

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 8-K/A
November 05, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K/A

CURRENT REPORT

(Amendment No. 1)

Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) November 5, 2004 (August 24, 2004)

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

0-28931
(Commission File Number)

35-2089858
(IRS Employer

Identification No.)

UMDNJ Medical School

07103

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185 South Orange Avenue, Bldg #4

Newark, New Jersey
(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code (973) 972-0015

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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PORTIONS AMENDED:

The Registrant hereby amends Item 9.01 contained in the Registrant's Current Report on Form 8-K filed August 26, 2004 (the **Original 8-K**) to provide the financial statements required by Item 9.01(a) of Form 8-K and the pro forma financial information required by Item 9.01(b) of Form 8-K, which financial statements and information were excluded from the Original 8-K in reliance on Items 9.01(a)(4) and 9.01(b)(2), respectively, of Form 8-K. Except as set forth in Item 9.01 below, no other changes are made to the Original 8-K.

References herein to the Registrant or BDSI are to BioDelivery Sciences International, Inc. References herein to Arius or the Company are to Arius Pharmaceuticals, Inc. (now a wholly-owned subsidiary of the Registrant).

Item 9.01. Financial Statements and Exhibits.

(a) Financial statements of businesses acquired.

See pages F-1 through F-11 attached hereto.

(b) Pro forma financial information.

See pages F1-1 through F1-4 attached hereto.

(c) Exhibits

Set forth below is a list of Exhibits included as part of this Current Report.

2.1 Agreement and Plan of Merger and Reorganization, dated August 10, 2004, by and among the Registrant, Arius Acquisition Corp., Arius Pharmaceuticals, Inc. (Arius), Dr. Mark Sirgo and Dr. Andrew Finn. (1)

4.1 Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Registrant, dated August 20, 2004. (1)

4.2 Certificate of Correction to the Certificate of Designations of the Series A Non-Voting Convertible Preferred Stock of the Registrant, dated August 25, 2004. (3)

10.1 Facility Loan Agreement, dated August 2, 2004, by and between the Registrant and Hopkins Capital Group II, LLC. (2)

10.2 Binding Letter of Intent and Termination Agreement, dated August 23, 2004, between Hopkins Capital Group II, LLC and the Registrant. (3)

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10.3 Registration Rights Agreement, dated August 24, 2004, by and among the Registrant and the former stockholders of Arius. (3)

10.4 Employment Agreement, dated August 24, 2004, between the Registrant and Mark A. Sirgo. (3)

10.5 Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Registrant and Mark A. Sirgo. (3)

10.6 Employment Agreement, dated August 24, 2004, between the Registrant and Andrew L. Finn. (3)

10.7 Confidentiality and Intellectual Property Agreement, dated August 24, 2004, between the Registrant and Andrew L. Finn. (3)

10.8 Voting Agreement, dated August 24, 2004, by Mark A. Sirgo and Andrew L. Finn in favor of the Registrant. (3)

10.9 Voting Agreement, dated August 24, 2004, by certain stockholders of the Registrant in favor of the Company, Mark A. Sirgo and Andrew L. Finn. (3)

10.14 Loan Agreement, dated April 22, 2003, by and between the Registrant and Gold Bank. (3)

10.15 Security Agreement, dated April 22, 2003, by and between the Registrant and Gold Bank. (3)

10.16 Limited Waiver and Forbearance Agreement, dated effective May 14, 2004, by and between the Registrant and Gold Bank. (3)

99.1 Press Release of the Registrant, dated August 24, 2004, with respect to the closing of the Arius transaction. (3)

99.2 Press Release of the Registrant, dated August 24, 2004, with respect to the termination of the Facility and the Equity Line Agreement. (3)

(1) Previously filed as (or as part of) an exhibit to the Registrant's Current Report on Form 8-K filed on August 12, 2004.

(2) Previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on August 6, 2004.

(3) Previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed on August 26, 2004.

This Current Report on Form 8-K may contain, among other things, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements with respect to the Registrant's plans, objectives, expectations and intentions and other statements identified by words such as may, could, would, should, believes, expects, anticipates, estimates, plans or similar expressions. These statements are based upon the current beliefs and expectations of the Registrant's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Registrant's control).

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

November 5, 2004

BIODELIVERY SCIENCES INTERNATIONAL, INC.

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

Name: Francis E. O. Donnell, Jr.

Title: President and Chief Executive Officer

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. (a development stage enterprise) 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 August 24, 2004

Tampa, Florida

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ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

BALANCE SHEETS

	July 31,	December 31,
	2004 (unaudited)	2003
	<u> </u>	<u> </u>
ASSETS		
Current assets:		
Cash	\$ 57,675	\$ 3,235
	<u> </u>	<u> </u>
Total current assets	57,675	3,235
Purchased product rights, net of amortization Of \$18,000	1,082,000	
	<u> </u>	<u> </u>
Total assets	\$ 1,139,675	\$ 3,235
	<u> </u>	<u> </u>
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,239,348	\$ 111,250
Advances from stockholders	54,191	32,764
Deferred revenue	123,500	
	<u> </u>	<u> </u>
Total current liabilities	1,417,039	144,014
	<u> </u>	<u> </u>
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
Deficit accumulated during the development stage	(232,411)	(145,779)
	<u> </u>	<u> </u>
	(277,364)	(140,779)
	<u> </u>	<u> </u>
Total liabilities and stockholders' deficit	\$ 1,139,675	\$ 3,235
	<u> </u>	<u> </u>

See notes to financial statements.

ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

STATEMENTS OF OPERATIONS

	From Inception (April 22, 2003) to July 31, 2004 (unaudited)	Seven months ended July 31, 2004 (unaudited)	From Inception (April 22, 2003) through December 31, 2003
Revenues:			
License revenue	\$ 150,000	\$ 150,000	\$
Non-refundable fees	26,500	26,500	
	<u>176,500</u>	<u>176,500</u>	
Expenses:			
Legal	163,369	100,443	62,926
Insurance	23,471	21,921	1,550
Consulting	62,940	7,483	55,457
Travel and meals	27,241	12,759	14,482
Product development	146,744	140,269	6,475
Other	17,146	12,257	4,889
Amortization	18,000	18,000	
	<u>458,911</u>	<u>313,132</u>	<u>145,779</u>
Net loss	\$ (282,411)	\$ (136,632)	\$ (145,779)
Weighted average shares outstanding	<u>500,781</u>	<u>501,674</u>	<u>500,000</u>
Net loss per share	\$ (.56)	\$ (.27)	\$ (.29)

See notes to financial statements.

ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

STATEMENT OF STOCKHOLDERS DEFICIT

FROM INCEPTION (APRIL 22, 2003)

THROUGH JULY 31, 2004

	<u>Common Stock</u>		<u>Deficit Accumulated During the Development Stage</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>		
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.

ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

STATEMENTS OF CASH FLOWS

	From Inception (April 22, 2003) Through	Seven Months Ended	From Inception Through December 31, 2003
	July 31, 2004 (unaudited)	July 31, 2004 (unaudited)	
Cash flows from operating activities:			
Net loss	\$ (282,411)	\$ (136,632)	\$ (145,779)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Amortization	18,000	18,000	
Increase in cash resulting from changes in:			
Accounts payable	239,348	128,098	111,250
Deferred revenue	123,500	123,500	
Net cash flows from operating activities	98,437	132,966	(34,529)
Cash flows from investing activities:			
Purchase of license	(100,000)	(100,000)	
Net cash flows from investing activities	(100,000)	(100,000)	
Cash flows from financing activities:			
Proceeds from issuance of stock	5,047	47	5,000
Proceeds from stockholder advances	54,191	21,427	32,764
Net cash flows from financing activities	59,238	21,474	37,764
Net change in cash	57,675	54,440	3,235
Cash at beginning of period		3,235	
Cash at end of period	\$ 59,675	\$ 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.

ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO FINANCIAL STATEMENTS

FROM INCEPTION (APRIL 23, 2003) THROUGH

DECEMBER 31, 2003 AND 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 in the development stage and 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. The Company will focus on the development and commercialization of quick-to-market products bearing lower development and regulatory risk. Products will either be 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.

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ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO FINANCIAL STATEMENTS

FROM INCEPTION (APRIL 23, 2003) THROUGH

DECEMBER 31, 2003 AND JULY 31, 2004

1. Nature of business and summary of significant accounting policies (continued):

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 (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:

The Company is in an early development stage with no ongoing fixed overhead for rent or salaries. Operations to date have been funded by capital contributions and advances from the founding stockholders.

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 realize its plan of operations.

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Such plan of operations includes the pursuit of both licenses 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.

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ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO FINANCIAL STATEMENTS

2. Liquidity and management's plan of operation (continued):

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.

ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO FINANCIAL STATEMENTS

4. Income taxes (continued):

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

	<u>2003</u>	<u>2002</u>
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)
	<u> </u>	<u> </u>
	%	%

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		From inception	
	July 31, 2004		(April 22, 2003) through	
	(unaudited)		December 31, 2003	
	<u>Shares</u>	<u>Exercise Price</u>	<u>Shares</u>	<u>Exercise Price</u>
Outstanding - beginning of period	5,000	\$ 0.01		\$

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Granted	11,375	0.01	5,000	0.01
Exercised	(4,688)	0.01		
Canceled, forfeited or expired				
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Outstanding - end of period	11,687	\$ 0.01	5,000	\$ 0.01
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Exercisable - end of period	2,749	\$ 0.01		\$
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

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ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO FINANCIAL STATEMENTS

5. Stock option plan (continued):

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	\$
Volatility	0%

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.

ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO FINANCIAL STATEMENTS

6. Licensing and distribution agreements (continued):

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 subsidiary of Accentia Biopharmaceuticals, Inc., a portfolio company of 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.

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.

ARIUS PHARMACEUTICALS, INC.

(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO FINANCIAL STATEMENTS

6. Licensing and distribution agreements (continued):

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.

BioDelivery Sciences International, Inc.

PRO FORMA CONSOLIDATED BALANCE SHEET

As of July 31, 2004

(Unaudited)

	Historical		Proforma Adjustments	Proforma Consolidated July 31, 2004
	BDSI July 31, 2004	Arius 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)

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Accumulated other comprehensive gain	1,094		1,094
	<u> </u>	<u> </u>	<u> </u>
Total stockholders' equity	567,046	(277,364)	4,172,929
	<u> </u>	<u> </u>	<u> </u>
	\$ 1,772,632	\$ 1,139,675	\$ 7,045,554
	<u> </u>	<u> </u>	<u> </u>

See notes to Proforma unaudited consolidated financial statements.

F1-1

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
	<u>2,913,231</u>			<u>2,913,231</u>
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
	<u>5,470,591</u>	<u>145,779</u>		<u>5,716,370</u>
Total expenses				
Interest income (expense), net	69,254			69,254
Loss before income taxes	<u>(2,488,106)</u>	<u>(145,779)</u>		<u>(2,633,885)</u>
Income tax benefit				
Net loss	<u>\$ (2,488,106)</u>	<u>\$ (145,779)</u>		<u>\$ (2,633,885.00)</u>
Weighted average shares outstanding				8,663,738
Earnings per share				\$ (0.30)

See notes to Proforma unaudited consolidated financial statements.

BioDelivery Sciences International, Inc.

Proforma Consolidated Income Statement

For the 7 months ended July 31, 2004

(Unaudited)

	<u>BioDelivery Sciences</u>	<u>Arius Pharmaceuticals</u>	<u>Proforma Adjustments</u>	<u>Proforma Seven months ended July 31, 2004</u>
License revenues		150,000		150,000
Non-refundable fees		26,500		26,500
Sponsored research revenues	601,096			601,096
	<u>601,096</u>	<u>176,500</u>		<u>751,096</u>
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	<u>3,408,908</u>	<u>313,132</u>		<u>3,822,040</u>
Interest income (expense), net	<u>(30,163)</u>			<u>(30,163)</u>
Loss before income taxes	<u>(2,837,975)</u>	<u>(136,632)</u>		<u>(2,974,607)</u>
Income tax benefit	<u>(2,000)</u>			<u>(2,000)</u>
Net loss	<u>(2,839,975)</u>	<u>(136,632)</u>		<u>(2,976,607)</u>
Weighted average shares outstanding				8,632,922
Earnings per share				\$ (0.34)

BioDelivery Sciences International, Inc.

Notes 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.