of which are currently exercisable. Mr. Ferguson s address is 11477 Olde Cabin Road, Suite 110, St. Louis, MO 63141.

(10) Includes 8,300 shares owned by Dr. Sirgo, our President and Chief Executive Officer and a Director. Includes options to purchase 20,000 shares of our common stock, all of which are currently exercisable. Dr. Sirgo also owns 797,414 shares of our Series A Convertible Preferred Stock, of which none are presently convertible into shares of our common stock. Excludes 14,076 options to purchase common stock which are currently exercisable. Dr. Sirgo s address is 3100 Stone Gap Court Raleigh, NC 27612.

(11) Dr. Finn is our Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn owns 797,414 shares of our Series A Convertible Preferred Stock, of which none are presently convertible into shares of our common stock. Dr. Finn also holds 14,076 options to purchase common stock which are not currently exercisable. Dr. Finn s address is 737 West Hargett Street, Raleigh, NC 27603.

(12) Dr. Mannino is our Executive Vice President, Chief Scientific Officer and a Director. Includes options to purchase 272,499 shares of our common stock, all of which are currently exercisable and excludes 27,373 options which are not currently exercisable. Dr. Mannino s address is 36 Meadowview Drive, Annondale, NJ 08801.

(13) Mr. McNulty is our Chief Financial Officer, Secretary and Treasurer. Includes options to purchase 12,411 shares of our common stock, all of which are currently exercisable and 2,288 shares owned by his wife, as to which he disclaims beneficial interest and excludes 35,629 options which are not currently exercisable. His address is 4419 W. Sevilla Street, Tampa, FL 33629.

(14) Includes options to purchase 120,000 shares of our common stock, all of which are currently exercisable. Dr. Stephenson s address is 2401 Pennsylvania Ave., Apt. 5B, Philadelphia, PA 19130.

(15) Includes options to purchase 150,000 shares of our common stock, all of which are currently exercisable. Mr. Stone s address is 11120 Geyer Downs Lane, Frontenac, MO 63131.

(16) Includes options to purchase 95,000 shares of our common stock, all of which are currently exercisable. Mr. Shea s address is 90 Poteskeet Trail, Kitty Hawk, NC 27949.

(17) Includes options to purchase 35,000 shares of our common stock, all of which are currently exercisable. Mr. Poole owns 3,190 shares of our Series A Convertible Preferred Stock, of which none are presently convertible into shares of our common stock. Mr. Poole s address is 1301 Kings Grant Drive, Raleigh, NC 27614.

Table of Contents

DESCRIPTION OF SECURITIES

General

The following description of our capital stock does not purport to be complete and is subject to and qualified in its entirety by our certificate of incorporation and bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and by the applicable provisions of Delaware law.

Our authorized capital stock consists of 45,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of the date of this prospectus, our outstanding capital stock consists of 7,269,196 shares of common stock, $.001 par value, 1,647,059 shares of Series A Preferred, $.001 par value, and 341,176 shares of Series B Preferred, $.001 par value. There are also 2,085,000 outstanding Class A warrants to purchase 2,085,000 shares of common stock in the aggregate. These figures do not include securities to be issued: (i) as part of the unit purchase option granted to the underwriter of our initial public offering, (ii) pursuant to other unregistered warrants issued since our initial public offering or (ii) pursuant to our Amended and Restated 2001 Incentive Stock Option Plan.

Common Stock

As of the date of this prospectus, there are 7,269,196 shares of common stock outstanding, held of record by approximately 226 stockholders. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Subject to preferential rights with respect to any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and satisfaction of preferential rights of any outstanding preferred stock.

Our common stock has no preemptive or conversion rights or other subscription rights. There are no sinking fund provisions applicable to the common stock. The outstanding shares of common stock are fully paid and non-assessable.

Publicly-Traded Class A Warrants

Each Class A warrant entitles the holder to purchase one share of our common stock at a price of $6.30. The exercise price of the Class A warrants is subject to adjustment, including anti-dilution provisions for corporate events, such as stock splits and for issuance of securities at less than the current exercise price. The warrants are exercisable, unless we have redeemed them, until June 24, 2007. We may redeem the outstanding Class A warrants for $.10 per warrant upon no less than 30 days written notice to the warrant holder; provided: (i) that there is then an effective registration statement under the Securities Act allowing the issuance of the shares issuable upon exercise of the Class A warrants, and (ii) the average closing sale price of the common stock equals or exceeds 150% of the offering price of the units issued in our initial public offering for the 10 trading days prior to the date of the notice of redemption.

The Class A warrants were issued pursuant to a warrant agreement among us, Kashner Davidson Securities Corporation and American Stock Transfer and Trust Company, as warrant agent. The shares of common stock underlying the Class A warrants, when issued upon exercise of the Class A warrants, will be fully paid and non-assessable.

Preferred Stock

We have authorized 5,000,000 shares of preferred stock, of which an aggregate of 2,588,236 have been designated and of which 1,988,235 are outstanding as of the date of this prospectus. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including voting rights, of the holders of common stock. In certain circumstances, such issuance could have the

Table of Contents

effect of decreasing the market price of the common stock. Notwithstanding the broad discretion granted to our Board of Directors with respect to designating the terms and conditions of any series of preferred stock, our Board of Directors has agreed to refrain from issuing shares of preferred stock, unless such designation and issuance are approved by a majority of our independent directors who do not have an interest in the transactions and who have access to and consulted with (at our expense) our counsel or counsel of their choosing.

Series A Preferred Stock

As part of the acquisition of Arius in August 2004, we issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of convertible preferred stock.

Type of Security: The Series A Preferred Stock is non-voting, and are entitled to dividends, without preference over the holders of common stock, only when, or if, declared by our board of directors.

Conversion: The Series A Preferred is convertible (upon the satisfaction of certain conditions) into shares of our common stock on a one for one basis. Shares of Series A Preferred are eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first proposed product, (ii) 30 days notice to us of a Conversion Event (hereinafter defined) or (iii) August 24, 2009 (five years from the closing date of the acquisition). The term Conversion Event is defined in the Certificate of Designation of the Series A Preferred to mean our failure to provide at least $3,000,000 to Arius as required to: (i) pay Atrix $1,000,000 by August 24, 2004 pursuant to the terms of a license agreement between Arius and Atrix and (ii) fund, in a total amount of no less than $2,000,000, the operations of Arius. We believe we have satisfied both of these conditions.

Anti-Dilution Protection: The Certificate of Designations of the Series A Preferred provides that in the event that we issue stock in connection with a dividend, distribution, classification, merger or consolidation the number of shares of common stock that the Series A Stock is convertible into will be adjusted accordingly.

Liquidation Preference: In the event of any dissolution or winding up of the company, whether voluntary or involuntary, holders of each outstanding share of Series A Preferred Stock will be entitled to be paid pari passu with the holders of common stock.

In addition, the terms of the Series A Preferred include a provision that if, at the time that any shares of Series A Preferred are converted, our common stock is listed for quotation on The Nasdaq SmallCap Market or The Nasdaq National Market, then, without the prior approval of our stockholders in accordance with the rules of Nasdaq, we shall be prohibited from issuing shares of our common stock to the extent that the total aggregate number of shares of common stock issued or deemed to be issued would exceed 19.99% of the issued and outstanding shares of common stock immediately prior to the effective time of the Arius acquisition. On July 28, 2005, at our annual meeting of stockholders, our stockholders approved the authorization of the issuance in excess of this 19.99% limit, so this restriction no longer applies to the potential conversion of shares of our Series A Preferred.

Series B Preferred Stock

In August 2004, we entered into an Equity Line Agreement with HCG under which, at our request, HCG will invest up to $4 million in our company in consideration of a newly-created class of preferred stock, the Series B Preferred. As of the date of this prospectus, $1.45 million has been drawn on the HCG equity line.

Type of Security: The Series B Preferred is non-voting and is entitled to receive a 4.5% annual cumulative dividend.

Conversion: The Series B Preferred shares are 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.

Table of Contents

Anti-Dilution Protection: The Certificate of Designations of the Series B Preferred Stock provides that in the event that we issue stock in connection with a dividend, distribution, classification, merger or consolidation the number of shares of common stock that the Series B Preferred Stock is convertible into will be adjusted accordingly.

Liquidation Preference: In the event of any dissolution or winding up of the company, whether voluntary or involuntary, holders of each outstanding share of Series B Preferred will be entitled to be paid, first out of the assets of the company available for distribution to stockholders, an amount equal to $4.25 per share (as may be adjusted for splits and other similar events) plus any declared but unpaid dividends, before any payment shall be made to the holders of the Series A Preferred and the holders of common stock.

In addition, the Certificate of Designations for the Series B Preferred provides that without the prior approval of the our stockholders, in no event shall we issue shares of common stock at any time upon conversion of: (i) the first $1.25 million face value of Series B Preferred (representing 294,117 shares of Series B Preferred), plus (ii) any additional shares of Series B Preferred, the proceeds from the sale of which were used by us in connection with the acquisition Arius *plus* (iii) all shares of Series A Preferred, to the extent that the total aggregate number of shares of common stock issued or deemed to be issued at any time to any holder or all holders of the above mentioned preferred stock would exceed 19.99% of the issued and outstanding shares of common stock immediately prior to the effective time of the acquisition of Arius. On July 28, 2005, at our annual meeting of stockholders, our stockholders approved the authorization of the issuance in excess of this 19.99% limit, so this restriction no longer applies to the potential conversion of the shares of our Series B Preferred.

February 2005 Laurus Convertible Note Financing

On February 22, 2005, we consummated a $2.5 million secured convertible debt financing with Laurus in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act. 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 will be 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. FBW, the lead underwriter of this offering, advised us on this transaction, for which it received an advisory fee of $175,000.

The February 2005 Laurus investment, which takes the form of a convertible note secured by certain of our assets, 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 the our common stock at a price equal to $3.88 per share. We agreed, pursuant to a registration rights agreement, to register the shares of common stock underlying the note and the warrant with the SEC. Such registration statement was declared effective on June 20, 2005.

The following describes certain of the material terms of the February 2005 financing transaction with Laurus. The description below is not a complete description of the material terms of the financing transaction and is qualified in its entirety by reference to the agreements entered into in connection with the financing which are included as exhibits to the registration statement of which this prospectus is a part:

Note Maturity Date and Interest Rate. The note matures on February 22, 2008, absent earlier redemption by us or earlier conversion by Laurus, as described below. Annual interest on the note is equal to the prime rate published in The Wall Street Journal from time to time, plus two percent (2.0%), provided, that, such annual rate of interest may not be less than seven and one-half percent (7.5%).

Payment of Interest and Principal. Interest on the note is payable monthly in arrears on the first day of each month during the term of the note, which commenced April 1, 2005. In addition, commencing June 1, 2005, we were required to make monthly principal payments of $75,758 per month, which we refer to herein as the

Table of Contents

February note monthly payment amount. Such monthly principal payments were deferred until December 1, 2005 pursuant to our June 29, 2005 amendment with Laurus to the Laurus financing documents.

Note Conversion Rights. All or a portion of the outstanding principal and interest due under the February note may be converted into shares of our common stock upon satisfaction of certain conditions. The initial fixed conversion price under the note is $3.10 per share. The fixed conversion price is subject to anti-dilution protection adjustments, on a weighted average basis, upon issuance by us of additional shares of common stock at a price that is less than the then current fixed conversion price of the note.

Laurus may, at any time, convert the outstanding indebtedness of the note into shares of common stock at the then applicable fixed conversion price.

Subject to the restrictions on conversion described below, Laurus shall convert the February note monthly payment amount into shares of common stock in the event that: (i) the average closing price of our common stock for the five trading days preceding the due date of a February note monthly payment amount is greater than 115% of the fixed conversion price, and (ii) the amount of such conversion does not exceed 25% of the aggregate dollar trading volume of our common stock for the 22 trading days preceding the payment date.

In the event that all or any portion of the February note monthly payment amount is paid in cash, we shall be required to pay Laurus an amount equal to 103% of the principal amount of the cash portion of the February note monthly payment amount being paid plus 100% of the interest portion of such February note monthly payment amount.

Warrant Terms. The warrant grants Laurus the right to purchase up to 350,000 shares of common stock at an exercise price of $3.88 per share. The warrant expires on February 22, 2012 and must be exercised by the payment of cash.

Restrictions on Conversion of Note and Exercise of Warrant. Notwithstanding anything to the contrary set forth above, we may pay amounts due under the note in shares of our common stock only so long as there is an effective registration statement on file covering the resale of such shares or an exemption from such registration is available under Rule 144 of the Securities Act. A registration statement covering such shares was declared effective by the SEC on June 20, 2005. In addition, Laurus is not entitled to receive shares upon exercise of the warrant, upon payment of principal and interest on the note, or upon conversion of the note if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% of the outstanding shares of our common stock on the date of issuance of such shares (such provision may be waived by Laurus upon 75 days prior written notice to us or without notice upon an event of default). Further, in accordance with Nasdaq Stock Market rules, the aggregate number of shares of common stock issuable by us and acquirable by Laurus at an average price below $3.10 per share pursuant to the terms of the note or the warrant, shall not exceed an aggregate of 1,428,458 shares of common stock (representing 19.99% of our issued and outstanding shares of common stock on February 22, 2005, and subject to appropriate adjustment for stock splits, stock dividends, or other similar recapitalizations affecting the common stock), unless the issuance of common stock in excess of such maximum amount shall first be approved by our stockholders. On July 28, 2005, at our annual meeting of stockholders, our stockholders approved the authorization of share issuances in excess of this 19.99% limit, so this restriction no longer applies to the conversion of this note.

Right to Redeem Note. We have the option of prepaying the outstanding principal amount under the note in whole or in part by paying an amount equal to 130% of the principal amount being redeemed by giving at least 7 business days prior written notice of redemption to Laurus.

Security for Note. The note is secured by a lien on certain of our assets, pursuant to the terms of a security agreement executed by us. Certain of our present and future intellectual property rights are not included in the collateral subject to this security agreement. If an event of default occurs under the security agreement or note,

Table of Contents

Laurus has the right to accelerate payments under the note and, in addition to any other remedies available to it, foreclose upon the assets securing the note.

Registration Rights. Pursuant to the terms of a registration rights agreement between us and Laurus, we were obligated to file a registration statement registering the resale of shares of our common stock issuable upon conversion of the note and exercise of the warrant. We were required to file a registration statement by March 24, 2005 (which we complied with) and were required to have the registration statement declared effective by June 7, 2005. Such registration statement was declared effective by the SEC on June 20, 2005. Since the registration statement was not declared effective within the timeframe described (or, following effectiveness, if such registration is suspended other than as permitted in the registration rights agreement), we are obligated to pay Laurus a fee equal to 1.5% of the then-oustanding principal amount of the note for the first 30 day period, and 2.0% for each 30 day period thereafter (pro rated for partial periods), that such registration conditions are not satisfied.

Right of First Refusal. Subject to certain exceptions, we have granted Laurus a right of first refusal (through the date that the note is fully repaid or converted) to provide additional financing to us.

Additional Restrictions. The Laurus financing documents contain certain restrictions regarding our operations while the note remains outstanding. Such restrictions include our agreement that, except with Laurus prior written consent (such consent not to be unreasonably withheld), we will not issue certain classes of debt securities or equity securities.

In addition, so long as 25% of the note remains outstanding, the financing documents, among other things, prohibit, except with Laurus prior written consent: (i) our payment of dividends or a redemption of our shares, (ii) the incurring of additional debt in excess of five percent (5%) of the fair market value of our and our subsidiaries assets other than debt incurred in connection with the purchase of assets in the ordinary course of business, or any refinancings or replacements thereof on terms no less favorable than the indebtedness being refinanced or replaced, so long as any lien relating thereto shall only encumber the fixed assets so purchased and no other assets of ours or our subsidiaries.

Ferris, Baker Watts. On November 29, 2004, we engaged FBW, the lead underwriter of this offering, to be our exclusive financial advisor for a period of one year in connection with the exploration of a number of potential strategic transactions. FBW advised us in connection with our recent financings with Laurus. In consideration for services provided by FBW, we paid to FBW in November 2004 a non-refundable initial cash fee of $25,000 and issued to FBW a warrant to purchase 225,000 shares of our common stock at an exercise price equal to $5.25. The warrant is not exercisable until August 22, 2005. The warrant expires on November 29, 2010. The warrant does not contain any cashless exercise or non-standard anti-dilution provisions, but does contain customary provisions for stock splits and stock dividends. We also agreed to pay FBW certain transaction-based fees at the closing of transactions introduced to us by FBW. We paid such fees to FBW in connection with the February 2005 Laurus financing.

May 2005 Laurus Convertible Note Financing

On May 31, 2005, we closed an additional $2.5 million secured convertible debt financing from Laurus in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act. Net proceeds from the May financing are to be 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. FBW, the lead underwriter of this offering, advised us on this transaction, for which it received an advisory fee of $175,000.

Like the February 2005 financing, the May investment takes the form of a convertible note secured by substantially all of our assets. Such note has a 3-year term (subject to certain contingencies discussed below) and

Table of Contents

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 issued to Laurus an additional common stock purchase warrant to purchase up to 483,871 shares common stock at a price equal to $3.88 per share.

The following describes certain of the material terms of the May 2005 financing transaction with Laurus. The description below is not a complete description of the material terms of the financing transaction and is qualified in its entirety by reference to the agreements entered into in connection with the financing which are included as exhibits to the registration statement of which this prospectus is a part:

Note Maturity Date and Interest Rate. The May note matures on May 31, 2008. The note is further subject to earlier redemption, as well as earlier conversion by Laurus, each as described below. Annual interest on the May note is equal to the prime rate published in The Wall Street Journal from time to time, plus two percent (2.0%), provided, that, such annual rate of interest may not be less than eight percent (8.0%).

Payment of Interest and Principal. Provided that our stockholders give their approval as described above, interest on the May note is payable monthly in arrears on the first day of each month during the term of such note, commencing September 1, 2005. In addition, commencing September 1, 2005, we are required to make monthly principal payments of $75,758 per month which, together, with monthly interest payments, we refer to herein as the May note monthly payment amount. Such monthly principal payments were deferred until December 1, 2005 pursuant to our June 29, 2005 amendment with Laurus to the Laurus financing documents.

Note Conversion Rights. All or a portion of the outstanding principal and interest due under the May note may be converted into shares of our common stock upon satisfaction of certain conditions. The initial fixed conversion price under the note is $3.10 per share. The fixed conversion price is subject to anti-dilution protection adjustments, on a weighted average basis, upon issuance by us of additional shares of common stock at a price that is less than the then current fixed conversion price of the note.

Laurus may, at any time, convert the outstanding indebtedness of the note into shares of common stock at the then applicable fixed conversion price.

Subject to the restrictions on conversion described below, Laurus shall convert into shares of common stock the May note monthly payment amount in the event that: (i) the average closing price of our common stock for the five trading days preceding the due date of a May note monthly payment amount is greater than 115% of the fixed conversion price, and (ii) the amount of such conversion does not exceed 25% of the aggregate dollar trading volume of the our common stock for the 22 trading days preceding the payment date.

In the event that all or any portion of the May note monthly payment amount is paid in cash, we shall be required to pay Laurus an amount equal to 103% of the principal amount of the cash portion of the May note monthly payment amount being paid plus 100% of the interest portion of such May note monthly payment amount.

Warrant Terms. The warrant issued in connection with the May financing grants Laurus the right to purchase up to 483,871 shares of our common stock at an exercise price of $3.88 per share. Such warrant expires on May 31, 2012 and must be exercised by the payment of cash.

Restrictions on Conversion of Note and Exercise of Warrant. Notwithstanding anything to the contrary set forth above, we may pay amounts due under the May note in shares of common stock only so long as there is an effective registration statement on file covering the resale of such shares or an exemption from such registration is available under Rule 144 of the Securities Act. In addition, Laurus is not entitled to receive shares upon exercise of the warrant, upon payment of principal and interest on the note, or upon conversion of the note if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% of the outstanding shares of our common stock on the date of issuance of such shares (such provision may be waived by Laurus upon 75 days

Table of Contents

prior written notice to us). Further, in accordance with Nasdaq Stock Market rules, the aggregate number of shares of common stock issuable by us and acquirable by Laurus at an average price below $3.10 per share pursuant to the terms of the February and May notes and warrants, aggregated together, shall not exceed an aggregate of 1,428,458 shares of common stock (representing 19.99% of our issued and outstanding shares of common stock on February 22, 2005, and subject to appropriate adjustment for stock splits, stock dividends, or other similar recapitalizations affecting the common stock), unless the issuance of common stock in excess of such maximum amount shall first be approved by our stockholders. On July 28, 2005, at our annual meeting of stockholders, our stockholders approved the authorization of share issuances in excess of this 19.99% limit, so this restriction no longer applies to potential conversions of this note.

Right to Redeem Note. We have the option of prepaying the outstanding principal amount under the note in whole or in part by paying an amount equal to 130% of the principal amount being redeemed by giving at least 7 business days prior written notice of redemption to Laurus.

Right of Laurus to Demand Payment. During the period beginning on May 31, 2005 and ending on May 31, 2008, but solely in the event that we effect a Qualified Financing (as defined below), Laurus shall have the right, for a period of 90 days following the closing of a Qualified Financing, 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, from the proceeds of such Qualified Financing. The term Qualified Financing means any firm commitment public underwriting or any private investment in public equity (i.e, PIPE) transaction in which we raise as amount (net of brokerage fees and commissions and legal, accounting and other expenses, in each case reasonably related to the Qualified Financing) equal to or greater than $5 million. The offering described in this prospectus is a Qualified Financing for purposes of the May Laurus note.

Security for Note. The note is secured by a lien on substantially all of our assets, pursuant to the terms of a security agreement executed by us on February 22, 2005 and reaffirmed on May 31, 2005; however, certain of our present and future in-licensed intellectual property rights are not included in the collateral subject to this security agreement. If an event of default occurs under the security agreement or note, Laurus has the right to accelerate payments under the note and, in addition to any other remedies available to it, foreclose upon the assets securing the note.

Registration Rights. Pursuant to the terms of a registration rights agreement between us and Laurus entered into in connection with the May financing, we are obligated to file a registration statement registering the resale of shares of the our common stock issuable upon conversion of the May note and exercise of the May warrant. We were required to file a registration statement within 30 days of May 31, 2005 and have the registration statement declared effective within 105 days of such date. We filed such registration statement on July 1, 2005 and such registration statement was declared effective on July 11, 2005, thereby meeting our obligations regarding registration. If the registration is suspended other than as permitted in the registration rights agreement, we will be obligated to pay Laurus a fee equal to 1.5% of the then-oustanding principal amount of the May note for the first 30 day period, and 2.0% for each 30 day period thereafter (pro rated for partial periods), that such registration conditions are not satisfied.

Right of First Refusal. Subject to certain exceptions, we have granted Laurus a right of first refusal to provide additional financing to us.

Additional Restrictions. The May Laurus financing documents contain certain restrictions regarding our operations while the May note remains outstanding. Such restrictions include our agreement that, except with Laurus prior written consent (such consent not to be unreasonably withheld), it will not issue certain classes of debt securities or equity securities.

In addition, so long as 25% of the May note remains outstanding, the financing documents, among other things, prohibit, except with Laurus prior written consent (i) our payment of dividends or redeeming shares, (ii) the incurrence by us additional debt in excess of five percent (5%) of

the fair market value of our and its

Table of Contents

subsidiaries assets other than debt incurred in connection with the purchase of assets in the ordinary course of business, or any refinancings or replacements thereof on terms no less favorable than the indebtedness being refinanced or replaced, so long as any lien relating thereto shall only encumber the fixed assets so purchased and no other assets of ours or our subsidiaries.

June 2005 Amendment to Laurus Documents

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 June warrants with the SEC, which registration statement was declared effective on July 11, 2005.

Clinical Development Capital Warrant

As part of our transaction with CDC, on July 15, 2005, we issued CDC a warrant to purchase 500,000 shares of our common stock at $3.50 per share. Such warrant 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.

Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, which restricts certain transactions and business combinations between a corporation and an interested stockholder (as defined in Section 203) owning 15% or more of the corporation s outstanding voting stock, for a period of three years from the date the stockholder becomes an interested stockholder. Subject to certain exceptions, unless the transaction is approved by the board of directors and the holders of at least two-thirds of our outstanding voting stock (excluding shares held by the interested stockholder), Section 203 prohibits significant business transactions such as a merger with, disposition of assets to, or receipt of disproportionate financial benefits by the interested stockholder, or any other transaction that would increase the interest stockholder s proportionate ownership of any class or series of the corporation s stock. The statutory ban does not apply if, upon consummation of the transaction in which any person becomes an interested stockholder, the interested stockholder owns at least 85% of the outstanding voting stock of the corporation (excluding shares held by persons who are both directors and officers or by certain employee stock plans).

Transfer Agent and Registrar

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock and warrant agent for the Class A warrants.

Table of Contents

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

We have several business relationships with Accentia and its affiliates. HCG, which is controlled by Dr. Frank O Donnell, our Chairman of the Board and a director and which owns a significant percentage of our common stock as of the date of this prospectus, as well as all of our Series B Convertible Preferred Stock, is a significant stockholder of Accentia. In addition, Dr. Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, is the Treasurer and Corporate Secretary of Accentia.

Amphotericin B License. On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from the Mayo Foundation for the treatment of CRS and asthma on a worldwide basis. The license agreement was amended effective June 1, 2004, then modified in September 2004 by our asset purchase agreement with Accentia, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

Arius/TEAMM Distribution Agreement. On March 17, 2004, Arius granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc., or TEAMM, with respect to our Emezine® product for the treatment of nausea and vomiting. TEAMM is a specialty pharmaceutical company and wholly owned subsidiary of Accentia. As part of this agreement, TEAMM has agreed to pay for the development costs of Emezine®. We received development cost reimbursements of $1.0 million in 2004 from Accentia in connection with this agreement.

Analytica International Market Studies. During 2004, Analytica International, a provider of research, commercialization, and communications services to the pharmaceutical and biotechnology industries and a subsidiary of Accentia, performed two market studies for us. We paid Analytica $47,800 for these reports, some of which we paid in 2005.

Mr. James McNulty, our current Secretary, Treasurer and part-time Chief Financial Officer, is also the Chief Financial Officer of The Hopkins Capital Group II, LLC, which is affiliated with Dr. Francis E. O Donnell, our Chairman of the Board.

During 2001, we entered into agreements with RetinaPharma, Inc. (now called RetinaPharma Technologies, Inc.) and Tatton Technologies, LLC (now a part of RetinaPharma). Both are biotechnology companies which are developing nutraceutical neuroprotective therapies for treating neurodegenerative disease such as macular degeneration and Parkinson s disease. To the extent that such drugs utilize Bioral® cochleate technology, we will support drug development and will share in ten percent (10%) of all net revenue from such sales of Bioral® encapsulated drugs. HCG, one of our significant stockholders, and Dr. Francis E. O Donnell, Jr., our Chairman of the Board and a director, are affiliated as stockholders and a director of RetinaPharma Technologies, Inc. Dr. O Donnell is the managing director of HCG.

We have also entered into an agreement with Biotech Specialty Partners, LLC, an emerging alliance of early stage biotechnology and specialty pharmaceutical companies. Biotech Specialty Partners, LLC is in its formative stage and to date has not distributed any pharmaceutical products. Under this agreement, BSP will serve as a nonexclusive distributor of our Bioral® drugs in consideration of a ten (10%) discount to the wholesale price, which our board of directors has determined to be commercially reasonable. BSP has waived its rights under this agreement with respect to Arius products. HCG, which is affiliated with Dr. Francis E. O Donnell, Jr., our Chairman of the Board and a director, are affiliated as stockholders, and a member of the management, of Biotech Specialty Partners, LLC.

91

Table of Contents

On July 19, 2002, we issued Ellenoff Grossman & Schole LLP, our outside legal counsel, 25,000 options to purchase shares of our common stock at $7.00 per share. In 2004, we issued Ellenoff Grossman & Schole LLP 44,510 shares of our common stock as compensation for services rendered. Ellenoff Grossman & Schole LLP is also counsel to our subsidiary, Bioral Nutrient Delivery, LLC. During 2003, Bioral Nutrient Delivery, LLC issued 37,500 Class B Shares of BND to Ellenoff Grossman & Schole LLP. These Class B Shares were issued at the inception of Bioral Nutrient Delivery, LLC at nominal value.

As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to promoters as that term is commonly understood by the SEC and state securities authorities.

We believe that the terms of the above transactions with affiliates were as favorable to us or our affiliates as those generally available from unaffiliated third parities. At the time of certain of the above referenced transactions, we did not have sufficient disinterested directors to ratify or approve the transactions; however, the present board of directors includes four independent directors which constitutes a majority as required by NASD rules. We believe that William B. Stone, L.M. Stephenson, John J. Shea and William S. Poole qualify as independent directors for Nasdaq Stock Market purposes.

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $60,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

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Table of Contents

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock and Class A warrants are listed for quotation on the Nasdaq SmallCap Market under the symbols BDSI and BDSIW respectively. Also, such securities are listed on the Boston Stock Exchange under the symbols BDS and BDS&W. The range of reported high and reported low bid prices per share for our common stock and warrants for each fiscal quarter during 2004 and the first two quarters of 2005, as reported by the Nasdaq SmallCap Market, is set forth below. The quotations merely reflect the prices at which transactions were proposed, and do not necessarily represent actual transactions.

Quarterly Common Stock/Warrant Price Ranges

	Common Stock		Warrants	
Quarter Ended:	**High**	**Low**	**High**	**Low**
March 31, 2004	$ 4.34	$ 2.52	$ 1.06	$ 0.50
June 30, 2004	$ 4.60	$ 2.79	$ 1.24	$ 0.80
September 30, 2004	$ 3.00	$ 1.52	$ 0.99	$ 0.20
December 31, 2004	$ 4.25	$ 2.56	$ 0.94	$ 0.48
March 31, 2005	$ 3.85	$ 2.33	$ 0.90	$ 0.20
June 30, 2005	$ 3.79	$ 2.63	$ 0.70	$ 0.20

As of September 22, 2005, we had approximately 226 holders of record of our common stock.

Securities Authorized for Issuance Under Equity Compensation Plans

Plan category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance**
	(a)	**(b)**	**(c)**
Equity compensation plans approved by security holders	2,054,595	$ 4.50	45,405
Equity compensation plans not approved by security holders			

Total	2,054,595	$ 4.50	45,405

Table of Contents

EXECUTIVE COMPENSATION

The following table provides certain summary information concerning compensation paid to the named executive officers and directors for the years stated.

SUMMARY COMPENSATION TABLE*

				Long Term Compensation				
		Annual Compensation[1]			Awards		Payouts	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)
Name and Principal Position	Year	Salary	Bonus	Other Annual Compensation	Restricted Stock Award(s)	Securities Underlying Options/SARs	LTIP Payouts	All Other Compensation
		($)	($)	($)	($)	(#)	($)	($)
Francis E. O Donnell, Jr., M.D.	2004	$ 117,692				35,000		
	2003	145,962				35,000		
Chairman of the Board	2002	112,500				61,991		
709 The Hamptons Lane								
Chesterfield, MO 63017								
Mark A. Sirgo, Pharm.D. [2],	2004	$ 62,596	$ 31,177.90			5,147		
	2003							
President and Chief Executive Officer	2002							
3100 Stone Gap Court								
Raleigh, North Carolina 27612								
Andrew L. Finn, Pharm.D. [3],	2004	$ 62,596	$ 28,092.04			5,147		
	2003							
Executive Vice President of Clinical	2002							
Development and Regulatory Affairs								
737 West Hargett Street								
Raleigh, NC 27603								
James A. McNulty,	2004	$ 105,866				3,235		
	2003	141,769	$			18,616		
Chief Financial Officer, Secretary and	2002	170,922	35,000					
Treasurer								
4419 W. Sevilla Street								

Tampa, FL 33629						
Raphael J. Mannino, Ph.D [4],	2004	$ 88,788		11,423	26,176	$ 5,015
	2003	90,000	52,500		111,449	5,015
Executive Vice President and	2002	91,500			35,423	5,015
Chief Scientific Officer						
36 Meadowview Drive						
Annondale, NJ 08801						

* Salary reflects total compensation paid to these executives.

(1) Except as reflected in column (e) with respect to Dr. Mannino, the annual amount of perquisites and other personal benefits, if any, did not exceed the lesser of $50,000 or 10% of the total annual salary reported for each named executive officer and has therefore been omitted.

(2) Dr. Sirgo joined our company on August 24, 2004. Under his employment agreement with us, he is entitled to an annual base salary of $175,000. The amounts reflected under column (c) reflect the amount of base salary paid to him from August 24 through December 31, 2004.

(3) Dr. Finn joined our company on August 24, 2004. Under his employment agreement with us, he is entitled to an annual base salary of $175,000. The amounts reflected under column (c) reflect the amount of base salary paid to him from August 24 through December 31, 2004.

(4) Includes: (a) a car allowance of $6,750 and 401(k) matching of $4,673 paid in 2004 as reflected in column (e) and (b) premiums paid on key-man life insurance has set forth in column (i). As of the date of this prospectus, we no longer maintain this insurance on the life of Dr. Mannino. Excludes $126,286, which funds were reimbursed by us to the University of Medicine and Dentistry of New Jersey during 2004 (pursuant to a contractual arrangement) for services rendered by Dr. Mannino to such university.

Table of Contents

Option Grants During Year Ended December 31, 2004

	Individual Grants			Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term		
(a)	(b)	(c)	(d)	(e)	(f)	(g)
Name	Number of Securities Underlying Options/SARs Granted(#)	Percent of Total Options/SARs Granted to Employees in Fiscal Year	Exercise or Base Price ($/Sh)	Expiration Date	5%($)	10%($)
Francis E. O Donnell, Jr.	35,000	12.04%	$ 2.29	August 29, 2014	$ 4,007.50	$ 8,015.00
Mark A. Sirgo	5,147	1.77%	$ 3.40	October 21, 2014	$ 874.99	$ 1,749.98
Andrew L. Finn	5,147	1.77%	$ 3.40	October 21, 2014	$ 874.99	$ 1,749.98
Raphael J. Mannino	6,176	2.12%	$ 3.40	October 21, 2014	$ 1,049.92	$ 2,099.84
	20,000	6.887%	$ 2.29	August 29, 2014	$ 2,290.00	$ 4,580.00
James A. McNulty	3,235	1.11%	$ 3.40	October 21, 2014	$ 549.95	$ 1,099.90

In July and August 2004, certain of our directors exercised an aggregate of 160,000 options to acquire shares of our common stock. We raised $272,000 from such exercises.

AGGREGATED OPTIONS/SAR EXERCISES IN LAST FISCAL YEAR

AND FY-END OPTION/SAR VALUES

Name and Principal Position	Shares Acquired On Exercise(#)	Value Realized($)	Number of Securities Underlying Unexercised Options/SARs At Fiscal Year-End(#) Exercisable Unexercisable	Value of Unexercised Unexercisable In-The-Money Options/SARs At Fiscal Year-End($) Exercisable Unexercisable
(a)	(b)	(c)	(d)	(e)
Francis E. O Donnell, Jr., M.D.	35,000		105,000/0	$ 46,734/0
Mark A. Sirgo, Pharm.D.			0/5,147	$ 0/617
Andrew L. Finn, Pharm.D.			0/5,147	$ 0/617
Raphael J. Mannino, Ph.D.			242,016/27,142	$ 197,558/741
James A. McNulty			6,206/15,645	$ 0/388

Employment Agreements

Except as set forth below, we currently have no written employment agreements with any of our officers, directors, or key employees. All directors and officers have executed confidentiality and non-compete agreements with us.

The following is a description of our current executive employment agreements:

(a) Dr. Francis E. O Donnell, Chairman of the Board On March 29, 2002, Dr. O Donnell executed an employment agreement to be our full-time President and CEO at an annual salary of $150,000. Dr. O Donnell s term of employment was to no longer than three years or until another CEO candidate is appointed. However, in January 2005, we entered into an amendment to Dr. O Donnell s employment agreement pursuant to which: (i) he agreed to serve solely in the position of CEO and Chairman of the Board, (ii) the term of his employment was extended until March 22, 2008 and (iii) his annual salary was, effective February 1, 2005, reduced to $1.00. Dr. O Donnell relinquished the title of Chief Executive Officer in August 2005.

(b) Mark A. Sirgo, Pharm.D., President and Chief Executive Officer On August 24, 2004, Dr. Sirgo executed a three-year employment agreement to be our Senior Vice President of Commercial and Corporate

Table of Contents

Development and the President of Arius at an annual salary of $175,000. He was subsequently promoted three times and now holds the position of President and Chief Executive Officer of our company. Dr. Sirgo also received a signing bonus in the amount of $31,177.90 at the signing of this agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(c) Andrew L. Finn, Pharm.D., Executive Vice President of Clinical Development and Regulatory Affairs On August 24, 2004, Dr. Finn executed a three-year employment agreement to be our Senior Vice President of Product Development and the Senior Vice President and Chief Operating Officer of Arius at an annual salary of $175,000. He was subsequently promoted and now holds the position of Executive Vice President of Clinical Development and Regulatory Affairs of our company. Dr. Finn also received a signing bonus in the amount of $28,092.04 at the signing of this agreement. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(d) James A. McNulty, CPA, Chief Financial Officer, Secretary and Treasurer Although he is a part-time CFO, Mr. McNulty has an employment agreement with us (which was amended on August 31, 2002 and subsequently in June 2003) for a base salary of $185,000, reduced to $110,000 in June 2003, which agreement terminates on June 15, 2006. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

(e) Dr. Raphael Mannino, Ph.D., Executive Vice President and Chief Scientific Officer On September 1, 2002, Dr. Mannino executed an employment agreement with us at an annual salary of $210,000. Such agreement was to terminate on September 1, 2005 but an amendment to extend such agreement for an additional one year period was approved by our board of directors in late April 2005. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental and disability and 401(k).

Dr. Mannino had outstanding debt payable to us that was incurred with their purchase of stock in our predecessor, BioDelivery Sciences, Inc., in 1999. Simultaneously with the closing of our public offering in June 2002, we forgave those notes and provided these same individuals with a total of approximately $200,000 as compensation for their tax liability.

Effective April 14, 2005, Dr. Susan Gould-Fogerite, our Vice President and Director of Innovation and Discovery, resigned from BDSI. Previously, in November 2004, Dr. Gould-Fogerite accepted a permanent employment position at UMDNJ. Simultaneously with her resignation, we agreed with Dr. Gould-Fogerite to terminate her employment agreement with us, and in connection therewith, we entered into a termination agreement and release with her and made a one-time payment to her of $7,708.68. In addition, we entered into a consulting agreement with Dr. Gould-Fogerite pursuant to which, through November 15, 2005, Dr. Gould-Fogerite will continue to consult with us on matters relating to our patent estate for up to 8 hours per week at an hourly rate of $150. Finally, effective April 14, 2005, we terminated the 58,057 of our incentive stock options held Dr. Gould-Fogerite and entered into a new option agreement with her pursuant to which we granted her 58,057 non-qualified options (at the same exercise prices as her former incentive stock options), which options terminate on November 15, 2007.

Amended and Restated 2001 Stock Option Plan

The purpose of the Amended and Restated 2001 Stock Option Plan is: (i) to align our interests and recipients of options under the 2001 Stock Option Plan by increasing the proprietary interest of such recipients in our growth and success, and (ii) to advance our interests by providing additional incentives to officers, key employees and well-qualified non-employee directors and consultants who provide services to us, who are responsible for our management and growth, or otherwise contribute to the conduct and direction of its business, operations and affairs.

Our board of directors administers our stock option plan, selects the persons to whom options are granted and fixes the terms of such options.

Under our original 2001 Stock Option Plan, we reserved 572,082 shares. The plan was approved by our stockholders at our October 2001 annual meeting. Our board of directors subsequently voted to amend the 2001

Table of Contents

Stock Option Plan to increase the plan to 1,100,000 shares, and later, through an amendment and restatement of the 2001 Stock Option Plan, to 2,100,000 shares, which was amendment and restatement was approved by our stockholders at the annual meeting in August 2003. Options to purchase 1,735,255 shares of common stock are outstanding as of June 30, 2005 under the Amended and Restated 2001 Stock Option Plan. All options were issued under our stock option plan, as the same may be amended. Options may be awarded during the ten-year term of the stock option plan to our employees (including employees who are directors), consultants who are not employees and our other affiliates. Our stock option plan provides for the grant of options intended to have been approved by our board of directors and qualify as incentive stock options, or Incentive Stock Options, under Section 422A of the Internal Revenue Code of 1986, as amended, and options which are not Incentive Stock Options, or Non-Statutory Stock Options.

Only our employees or employees of our subsidiaries may be granted Incentive Stock Options. Our affiliates or consultants or others as may be permitted by our board of directors, may be granted Non-Statutory Stock Options.

Directors are eligible to participate in our stock option plan. The Amended and Restated 2001 Stock Option Plan provides for an initial grant of an option to purchase up to 20,000 shares of common stock to each director upon first joining our board of directors and subsequent grants of options to purchase 20,000 shares upon each anniversary of such director s appointment. Additionally, directors will be granted 10,000 options for each committee chairmanship and 5,000 options for each committee membership. Such options are granted at an exercise price equal to the fair market value of the common stock on the grant date and immediately vest.

Options and warrants to purchase 2,709,229 shares of our common stock at prices ranging from $1.63 to $17.48 are outstanding at June 30, 2005. None of our options have been granted at less than 85% of the fair market value at the time of grant. Options issued during 2004 to employees and directors totaled 286,296 shares, at exercise prices ranging from $2.29 and $3.40. In addition, in November 2004, we issued warrants to purchase 225,000 shares of common stock at exercise an exercise price of $5.25 to Ferris, Baker Watts and in February and May 2005, we issued warrants to Laurus, although none of such warrants were issued under our stock option plan.

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Table of Contents

UNDERWRITING

Subject to the terms and conditions of an underwriting agreement, dated , 2005, the underwriters named below have severally agreed to purchase from us the number of shares of common stock indicated in the following table. Ferris, Baker Watts, Incorporated is acting as the lead underwriter of this offering and, together with Maxim Group LLC and GunnAllen Financial, Inc., are acting as representatives of the underwriters.

Underwriters	Number of Shares
Ferris, Baker Watts, Incorporated	
Maxim Group LLC	
GunnAllen Financial, Inc.	
Total	

This offering will be underwritten on a firm commitment basis. The underwriters propose to offer shares of our common stock, directly to the public at the public offering price set forth on the cover page of this prospectus. Any shares sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of $ per share. The underwriters may allow, and these selected dealers may re-allow, a concession of not more than $ per share to other brokers and dealers. After the shares of common stock are released for sale to the public, the offering price and other selling terms may, from time to time, be changed by the underwriters.

The underwriters obligations to purchase shares of our common stock are subject to conditions contained in the underwriting agreement. The underwriters are obligated to purchase all of the shares of common stock that they have agreed to purchase under the underwriting agreement, other than those covered by the over-allotment option, if they purchase any shares. The offering of the shares of common stock is made for delivery when, as and if accepted by the underwriters and subject to prior sale and to withdrawal, cancellation and modification of the offering without notice. The underwriters reserve the right to reject any order for the purchase of shares of common stock.

The following table summarizes the underwriting discount to be paid to the underwriters by us.

	Per Share	Total, with no exercise of over-allotment option	Total, with full exercise of over-allotment option
Underwriting discount	$	$	$

We have agreed to sell the shares of common stock to the underwriters at the public offering price of $ per share, which represents the public offering price of the shares of common stock less the 6.5% underwriting discount. We have also agreed to pay certain expenses of the underwriters whether or not the public offering is consummated. We have also agreed to pay FBW, the lead underwriter of this offering, 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.

Over-allotment Option

We have granted to the underwriters an option, exercisable not later than 30 days after the date of this prospectus, to purchase up to 750,000 additional shares of our common stock at the public offering price, less the underwriting discount, set forth on the cover page of this prospectus. This amount of shares represents 15% of the shares sold by us in this offering. The underwriters may exercise the option solely to cover over-allotments, if any, made in connection with this offering. To the extent that the underwriters exercise the option, each underwriter will become obligated, as long as the conditions of the underwriting agreement are satisfied, to purchase a number of additional shares of common stock approximately proportionate to that underwriter s initial commitment as indicated in the table above. We will be obligated, pursuant to the option, to sell these additional

Table of Contents

shares of common stock to the underwriters to the extent the option is exercised. If any additional shares of common stock are purchased pursuant to the option, the underwriters will offer the additional shares on the same terms as those on which the other shares are being offered hereby.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of any of these liabilities.

Lock-Up Agreements

All of our executive officers, directors and certain of our stockholders beneficially owning 5% or more of our common stock have agreed not to make any sales, transfers or other dispositions of their shares for a period of six months from the date of this prospectus.

Stabilization, Short Positions and Penalty Bids

In connection with the offering, the underwriters may engage in over-allotment, syndicate covering transactions, stabilizing transactions and penalty bids or purchases for the purpose of stabilizing, maintaining or otherwise affecting the price of our common stock.

These syndicate covering transactions, stabilizing transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock above that which might otherwise prevail in the open market or preventing or retarding a decline in the market price of our common stock. The imposition of a penalty bid may also affect the price of the common stock to the extent that it discourages resales. These transactions may be effected on the Nasdaq SmallCap Market and Boston Stock Exchange or otherwise and, if commenced, may be discontinued at any time.

Neither we nor the underwriters make any representation or prediction as to the magnitude or effect of any such transaction. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Pricing of the Offering

The offering price for our common stock has been determined by negotiations between us and Ferris, Baker Watts, Incorporated. Among the primary factors considered in determining the public offering price were:

- prevailing market and economic conditions;

our capital structure;

our limited operating history;

the valuation multiples of publicly traded companies that Ferris, Baker Watts, Incorporated believes to be comparable to us; and

estimates of our business potential and earning prospects.

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 achieved or 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.

Table of Contents

Listing of Shares

Our common stock and warrants are quoted on the Nasdaq SmallCap Market under the symbols BDSI and BDSIW, respectively, and are listed on the Boston Stock Exchange under the symbols BDS and BDS&W, respectively.

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Table of Contents

DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR

SECURITIES ACT LIABILITIES

Our certificate of incorporation provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted under the Delaware General Corporation Law, provided that they acted in good faith and that they reasoned their conduct or action was in, or not opposed to, the best interest of our company.

Our Bylaws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the Delaware General Corporation Law. Further, we maintain officer and director liability insurance.

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

LEGAL MATTERS

The legality of the securities offered in this prospectus has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York. Gersten Savage LLP has served as counsel to the underwriters in connection with this offering. Ellenoff Grossman & Schole LLP is a beneficial owner of certain of our securities. Please see Certain Relationships and Related Transactions above for further information. In addition, Ellenoff Grossman & Schole LLP has previously represented Maxim Group LLC, an underwriter in this offering, and expects to do so again in the future.

EXPERTS

The audited financial statements for the years ended December 31, 2004 and 2003 for BioDelivery Sciences International, Inc. and the audited financial statements of Arius Pharmaceuticals, Inc. for the year ended December 31, 2003 are included in this prospectus and have been included in reliance on the reports of Aidman Piser & Company, P.A., independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

AVAILABLE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the Commission s public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the

operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We also make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please contact James A. McNulty at 324 Hyde Park Avenue, Suite 350, Tampa, FL 33606. Additionally, please note that we file our SEC reports electronically. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. Our Internet address is http://www.bdsinternational.com. Our website and the information contained therein or connected thereto are not incorporated into this prospectus.

Table of Contents

We have filed with the Commission a registration statement (which contains this prospectus) on Form SB-2 under the Securities Act relating to the common stock being offered pursuant to this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us and the common stock. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the registration statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC.

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Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Index to Financial Statements

BioDelivery Sciences International, Inc.

Arius Pharmaceuticals, Inc.

Pro forma financial information

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors

BioDelivery Sciences International, Inc.

We have audited the accompanying consolidated balance sheet of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2004, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the two years in the period then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2004, and the consolidated results of their operations and their cash flows for each of the two years in the period then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Aidman, Piser & Company, P.A.

Tampa, Florida

February 8, 2005, except for Note 13, for which

the date is July 15, 2005

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

DECEMBER 31, 2004

ASSETS	
Current assets:	
Cash and cash equivalents	$ 749,932
Accounts receivable	27,145
Due from related party	9,290
Prepaid expenses and other current assets	242,849
Total current assets	1,029,216
Equipment, net	895,294
Goodwill	2,715,000
Other intangible assets:	
Licenses	2,417,445
Non-compete agreements	500,000
Accumulated amortization	(211,658)
Total other intangible assets	2,705,787
Other assets	24,726
Total assets	$ 7,370,023
LIABILITIES AND STOCKHOLDERS EQUITY	
Current liabilities:	
Current maturities of note payable, bank	$ 333,333
Accounts payable and accrued expenses	758,220
Due to related party	171,327
Deferred revenue	123,311
Total current liabilities	1,386,191
Commitments and contingencies (Note 10)	
Stockholders equity:	
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 1,647,059 issued and outstanding	3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized, 7,245,863 shares issued; 7,145,863 shares outstanding	7,246
Additional paid-in capital	14,619,701
Treasury stock, at cost, 100,000 shares	(303,894)
Accumulated deficit	(13,495,104)
Total stockholders equity	5,983,832
Total liabilities and stockholders equity	$ 7,370,023

See notes to consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2004 AND 2003

	2004	2003
Sponsored research revenues	$ 778,898	$ 913,231
License fees, related parties	1,000,000	2,000,000
	1,778,898	2,913,231
Expenses:		
Research and development:		
Related party	807,524	298,251
Other	3,180,513	2,335,694
General and administrative:		
Stock-based compensation	263,798	200,039
Related party	263,804	220,266
Other	2,747,087	2,416,341
	7,262,776	5,470,591
Loss from operations	(5,483,828)	(2,557,360)
Other income (expense):		
Sale of royalty rights, related party	2,500,000	
Sale of tax loss carryforwards	216,674	
Interest income (expense), net	(59,361)	69,254
	2,657,313	69,254
Loss before income taxes	(2,826,515)	(2,488,106)
Income tax benefit		
Net loss	(2,826,515)	(2,488,106)
Preferred stock dividends	(22,303)	
Loss attributable to common stockholders	$ (2,848,818)	$ (2,488,106)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (0.40)	$ (0.35)
Weighted average common stock shares outstanding:		
Basic and diluted	7,054,616	7,016,679

See notes to consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2004 AND 2003

	Series A Preferred Stock		Series B Preferred stock						Total
	Shares	Amount	Shares	Amount	Common Stock		Additional Paid-In	Treasury Equity	Accumulated Deficit	Stockholders Equity
Balances, January 1, 2003		$		$	7,085,863	$ 7,086	$ 13,956,327	$	$ (8,180,483)	$ 5,782,930
Stock-based compensation							200,039			200,039
Stock offering costs							(50,000)			(50,000)
Purchase of treasury stock								(303,894)		(303,894)
Net loss									(2,488,106)	(2,488,106)
Balances, December 31, 2003					7,085,863	7,086	14,106,366	(303,894)	(10,668,589)	3,140,969
Stock-based compensation							263,798			263,798
Exercise of stock options					160,000	160	271,840			272,000
Series A Preferred Stock issuance in connection with business acquisition	1,647,059	3,705,883								3,705,883
Issuance of Series B Preferred Stock for cash			341,176	1,450,000						1,450,000
Series B Preferred Dividends							(22,303)			(22,303)
Net loss									(2,826,515)	(2,826,515)
Balances, December 31, 2004	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,245,863	$ 7,246	$ 14,619,701	$ (303,894)	$ (13,495,104)	$ 5,983,832

See notes to consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2004 AND 2003

	2004	2003
Operating activities:		
Net loss	$ (2,826,515)	$ (2,488,106)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation	284,251	200,048
Amortization	174,081	41,706
Loss on sale of marketable securities	9,899	
Stock-based compensation expense	263,798	200,039
Expense in-process research and development from acquisition	200,000	
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(27,145)	2,000,000
Prepaid expenses and other assets	(20,359)	(20,972)
Accounts payable and accrued expenses	(1,089,023)	(413,617)
Deferred revenue	99,337	(1,942,271)
Net cash flows from operating activities	(2,931,676)	(2,423,173)
Investing activities:		
Purchase of equipment	(111,949)	(832,583)
Cash acquired in business acquisition	57,675	
Proceeds from disposal (purchase) of investments	2,017,753	(2,027,652)
Net cash flows from investing activities	1,963,479	(2,860,235)
Financing activities:		
Proceeds from exercise of stock options	272,000	
Expense associated with stock offering		(50,000)
Proceeds from issuance of Series B Preferred stock	1,450,000	
Proceeds from notes payable		1,000,000
Repurchase of treasury stock		(303,894)
Proceeds from related party borrowings	100,201	10,111
Payment on capital lease obligations	(4,742)	(12,775)
Payment on notes payable	(625,000)	(41,667)
Net cash flows from financing activities	1,192,459	601,775
Net change in cash	224,262	(4,681,633)
Cash at beginning of year	525,670	5,207,303
Cash at end of year	$ 749,932	$ 525,670

The Company paid interest of $0.06 million and $0.04 million during 2004 and 2003, respectively.

In August 2004, the Company issued 1,647,059 shares of Series A Preferred stock at a value of $3.7 million for the acquisition of Arius Pharmaceuticals, Inc.

The Company accrued $0.02 million in annual cumulative dividends in connection with its Series B Preferred stock during 2004.

See notes to consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

1. Nature of business and summary of significant accounting policies:

Organization:

BioDelivery Sciences International, Inc. (BDSI or the Company) was incorporated in the State of Indiana on January 6, 1997 and later reincorporated as a Delaware corporation in 2002. BDSI and its subsidiaries are collectively referred to as the Company.

BDSI is a specialty biopharmaceutical company that is exploiting its licensed and proprietary patented drug delivery technologies to develop and commercialize clinically-significant new formulations of proven therapeutics and micronutrients. The Company s drug delivery technologies include: (i) the licensed and patented Bioral® nanocochleate technology, designed for a potentially broad base of applications, and (ii) the licensed and patented BEMA (transmucosal, or applied to the inner cheek membrane) drug delivery technology being developed by the Company s Arius Pharmaceuticals, Inc. subsidiary (Arius), which was acquired in August 2004. Arius is developing products for acute treatment opportunities such as pain, anxiety, nausea and vomiting.

Principles of consolidation:

The financial statements include the accounts of BDSI and its majority-owned subsidiaries, Arius (from the date of acquisition of August 24, 2004) and Bioral Nutrient Delivery, LLC (BND), which is currently an inactive subsidiary. All significant inter-company balances have been eliminated.

Revenue recognition:

Sponsored research amounts are recognized as revenue when the research underlying such funding 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.

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.

In April 2004, the Company entered into a sublicensing agreement (the Accentia License Agreement) with Accentia Biopharmaceuticals, Inc., f/k/a Accentia, Inc. (Accentia), a related company, pursuant to which the Company was entitled to a 12% to 14% royalty stream from an oral compound for the treatment of chronic rhinosinusitus. Under the terms of the Accentia License Agreement, all development costs are paid by Accentia. The Company is entitled to that royalty stream based on its application of encochleated technology to licensed drugs. In September 2004, in part to address the Company s liquidity, the Company entered into an asset purchase

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

agreement with Accentia whereby the Company sold to Accentia an asset consisting of 50% of a portion of the future revenue stream under the Accentia License Agreement (and a resulting reduction of future royalty payments) for a one-time non-refundable payment of $2.5 million. The Company has no material ongoing obligations under the agreement or its asset purchase agreement with Accentia, and the Company has subsequently clarified with Accentia the actual original agreement between the parties regarding the Company s and Accentia s obligations. As such, the $2.5 million, which was paid in September, is recognized as other income in the 2004 financial statements.

Research and development:

Research and development expenses are charged to operations as incurred. Research and development expenses principally include consulting fees and cost reimbursements to The University of Medicine and Dentistry of New Jersey (UMDNJ), testing of compounds under investigation, and salaries and benefits of employees engaged in research and development activities.

Cash and cash equivalents:

The Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. The Company maintains its financial instruments in a variety of high-credit quality financial institutions. At December 31, 2004, approximately $0.5 million exceeded those amounts insured by the FDIC.

Fair value of financial instruments:

At December 31, 2004, the carrying amount of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and note payable approximate fair value based either on the short term nature of the instruments or on the related interest rate approximating the current market rate.

Equipment:

Office and laboratory equipment are carried at cost less accumulated depreciation, which is computed on a straight-line basis over their estimated useful lives, generally 5 years. Accelerated depreciation methods are utilized for income tax purposes.

Goodwill and other intangible assets:

Other intangible assets include licenses and noncompete agreements, which are accounted for based on Financial Accounting Standard Statement No. 142 *Goodwill and Other Intangible Assets* (FAS 142). In that regard, goodwill and intangible assets that have indefinite useful lives are not amortized but are tested at least annually for impairment, or more frequently if events or changes in circumstances indicate that the asset might be impaired.

Intangible assets with finite useful lives are amortized over the estimated useful lives as follows:

	Estimated Useful Lives
Noncompete agreements	2 years
Licenses	13 years

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

Estimated aggregate future amortization expense for other intangible assets with finite lives for each of the next five years and thereafter is as follows:

Year ending December 31,	
2005	$ 289,800
2006	206,475
2007	39,804
2008	39,804
2009	39,804
Thereafter	238,818
	$ 854,505

Income taxes:

Deferred income tax assets and liabilities are determined based on differences between the financial statement and tax bases of assets and liabilities as measured by the enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

Use of estimates in financial statements:

The preparation of the accompanying financial statements conforms with accounting principles generally accepted in the United States of America and requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures 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 and assumptions.

Impairment of assets:

The Company periodically reviews long-lived assets, and intangible assets with finite lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company uses an estimate of the undiscounted cash flows over the remaining life of its long-lived assets, or related group of assets where applicable, in measuring whether the assets to be held and used will be realizable. In the event of an impairment, the Company would discount the future cash flows using its then estimated incremental borrowing rate to estimate the amount of the impairment.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

Net loss per common share:

The Company had net losses for all periods presented in which potential common shares were in existence. Diluted loss per share assumes conversion of all potentially dilutive outstanding common stock equivalents. Potential common shares outstanding are excluded from the calculation of diluted loss per share if their effect is anti-dilutive. As such, dilutive loss per share is the same as basic loss per share for all periods presented as the effect of all the following common stock equivalents outstanding is anti-dilutive:

The following table sets forth the calculations of basic and diluted net loss per share:

	2004	2003
Numerator:		
Net loss attributable to common stockholders	$ (2,848,818)	$ (2,488,106)
Denominator:		
For basic loss per share weighted average shares	7,054,616	7,016,679
Effect of dilutive securities		
Weighted average shares for dilutive loss per share	7,054,616	7,016,679
Net loss per share attributable to common Stockholders, basic and dilutive	$ (0.40)	$ (0.35)

The effect of common stock equivalents are not considered in the calculation of diluted loss per share because the effect would be anti-dilutive. They are as follows:

	2004	2003
Options and warrants to purchase common stock	2,086,480	1,744,043
Preferred stock convertible to common stock	1,988,235	

Stock-based compensation:

The Company has elected to account for its employee stock compensation plans using the intrinsic value method under Accounting Principles Board Opinion No. 25 with pro forma disclosures of net earnings and earnings per share, as if the fair value based method of accounting defined in Statement of Financial Accounting Standards (SFAS) 123 had been applied.

Had compensation cost for the Company s stock option plan been determined based on the fair value at the grant dates for stock-based employee compensation arrangements consistent with the method required by SFAS 123, the Company s net loss and net loss per common share would have been the pro forma amounts indicated below (see Note 12):

	Years ended December 31,	
	2004	**2003**
Loss attributable to common stockholders, as reported	$ (2,848,818)	$ (2,488,106)
Stock-based employee compensation, as reported		19,200
Stock-based employee compensation cost under the fair value based method	(620,467)	(640,091)
Pro forma loss attributable to common stockholders under fair value method	$ (3,469,285)	$ (3,108,997)
Loss per share attributable to common stockholders basic and diluted:		
As reported	$ (0.40)	$ (0.35)
Pro forma under fair value method	$ (0.49)	$ (0.44)

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

Accounting and reporting developments:

In June 2003, the Securities and Exchange Commission (SEC) adopted final rules under Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404). Commencing with the Company s 2006 Annual Report, the Company is required to include a report of management on the Company s internal control over financial reporting. The internal control report must include a statement of management s responsibility for establishing and maintaining adequate internal control over financial reporting for the Company; of management s assessment of the effectiveness of the Company s internal control over financial reporting as of year end; of the framework used by management to evaluate the effectiveness of the Company s internal control over financial reporting; and that the Company s independent accounting firm has issued an attestation report on management s assessment of the Company s internal control over financial reporting, which report is also required to be filed as part of the Annual Report on Form 10-K.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs. The statement amends Accounting Research Bulletin (ARB) No. 43, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material. ARB No. 43 previously stated that these costs must be so abnormal as to require treatment as current-period charges. SFAS No. 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, this statement requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005, with earlier application permitted for fiscal years beginning after the issue date of the statement. The adoption of SFAS No. 151 is not expected to have any significant impact on the Company s current financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets An Amendment of APB Opinion No. 29. APB Opinion No. 29, Accounting For Nonmonetary Transactions, is based on the opinion that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. SFAS No. 153 amends Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets whose results are not expected to significantly change the future cash flows of the entity. The adoption of SFAS No. 153 is not expected to have any impact on the Company s current financial condition or results of operations.

In December 2004, the FASB revised its SFAS No. 123 (SFAS No. 123R), Accounting for Stock Based Compensation. The revision establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, particularly transactions in which an entity obtains employees services in share-based payment transactions. The revised statement requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is to be recognized over the period during which the employee is required to provide service in exchange for the award. The provisions of the revised statement are effective for financial statements issued for the first interim or annual reporting period beginning after December 15, 2005 for small business issuers, with early adoption encouraged. The Company plans to adopt this standard on January 1, 2005.

This Statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date.

As of the required effective date, the Company will apply this Statement using a modified version of prospective application. Under that transition method, compensation cost is recognized on or after the required effective date for the portion of outstanding awards for which the requisite service has not yet been rendered, based on the grant-date fair value of those awards calculated under Statement 123 for pro forma disclosure purposes.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

2. Bioral Nutrient Delivery, LLC corporate structure:

On January 8, 2003, the Company formed BND as a majority-owned subsidiary. BND presently has two classes of equity interests: Class A Shares and Class B Shares. As of the date of this report, BDSI owns approximately 94.5% of BND s Class B Shares and all 708,587 of BND s Class A Shares.

During 2003, BND filed a registration statement on Form SB-1 on behalf of BDSI. In connection therewith, the Company made plans to distribute to BDSI stockholders 3,545,431 of BND s Class B Shares, or approximately 43% of BND s outstanding equity interests, including the Class A Shares. After having reevaluated this strategic opportunity, the Company decided in early 2005 to forego the planned distribution of Class B Shares and presently have no intention of effecting any such distribution. Offering costs aggregating approximately $0.3 million have been expensed in the accompanying 2003 statement of operations. BND is substantially inactive at December 31, 2004.

3. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, through short-term borrowings, which were subsequently repaid, and from funded research arrangements. The Company has not generated revenue from the sale of any product but has generated revenues from licensing arrangements in 2004 and 2003 and the sale of royalty rights in 2004. The Company intends to finance its research and development efforts and its working capital needs from existing cash, new sources of financing and licensing agreements.

In July and August 2004, certain directors of the Company exercised certain of their options to acquire shares of Company common stock (the Common Stock) and, as a result, $0.3 million in equity proceeds was generated.

On September 3, 2004, the Company entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC (HCG), a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman and CEO. Pursuant to the Equity Line Agreement, HCG will, at the Company s request, invest up to $4.0 million in the 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 December 31, 2004, $1.45 million had been drawn under the Equity Line Agreement.

On February 22, 2005, the Company consummated a $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., a Cayman Islands corporation (Laurus). Net proceeds from the financing were used primarily to retire the 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 research and

development opportunities and for general working capital purposes.

The Laurus investment takes the form of a convertible note secured by certain 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 Common Stock at a price equal to $3.10 per share. In connection with the financing, Laurus was issued a common stock purchase warrant to purchase up to 350,000 shares of Common Stock at a price equal to $3.88 per share. The Company agreed, pursuant to a registration rights agreement, to register the shares of Common Stock underlying the Laurus note and the warrant.

The Company s existing cash and cash equivalents, together with available financing, including the remaining balances of the Company s existing equity line of credit and grant, and potential new license revenue

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

is considered by management to be sufficient to finance the planned operations and capital expenditures through at least December 31, 2005. Based on product development timelines and agreements with the Company s 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, the Company anticipates it may be required to raise additional capital through a variety of sources, including:

- the public equity markets;
- private equity financings;
- collaborative arrangements;
- 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, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company, financial condition and 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.

4. Business acquisition:

On August 24, 2004, the Company completed the acquisition of Arius through a stock transaction. The transaction was structured as a reorganization of Arius by way of merger with and into a newly formed, wholly-owned subsidiary of the Company. As part of the transaction, the Company issued to the former stockholders of Arius 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of

convertible preferred stock, designated as Series A Non-Voting Convertible Preferred Stock (the Series A Preferred). The Series A Preferred will be convertible (upon the satisfaction of certain conditions) into shares of Common Stock on a one for one basis. The Series A Preferred is eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date.

The Company engaged an independent valuation firm to prepare a valuation of the Series A Preferred issued, and the intangibles acquired, in connection with the Arius transaction. The Series A Preferred was valued at $2.25 per share, which included a 30% discount from the public trading price. The stock contains an enforced holding period of up to six years and as such the value was measured by calculating the cost of a put option resulting in the $2.25 per share value.

Arius is a specialty pharmaceutical company created to develop and commercialize products for acute conditions associated with surgery and cancer. The Company believes its acquisition of Arius will assist the Company in the furtherance of its strategy of shifting its corporate focus from being solely a drug delivery concern to a company focusing on the area of specialty pharmaceuticals , namely, applying the Company s licensed drug delivery technologies to existing therapeutics to create the Company s own proprietary formulations, for which the Company will then seek to obtain FDA approval and subsequently commercialize.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

This strategy seeks to avoid the high risk and cost of developing new chemical entities by focusing on the development and commercialization of new formulations of existing, FDA-approved therapeutic pharmaceuticals to which the Company s delivery technologies are applied.

The Arius acquisition was treated as a business acquisition as opposed to an asset acquisition, pursuant to guidance provided by Statement of Financial Accounting Standard 141, *Business Combinations* (SFAS 141) and Emerging Issues Task Force Release 98-3 *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business* (EITF 98-3).

Arius had entered into licensing arrangements which resulted in revenue recognized of $176,000 at the time of the acquisition, with deferred revenue recognizable in the future of $123,500. Pursuant to EITF 98-3, if the business involves a self-sustaining integrated set of activities and assets conducted and managed for the purpose of providing a return to investors, absence of significant revenues does not preclude treatment as a business acquisition as opposed to an asset acquisition. Further, Arius possessed all elements necessary to continue to conduct normal operations and met other criteria specified in EITF 98-3 to qualify as a business acquisition.

Intangible assets acquired consisted of $1.9 million in licenses which have estimated lives of 13 years, $0.5 million in non-compete agreements which have estimated lives of 2 years and $2.7 million of purchased goodwill.

As noted above, Arius business focus is to develop and commercialize products for pain associated with surgery and cancer, incorporating a novel delivery system that improves the speed of onset and provides convenience to the patient and healthcare provider.

The BEMA technology was licensed from a third party and is associated with several products that have INDs (investigational new drug applications). As an example, one of these products is BEMA Fentanyl, a mucosal analgesic targeted for use in breakthrough treatment for cancer pain. The Company will sell its products containing the BEMA technology to wholesalers.

The license acquired for the BEMA technology did not qualify as in-process research and development since the technology was licensed from a third party, Atrix, which granted the BEMA technology to Arius, and which grants Arius an exclusive worldwide license to utilize the technology in its developed products or license the technology to others. This license is a contract-based intangible asset and recognizable as an asset apart from goodwill in accordance with SFAS 141.

Emezine® is a special delivery anti-emetic, which is used to treat nausea and vomiting that may result from chemotherapy and other surgical procedures. The Company, through Arius, has finalized a product distribution agreement for Emezine®, which will generate royalties once product development is complete.

Emezine® is a product that has substance and is a project that is measurable; however, because Emezine® is a new drug not yet approved by the FDA, it is incomplete, and as such, was determined to be in-process research and development based on accepted valuation methodology, specifically the AICPA Practice Aid Assets Acquired in a Business Combination to be Used in Research and Development Activities: a Focus on Software, Electronic Devices and Pharmaceutical Industries.

Goodwill was calculated using the residual method, and after deduction of the above values, including amounts allocable to cash and covenants not to compete, was determined to be $2.7 million, pursuant to SFAS 141.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

Pro forma results of operations as if the acquisition of Arius Pharmaceuticals, Inc. had taken place on January 1, 2004 are as follows:

	As presented for the year ended December 31, 2004	Arius January 1, 2004 through August 23, 2004	Pro forma year ended December 31, 2004
Revenues	$ 1,778,898	$ 176,500	$ 1,955,398
Loss attributable to common stockholders	$ (2,848,818)	$ (136,597)	$ (2,985,415)
Loss per common share attributable to common stockholders	$ (0.40)		$ (0.42)

Pro forma results of operations as if the acquisition of Arius Pharmaceuticals, Inc. had taken place on January 1, 2003 are as follows:

	As presented for the year ended December 31, 2003	Arius for year ended December 31, 2003	Pro forma year ended December 31, 2003
Revenues	$ 2,913,231	$	$ 2,913,231
Net loss	$ (2,488,106)	$ (145,814)	$ (2,633,920)
Net loss per common share	$ (0.35)		$ (0.38)

Purchased in-process research and development:

As discussed above, in connection with its acquisition of Arius, the Company determined that $0.2 million of the acquisition price qualifies as purchased in-process research and development (for Emezine®), and as such, this amount was expensed as research and development expense on the acquisition date.

5. Research and development arrangements and related party transactions:

Upon its formation, BDSI originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, BDSI issued shares of Common Stock with anti-dilution provisions and agreed to make future royalty payments to the universities upon (a) the licensing of rights to sub-licensees (up to 5% of fees as amended on December 16, 2002); (b) sales by sub-licensees (25% of BDSI proceeds); or (c) BDSI sales (3% of revenue). The amendment to the agreement on December 16, 2002 also provided for the granting of options to purchase 75,000 shares of the Common Stock to each of the two universities.

During 2004, the Company entered into a license agreement with TEAMM Pharmaceuticals, Inc., a subsidiary of a company in which BDSI s Chairman and CEO is a significant stockholder. The license agreement granted exclusive rights to Emezine®, revenues of which aggregated $1.0 million and which were earned upon satisfaction of milestones specified in the agreement. BDSI will earn future royalties commencing with FDA approval of the product.

During 2003, the Company entered into a licensing agreement with a company that is also a stockholder. The agreement included a non-refundable payment of $2.0 million in license fee revenue, which the Company

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

deferred and recognized monthly from January through October 2003 (the period of the related research and development commitment). The agreement also provides for milestone payments for each licensed product upon the filing, acceptance and approval of a new drug application by the Food and Drug Administration. During the year ended December 31, 2003, the Company recognized $2.0 million in license fee revenue from this related party. No milestone payments were earned during 2004 or 2003.

The Company has a collaborative research agreement with UMDNJ, an entity that is also a Company stockholder, under which BDSI pays salaries for UMDNJ employees of approximately $0.2 million per year, laboratory supplies and employee parking costs of approximately $0.04 million annually. In addition, the Company paid to UMDNJ approximately $0.05 million for leasehold improvements in 2003. The Company has approximately $0.1 million recorded as due to related party for each year presented. The agreement expires at the end of 2005. As further discussed in Note 10, the Company also leases its Newark, New Jersey facility from UMDNJ under a non-cancelable operating lease agreement.

The Company has also entered into various agreements with other biotechnology/pharmaceutical companies in which the Company s Chairman and CEO is affiliated. These agreements provide for future royalties to the Company. The Company received a total of $1.0 million in development cost reimbursements from Accentia in connection with the Company s Emezine® license.

The Company has an agreement with Pharmaceutical Product Development, Inc., a Company stockholder, for research work in connection with a product under development. The Company had expense of $0.5 million under this agreement in 2004.

The Company paid research-related costs for a product under development to a subsidiary of Accentia in the amount of $0.04 million in 2004.

The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia, and shares three employees, with costs paid based on the approximate time spent on Company activities.

The Company pays costs for business-related aircraft travel to a company that is partially-owned by the Company s Chairman and CEO. Payments of $0.1 million were made in each year presented and are included in general and administrative costs, related party.

6. Equipment:

Equipment consists of the following at December 31, 2004:

Office and laboratory equipment	1,862,977
Less accumulated depreciation and amortization	(967,683)
	$ 895,294

Depreciation and amortization expense related to equipment for the years ended December 31, 2004 and 2003 was approximately $0.3 million and $0.2 million, respectively.

7. Note payable, bank:

Note payable, bank consists of borrowings under a $1.0 million four-year term loan to Gold Bank. Principal and interest at 7.5% per annum is payable in monthly installments of $0.02 million through maturity in October 2007. The note is secured by all equipment of the Company.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

The loan agreement contains various restrictive covenants, including a minimum cash-to-liability ratio. The Company was not in compliance with this covenant as of December 31, 2004, and as such, the entire note subject to being called by the lender and has been classified as a current liability in the accompanying financial statements. Further, the balance was repaid subsequent to December 31, 2004.

8. Income taxes:

The Company has no income tax expense or benefit for 2004 or 2003 as the Company has incurred net operating losses and has recognized valuation allowances for all deferred tax assets.

The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	Year Ended December 31,	
	2004	2003
Federal statutory income tax rate	34.00%	34.00%
State taxes, net of federal benefit	3.45	3.00
Permanent differences compensation expense	(8.77)	(9.00)
Acquisition	24.09	
Valuation allowance	(52.77)	(28.00)
	%	%

The tax effects of temporary differences and net operating losses that give rise to significant portions of deferred tax assets and liabilities consisted of the following:

	December 31,	
	2004	2003
Deferred tax assets (liabilities)		

Basis difference in equipment	$ (200,000)	$ (324,000)
Basis difference in intangibles	(1,623,000)	
Accrued liabilities and other	70,000	22,000
Net operating loss carry-forward	3,931,000	3,156,000
	2,178,000	2,854,000
Less: valuation allowance	(2,178,000)	(2,854,000)
Net deferred tax	$	$

In 2004, the Company sold New Jersey net operating losses for aggregate proceeds of $0.2 million. As a result of this sale $3.2 million in state tax operating loss carryforwards are no longer available. At December 31, 2004, the Company has a federal and state net operating loss carryforwards of approximately $10.5 million which principally expire beginning in 2020 and 2007 for federal and state purposes, respectively.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

9. Stockholders equity:

Preferred stock:

The Company has authorized five million shares of $.001 par value preferred stock. At December 31, 2004, 2,588,236 shares were designated as follows:

Convertible Preferred Shares:	
Series A	1,647,059
Series B	941,177
	2,588,236

The holders of outstanding shares of Series A Preferred stock have the right to convert one (1) share of Series A Preferred stock into one (1) share of fully paid and non-assessable Common Stock. The Series A Preferred is eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date. The Series A Preferred enjoys certain other rights and privileges.

The Series B Preferred is convertible into shares of Common Stock at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to shares of the Company s Common Stock and the Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges.

On August 23, 2004, the Company entered into a private, unregistered Equity Line Agreement with HCG, a principal stockholder of the Company, whereby HCG will, as requested by the Company, invest up to $4.0 million in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock of BDSI (the Series B Preferred). As of December 31, 2004, $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 Common Stock at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to shares of the Company s Common Stock and the Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. HCG is an affiliated entity of the Company which is controlled and partially-owned by the Company s Chairman and CEO.

Additionally, the Company has the right, in its 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 Company s stockholders. Finally, HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

Treasury stock:

During the second quarter of 2003, the Company purchased 100,000 shares of Common Stock with a per share price between $2.80 and $3.20 for a total cost of $303,894.

Stock options:

The Company has a stock option plan, which covers a total of 2,100,000 shares of Common Stock (as amended). Options may be awarded during the ten-year term of the 2001 stock option plan to Company employees, directors, consultants and other affiliates.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

For the purpose of determining non-employee stock-based compensation and the pro forma presentation in Note 1, the fair value of each option grant is estimated on the date of grant using the Black Scholes options-pricing model with the following weighted-average assumptions used for grants in 2004 and 2003: no dividend yield, expected volatility of 73%; risk-free interest rates between 2.62% and 4.50% and expected lives of 5 years.

Activity related to options is as follows and excludes 2,085,000 warrants issued in connection with the 2002 public offering of securities.

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding at January 1, 2003	1,289,383	$ 5.76
Granted in 2003:		
Officers and Directors	205,000	3.82
Others	409,149	3.46
Forfeitures	(159,489)	6.89
Outstanding at December 31, 2003	1,744,043	4.81
Granted in 2004:		
Officers and Directors	225,000	2.29
Others	132,591	3.63
Exercised	(160,000)	1.70
Forfeitures	(80,154)	2.85
Outstanding at December 31, 2004	1,861,480	$ 5.03

Options outstanding at December 31, 2004 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
$ 1.00 5.00	1,430,480	5.5	$ 3.06
$ 5.01 10.00	201,024	2.5	$ 5.81

$10.01	15.00	114,988	1.8	$ 11.80
$15.01	20.00	114,988	1.8	$ 17.48
		1,861,480		

Options exercisable at December 31, 2004 are as follows:

Range of Exercise Prices		Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
$ 1.00	5.00	1,256,601	5.7	$ 2.98
$ 5.01	10.00	180,192	2.5	$ 5.84
$10.01	15.00	114,988	1.8	$ 11.80
$15.01	20.00	114,988	1.8	$ 17.48
		1,666,769		

The weighted average grant date fair value of options granted during 2004 and 2003 whose exercise price is equal to the market price of the stock at the grant date was $2.54 and $1.96, respectively. The weighted average grant date fair value of options granted whose exercise price is less than the estimated market price of the stock at the grant date is $1.83 in 2003. The weighted average grant date fair value of options granted during 2004 and 2003 whose exercise price is greater than the estimated market price of the stock at the grant date is $2.15 and $4.54, respectively.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

10. Commitments and contingencies:

Employment agreements:

The Company has employment agreements with certain employees, which extend for 36 months. These agreements provide for base levels of compensation and separation benefits. Future minimum payments under these employment agreements as of December 31, 2004 are $0.7 million, $0.4 million and $0.2 million for the years ended December 31, 2005, 2006 and 2007, respectively.

Operating lease:

Since April 2001, the Company has leased a facility from UMDNJ (a stockholder), under an operating lease that runs through December 31, 2005. Lease expense for the years ended December 31, 2004 and 2003 was approximately $0.06 million and $0.05 million, respectively. During 2004, the Company entered into two additional operating lease agreements for office space and equipment. Related party rent expense was $0.01 million for each year presented.

The future minimum commitments on all operating leases at December 31, 2004 are as follows:

Years ending December 31,	
2005	$ 101,585
2006	41,237
2007	33,295
2008	7,188
2009	5,092
	$ 188,397

Indemnifications:

The Company indemnified its officers and directors against costs and expenses related to stockholder and other claims (i.e., only actions taken in their capacity as officers and directors) that are not covered by the Company s directors and officers insurance policy. This indemnification is ongoing and does not include a limit on the maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost. As of December 31, 2004, the Company has not recorded a liability for any obligations arising as a result of these indemnifications as the cause thereof is deemed nominal.

Litigation:

During 2004, the Company was named as the defendant in an action commenced by MAS Capital Inc. (MAS Capital). In the lawsuit, plaintiff seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital, at the Company s request, procured an underwriter to raise capital for us through an initial public offering. The Company has answered the complaint, denying the material allegations asserted by plaintiff. The case is presently in the pre-trial discovery stage. Management believes that plaintiff s claims are without merit and intends to vigorously defend the lawsuit.

The Company may, from time to time, be involved in other actual or potential legal proceedings that are considered to be in the normal course of our business. Management does not believe that any of these proceedings will have a material adverse effect on the Company s business.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

11. Retirement Plan:

During 2003, the Company became the sponsor of a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation requirements. Participants may contribute up to 90% of their eligible earnings, as limited by law. The Company makes a matching contribution equal to 100% on the first 5% that a participant contributes to the plan. The Company made contributions of approximately $0.06 million and $0.05 million in 2004 and 2003, respectively.

12. National Institutes of Health Grant:

In 2001, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (the SBIR), which has been utilized in research and development efforts. The grant consisted of a 2003 grant of $1.0 million (which was fully-funded through August 2004), a 2002 grant of $0.8 million and a 2001 grant of $0.9 million, a total of approximately $2.7 million related to its initial application for the grant through August 2004.

The grant is subject to provisions for monitoring set forth in NIH Guide for Grants and Contracts dated February 24, 2000, (specifically, the NIAID Policy on Monitoring Grants Supporting Clinical Trials and Studies). The Company incurred approximately $0.9 million and $0.8 million of costs related to this agreement for the year ended December 31, 2004 and 2003, respectively.

During the years ended December 31, 2004 and 2003, the Company received $0.7 million and $0.6 million, respectively, and recognized revenue of $0.7 million and $0.6 million, respectively, from this grant. These amounts are included in sponsored research revenues in the accompanying statements of operations. The grant provides for reimbursement of or advances for future research and development efforts. Upon receiving funding under the grant and utilizing the funds as specified, no amounts are refundable.

In August 2002, the NIH awarded the Company a second grant for $0.6 million over two years. The Company incurred approximately $0.2 million of costs related to this agreement and received and recognized revenue of $0.1 million from this grant for the year ended December 31, 2004.

13. Subsequent events:

On May 31, 2005, the Company 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 the research, development and commercialization opportunities and for general working capital purposes. Like the February 2005 financing, the May Laurus investment takes the form of a convertible note secured by substantially all of the Company s assets. Such note has a 3-year term (subject to certain contingencies) and bears interest at a rate equal to prime plus 2% per annum. The note is convertible, under certain conditions, into shares of Common Stock at a price equal to $3.10 per share. In connection with the financing, we issued to Laurus an additional Common Stock purchase warrant to purchase up to 483,871 shares common stock at a price equal to $3.88 per share. The Company agreed, pursuant to a registration rights agreement, to register the shares of Common Stock underlying the Laurus notes and the warrants.

On June 29, 2005, the Company entered into two separate amendments to the February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments of principal under the February and May 2005 Laurus notes until December 1, 2005. In consideration of Laurus agreement, the Company issued

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2004 AND 2003

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 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 amendments are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005. The Company agreed to register the shares of Common Stock underlying the June warrants with the SEC, which registration statement was declared effective on July 11, 2005.

On July 15, 2005, the Company entered into a clinical development and license agreement with Clinical Development Capital, LLC (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 the Company s BEMA Fentanyl product. All funds made available under the 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. As part of the transaction with CDC, the Company issued a warrant to purchase 500,000 shares of common stock at $3.50 per share. Such warrant 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 numbers 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) 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.

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Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF JUNE 30, 2005 AND DECEMBER 31, 2004

	June 30, 2005 (unaudited)	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,790,161	$ 749,932
Accounts receivable	30,297	27,145
Due from related party	319,535	9,290
Prepaid expenses and other current assets	193,247	242,849
Total current assets	2,333,240	1,029,216
Equipment, net	768,405	895,294
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	2,442,171	2,417,445
Non-compete agreements	500,000	500,000
Accumulated amortization	(429,631)	(211,658)
Total other intangible assets	2,512,540	2,705,787
Other assets	823,361	24,726
Total assets	$ 9,152,546	$ 7,370,023
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current maturities of notes payable	$ 1,515,160	$ 333,333
Accounts payable and accrued liabilities	1,783,983	735,917
Due to related parties	136,026	171,327
Deferred revenue	70,361	123,311
Dividends payable	54,660	22,303
Total current liabilities	3,560,190	1,386,191
Notes payable	1,097,626	
Total liabilities	4,657,816	1,386,191
Commitments (Note 10)		
Stockholders equity:		
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 1,647,059 issued and outstanding	3,705,883	3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000	1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized, 7,304,687 and 7,245,863 shares issued; 7,269,196 and 7,145,863 shares outstanding in 2005 and 2004, respectively	7,305	7,246

Additional paid-in capital	17,711,893	14,619,701
Treasury stock, at cost, 35,490 and 100,000 shares, 2005 and 2004, respectively	(107,783)	(303,894)
Accumulated deficit	(18,272,568)	(13,495,104)
Total stockholders equity	4,494,730	5,983,832
Total liabilities and stockholders equity	$ 9,152,546	$ 7,370,023

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Sponsored research revenues	$ 116,204	$ 247,338	$ 189,616	$ 518,650
License fees and royalties, related parties	369,464		383,853	
Research fees	24,995		24,995	
	510,663	247,338	598,464	518,650
Expenses:				
Research and development	1,864,767	826,499	2,876,237	1,525,614
General and administrative	1,134,980	671,198	2,116,185	1,341,267
Stock-based compensation	1,735	45,096	28,715	77,958
Total expenses	3,001,482	1,542,793	5,021,137	2,944,839
Interest income (expense), net	(196,324)	(30,856)	(354,791)	(25,066)
Loss before income taxes	(2,687,143)	(1,326,311)	(4,777,464)	(2,451,255)
Income tax benefit (expense)				
Net loss	(2,687,143)	(1,326,311)	(4,777,464)	(2,451,255)
Preferred stock dividends	(16,268)		(32,357)	
Other comprehensive gain:				
Unrealized gain on marketable equity securities		1,094		1,094
Loss attributable to common stockholders	$ (2,703,411)	$ (1,325,217)	$ (4,809,821)	$ (2,450,161)
Per share amounts, basic and diluted:				
Loss attributable to common stockholders	$ (0.37)	$ (0.19)	$ (0.66)	$ (0.35)
Weighted average common stock shares outstanding basic and diluted	7,269,196	6,985,863	7,236,856	6,985,863

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STOCKHOLDERS EQUITY

FOR THE SIX MONTHS ENDED JUNE 30, 2005

(Unaudited)

	Series A Preferred Stock		Series B Preferred stock		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances, January 1, 2005	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,245,863	$ 7,246	$ 14,619,701	$ (303,894)	$ (13,495,104)	$ 5,983,832
Stock-based compensation							8,715			8,715
Issuance of common stock					58,824	59	249,941			250,000
Issuance of treasury stock							(76,111)	196,111		120,000
Beneficial conversion feature of convertible debentures							1,259,744			1,259,744
Issuance of warrants with convertible debentures							1,292,002			1,292,002
Issuance of warrants for financing costs							390,258			390,258
Series B Preferred Dividends							(32,357)			(32,357)
Net loss									(4,777,464)	(4,777,464)
Balances, June 30, 2005	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,304,687	$ 7,305	$ 17,711,893	$ (107,783)	$ (18,272,568)	$ 4,494,730

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

CONDENSED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

	Six Months Ended June 30,	
	2005	**2004**
Operating activities:		
Net loss	$ (4,777,464)	$ (2,451,255)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of treasury stock	20,000	
Depreciation	141,638	142,115
Amortization	295,310	19,901
Accretion of interest on convertible debentures	164,532	
Expenses paid through issuance of warrants	84,573	
Loss on sale of marketable securities		9,483
Stock-based compensation	8,715	77,958
Changes in assets and liabilities:		
Accounts receivable	(303,152)	(27,145)
Prepaid expenses	49,589	69,228
Accounts payable and accrued liabilities	1,148,068	316,057
Deferred revenue	(52,950)	(23,974)
Net cash flows from operating activities	(3,221,141)	(1,867,632)
Investing activities:		
Purchase of equipment	(14,750)	(60,288)
Investments, net		1,734,263
Net cash flows from investing activities	(14,750)	1,673,975
Financing activities:		
Proceeds from issuance of common stock	250,000	
Proceeds from convertible debentures	5,000,000	
Repayment of borrowings from related parties	(45,547)	(61,836)
Payment on notes and capital leases	(333,333)	(127,370)
Cash paid for loan costs	(595,000)	
Net cash flows from financing activities	4,276,120	(189,206)
Net change in cash and cash equivalents	1,040,229	(382,863)
Cash and cash equivalents at beginning of period	749,932	525,670

Cash and cash equivalents at end of period	$ 1,790,161	$ 142,807

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Non-cash investing and financing activities:

The Company accrued $32,357 in annual cumulative dividends in connection with its Series B Preferred stock through the second quarter of 2005.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheets of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiary, Arius Pharmaceuticals, Inc. (Arius), and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND and, collectively with Arius, the Company) as of June 30, 2005, and the condensed consolidated statements of operations for the six months ended June 30, 2005 and 2004 have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows at June 30, 2005 and for all periods presented, have been made. The condensed consolidated balance sheet at December 31, 2004, has been derived from the Company s audited consolidated financial statements at that date.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2004, included in the Company s 2004 Annual Report on Form 10-KSB/A, filed with the SEC on April 29, 2005 (2004 Annual Report).

The results of operations for the six months ended June 30, 2005, are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

The accompanying consolidated financial statements include the accounts of BioDelivery Sciences International, Inc. and its subsidiaries, Arius and BND. All intercompany accounts and transactions have been eliminated.

2. Summary of significant accounting policies:

General:

The Company currently generates revenue from licensing, milestone payments and royalties, as well as from grants. Ultimately, if approval of licensed products and formulations is secured from the FDA, the Company s goal is to augment these revenues from sales of such products and formulations, on which royalties and other fees will be paid to licensors and/or third party collaborators. The Company is also required to make

certain license payments to such licensors in accordance with applicable agreements.

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 technologies. 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.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

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.

Other assets:

Other assets consist principally of deferred loan costs, which are being amortized over the life of the related debt.

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.

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 practible 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.

3. Corporate structure:

On August 24, 2004, the Company completed the acquisition of all of the capital stock of Arius. The transaction was structured as a reorganization of Arius with and into a newly formed, wholly-owned subsidiary of the Company. As part of the transaction, the Company issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of a newly designated, non-voting and

non-interest bearing, series of convertible preferred stock, designated as Series A Non-Voting Convertible Preferred Stock (the Series A Preferred). The Series A Preferred will be convertible (upon the satisfaction of certain conditions) into shares of Company common stock (Common Stock) on a one for one basis. The Series A Preferred is eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first product or (ii) five years from the closing date. The Series A Preferred enjoys certain other rights and privileges.

The Company engaged a valuation firm to prepare a valuation of the Series A Preferred issued, and the intangibles acquired, in connection with the Arius transaction. The Series A Preferred has been valued at $2.25, which includes a 30% discount. Cash acquired in the transaction of $57,675 is recorded at cost, as were the liabilities assumed of $1,417,041. Intangibles which are subject to purchase price allocation of $5,315,249, include a license agreement, non-compete agreements with the principals of Arius, in process research and development, and goodwill.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

On January 8, 2003, the Company formed BND as a majority-owned subsidiary. BND presently has two classes of equity interests: Class A Shares and Class B Shares. As of the date of this report, BDSI owns approximately 94.5% of BND s Class B Shares and all 708,587 of BND s Class A Shares.

During 2003, BND filed a registration statement on Form SB-1 on behalf of BDSI. In connection therewith, the Company made plans to distribute to BDSI stockholders 3,545,431 of BND s Class B Shares, or approximately 43% of BND s outstanding equity interests, including the Class A Shares. After having reevaluated this strategic opportunity, the Company decided in early 2005 to forego the planned distribution of Class B Shares and presently have no intention of effecting any such distribution. BND is substantially inactive at June 30, 2005.

4. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, through short-term borrowings, which were subsequently repaid, and from funded research arrangements. The Company has not generated revenue from the sale of any product but has generated revenues from licensing arrangements, milestone payments, and the sale of royalty rights. The Company intends to finance its research and development efforts and its working capital needs from existing cash, new sources of financing and licensing agreements.

On September 3, 2004, the Company entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC (HCG), a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman and CEO. Pursuant to the Equity Line Agreement, HCG will, at the Company s request, invest up to $4.0 million in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock (Series B Preferred). The Series B Preferred will be convertible at any time as of or after April 1, 2006 at a price equal to $4.25 per share. As of June 30, 2005, $1.45 million had been drawn under the Equity Line Agreement.

On February 22, 2005, the Company consummated a three year $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., a Cayman Islands corporation (Laurus). The Laurus investment takes the form of a convertible note secured by substantially all of the assets of the Company, including Arius and BND. Net proceeds from the financing were used primarily to retire the Company s $1.0 million 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 research and development opportunities and for general working capital purposes. Also, on May 31, 2005, the Company 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 the research, development and commercialization opportunities and for general working capital purposes.

In connection with the February financing, Laurus was issued a Common Stock purchase warrant to purchase up to 350,000 shares of Common Stock at a price equal to $3.88 per share. The note bears interest at the prime rate plus 2% (7.5% at February 22, 2005), but not less than 7.5%, and is payable in monthly principal and interest installments of $75,758 beginning June 1, 2005. The note is convertible, under certain conditions, into shares of Common Stock at a price equal to $3.10 per share.

Like the February 2005 financing, the May Laurus investment takes the form of a convertible note secured by substantially all of the Company s assets. Such note has a 3-year term (subject to certain contingencies) and bears interest at a rate equal to prime plus 2% per annum. The note is convertible, under certain conditions, into shares of Common Stock at a price equal to $3.10 per share. In connection with the financing, the Company issued to Laurus an additional Common Stock purchase warrant to purchase up to 483,871 shares Common Stock

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

at a price equal to $3.88 per share. The Company agreed, pursuant to a registration rights agreement, to register the shares of Common Stock underlying the Laurus notes and the warrants with the SEC, and such shares have been so registered as of the date of this prospectus.

On June 29, 2005, the Company entered into two separate amendments to the February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments of principal under the February and May 2005 Laurus notes until December 1, 2005. In consideration of Laurus agreement, the Company 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 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 amendments are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005. The Company agreed to register the shares of Common Stock underlying the June warrants with the SEC, which registration statement was declared effective on July 11, 2005.

On July 15, 2005, the Company entered into a clinical development and license agreement with Clinical Development Capital, LLC (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 the Company s BEMA Fentanyl product. All funds made available under the 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. As part of the transaction with CDC, the Company issued a warrant to CDC to purchase 500,000 shares of Common Stock at $3.50 per share. Such warrant 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 is 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 Common Stock. Finally, such warrant expires after the earlier of: (i) 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 the Company s assets or the acquisition of the Company by another entity by means of merger or other transaction as a result of which the Company s 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 the Company.

The Company s existing cash and cash equivalents, together with available financing, including the remaining balances of the Company s equity line of credit and the remaining balance of our NIH grant, and potential new license revenue is considered by management to be sufficient to finance the planned operations and capital expenditures through at least January 1, 2006. Based on product development timelines and agreements with the Company s 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, the Company anticipates it may be required to raise additional capital through a variety of sources, including:

The public equity markets;

Private equity financings

Collaborative agreements;

Grants and new license revenues;

Bank loans;

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

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, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company, financial condition and 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.

5. Goodwill and other intangible assets:

Estimated aggregate future amortization expense for other intangible assets for each of the next five years is as follows:

Year ending June 30	
2006	$ 435,957
2007	227,624
2008	185,957
2009	185,957
2010	185,957
Thereafter	1,291,088
	$ 2,512,540

6. Notes payable:

On February 22, 2005, the Company consummated its first three-year $2.5 million secured convertible debt financing from Laurus. The Laurus investment takes the form of a convertible note secured by certain assets of the company.

On May 31, 2005, the Company consummated its second three-year $2.5 million secured convertible debt financing from Laurus. The second Laurus investment also takes the form of a convertible note secured by certain assets of the company.

The combined Laurus financing is shown on the balance sheet under the following accounts:

Principal balance of note	$ 5,000,000
Less reduction for:	
Beneficial conversion feature	(1,259,744)
Value of warrants	(1,292,002)
Recorded at closing	2,448,254
Accretion (interest expense) through June 30, 2005	164,532
Carrying value at June 30, 2005	$ 2,612,786
As presented on balance sheet:	
Current maturities of notes payable	$ 1,515,160
Notes payable	1,097,626
	$ 2,612,786

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

The Company s debt arrangements with Laurus include beneficial conversion features. Pursuant to EITF 98-5 Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios and 00-27 Application of Issue No. 98-5 to Certain Convertible Instruments, the Company determined that the effective conversion price should be used to compute intrinsic value and allocated the proceeds based on the relative fair values of the convertible debt instrument and warrants. The 98-5 model was then applied to the amount allocated to the convertible debt and an effective conversion price was calculated and used to measure the intrinsic value of the embedded conversion options.

The fair value of the proceeds was allocated as follows:

February 2005 Financing	
Convertible Debt	$ 1,945,465
Beneficial Conversion feature associated with Warrants	554,535
	$ 2,500,000
May 2005 Financing	
Convertible Debt	$ 1,762,533
Beneficial Conversion feature associated with Warrants	737,467
	$ 2,500,000

The discounts on these notes is being amortized over the life of the debt using the straight-line method, which approximates the effective interest method.

7. Stockholders equity:

Common stock:

During the first quarter of 2005, the Company issued 58,824 shares of Common Stock with a per share price of $4.25 for $250,000 in connection with a transaction with a strategic partner.

Treasury stock:

During the first quarter of 2005, the Company issued 64,510 shares of Treasury Stock with a per share price between $2.04 and $3.00 and a total value of $196,111. These shares satisfied $170,000 in legal fees to the Company s attorneys.

Warrants:

The Company issued to Laurus Common Stock purchase warrants to purchase 833,871 shares of Common Stock in connection with the sale of the convertible notes described in Notes 4 and 6. The warrants have seven-year terms and can be exercised at a price of $3.88.

The Company also issued a warrant to an investment banking firm in connection with the Laurus financing to purchase 225,000 shares of Common Stock. This warrant has a four-year term and can be exercised at a price of $5.25. The fair value of this warrant, determined using the Black-Scholes model, was $554,535.

The Company issued to Laurus a Common Stock purchase warrant to purchase 30,000 shares of Common Stock in connection with the deferment of certain principal payments. The warrant has a seven-year term and can be exercised at a price of $.001.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

8. Net loss per common share:

The Company computes loss per share under Statement of Financial Accounting Standards No. 128, Earnings Per Share. The statement requires presentation of two amounts; basic and diluted loss per share. Basic loss per share is computed by dividing the loss available to common stockholders by the weighted average common shares outstanding. Dilutive earnings per share would include all Common Stock equivalents unless anti-dilutive. The Company has not included the outstanding options, warrants, or convertible preferred stock as Common Stock equivalents because the effect would be anti-dilutive.

The following table sets forth the shares issuable upon exercise of outstanding options and warrants and conversion of debentures that is not included in the basic and diluted net loss per share available to common stockholders:

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Loss attributable to common stockholders, as reported	$ (2,703,411)	$ (1,325,217)	$ (4,809,821)	$ (2,450,161)
Basic:				
Weighted average shares outstanding (denominator)	7,269,196	6,985,863	7,236,856	6,985,863
Net loss per common share basic	$ (0.37)	$ (0.19)	$ (0.66)	$ (0.35)
Diluted:				
Weighted average shares outstanding	7,269,196	6,985,863	7,236,856	6,985,863
Net loss per common share diluted	$ (0.37)	$ (0.19)	$ (0.66)	$ (0.35)

The effect of Common Stock equivalents are not considered in the calculation of diluted loss per share because the effect would be anti-dilutive. They are as follows at June 30, 2005 and 2004:

	2005	2004
Options and warrants to purchase common stock	4,976,126	3,791,777
Preferred stock (convertible to common stock)	1,988,235	
Shares issuable for convertible debt	1,612,904	

9. Stock-based compensation:

The Company follows Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation (SFAS 123), which establishes a fair value based method of accounting for stock-based employee compensation plans; however, the Company has elected to account for its employee stock compensation plans using the intrinsic value method under Accounting Principles Board Opinion No. 25 with pro forma disclosures of net earnings and earnings per share, as if the fair value based method of accounting defined in SFAS 123 had been applied.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDAIRIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS (Continued)

FOR THE SIX MONTHS ENDED JUNE 30, 2005 AND 2004

(Unaudited)

The following table reflects supplemental financial information related to stock-based employee compensation, as required by Statement of Financial Accounting Standards No. 148, ACCOUNTING FOR STOCK-BASED COMPENSATION TRANSITION AND DISCLOSURE.

	Three months ended		Six months ended	
	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
Loss-attributable to common stockholders, as reported	$ (2,703,411)	$ (1,325,217)	$ (4,809,821)	$ (2,450,161)
Stock-based employee compensation, as reported	$ 1,735	$ 45,096	$ 28,715	$ 77,958
Stock-based employee compensation under fair value method	$ 65,952	$ 84,742	$ 124,326	$ 157,250
Pro forma loss attributable to common stockholders under fair value method	$ (2,767,628)	$ (1,364,863)	$ (4,925,432)	$ (2,529,453)
Loss attributable to common stockholders basic and diluted:				
As reported	$ (0.37)	$ (0.19)	$ (0.66)	$ (0.35)
Pro forma under fair value method	$ (0.38)	$ (0.20)	$ (0.68)	$ (0.36)

10. National Institutes of Health Grant:

In 2001, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (the SBIR), which has been utilized in research and development efforts. The grant consisted of a 2003 grant of $1.0 million (which was fully-funded through August 2004), a 2002 grant of $0.8 million and a 2001 grant of $0.9 million, a total of approximately $2.7 million related to its initial application for the grant through August 2004.

The grant is subject to provisions for monitoring set forth in NIH Guide for Grants and Contracts dated February 24, 2000, (specifically, the NIAID Policy on Monitoring Grants Supporting Clinical Trials and Studies). The Company incurred approximately $617,285 and $643,000 of costs related to this agreement for the six months ended June 30, 2005 and 2004, respectively.

During the six months ended June 30, 2005 and 2004, the Company received $-0- and $495,000 respectively, and recognized revenue of $-0- and $519,000, respectively, from this grant. These amounts are included in sponsored research revenues in the accompanying statements of operations. The grant provides for reimbursement of or advances for future research and development efforts. Upon receiving funding under the grant and utilizing the funds as specified, no amounts are refundable.

In August 2002, the NIH awarded the Company a second grant for $0.6 million over two years, which was extended to July 31, 2005 and for which an additional extension has been requested. A balance of $0.2 million remains unexpended under this grant at June 30, 2005. The Company incurred approximately $183,082 and $33,032 of costs related to this agreement for the six months ended June 30, 2005 and 2004, respectively. During the six months ended June 30, 2005 and 2004, the Company received $189,616 and $-0- respectively, and recognized revenue of $189,616 and $-0-, respectively, from this grant.

Table of Contents

Report of Independent Registered Public Accountants

Board of Directors

Arius Pharmaceuticals, Inc.

Raleigh, North Carolina

We have audited the accompanying balance sheet of Arius Pharmaceuticals, Inc. as of December 31, 2003 and the related statements of operations, stockholders deficit and cash flows for the period from inception (April 22, 2003) through December 31, 2003. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Arius Pharmaceuticals, Inc. as of December 31, 2003, and the results of its operations and its cash flows for the period from inception (April 22, 2003) through December 31, 2003 in conformity with United States generally accepted accounting principles.

/s/ Aidman, Piser & Company, P.A.

July 1, 2004, except for Note 2, as to which the date is June 3, 2005

Tampa, Florida

Table of Contents

ARIUS PHARMACEUTICALS, INC.

BALANCE SHEETS

	July 31, 2004 (unaudited)	December 31, 2003
ASSETS		
Current assets:		
Cash	$ 57,675	$ 3,235
Total current assets	57,675	3,235
Purchased product rights, net of amortization of $18,000	1,082,000	
Total assets	$ 1,139,675	$ 3,235
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 1,239,348	$ 111,250
Advances from stockholders	54,191	32,764
Deferred revenue	123,500	
Total current liabilities	1,417,039	144,014
Commitments (Note 6)		
Stockholders deficit:		
Common stock, $0.01 par value; 1,000,000 shares authorized, shares issued and outstanding, 504,688 in 2004; 500,000 in 2003	5,047	(5,000)
Accumulated deficit	(232,411)	(145,779)
	(277,364)	(140,779)
Total liabilities and stockholders deficit	$ 1,139,675	$ 3,235

See notes to financial statements.

Table of Contents

ARIUS PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

	Seven months ended July 31, 2004	From Inception (April 22, 2003) through December 31, 2003
	(unaudited)	
Revenues:		
License revenue	$ 150,000	$
Non-refundable fees	26,500	
	176,500	
Expenses:		
Legal	100,443	62,926
Insurance	21,921	1,550
Consulting	7,483	55,457
Travel and meals	12,759	14,482
Product development	140,269	6,475
Other	12,257	4,889
Amortization	18,000	
	313,132	145,779
Net loss	$ (136,632)	$ (145,779)
Weighted average shares outstanding	501,674	500,000
Net loss per share	$ (.27)	$ (.29)

See notes to financial statements.

Table of Contents

ARIUS PHARMACEUTICALS, INC.

STATEMENT OF STOCKHOLDERS DEFICIT

FROM INCEPTION (APRIL 22, 2003)

THROUGH JULY 31, 2004

	Common Stock		Deficit	
	Shares	Amount	Accumulated	Total
Initial capitalization of the company	500,000	$ 5,000	$	$ 5,000
Net loss for the period			(145,779)	(145,779)
Balances, December 31, 2003	500,000	5,000	(145,779)	(140,779)
Exercised option	4,688	47		47
Net loss for the period (unaudited)			(136,632)	(136,632)
Balances, July 31, 2004 (unaudited)	504,688	$ 5,047	$ (282,411)	$ (282,364)

See notes to financial statements.

Table of Contents

ARIUS PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

	Seven Months Ended July 31, 2004	From Inception Through December 31, 2003
	(unaudited)	
Cash flows from operating activities:		
Net loss	$ (136,632)	$ (145,779)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Amortization	18,000	
Increase in cash resulting from changes in:		
Accounts payable	128,098	111,250
Deferred revenue	123,500	
Net cash flows from operating activities	132,966	(34,529)
Cash flows from investing activities Purchase of license	(100,000)	
Net cash flows from investing activities	(100,000)	
Cash flows from financing activities:		
Proceeds from issuance of stock	47	5,000
Proceeds from stockholder advances	21,427	32,764
Net cash flows from financing activities	21,474	37,764
Net change in cash	54,440	3,235
Cash at beginning of period	3,235	
Cash at end of period	$ 57,675	$ 3,235

Non-cash financing and investing activities

During the seven months ended July 31, 2004 (unaudited) the Company acquired product rights for an aggregate purchase price of $1,000,000, which is included in accounts payable at July 31, 2004.

See notes to financial statements.

Table of Contents

ARIUS PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

FROM INCEPTION (APRIL 23, 2003) THROUGH

DECEMBER 31, 2003 AND SEVEN MONTHS ENDED JULY 31, 2004

1. Nature of business and summary of significant accounting policies:

Nature of business:

Arius Pharmaceuticals, Inc. (the Company), incorporated in the State of Delaware, is being established as a quick-to-market specialty pharmaceutical company to develop and commercialize products for acute conditions common in surgical and cancer patients such as pain and nausea. Planned principal operations commenced in April 2004. The Company is focused on the licensing of technologies and related development and commercialization of quick-to-market products bearing lower development and regulatory risk. Products or rights thereto presently are, and are expected to continue to be, either licensed from companies marketing them outside the United States or developed by the Company.

Interim financial statements:

The financial statements of the Company, in the opinion of management, include all normal and recurring adjustments necessary for a fair presentation of results as of the dates and for all the periods covered by the financial statements. Operating results for the seven months ended July 31, 2004 are not necessarily indicative of the results that may be expected for the entire fiscal year.

Accounting estimates:

The preparation of financial statements in conformity with generally accepted accounting principles requires management 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 income and expenses during the reporting period. Actual results could differ from those estimates.

Impairment of assets:

The Company periodically reviews purchased products rights for impairment, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company uses an estimate of the undiscounted cash flows over the remaining life of its

purchased product rights, or related group of assets where applicable, in measuring whether the assets to be held and used will be realizable. In the event of an impairment, the Company would discount the future cash flows using its then estimated incremental borrowing rate to estimate the amount of the impairment.

Revenue recognition:

The Company recognizes revenue pursuant to licensing agreements over the term of the licensing agreement in proportion to milestones achieved. For arrangements where non-refundable upfront fees exist and there are further payments due upon achieving certain milestones, the Company 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.

Accounting for stock-based compensation:

The Company accounts for stock-based employee compensation arrangements using the intrinsic value method as prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*

Table of Contents

ARIUS PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

FROM INCEPTION (APRIL 23, 2003) THROUGH

DECEMBER 31, 2003 AND SEVEN MONTHS ENDED JULY 31, 2004

(APB No. 25) and Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* (FIN 44). Accordingly, compensation cost for stock options is measured as the excess, if any, of the fair value of the Company s stock at the date of grant over the stock option exercise price. The Company accounts for stock issued to non-employees at their fair value in accordance with the provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123) and Emerging Issues Task Force Consensus No. 96-18 Accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling goods or services. Stock option fair values are determined using the Black-Scholes option pricing method. There were no employee options issued for the seven months ended July 31, 2004 and the year ended December 31, 2003.

2. Liquidity and management s plan of operation and subsequent event:

On August 24, 2004, the Company was acquired by BioDelivery Sciences International, Inc. (BDSI) through a tax-deferred exchange of all the outstanding shares of its common stock for 1,647,059 shares of BDSI Series A Convertible Preferred Stock, valued at $3,705,883. The Preferred Stock is convertible into shares of BDSI common stock upon the earlier of: (i) the first FDA approval received by Arius with respect to an Arius product or (ii) 5 years after the closing of this transaction. The merger with BDSI is intended to provide the Company with sufficient capital to further its business plans.

Such plan includes the pursuit of additional licenses and other similar agreements with third parties relative to products and technologies which the Company intends to commercially exploit, and the consummation of agreements to finance the necessary product development and commercialization activities. To this end, the Company has been in substantive discussions (together with BDSI) with a major pharmaceutical development company and several venture capital funds, which specialize in pharmaceutical and biotechnology investments.

The Company has completed a sublicensing agreement with a marketing partner for its first planned commercial product. This agreement is expected to provide sufficient funds from advances and milestone payments to carry this product through to commercial sales under the current financial plan.

The Company believes that it will be able to attract sufficient investment to sustain operations through 2004 through the BDSI acquisition and recently completed sublicensing agreements. The Company expects to continue with the plan for development and commercialization of the first product using resources available from the founding stockholders and the commercial development partner.

Given the absence of fixed ongoing overhead, management believes that the funds provided by BDSI and milestone payments already received coupled with those anticipated to be collected through July 31, 2005, will be sufficient to sustain operations through that date. Further, since

expenses are controllable, they can be curtailed if deemed necessary.

3. Advances from stockholders:

Advances from stockholders represent unsecured, non-interest bearing obligations to the stockholders, which are due upon demand.

4. Income taxes:

Deferred tax assets consist of the tax effects of net operating loss carryforwards. Realization of deferred tax assets is dependent upon sufficient future taxable income during the periods that carryforwards are expected to be available to reduce taxable income. At July 31, 2004 (unaudited) and December 31, 2003, the Company has recorded a valuation allowance for the entire amount of the deferred tax assets since it is more likely than not that such benefits will not be realized due to expiration of its operating loss carryforwards and ownership changes.

Table of Contents

ARIUS PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

FROM INCEPTION (APRIL 23, 2003) THROUGH

DECEMBER 31, 2003 AND SEVEN MONTHS ENDED JULY 31, 2004

The reconciliation of the Federal statutory income tax rate of 35% to the effective rate is as follows:

	2003	2002
Federal statutory income tax rate	35.00%	35.00%
State taxes, net of federal benefit	4.00	4.00
Valuation allowance	(39.00)	(39.00)
	%	%

Net operating loss carryforwards, which aggregated approximately $146,000 and $264,000 in 2003 and 2004, respectively expire in 2023 and 2024.

5. Stock option plan:

On April 22, 2003, the Company s Board of Directors (the Board) adopted the 2003 Stock Plan (the Plan) and approved the reservation of 125,000 shares of the Company s common stock for issuance thereunder. Under the Plan, the Board or a committee appointed by the Board (the Committee) determines the directors, employees or consultants to whom stock options may be granted and the vesting schedules. The price per share specified in the agreement relating to each stock option shall be established by the Board or Committee except that the price per share relating to each incentive stock option granted under the Plan shall not be less than the fair market value per share of the Company s common stock on the date of such grant. Options issued under the Plan, unless subject to earlier termination as described, shall generally expire 10 years from the date of grant.

The following table summarizes stock option activity under the Company s Plan:

	Seven months ended July 31, 2004 (unaudited)		From inception (April 22, 2003) through December 31, 2003	
	Shares	Exercise Price	Shares	Exercise Price

Outstanding beginning of period	5,000	$ 0.01		$
Granted	11,375	0.01	5,000	0.01
Exercised	(4,688)	0.01		
Canceled, forfeited or expired				
Outstanding end of period	11,687	$ 0.01	5,000	$ 0.01
Exercisable end of period	2,749	$ 0.01		$

Options granted during the period from inception (April 22, 2003) through July 31, 2004 had nominal fair value and weighted average grant date fair values. Options outstanding at December 31, 2003 and July 31, 2004 had a weighted-average remaining life of 9.8 and 9.2 years, respectively.

Assumptions used in developing the Black-Scholes fair values were as follows:

Risk-free interest rate	4.75%
Expected life	10 years
Expected dividend	$

Table of Contents

ARIUS PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

FROM INCEPTION (APRIL 23, 2003) THROUGH

DECEMBER 31, 2003 AND SEVEN MONTHS ENDED JULY 31, 2004

6. Licensing and distribution agreements:

Agreement with Reckitt Benckiser Healthcare (UK) Limited:

On May 14, 2004, the Company entered into an Agreement for the License and Supply of Buccal Prochlorperazine Maleate with Reckitt Benckiser Healthcare (UK) Limited. The agreement grants the Company the exclusive right to import, promote and sell buccal prochlorperazine maleate in the United States and its territories under the trademark Emezine . Emezine is a drug used in the treatment of nausea and vomiting.

In consideration of the rights granted under the agreement, the Company paid $100,000 on the commencement date. The Company is obligated to pay another $100,000 upon grant of the product registration in the United States (FDA approval). In addition to paying for delivered product, the Company shall make royalty payments each calendar year based on scheduled percentages of product net sales. The percentages are adjusted if a competitor enters the market with a generic product. The $100,000 paid upon grant of the product registration can apply against royalty payments due for the first calendar year of product sales. The term of the agreement is ten years.

Future annual amortization of this acquired product right is $10,000 annually assuming a 10 year expected life.

Distribution Agreement with TEAMM Pharmaceuticals, Inc.:

On March 17, 2004, the Company entered into an agreement with TEAMM Pharmaceuticals, Inc. (TEAMM), an entity related through common control with BDSI, granting TEAMM the exclusive rights to sell, market, promote and distribute Emezine within the United States and its territories. TEAMM is a portfolio company of The Hopkins Capital Group, which owns a large portion of BDSI s common stock and is controlled by Frank O Donnell, BDSI s Chairman, President and Chief Executive Officer. The agreement calls for the Company to use commercially reasonable efforts to obtain regulatory approval from FDA for the sale and marketing of Emezine in the United States provided that the Company shall not be required to expend more than an aggregate of $2 million on such efforts. TEAMM is entitled to terminate the agreement if FDA approval is not obtained by the Company within 30 months of the effective date of the agreement, despite the Company s commercially reasonable efforts to obtain approval. If the Company determines that the costs to obtain FDA approval will exceed $2 million, the parties can agree to share the additional costs and continue the agreement.

Subsequent to FDA approval, TEAMM shall purchase all of its requirements for Emezine from the Company. Should the agreement terminate because of ultimately not obtaining FDA approval, the Company shall issue a warrant to TEAMM exercisable for a number of shares of the Company s common stock proportionate to TEAMM s payments made under the agreement.

Upon execution of the agreement, TEAMM paid to the Company a non-refundable fee of $150,000. Payments of $150,000, $300,000, and $400,000 shall be payable to the Company upon achieving certain milestone events as described under the agreement. As of June 22, 2004, the Company has received the non-refundable fee of $150,000 in addition to the first milestone payment of $150,000.

TEAMM shall also pay the Company an additional non-refundable fee of $1,000,000 in six equal monthly installments upon the initiation of a clinical study on Emezine. The Company shall also receive royalty payments equal to 30% of net Emezine sales with certain minimum annual royalties commencing as of the first quarter following FDA approval.

Table of Contents

ARIUS PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

FROM INCEPTION (APRIL 23, 2003) THROUGH

DECEMBER 31, 2003 AND SEVEN MONTHS ENDED JULY 31, 2004

The term of the agreement shall continue from March 17, 2004 until the termination or expiration of the license from Reckitt Benckiser Healthcare (UK) Limited.

License Agreement with Atrix Laboratories:

On May 27, 2004, *Atrix* Laboratories, Inc. (Atrix) granted an exclusive license to the Company to develop, manufacture (or have manufactured), market, and distribute fentanyl and other products developed under Atrix s bioerodible, mucoadhesive, multi-layer polymer film (BEMA) technology. Products containing fentanyl are used for the treatment of pain. The agreement also grants to the Company the exclusive, royalty-free license to use trademarks associated with the products under the agreement.

Under the agreement, the Company shall use commercially reasonable efforts to pursue product development for the fentanyl product pursuant to a development plan, which may, at the Company s sole discretion, be amended or revised from time to time.

The Company shall pay to Atrix an initial one-time non-refundable license fee of $1,000,000 on the earlier of 90 days from the execution date or five business days after the receipt by the Company of at least $6 million of gross cash proceeds from the sale of equity or debt securities. This amount was paid on August 24, 2004 in connection with the acquisition discussed in Note 2. Subject to the terms of the agreement, the Company has the right to sublicense with respect to additional products. The Company shall make royalty payments equal to 30% of any sublicense revenue. The Company shall also make royalty payments based on scheduled percentages of first or subsequent product net sales. Royalty payments are subject to certain minimum amounts as specified under the agreement.

The Company will be required to pay additional licensing fees upon reaching certain development milestones. Should all development milestones be achieved the total additional licensing fees would equal $6 million. In addition, the Company shall pay $2 million as an additional licensing fee the first time that cumulative net sales exceed $400 million.

The term of the agreement shall continue until the expiration of the last applicable BEMA patent right.

Future annual amortization of this acquired product right is $100,000 annually assuming a 10 year expected life.

Table of Contents

BioDelivery Sciences International, Inc.

PRO FORMA CONSOLIDATED BALANCE SHEET

As of July 31, 2004

(Unaudited)

	Historical			Proforma
	BDSI \July 31, 2004	Arius - July 31, 2004	Proforma Adjustments	Consolidated July 31, 2004
Assets				
Cash	$ 89,603	$ 57,675		$ 147,278
Accounts receivable	27,146			27,146
Prepaid expenses and other current assets	212,460			212,460
Total Current Assets	329,209	57,675		386,884
Equipment, net	962,048			962,048
Licenses	455,532			455,532
Purchased product rights		1,082,000	(1,082,000)(c)	
Intangibles subject to purchase price allocation			5,215,247(a), (b), (c), (d)	5,215,247
Other Assets	25,843			25,843
	$ 1,772,632	$ 1,139,675		$ 7,045,554
Liabilities and stockholders equity				
Current liabilities:				
Note Payable, bank	$ 225,978			$ 225,978
Accounts payable and accrued expenses	391,111	1,239,348	250,000(b)	1,880,459
Stockholder advances		54,191		54,191
Deferred Revenue		123,500		123,500
Capital lease obligations	1,976			1,976
Total Current Liabilities	619,065	1,417,039		2,286,104
Notes Payable, less current maturities	586,521			586,521
Total Liabilities	1,205,586	1,417,039		2,872,625
Stockholders equity:				
Common Stock	8,186	5,047	(5,047)(a)	8,186
Preferred Stock				
Series A			3,705,883(a)	3,705,883
Series B				
Additional paid-in capital	14,370,224			14,370,224
Treasury Stock	(303,894)			(303,894)
Retained deficit	(13,508,564)	(282,411)	182,411(a), (d)	(13,608,564)
Accumulated other comprehensive gain	1,094			1,094
Total stockholders equity	567,046	(277,364)		4,172,929
	$ 1,772,632	$ 1,139,675		$ 7,045,554

See notes to Proforma unaudited consolidated financial statements.

Table of Contents

BioDelivery Sciences International, Inc.

Proforma Consolidated Income Statement

For the year ended December 31, 2003

(Unaudited)

	BioDelivery Sciences	Arius Pharmaceuticals	Proforma Adjustments	Proforma Year ended December 31, 2003
License revenues	$ 2,000,000	$		$ 2,000,000
Non-refundable fees				
Sponsored research revenues	913,231			913,231
	2,913,231			2,913,231
Expenses:				
Research & development	2,633,945		100,000(d)	2,733,945
General & Administrative:				
General & Administrative	2,636,607	145,779		2,782,386
Stock-based compensation	200,039			200,039
Total expenses	5,470,591	145,779		5,716,370
Interest income (expense), net	69,254			69,254
Loss before income taxes	(2,488,106)	(145,779)		(2,633,885)
Income tax benefit				
Net loss	$ (2,488,106)	$ (145,779)		$ (2,633,885.00)
Weighted average shares outstanding				8,663,738
Earnings per share				$ (0.30)

See notes to Proforma unaudited consolidated financial statements.

Table of Contents

BioDelivery Sciences International, Inc.

Proforma Consolidated Income Statement

For the 7 months ended July 31, 2004

(Unaudited)

	BioDelivery Sciences	Arius Pharmaceuticals	Proforma Adjustments	Proforma Seven months ended July 31, 2004
License revenues		150,000		150,000
Non-refundable fees		26,500		26,500
Sponsored research revenues	601,096			601,096
	601,096	176,500		751,096
Expenses:				
Research & development	1,791,670		100,000(d)	1,891,670
General & Administrative:				
General & Administrative	1,539,280	313,132		1,852,412
Stock-based compensation	77,958			77,958
Total expenses	3,408,908	313,132		3,822,040
Interest income (expense), net	(30,163)			(30,163)
Loss before income taxes	(2,837,975)	(136,632)		(2,974,607)
Income tax benefit	(2,000)			(2,000)
Net loss	(2,839,975)	(136,632)		(2,976,607)
Weighted average shares outstanding				8,632,922
Earnings per share				$ (0.34)

See notes to Proforma unaudited consolidated financial statements.

Table of Contents

BioDelivery Sciences International, Inc.

Note to Proforma Consolidated Financial Statements.

On August 24, 2004, BioDelivery Sciences International, Inc. (BDSI) completed its acquisition of Arius Pharmaceuticals, Inc. In connection therewith, BDSI issued 1,647,059 shares of preferred stock and assumed certain liabilities of Arius. The following adjustments are necessary to present the acquisition of Arius as of July 31, 2004 and December 31, 2003.

a. To record issuance of 1,647,059 shares of preferred stock valued at $2.25 per share for acquisition of Arius Pharmaceuticals, Inc. and eliminate the prior equity of Arius.

b. To record capitalized acquisition costs of $250,000.

c. To reclassify existing intangibles acquired to intangibles subject to purchase price allocation. Additional identifiable intangibles or goodwill will be determined upon completion of the fair value appraisal thereof. At the time this process is completed, the allocation of the purchase price may include goodwill and other identifiable intangibles.

d. To expense $100,000 in purchased in process research and development.

Table of Contents

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Until , 2005 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

BioDelivery Sciences International, Inc.

5,000,000

shares of common stock

PROSPECTUS

Ferris, Baker Watts

Incorporated

Maxim Group LLC

GunnAllen Financial, Inc.

, 2005

Table of Contents

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 24. Indemnification of Directors and Officers.

Our certificate of incorporation provides that all our directors, officers, employees and agents shall be entitled to be indemnified by us to the fullest extent permitted under the Delaware General Corporation Law, provided that they acted in good faith and that they reasoned their conduct or action was in, or not opposed to, the best interest of our company.

Our Bylaws provide for indemnification of our officers, directors and others who become a party to an action on our behalf by us to the fullest extent not prohibited under the Delaware General Corporation Law. Further, we maintain officer and director liability insurance.

Item 25. Other Expenses of Issuance and Distribution.

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

Securities and Exchange Commission Registration Fee	$ 2,707.10
NASD Filing Fee	$ 2,800.00
Edgarization, Printing and Engraving Expenses	$ 75,000.00
Accounting Fees and Expenses	$ 40,000.00
Legal Fees and Expenses	$ 150,000.00
Blue Sky Fees and Expenses (including legal fees)	$ 35,000.00
Registrar and Transfer Agent Fee	$ 3,500.00
Miscellaneous	$ 25,000.00
TOTAL	**$ 334,007.10**

Item 26. Recent Sales of Unregistered Securities.

In the last three years, we sold the following unregistered securities:

(a) As part of our transaction with CDC, on July 15, 2005, we issued CDC a warrant to purchase 500,000 shares of our common stock at $3.50 per share. Such warrant 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.

(b) On June 29, 2005, we entered into amendments to our February and May 2005 financing agreements with Laurus such that, in consideration of our issuance to Laurus of a warrant to purchase 22,500 shares (in connection with the February amendment) and another warrant to purchase 7,500 shares (in connection with the May amendment) of our common stock, in each case for $.001 per share, Laurus has agreed to defer payments by us of principal under the February and May 2005 Laurus notes until December 1, 2005.

Table of Contents

(c) On May 31, 2005, we consummated a $2.5 million secured convertible debt financing with Laurus in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act. This Laurus investment takes the form of a convertible note secured by substantially all of our assets. The note was due on September 1, 2005 but was extended to May 31, 2008. 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 483,871 shares of our common stock at a price equal to $3.88 per share. As part of the transactions we paid fees and commissions totaling approximately $108,000.

(d) On February 22, 2005, we consummated a $2.5 million secured convertible debt financing with Laurus in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act. The Laurus investment takes the form of a convertible note secured by substantially all 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. We also granted Laurus the right, exercisable until June 2005 (and subject to certain limitations), to invest an additional amount in our company of no less than $1,000,000 and up to $2,500,000 on substantially the same terms and conditions as the financing transaction described above, except that (i) any additional note shall, unless otherwise agreed, have a fixed conversion price equal to the greater of (x) 85% of the average closing price of our common stock for the ten trading days immediately prior to the date of the issuance of such additional note and (y) $4.25. As part of the transactions we paid fees and commissions totaling approximately $310,000.

(e) Simultaneously with our entry into a licensing agreement with Sigma-Tau Pharma in January 2005, 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 made in consideration of unregistered shares of our common stock priced at $4.25 a share, and was made in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act.

(f) In consideration for services provided by Ferris, Baker Watts, the lead underwriter of this offering, we paid to FBW, among other consideration, a warrant to purchase 225,000 shares of our common stock at an exercise price equal to $5.25. The warrant is not exercisable until August 22, 2005. The warrant expires on November 29, 2010. The warrant does not contain any cashless exercise or non-standard anti-dilution provisions, but does contain customary provisions for stock splits and stock dividends.

(g) In August 2004, we entered into an Equity Line Agreement with HCG under which, at our request, HCG will invest up to $4 million in our company in consideration of a newly-created class of preferred stock, the Series B Preferred, in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act of 1933. As of August 3, 2005, $1.45 million has been drawn on the HCG equity line.

(h) As part of the acquisition of Arius in August 2004, we issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of convertible preferred stock in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act. The newly-created Series A Preferred is convertible (upon the satisfaction of certain conditions) into shares of our common stock on a one for one basis. Shares of Series A Preferred are eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first proposed product (ii) 30 days notice to us of a Conversion Event (hereinafter defined) or (iii) five (5) years from the closing date of the acquisition. The term Conversion Event is defined in the Certificate of Designation of the Series A Preferred to mean our failure to provide at least $3,000,000 to Arius as required to: (i) pay Atrix $1,000,000 by August 24, 2004 pursuant to the terms of a license agreement between Arius and Atrix and (ii) fund, in a total amount of no less than $2,000,000, the operations of Arius. We believe we have satisfied these conditions. The holders of the Series A Preferred enjoy certain other rights and privileges.

(i) On July 19, 2002, we issued Ellenoff Grossman & Schole LLP, our outside legal counsel, 25,000 options to purchase shares of our common stock at $7.00 per share. In 2004, we issued Ellenoff Grossman &

Table of Contents

Schole LLP 44,510 shares of our common stock as compensation for services rendered. Ellenoff Grossman & Schole LLP is also counsel to our subsidiary, Bioral Nutrient Delivery, LLC. During 2003, Bioral Nutrient Delivery, LLC issued 37,500 Class B Shares of BND to Ellenoff Grossman & Schole LLP. These Class B Shares were issued at the inception of Bioral Nutrient Delivery, LLC at nominal value.

Item 27. Exhibits and Reports on Form 8-K.

The following exhibits are filed with this registration statement.

Number	Description
1.1	Form of Underwriting Agreement for initial public offering (11)
1.2	Form of Underwriting Agreement for present offering
2.1	Agreement and Plan of Merger and Reorganization, dated August 10, 2004, by and among the Company, Arius Acquisition Corp., Arius, Dr. Mark Sirgo and Dr. Andrew Finn (21)
2.2	Asset Purchase Agreement, dated September 8, 2004, by and between the Company and Accentia, Inc. (24)
3.1	Articles of Incorporation of the Company as an Indiana corporation (6)
3.2	Articles of Amendment of the Article of Incorporation as an Indiana corporation (5)
3.3	Bylaws of the Company as an Indiana corporation (6)
3.4	Articles of Incorporation of the Company after reincorporation merger into Delaware (8)
3.5	Bylaws of the Company after reincorporation merger into Delaware (8)
3.6	Secretary s Certificate regarding amendments to Company s Bylaws, dated August 23, 2005 (34)
4.1	Form of Class A Warrant Agreement with Forms of Class A Warrant Certificate (9)
4.2	Form of Representative s Unit Purchase Option (11)
4.3	Form of Specimen of Unit Certificate (12)
4.4	Form of Specimen of Common Stock Certificate (12)
4.5	Form of Specimen of Warrant Certificate (12)
4.6	Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 20, 2004 (21)
4.7	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 25, 2004. (22)
4.8	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated September 2, 2004 (23)
4.9	Certificate of Designations of the Series B Convertible Preferred Stock of the Company, dated September 3, 2004 (23)
4.10	Secured Convertible Term Note, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.11	Common Stock Purchase Warrant, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.12	Common Stock Purchase Warrant (22,500 shares), dated June 29, 2005, by the Company in favor of Laurus Master Fund, Ltd. (32)

Table of Contents

Number	Description
4.13	Common Stock Purchase Warrant (7,500 shares), dated June 29, 2005, by the Company in favor of Laurus Master Fund, Ltd. (32)
4.14	Common Stock Purchase Warrant, dated July 15, 2005, by the Company in favor of Clinical Care Development, LLC. (33)
5.1	Opinion of Ellenoff Grossman & Schole LLP (*)
10.1	Research Agreement with the University of Medicine and Dentistry of New Jersey (2)
10.2	Licensing Agreement with the University of Medicine and Dentistry of New Jersey (3)
10.3	Licensing Agreement with Albany Medical College (3)
10.4	License Agreement with BioKeys Pharmaceuticals, Inc. (8)
10.5	License Agreement with Tatton Technologies, LLC (8)
10.6	Addendum to License Agreement with Tatton Technologies, LLC (10)
10.7	License Agreement with RetinaPharma, Inc. (28)
10.8	Addendum to License Agreement with RetinaPharma, Inc. (9)
10.9	License Agreement with Biotech Specialty Partners, LLC (8)
10.10	National Institutes of Health Grant Letter (8)
10.11	Merger Agreement with BioDelivery Sciences, Inc., dated July 20, 2001 (2)
10.12	Settlement Agreement and Stock Purchase Agreement with Irving Berstein, et al. (2)
10.13	Employment Agreement with Christopher Chapman (2)
10.14	Employment Agreement with James A. McNulty (2)
10.15	Employment Agreement with Dr. Frank E. O Donnell (10)
10.16	Confidentiality Agreement for Dr. Frank E. O Donnell (10)
10.17	Covenant Not to Compete with Dr. Frank E. O Donnell (10)
10.18	2001 Incentive Stock Option Plan (8)
10.19	Promissory Note for BioKeys Pharmaceuticals, Inc. dated August 22, 2001 (11)
10.20	Research Agreement with PharmaResearch Corporation (9)
10.21	Credit Facility Loan Agreement (10)
10.22	Purchase Agreement between MAS Capital, Inc. and Hopkins Capital Group II, LLC (10)
10.23	Amendment to Purchase Agreement dated March 29, 2002 (10)
10.24	Agreement between Mr. Aaron Tsai and the Company (10)
10.25	Employment Agreement with Raphael Mannino (13)
10.26	Employment Agreement with Susan Gould-Fogerite (13)
10.27	Employment Agreement with James A. McNulty (13)
10.28	Sub-License Agreement, effective as of December 31, 2002, by and between the Company and Pharmaceutical Product Development, Inc. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (14)

Table of Contents

Number	Description
10.29	Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated January 8, 2003, by the Company, as Managing Member and the other members signatory thereto, as Class B Members. (15)
10.30	Promissory Note, dated February 13, 2003, by Bioral Nutrient Delivery, LLC in favor of the Company. (15)
10.31	First Amendment to Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, dated March 31, 2003. (17)
10.32	Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (17)
10.33	Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (17)
10.34	Distribution Agent Agreement, effective June 1, 2003, by and between Kashner Davidson Securities Corporation and Bioral Nutrient Delivery, LLC (17)
10.35	Amended and Restated Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated October 1, 2003, by the Company, as Managing Member (18)
10.35	First Amendment to Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (18)
10.36	First Amendment to Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (18)
10.37	License Agreement, dated effective April 12, 2004, between the Company and Accentia, Inc. (19)
10.38	Amendment to License Agreement, dated effective June 1, 2004, between the Company and Accentia, Inc. (19)
10.39	Facility Loan Agreement, dated effective August 2, 2004, between the Company and Hopkins Capital Group II, LLC (20)
10.40	Binding Letter of Intent and Termination Agreement, dated August 23, 2004, between Hopkins Capital Group II, LLC and the Company (22)
10.41	Registration Rights Agreement, dated August 24, 2004, by and among the Company and the former stockholders of Arius (22)
10.42	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.43	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.44	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.45	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.46	Voting Agreement, dated August 24, 2004, by Mark A. Sirgo and Andrew L. Finn in favor of the Company (22)
10.47	Voting Agreement, dated August 24, 2004, by certain stockholders of the Company in favor of the Company, Mark A. Sirgo and Andrew L. Finn (22)
10.48	Loan Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)
10.49	Security Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)

Table of Contents

Number	Description
10.50	Limited Waiver and Forbearance Agreement, dated effective May 14, 2004, by and between the Company and Gold Bank (22)
10.51	Equity Line of Credit Agreement, dated September 3, 2004, by and between the Company and Hopkins Capital Group II, LLC (23)
10.52	Common Stock Purchase Agreement, dated January 20, 2005, between BDSI and Sigma Tau Finanziaria S.p.A. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (25)
10.53	Licensing Agreement, dated January 20, 2005, between the Company and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (25)
10.54	First Amendment to Employment Agreement, dated January 31, 2005, by and between the Company and Francis E. O Donnell, Jr. (26)
10.55	Securities Purchase Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.56	Registration Rights Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.57	Subsidiary Guaranty, dated February 22, 2005, by Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.58	Master Security Agreement, dated February 22, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.59	Stock Pledge Agreement, dated February 22, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.60	Grant of Security Interest in Patents and Trademarks, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
10.61	Control Agreement Regarding Limited Liability Company Interests, dated February 22, 2005, by and among the Company and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.62	Letter Amendment to License Agreement, dated March 28, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (28)
10.63	Letter Amendment to License Agreement, dated April 25, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (28)
10.64	Consulting Agreement, executed as of April 14, 2005, by and between the Company and Susan Gould-Fogerite (29)
10.65	Termination Agreement and Release, dated April 14, 2005, by and between the Company and Susan Gould-Fogerite (29)
10.66	Non-Qualified Stock Option Agreement, dated April 14, 2005, between the Company and Susan Gould-Fogerite (29)
10.67	Securities Purchase Agreement, dated May 31, 2005, by and between the Company and Laurus Master Fund, Ltd. (30)
10.68	Secured Convertible Term Note, dated May 31, 2005, by the Company in favor of Laurus Master Fund, Ltd. (30)
10.69	Common Stock Purchase Warrant, dated May 31, 2005, by the Company in favor of Laurus Master Fund, Ltd. (30)

Table of Contents

Number	Description
10.70	Registration Rights Agreement, dated May 31, 2005, by and between the Company and Laurus Master Fund, Ltd. (30)
10.71	Reaffirmation and Ratification Agreement and Amendment, dated May 31, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (30)
10.72	Grant of Security Interest in Patents and Trademarks, dated May 31, 2005, by the Company in favor of Laurus Master Fund, Ltd. (30)
10.73	Letter Amendment to License Agreement, dated June 6, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (31)
10.74	Amendment, dated June 29, 2005, to February 22, 2005 Laurus Master Fund, Ltd. financing documents (32)
10.75	Amendment, dated June 29, 2005, to May 31, 2005 Laurus Master Fund, Ltd. financing documents (32)
10.76	Clinical Development and License Agreement, dated as of July 14, 2005, among Clinical Development Capital LLC, the Company and Arius Pharmaceuticals, Inc. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (33)
10.77	Form of Security Agreement to be entered into by and among the Company, Arius Pharmaceuticals, Inc and Clinical Development Capital LLC (33)
10.78	Registration Rights Agreement, dated as of July 14, 2005, by and between the Company and Clinical Development Capital LLC (33)
21.1	Subsidiaries of the Registrant (*)
23.1	Consent of Ellenoff Grossman & Schole LLP (contained in Exhibit 5.1) (*)
23.2	Consent of Aidman Piser & Company, P.A.

* Previously filed.
(2) Previously filed with Form 10QSB, for the quarter ended March 31, 2001.
(3) Previously filed with Form 10KSB, for the fiscal year ended December 31, 2000 filed on August 15, 2001.
(5) Previously filed with Form 8K filed October 26, 2000 under our prior name of MAS Acquisition XXIII Corp.
(6) Previously filed with Form 10SB filed January 18, 2000 under our prior name of MAS Acquisition XXIII Corp.
(8) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(9) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.
(10) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.
(11) Previously filed with Form SB-2, Amendment No. 5, May 23, 2002.
(12) Previously filed with Form SB-2, Amendment No. 6, June 24, 2002.
(13) Previously filed with Form 10-QSB, November 15, 2002.
(14) Previously filed with Form 8-K, January 7, 2003.
(15) Previously filed with Form 8-K, February 26, 2003.
(16) Previously filed with Form 8-K, April 25, 2003.
(17) Previously filed with Form 10-QSB/A, September 2, 2003.
(18) Previously filed with Form 8-K, November 19, 2003.
(19) Previously filed with Form 8-K, June 4, 2004.
(20) Previously filed with Form 8-K, August 6, 2004.
(21) Previously filed with Form 8-K, August 12, 2004.

Table of Contents

(22) Previously filed with Form 8-K, August 26, 2004.
(23) Previously filed with Form 8-K, September 8, 2004.
(24) Previously filed with Form 8-K, September 8, 2004.
(25) Previously filed with Form 8-K, January 24, 2005.
(26) Previously filed with Form 8-K, February 3, 2005.
(27) Previously filed with Form 8-K, February 25, 2005.
(28) Previously filed with Form 10-KSB/A, April 29, 2005.
(29) Previously filed with Form SB-2/A, April 29, 2005.
(30) Previously filed with Form 8-K, June 3, 2005.
(31) Previously filed with Form 10-KSB/A, June 10, 2005.
(32) Previously filed with Form 8-K, June 30, 2005.
(33) Previously filed with Form 8-K, July 21, 2005.
(34) Previously filed with Form 8-K, August 24, 2005.

Item 28. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

(i) Include any prospectus required by Sections 10(a)(3) of the Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

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

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

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

Table of Contents

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form SB-2 and authorized this Amendment No. 3 to the registration statement to be signed on its behalf by the undersigned, in the City of Morrisville, State of North Carolina on September 23, 2005.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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

(Principal Executive Officer)

By: /s/ JAMES A. MCNULTY
Name: James A. McNulty
Title: Chief Financial Officer, Secretary and Treasurer

(Principal Accounting Officer)

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

Person	Capacity	Date
/s/ FRANCIS E. O DONNELL, JR.	Chairman of the Board and Director	September 23, 2005
Francis E. O Donnell, Jr.		
*	President, Chief Executive Officer and	September 23, 2005
Mark A. Sirgo	Director	
*	Executive Vice President,	September 23, 2005
Raphael J. Mannino	Chief Scientific Officer and Director	
*	Director	September 23, 2005
William B. Stone		
*	Director	September 23, 2005

John J. Shea		
*	Director	September 23, 2005
L.M. Stephenson		
*	Director	September 23, 2005
William S. Poole		

* By: /s/ FRANCIS E. O DONNELL, JR.
Francis E. O Donnell, Jr.
Attorney-in-fact