BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB/A
June 10, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB/A

(Amendment No. 2)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ______ to ______

Commission file number 0-28931

BioDelivery Sciences International, Inc.

(Name of small business issuer in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2501 Aerial Center Parkway	
Suite 205	
Morrisville, NC	**27560**
(Address of principal executive offices)	**(Zip Code)**

Issuer s telephone number: (919) 653-5160

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 par value;

Class A common stock purchase warrants

(Title of class)

UMDNJ Medical School

185 South Orange Avenue, Bldg. #4

Newark, New Jersey 07103

(Former name, former address and former fiscal year, if changed since last report)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of issuer s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. x

Issuer s revenues for fiscal year 2004 were $1,778,898.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 22, 2005 was approximately $8,648,748.20 based on the closing sale price of the company s common stock on such date of U.S. $3.70 per share, as reported by the Nasdaq SmallCap Market.

Transitional Small Business Disclosure Format: Yes ¨ No x

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EXPLANATORY NOTE

This Amendment No. 2 (Amendment No. 2) to the Annual Report on Form 10-KSB of BioDelivery Sciences International, Inc. (the Company) for the fiscal year ended December 31, 2004, as filed with the Securities and Exchange Commission on March 24, 2005 (the Original Form 10-KSB) and as amended by that certain Amendment No. 1 thereto, filed April 29, 2005 (Amendment No. 1), amends and restates in its entirety Item 7 of the Original Form 10-KSB and the audited financial statements for the year ended December 31, 2004 included with the Original Form 10-KSB and Amendment No. 1.

Such audited financial statements have been amended solely in the footnotes thereto and solely to: (i) clarify that the Company has no material ongoing obligations under its license agreement with Accentia Biopharmaceuticals, Inc. (Accentia) and (ii) delete certain language therein relating to management s plans. Amendment No. 2 also adds, as an exhibit, a recent letter amendment to the Company s license agreement with Accentia.

This Amendment No. 2 does not, except for the exhibit referred to above, reflect events occurring after the filing of the Original Form 10-KSB, or otherwise modify or update the disclosures contained in the Original Form 10-KSB in any way other than as required to reflect the amendment set forth above. The filing of this Amendment No. 2 or the previous filing of Amendment No. 1 shall not be deemed an admission that the Original Form 10-KSB, when made, included any untrue statement of a material fact or omitted to state a material fact necessary to make a statement not misleading.

Item 7. Financial Statements.

Our Consolidated Financial Statements and Notes thereto and the report of Aidman, Piser & Company, P.A., our independent registered public accounting firm, are set forth on pages F-1 through F-24 of this Report.

Item 13. Exhibits and Reports on Form 8-K.

The following exhibits are filed with this Report.

Number	Description
1.1	Form of Underwriting Agreement (11)
2.1	Agreement and Plan of Merger and Reorganization, dated August 10, 2004, by and among the Company, Arius Acquisition Corp., Arius, Dr. Mark Sirgo and Dr. Andrew Finn (21)
2.2	Asset Purchase Agreement, dated September 8, 2004, by and between the Company and Accentia, Inc. (24)
3.1	Articles of Incorporation of the Company as an Indiana corporation (6)
3.2	Articles of Amendment of the Article of Incorporation as an Indiana corporation (5)

3.3	Bylaws of the Company as an Indiana corporation (6)

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3.4	Articles of Incorporation of the Company after reincorporation merger into Delaware (8)
3.5	Bylaws of the Company after reincorporation merger into Delaware (8)
4.1	Form of Class A Warrant Agreement with Forms of Class A Warrant Certificate (9)
4.2	Form of Representative s Unit Purchase Option (11)
4.3	Form of Specimen of Unit Certificate (12)
4.4	Form of Specimen of Common Stock Certificate (12)
4.5	Form of Specimen of Warrant Certificate (12)
4.6	Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 20, 2004 (21)
4.7	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated August 25, 2004. (22)
4.8	Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Company, dated September 2, 2004 (23)
4.9	Certificate of Designations of the Series B Convertible Preferred Stock of the Company, dated September 3, 2004 (23)
4.10	Secured Convertible Term Note, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
4.11	Common Stock Purchase Warrant, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
10.1	Research Agreement with the University of Medicine and Dentistry of New Jersey (2)
10.2	Licensing Agreement with the University of Medicine and Dentistry of New Jersey (3)
10.3	Licensing Agreement with Albany Medical College (3)
10.4	License Agreement with BioKeys Pharmaceuticals, Inc. (8)
10.5	License Agreement with Tatton Technologies, LLC (8)
10.6	Addendum to License Agreement with Tatton Technologies, LLC (10)
10.7	License Agreement with RetinaPharma, Inc. (28)
10.8	Addendum to License Agreement with RetinaPharma, Inc. (9)
10.9	License Agreement with Biotech Specialty Partners, LLC (8)
10.10	National Institutes of Health Grant Letter (8)
10.11	Merger Agreement with BioDelivery Sciences, Inc., dated July 20, 2001 (2)
10.12	Settlement Agreement and Stock Purchase Agreement with Irving Berstein, et al. (2)

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10.13	Employment Agreement with Christopher Chapman (2)
10.14	Employment Agreement with James A. McNulty (2)
10.15	Employment Agreement with Dr. Frank E. O Donnell (10)
10.16	Confidentiality Agreement for Dr. Frank E. O Donnell (10)
10.17	Covenant Not to Compete with Dr. Frank E. O Donnell (10)
10.18	2001 Incentive Stock Option Plan (8)
10.19	Promissory Note for BioKeys Pharmaceuticals, Inc. dated August 22, 2001 (11)
10.20	Research Agreement with PharmaResearch Corporation (9)
10.21	Credit Facility Loan Agreement (10)
10.22	Purchase Agreement between MAS Capital, Inc. and Hopkins Capital Group II, LLC (10)
10.23	Amendment to Purchase Agreement dated March 29, 2002 (10)
10.24	Agreement between Mr. Aaron Tsai and the Company (10)
10.25	Employment Agreement with Raphael Mannino (13)
10.26	Employment Agreement with Susan Gould-Fogerite (13)
10.27	Employment Agreement with James A. McNulty (13)
10.28	Sub-License Agreement, effective as of December 31, 2002, by and between the Company and Pharmaceutical Product Development, Inc. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (14)
10.29	Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated January 8, 2003, by the Company, as Managing Member and the other members signatory thereto, as Class B Members. (15)
10.30	Promissory Note, dated February 13, 2003, by Bioral Nutrient Delivery, LLC in favor of the Company. (15)
10.31	First Amendment to Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, dated March 31, 2003. (17)
10.32	Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (17)
10.33	Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (17)

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10.34	Distribution Agent Agreement, effective June 1, 2003, by and between Kashner Davidson Securities Corporation and Bioral Nutrient Delivery, LLC (17)
10.35	Amended and Restated Limited Liability Company Operating Agreement of Bioral Nutrient Delivery, LLC, dated October 1, 2003, by the Company, as Managing Member (18)
10.35	First Amendment to Sub-License Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (18)
10.36	First Amendment to Management Services and Administrative Agreement, dated effective April 1, 2003, by and between the Company and Bioral Nutrient Delivery, LLC (18)
10.37	Evaluation Agreement and Option to License, dated September 5, 2002 by and between the Company and ***** (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (18)
10.38	License Agreement, dated effective April 12, 2004, between the Company and Accentia, Inc. (19)
10.39	Amendment to License Agreement, dated effective June 1, 2004, between the Company and Accentia, Inc. (19)
10.40	Facility Loan Agreement, dated effective August 2, 2004, between the Company and Hopkins Capital Group II, LLC (20)
10.41	Binding Letter of Intent and Termination Agreement, dated August 23, 2004, between Hopkins Capital Group II, LLC and the Company (22)
10.42	Registration Rights Agreement, dated August 24, 2004, by and among the Company and the former stockholders of Arius (22)
10.43	Employment Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.44	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Mark A. Sirgo (22)
10.45	Employment Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.46	Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Company and Andrew L. Finn (22)
10.47	Voting Agreement, dated August 24, 2004, by Mark A. Sirgo and Andrew L. Finn in favor of the Company (22)
10.48	Voting Agreement, dated August 24, 2004, by certain stockholders of the Company in favor of the Company, Mark A. Sirgo and Andrew L. Finn (22)
10.49	Loan Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)

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10.50	Security Agreement, dated April 22, 2003, by and between the Company and Gold Bank (22)
10.51	Limited Waiver and Forbearance Agreement, dated effective May 14, 2004, by and between the Company and Gold Bank (22)
10.52	Equity Line of Credit Agreement, dated September 3, 2004, by and between the Company and Hopkins Capital Group II, LLC (23)
10.53	Common Stock Purchase Agreement, dated January 20, 2005, between BDSI and Sigma Tau Finanziaria S.p.A. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (25)
10.54	Licensing Agreement, dated January 20, 2005, between the Company and Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2) (25)
10.55	First Amendment to Employment Agreement, dated January 31, 2005, by and between the Company and Francis E. O Donnell, Jr. (26)
10.56	Securities Purchase Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.57	Registration Rights Agreement, dated February 22, 2005, by and between the Company and Laurus Master Fund, Ltd. (27)
10.58	Subsidiary Guaranty, dated February 22, 2005, by Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.59	Master Security Agreement, dated February 22, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.60	Stock Pledge Agreement, dated February 22, 2005, by and among the Company, Arius Pharmaceuticals, Inc. and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.61	Grant of Security Interest in Patents and Trademarks, dated February 22, 2005, by the Company in favor of Laurus Master Fund, Ltd. (27)
10.62	Control Agreement Regarding Limited Liability Company Interests, dated February 22, 2005, by and among the Company and Bioral Nutrient Delivery, LLC in favor of Laurus Master Fund, Ltd. (27)
10.63	Letter Amendment to License Agreement, dated March 28, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (29)
10.64	Letter Amendment to License Agreement, dated April 25, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (29)
10.65	Letter Amendment to License Agreement, dated June 6, 2005, between the Company and Accentia Biopharmaceuticals, Inc. (f/k/a Accentia, Inc.) (*)
20.1	Code of Ethical Conduct of the Registrant (28)

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21.1	Subsidiaries of the Registrant (+)
31.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
31.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)

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* Filed herewith
\+ Previously filed
** A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
(2) Previously filed with Form 10QSB, for the quarter ended March 31, 2001.
(3) Previously filed with Form 10KSB, for the fiscal year ended December 31, 2000 filed on August 15, 2001.
(5) Previously filed with Form 8K filed October 26, 2000 under our prior name of MAS Acquisition XXIII Corp.
(6) Previously filed with Form 10SB filed January 18, 2000 under our prior name of MAS Acquisition XXIII Corp.
(8) Previously filed with Form SB-2, Amendment No. 2, February 1, 2002.
(9) Previously filed with Form SB-2, Amendment No. 3, March 26, 2002.
(10) Previously filed with Form SB-2, Amendment No. 4, April 29, 2002.
(11) Previously filed with Form SB-2, Amendment No. 5, May 23, 2002.
(12) Previously filed with Form SB-2, Amendment No. 6, June 24, 2002.
(13) Previously filed with Form 10-QSB, November 15, 2002.
(14) Previously filed with Form 8-K, January 7, 2003.
(15) Previously filed with Form 8-K, February 26, 2003.
(16) Previously filed with Form 8-K, April 25, 2003.
(17) Previously filed with Form 10-QSB/A, September 2, 2003.
(18) Previously filed with Form 8-K, November 19, 2003.
(19) Previously filed with Form 8-K, June 4, 2004.
(20) Previously filed with Form 8-K, August 6, 2004.
(21) Previously filed with Form 8-K, August 12, 2004.
(22) Previously filed with Form 8-K, August 26, 2004.
(23) Previously filed with Form 8-K, September 8, 2004.
(24) Previously filed with Form 8-K, September 8, 2004.
(25) Previously filed with Form 8-K, January 24, 2005.
(26) Previously filed with Form 8-K, February 3, 2005.
(27) Previously filed with Form 8-K, February 25, 2005.
(28) Previously field with Form 10-KSB, March 28, 2003.
(29) Previously field with Form 10-KSB/A, April 29, 2005.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: June 10, 2005

By: /s/ Francis E. O Donnell, Jr.

Name: Francis E. O Donnell Jr.
Title: Chief Executive Officer and Chairman
(Principal Executive Officer)

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/s/ Francis E. O Donnell, Jr. Francis E. O Donnell, Jr.	Chief Executive Officer, Chairman of the Board and Director	June 10, 2005
/s/ James A. McNulty James A. McNulty	Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)	June 10, 2005
/s/ Raphael J. Mannino Raphael J. Mannino	Executive Vice President, Chief Scientific Officer and Director	June 10, 2005
/s/ William B. Stone William B. Stone	Director	June 10, 2005
/s/ John J. Shea John J. Shea	Director	June 10, 2005
/s/ L.M. Stephenson L.M. Stephenson	Director	June 10, 2005
/s/ Alan Pearce Alan Pearce	Director	June 10, 2005

/s/ William S. Poole	Director	June 10, 2005
William S. Poole		

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BIODELIVERY SCIENCES INTERNATIONAL, INC.

Report of Independent Registered Public Accounting Firm Aidman, Piser & Company, P.A.	F-2
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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

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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.

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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.

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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		Common Stock					
	Shares	Amount	Shares	Amount			Additional Paid-In	Treasury Equity	Accumulated Deficit	Total Stockholders Equity
Balances, January 1, 2003		$		$	7,085,862	$ 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					7,085,862	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	7,245,862	$ 7,246	$ 14,619,701	$ (303,894)	$ (13,495,104)	$ 5,983,832

See notes to consolidated financial statements.

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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.

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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.

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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 (continued):

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 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.

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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 (continued):

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

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.

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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 (continued):

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.

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	

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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 (continued):

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)

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.

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 (continued):

Accounting and reporting developments (continued):

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.

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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 (continued):

Accounting and reporting developments (continued):

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.

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

3. Liquidity and management s plans (continued):

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 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

3. Liquidity and management s plans (continued):

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. 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).

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

4. Business acquisition (continued):

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

4. Business acquisition (continued):

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

5. Research and development arrangements and related party transactions (continued):

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.

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

9. Stockholders equity (continued):

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.

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

9. Stockholders equity (continued):

Stock options (continued):

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2004 AND 2003

10. Commitments and contingencies (continued):

Litigation (continued):

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.

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.