Owens Corning
Form 4
July 28, 2014

FORM 4

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

OMB APPROVAL

OMB Number:	3235-0287
Expires:	January 31, 2005
Estimated average burden hours per response...	0.5

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. *See* Instruction 1(b).

(Print or Type Responses)

1. Name and Address of Reporting Person *
McMonagle James J

(Last) (First) (Middle)

ONE OWENS CORNING PARKWAY

(Street)

TOLEDO, OH 43659

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
Owens Corning [OC]

3. Date of Earliest Transaction (Month/Day/Year)
07/25/2014

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

__X__ Director _____ 10% Owner
_____ Officer (give title below) _____ Other (specify below)

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			
$.01 Par Value Common	07/25/2014		A		908 (1)	A	$ 0	64,880.33	D	

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

Persons who respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.

SEC 1474 (9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)		5. Number of Derivative Securities Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)		6. Date Exercisable and Expiration Date (Month/Day/Year)		7. Title and Amount of Underlying Securities (Instr. 3 and 4)		8. Price of Derivative Security (Instr. 5)	9. Nu Deriv Secur Bene Owne Follo Repo Trans (Instr
				Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares		

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
McMonagle James J ONE OWENS CORNING PARKWAY TOLEDO, OH 43659	X			

Signatures

Raj B. Dave by POA filed on 10/29/2013	07/28/2014
**Signature of Reporting Person	Date

Explanation of Responses:

***** If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

****** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) Deferred share portion of quarterly Director retainer/fees.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.
Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. ceding 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.

[remainder of page intentionally left blank]

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 29, 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.

[remainder of page intentionally left blank]

Table of Contents

UNDERWRITING

Subject to the terms and conditions of an underwriting agreement, dated September 29, 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	1,760,000
Maxim Group LLC	1,320,000
GunnAllen Financial, Inc.	1,320,000
Total	**4,400,000**

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 $0.75 per share. 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. No change in such terms will change the amount of proceeds to be received by us in this offering.

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	$ 0.13	$ 572,000	$ 657,800

We have agreed to sell the shares of common stock to the underwriters at the public offering price of $1.87 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 660,000 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.

[remainder of page intentionally left blank]

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.

[remainder of page intentionally left blank]

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.

[remainder of page intentionally left blank]

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

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	December 31, 2003
	(unaudited)	
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.

F-45

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 October 24, 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.

4,400,000

shares of common stock

PROSPECTUS

Ferris, Baker Watts

Incorporated

Maxim Group LLC

GunnAllen Financial, Inc.

September 29, 2005