

BIODELIVERY SCIENCES INTERNATIONAL INC

Form 10QSB

November 10, 2005

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D. C. 20549

**FORM 10-QSB**

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

For the quarterly period ended September 30, 2005

.. **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.**

(Exact name of small business issuer as specified in its charter)

Delaware

(State or other jurisdiction of

incorporation or organization)

**35-2089858**

**(I.R.S. Employer Identification No.)**

**2501 Aerial Center Parkway Suite 205**

**Morrisville, NC 27560**

**(Address of principal executive offices)**

**(919) 653-5160**

**(Issuer's telephone number)**

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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  No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes  No

The Issuer had 11,758,637 shares of common stock issued and 11,743,146 shares of common stock outstanding as of November 10, 2005.

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**BioDelivery Sciences International, Inc. and Subsidiaries**

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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF SEPTEMBER 30, 2005 AND DECEMBER 31, 2004

	September 30, 2005 (unaudited)	December 31, 2004	Proforma September 30, 2005 (unaudited)
			See Note 9
<b>ASSETS</b>			
<b>Current assets:</b>			
Cash and cash equivalents	\$ 130,488	\$ 749,932	\$ 7,990,755
Accounts receivable	32,132	27,145	32,132
Due from related party	206,195	9,290	206,195
Prepaid expenses and other current assets	380,883	242,849	134,428
<b>Total current assets</b>	<b>749,698</b>	<b>1,029,216</b>	<b>8,363,510</b>
Equipment, net	697,805	895,294	697,805
Goodwill	2,715,000	2,715,000	2,715,000
<b>Other intangible assets:</b>			
Licenses	2,442,171	2,417,445	2,442,171
Non-compete agreements	500,000	500,000	500,000
Accumulated amortization	(538,621)	(211,658)	(538,621)
<b>Total other intangible assets</b>	<b>2,403,550</b>	<b>2,705,787</b>	<b>2,403,550</b>
Other assets	747,730	24,726	747,730
<b>Total assets</b>	<b>\$ 7,313,783</b>	<b>\$ 7,370,023</b>	<b>\$ 14,927,595</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
<b>Current liabilities:</b>			
Current maturities of notes payable	\$ 1,969,708	\$ 333,333	\$ 1,969,708
Accounts payable and accrued liabilities	2,436,784	735,917	2,436,784
Due to related parties	158,297	171,327	158,297
Deferred revenue	70,360	123,311	70,360
Dividends payable	71,106	22,303	71,106
<b>Total current liabilities</b>	<b>4,706,255</b>	<b>1,386,191</b>	<b>4,706,255</b>
Notes payable	857,642		857,642
<b>Total liabilities</b>	<b>5,563,897</b>	<b>1,386,191</b>	<b>5,563,897</b>
Commitments (Note 10)			
<b>Stockholders equity:</b>			
Series A Preferred stock, \$.001 par value; 1,647,059 shares designated, 1,647,059 issued and outstanding	3,705,883	3,705,883	3,705,883

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Series B Preferred stock, \$.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000	1,450,000	1,450,000
Common stock, \$.001 par value; 45,000,000 shares authorized, 7,304,687 and 7,245,863 shares issued; 7,269,196 and 7,145,863 shares outstanding in 2005 and 2004, respectively	7,305	7,246	11,759
Additional paid-in capital	17,697,182	14,619,701	25,306,541
Treasury stock, at cost, 35,490 and 100,000 shares, 2005 and 2004, respectively	(107,783)	(303,894)	(107,783)
Accumulated deficit	(21,002,701)	(13,495,104)	(21,002,701)
	<u>1,749,886</u>	<u>5,983,832</u>	<u>9,363,698</u>
Total stockholders' equity			
	<u>\$ 7,313,783</u>	<u>\$ 7,370,023</u>	<u>\$ 14,927,595</u>

See notes to condensed consolidated financial statements.

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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Sponsored research revenues	\$ 16,415	\$ 164,892	\$ 206,031	\$ 683,542
Development cost reimbursement		500,000		500,000
License fees and royalties, related parties	17,827		426,680	
Research fees	25,000		24,995	
	<u>59,242</u>	<u>664,892</u>	<u>657,706</u>	<u>1,183,542</u>
Expenses:				
Research and development	1,562,990	1,366,882	4,439,228	2,882,089
General and administrative	896,359	741,275	3,012,542	2,092,949
Stock-based compensation	1,735	33,858	30,450	111,816
Total expenses	<u>2,461,084</u>	<u>2,142,015</u>	<u>7,482,220</u>	<u>5,086,854</u>
Other income (expense):				
Sale of future revenue stream		2,500,000		2,500,000
Interest income (expense), net	(328,292)	(14,115)	(683,083)	(39,181)
Gain (loss) before income taxes	<u>(2,730,134)</u>	<u>1,008,762</u>	<u>(7,507,597)</u>	<u>(1,442,493)</u>
Income tax expense		(2,400)		(2,400)
Net income (loss)	<u>(2,730,134)</u>	<u>1,006,362</u>	<u>(7,507,597)</u>	<u>(1,444,893)</u>
Preferred stock dividends	(16,447)		(48,803)	
Other comprehensive gain:				
Unrealized gain on marketable equity securities				1,094
(Loss) Income attributable to common stockholders	<u>\$ (2,746,581)</u>	<u>\$ 1,006,362</u>	<u>\$ (7,556,400)</u>	<u>\$ (1,443,799)</u>
Per share amounts, basic and diluted:				
Loss attributable to common stockholders	<u>\$ (0.37)</u>	<u>\$ 0.14</u>	<u>\$ (1.04)</u>	<u>\$ (0.21)</u>
Weighted average common stock shares outstanding basic and diluted	<u>7,348,209</u>	<u>7,098,635</u>	<u>7,274,500</u>	<u>7,023,728</u>

See notes to condensed consolidated financial statements.



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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STOCKHOLDERS EQUITY

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005

(Unaudited)

	Series A		Series B		Common Stock		Additional	Treasury Stock	Accumulated Deficit	Total Stockholders Equity
	Preferred Stock		Preferred stock				Paid-In			
	Shares	Amount	Shares	Amount	Shares	Amount	Capital			
Balances, January 1, 2005	1,647,059	\$ 3,705,883	341,176	\$ 1,450,000	7,245,863	\$ 7,246	\$ 14,619,701	\$ (303,894)	\$ (13,495,104)	\$ 5,983,832
Stock-based compensation							10,450			10,450
Issuance of common stock					58,824	59	249,941			250,000
Issuance of treasury stock							(76,111)	196,111		120,000
Beneficial conversion feature of convertible debentures							1,259,744			1,259,744
Issuance of warrants with convertible debentures							1,292,002			1,292,002
Issuance of warrants for financing costs							390,258			390,258
Series B Preferred Dividends							(48,803)			(48,803)
Net loss									(7,507,597)	(7,507,597)
Balances, September 30, 2005	1,647,059	\$ 3,705,883	341,176	\$ 1,450,000	7,304,687	\$ 7,305	\$ 17,697,182	\$ (107,783)	\$ (21,002,701)	\$ 1,749,886

See notes to condensed consolidated financial statements.



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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## CONDENSED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

	Nine Months Ended September 30,	
	2005	2004
<b>Operating activities:</b>		
Net loss	\$ (7,507,597)	\$ (1,444,893)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of treasury stock	20,000	
Depreciation	212,238	213,094
Amortization	479,931	29,851
Accretion of interest on convertible debentures	379,095	
Expenses paid through issuance of warrants	84,573	
Loss on sale of marketable securities		10,993
Stock-based compensation	10,450	111,816
Changes in assets and liabilities:		
Accounts receivable	(4,987)	(527,145)
Prepaid expenses	(138,047)	4,552
Other assets		20,000
Accounts payable and accrued liabilities	1,800,867	(355,693)
Deferred revenue	(52,950)	(23,974)
<b>Net cash flows from operating activities</b>	<b>(4,716,427)</b>	<b>(1,861,399)</b>
<b>Investing activities:</b>		
Purchase of equipment	(14,750)	(68,444)
Cash acquired through acquisition		57,675
Investments, net		2,017,753
<b>Net cash flows from investing activities</b>	<b>(14,750)</b>	<b>2,006,984</b>
<b>Financing activities:</b>		
Proceeds from issuance of common stock	250,000	272,000
Issuance of Series B Preferred Stock		1,450,000
Proceeds from convertible debentures	5,000,000	
Repayment of borrowings from related parties	(209,934)	(61,836)
Payment on notes and capital leases	(333,333)	(191,056)
Cash paid for loan costs	(595,000)	
<b>Net cash flows from financing activities</b>	<b>4,111,733</b>	<b>1,469,107</b>
<b>Net change in cash and cash equivalents</b>	<b>(619,444)</b>	<b>1,614,692</b>
Cash and cash equivalents at beginning of period	749,932	525,670

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Cash and cash equivalents at end of period	\$ 130,488	\$ 2,140,362
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See notes to condensed consolidated financial statements.

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CONDENSED STATEMENTS OF CASH FLOWS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION**

Non-cash investing and financing activities:

The Company accrued \$48,803 in annual cumulative dividends in connection with its Series B Preferred stock through the third quarter of 2005.

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**1. Basis of presentation:**

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

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

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

The accompanying consolidated financial statements include the accounts of BioDelivery Sciences International, Inc. and its subsidiaries, Arius and BND. All intercompany accounts and transactions have been eliminated. BND is substantially inactive at September 30, 2005.

**2. Summary of significant accounting policies:**

*General:*

The Company currently generates revenue from licensing, milestone payments and royalties, as well as from grants. Ultimately, if approval of licensed products and formulations is secured from the U.S. Food and Drug Administration ( FDA ), the Company's goal is to augment these revenues from sales of such products and formulations, on which royalties and other fees will be paid to licensors and/or third party collaborators. The Company is also required to make certain license payments to such licensors in accordance with applicable agreements.

*Revenue Recognition:*

Sponsored research amounts are recognized as revenue when the research underlying such payments has been performed or when the funds have otherwise been utilized, such as for the purchase of operating assets. Grant revenue is recognized to the extent provided for under the

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**2. Summary of significant accounting policies (continued):**

*Revenue Recognition (continued):*

related grant or collaborative research agreement. Research and development expenses are charged to operations as incurred.

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

In addition to license fees, the Company may also generate revenue from time to time in the form of milestone payments. Milestone payments are only received and recognized as revenues if the specified milestone is achieved and accepted by the customer and continued performance of future research and development services related to that milestone are not required. The Company, for arrangements where non-refundable upfront fees exist and there are further payments due upon achieving certain milestones, recognizes such revenue pursuant to Emerging Issues Task Force 00-21, Revenue Arrangements with Multiple Deliverables, whereby multiple deliverables are evaluated to determine whether such deliverables should be considered a single unit of accounting.

*Other assets:*

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

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

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In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections ( SFAS 154 ), which replaces Accounting Principles Board Opinions No. 20 Accounting Changes and SFAS No. 3, Reporting Accounting Changes in Interim Financial Statements An Amendment of APB Opinion No. 28. SFAS 154 provides guidance on accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS 154 is effective for accounting changes and

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**2. Summary of significant accounting policies (continued):**

*Other assets (continued):*

corrections of errors made in fiscal years beginning after December 15, 2005 and is required to be adopted by the Company in the first quarter of fiscal 2006. The Company is currently evaluating the effect that the adoption of SFAS 154 will have on its consolidated results of operations and financial condition, but does not expect it to have a material impact.

**3. Liquidity and management's plans:**

Since inception, the Company has financed its operations principally from the sale of equity or convertible debt securities, through short-term borrowings, which were subsequently repaid, and from funded research arrangements. The Company has not generated revenue from the sale of any product but has generated revenues from licensing arrangements, milestone payments, and the sale of royalty rights. The Company intends to finance its research, development and commercialization efforts and its working capital needs from existing cash, licensing agreements and private or public financings, including potential offerings of common stock such as the October 2005 offering described in Note 11.

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. Pursuant to the Equity Line Agreement, HCG will, at the Company's request, invest up to \$4.0 million in the Company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock ( Series B Preferred ). The Series B Preferred will be convertible at any time as of or after April 1, 2006 at a price equal to \$4.25 per share. As of September 30, 2005, \$1.45 million had been drawn under the Equity Line Agreement.

On February 22, 2005, the Company consummated a three year \$2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., a Cayman Islands corporation ( Laurus ). The Laurus investment takes the form of a convertible note secured by substantially all of the assets of the Company, including Arius and BND. Net proceeds from the financing were used primarily to retire the Company's \$1.0 million secured equipment loan with Gold Bank (on which approximately \$300,000 was owed and was paid at the closing of the Laurus transaction) and will be used to support research and development opportunities and for general working capital purposes. Also, on May 31, 2005, the Company closed an additional \$2.5 million secured convertible debt financing from Laurus. Net proceeds from this second Laurus financing will be used primarily to support the research, development and commercialization opportunities and for general working capital purposes.

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





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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**3. Liquidity and management's plans (continued):**

September 1, 2005. The note is convertible, under certain conditions, into shares of Common Stock at a price equal to \$3.10 per share.

The May Laurus investment, like the February 2005 Laurus investment, takes the form of a convertible note secured by substantially all of the Company's assets. Such note has a 3-year term (subject to certain contingencies) and bears interest at a rate equal to prime plus 2% per annum. The note is convertible, under certain conditions, into shares of Common Stock at a price equal to \$3.10 per share. In connection with the financing, the Company issued to Laurus an additional Common Stock purchase warrant to purchase up to 483,871 shares Common Stock at a price equal to \$3.88 per share. The Company agreed, pursuant to a registration rights agreement, to register the shares of Common Stock underlying the Laurus notes and the warrants with the SEC, and such shares have been so registered as of the date of this Report.

On June 29, 2005, the Company entered into two separate amendments to the February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments of principal under the February and May 2005 Laurus notes until December 1, 2005. In consideration of Laurus' agreement, the Company issued to Laurus two warrants, one to purchase 22,500 shares of Common Stock (in connection with the February amendment) and a second to purchase 7,500 shares of Common Stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of Common Stock at an exercise price of \$.001 per share and expire on September 29, 2012. Except for the exercise price of the warrants, the warrants issued to Laurus in connection with the amendments are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005. The Company agreed to register the shares of Common Stock underlying the September warrants with the SEC, which registration statement was declared effective on July 11, 2005.

On July 15, 2005, the Company entered into a clinical development and license agreement with Clinical Development Capital, LLC ( CDC ) pursuant to which CDC will provide, beginning in February 2006 and subject to certain conditions, up to \$7 million in funding (including a \$2 million upfront payment and subsequent monthly payments) for the clinical development of the Company's BEMA Fentanyl product. All funds made available under the transaction with CDC must be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and therefore will be accounted for as a refundable deposit. As part of the transaction with CDC, the Company issued a warrant to CDC to purchase 500,000 shares of Common Stock at \$3.50 per share. Such warrant contains certain antidilution provisions with respect to certain issuances of stock (or issuance of securities convertible into stock) at a price per share less than the exercise price stated in the warrant during the six months following its issuance. Also, the number of shares for which the warrant may be exercised is subject to adjustment based on the amount of funding provided by CDC, provided the warrant shall not, in any event, be exercisable for less than 100,000 shares of Common Stock. Finally, such warrant expires after the earlier of (i) the second anniversary of the approval by the FDA of the first NDA relating to BEMA Fentanyl, (ii) the closing of a sale of all or substantially all of the Company's assets or the acquisition of the Company by another entity by means of merger or other transaction as a result of which the

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**3. Liquidity and management's plans (continued):**

Company's stockholders immediately prior to such acquisition possess a minority of the voting power of the acquiring entity immediately following such acquisition, or (iii) any liquidation or winding up of the Company.

The Company's existing cash and cash equivalents, together with available financing, including proceeds from the October 2005 public offering, the remaining balances of the Company's equity line of credit, the proposed funding from CDC, the remaining balance of the Company's NIH grant and potential new license revenue is considered by management to be sufficient to finance the planned operations and capital expenditures through at least June 30, 2006, assuming that the Company does not accelerate the development of other opportunities available to it, engage in an extraordinary transaction or otherwise face unexpected expenses, events or contingencies, any of which could effect the Company's cash requirements. Additionally, available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, the Company anticipates it will likely be required to raise additional capital through one or more of a variety of potential sources, including:

The public equity markets;

Private equity financings

Collaborative agreements;

Grants and new license revenues;

Bank loans;

Public or private debt; and

Redemption and/or exercise of existing public warrants.

There can be no assurance that additional capital will be available on favorable terms, if at all. If adequate funds are not available, the Company may be required to significantly reduce or refocus its operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, any 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.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**4. Goodwill and other intangible assets:**

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

<u>Year ending September 30</u>	
2006	\$ 415,124
2007	185,957
2008	185,957
2009	185,957
2010	185,957
Thereafter	1,244,598
	<u>\$ 2,403,550</u>

**5. Notes payable:**

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

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

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

Principal balance of note	\$5,000,000
Less reduction for:	
Beneficial conversion feature	(1,259,744)
Value of warrants	<u>(1,292,002)</u>

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Recorded at closing	2,448,254
Accretion (interest expense) through September 30, 2005	379,096
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Carrying value at September 30, 2005	\$ 2,827,350
	<hr/>
As presented on balance sheet:	
Current maturities of notes payable	\$ 1,969,708
Notes payable	857,642
	<hr/>
	\$ 2,827,350
	<hr/>

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**5. Notes payable (continued):**

The fair value of the proceeds was allocated as follows:

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

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

**6. Net loss per common share:**

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

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

<b>Three months ended</b>	<b>Nine months ended</b>
<b>September 30,</b>	<b>September 30,</b>

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	2005	2004	2005	2004
(Loss) Income attributable to common stockholders, as reported	\$ (2,746,581)	\$ 1,006,362	\$ (7,556,400)	\$ (1,443,779)
Net loss (numerator)	\$ (2,730,134)	\$ 1,006,362	\$ (7,507,597)	\$ (1,444,893)
Basic:				
Weighted average shares outstanding (denominator)	7,348,209	7,098,635	7,274,500	7,023,728
Net loss per common share basic	\$ (0.37)	\$ 0.14	\$ (1.04)	\$ (0.21)
Diluted:				
Weighted average shares outstanding	7,348,209	7,098,635	7,274,500	7,027,064
Net loss per common share diluted	\$ (0.37)	\$ 0.14	\$ (1.04)	\$ (0.21)



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## BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

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

	<u>2005</u>	<u>2004</u>
Options and warrants to purchase common stock	5,814,424	3,844,262
Preferred stock (convertible to common stock)	1,988,235	
Shares issuable for convertible debt	2,094,680	

**7. Stock-based compensation:**

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

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

	<u>Three months ended</u>		<u>Nine months ended</u>	
	<u>September 30,</u> <u>2005</u>	<u>September 30,</u> <u>2004</u>	<u>September 30,</u> <u>2005</u>	<u>September 30,</u> <u>2004</u>
Loss-attributable to common stockholders, as reported	\$ (2,746,581)	\$ 1,006,362	\$ (7,556,400)	\$ (1,443,779)
Stock-based employee compensation, as reported	\$ 1,735	\$ 33,858	\$ 10,450	\$ 111,816
Stock-based employee compensation under fair value method	\$ 534,897	\$ 392,862	\$ 659,224	\$ 550,112
Pro forma loss attributable to common stockholders under fair value method	\$ (3,279,743)	\$ 647,358	\$ (8,205,174)	\$ (1,882,075)
Loss attributable to common stockholders basic and diluted: As reported	\$ (0.37)	\$ 0.14	\$ (1.04)	\$ (0.21)

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Pro forma under fair value method	\$	(0.45)	\$	0.09	\$	(1.13)	\$	(0.27)
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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

(Unaudited)

**8. National Institutes of Health Grant:**

The National Institutes of Health ( NIH ) has awarded the Company a Small Business Innovation Research Grant (the SBIR ), which has been utilized in research and development efforts. 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).

A balance of \$0.2 million remains unexpended under this grant at September 30, 2005 but the grant has been extended to January 31, 2006. The Company incurred approximately \$0.3 million and \$0.1 million of costs related to this agreement for the nine months ended September 30, 2005 and 2004, respectively. During the nine months ended September 30, 2005 and 2004, the Company received \$0.2 million and \$0 respectively, and recognized revenue of \$0.2 million and \$0, respectively, from this grant.

**9. Subsequent events:**

On October 5, 2005, the Company consummated its public offering of 4,400,000 shares of Common Stock, resulting in gross proceeds of \$8.8 million to the Company. The offering was underwritten by Ferris, Baker Watts, Incorporated, Maxim Group LLC and GunnAllen Financial, Inc. The underwriters were granted an option to purchase up to an additional 660,000 shares of Common Stock from the Company to cover over-allotments. Net proceeds amounted to \$7.8 million. On October 28, 2005 the underwriters exercised a portion of their over-allotment rights to purchase an additional 53,950 shares, resulting in additional gross proceeds to the Company of \$107,900. The public price per share for the offering was \$2.00. The balance sheet included in this Report includes a proforma statement giving effect to the transactions as if they had closed on September 30, 2005.

As a result of the pricing of this offering, and pursuant to the terms of the applicable agreements and instruments: (i) the conversion price of the Laurus notes was reduced from \$3.10 to \$2.38 and (ii) the exercise price of the warrants issued to CDC was reduced from \$3.50 to \$2.91. Based on its review of the applicable documents, the Company does not believe that October 2005 public offering requires any current adjustment to the exercise price of the Company's publicly-traded warrants.

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### **ITEM 2. Management's Discussion and Analysis of Financial Condition and Plan of Operations.**

The following discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-QSB. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company's actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-QSB.

#### **For the three months ended September 30, 2005 compared to the three months ended September 30, 2004**

***Sponsored Research Revenue.*** During the three-month period ended September 30, 2005, the Company reported \$.02 million of sponsored research revenues from a grant from the National Institutes of Health ( NIH ). In the prior year, revenue aggregating \$.16 million was derived from an SBIR grant, which was fully funded in August 2004. The remaining balance of the NIH grant at September 30, 2005 is \$.2 million.

***License Fee Revenues.*** There were no license or milestone revenues during the three-month periods ended September 30, 2005 or 2004.

***Royalty Revenues.*** During the three-month period ended September 30, 2005, the Company reported \$.02 million of royalty revenue from a related company. There were no such royalties in the prior year as this arrangement commenced in 2005.

***Research Fee Revenues.*** During the three-month period ended September 30, 2005, the Company reported \$.03 million of research fee revenue. There were no research fee revenues in 2004.

***Research and Development.*** Research and development expenses of approximately \$1.6 million and \$1.4 million were incurred during the three-month periods ended September 30, 2005 and 2004, respectively. The Company's scientific staff continued to work toward development and application of the Company's BEMA and BioRad<sup>®</sup>ochleate technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options in 2004 by directors, and funding of an equity line of credit from HCG. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA and BioRad<sup>®</sup> drug delivery technologies.

***General and Administrative Expenses.*** General and administrative expenses of approximately \$.9 million and \$.7 million were incurred in the three-month periods ended September 30, 2005 and 2004, respectively. These expenses are principally comprised of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, and other business development costs. Nominal stock-based compensation costs in 2005 were associated with vested options during the period. Employees' stock option grants were treated under APB 25 through December 31, 2004. The Company adopted FAS 123 beginning in 2005 for new options granted to employees. The increase in general and administrative expenses in 2005 is primarily due to increased staffing following the acquisition of Arius, and additional legal and patent costs, partially offset by reduced costs associated with BND.



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**Interest Income (Expense).** Interest income (expense) for the periods ended September 30, 2005 and 2004 was principally comprised of interest expense on the line of credit, notes payable and capital leases payable, and costs attributable to the February and May financings, partially offset by nominal earnings from invested cash. Interest expense in 2005 also includes accretion of interest on convertible debentures of \$0.2 million.

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

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

### **For the nine months ended September 30, 2005 compared to the nine months ended September 30, 2004**

**Sponsored Research Revenue.** During the nine-month period ended September 30, 2005, the Company reported \$.2 million of sponsored research revenues from a grant from the NIH. In the prior year, revenue aggregating \$.7 million was derived from an SBIR grant, which was fully funded in August 2004.

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

**Royalty Revenues.** During the nine-month period ended September 30, 2005, the Company reported \$.03 million of royalty revenue from a related company. There were no such royalties in the prior year as this arrangement commenced in 2005.

**Research Fee Revenues.** During the nine-month period ended September 30, 2005, the Company reported \$.02 million of research fee revenue. There were no research fee revenues in 2004.

**Development cost reimbursement.** The Company has an agreement whereby it is reimbursed by Accentia for expenses associated with the development of certain technology applications. During the quarter ended September 30, 2004, \$0.5 million is shown as development cost reimbursement in the Company's subsidiary, Arius. The associated expenses are included in research and development expenses as incurred.

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**Research and Development.** Research and development expenses of approximately \$4.4 million and \$2.9 million were incurred during the nine-month periods ended September 30, 2005 and 2004, respectively. The Company's scientific staff continued to work toward increased development and application of the Company's BEMA and BioRadiochleate technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options in 2004 by directors, and funding of an equity line of credit from HCG. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA and Bioral® drug delivery technologies.

**General and Administrative Expenses.** General and administrative expenses of approximately \$3.0 million and \$2.1 million were incurred in the nine-month periods ended September 30, 2005 and 2004, respectively. These expenses are principally comprised of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries, and other business development costs. Stock-based compensation costs of \$.03 million in 2005 were associated with vested options during the period. Employees' stock option grants were treated under APB 25 through December 31, 2004. The Company has adopted FAS 123 beginning in 2005 for new options granted to employees. The increase in general and administrative expenses in 2005 is primarily due to increased staffing following the acquisition of Arius, and additional legal and patent costs, partially offset by reduced costs associated with BND.

**Interest Income (Expense).** Interest income (expense) for the periods ended September 30, 2005 and 2004 was principally comprised of interest expense on the line of credit, notes payable and capital leases payable, and costs attributable to the February 2005 and May 2005 financings, partially offset by nominal earnings from invested cash. Interest expense in 2005 also includes accretion of interest on convertible debentures of \$0.4 million.

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

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

## **Liquidity and Capital Resources**

Since inception, the Company has financed its operations primarily from the sale of its securities and loans from third parties. Through September 30, 2005, the Company raised approximately \$20.9 million, net of issuance costs, through these issuances. On October 5, 2005 the Company consummated its public offering of 4,400,000 shares of common stock, resulting in gross proceeds of \$8.8 million to the Company. The offering was underwritten by Ferris, Baker Watts,

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Incorporated, Maxim Group LLC and GunnAllen Financial, Inc. The underwriters were granted an option to purchase up to an additional 660,000 shares of common stock from the Company to cover over-allotments. Net proceeds amounted to \$7.8 million. On October 28, 2005 the underwriters exercised a portion of their over-allotment rights to purchase an additional 53,950 shares, resulting in additional gross proceeds to the Company of \$107,900. The public price per share for the offering was \$2.00. The balance sheet includes a proforma statement giving effect to the transactions as if they had closed on September 30, 2005.

At September 30, 2005, the Company had \$0.1 million in cash and investments. At December 31, 2004, the Company had cash and investments totaling approximately \$0.8 million. With the completion of its public offering of Common Stock in October 2005, the Company's cash balance increased to approximately \$8.0 million. The adequacy of cash for the Company's continuing operations is dependent on, among other things, licensing opportunities that the Company will seek to negotiate in the coming year, as well as the funding of the HCG equity line of credit, further described below, which had a balance remaining of \$2.6 million at September 30, 2005, and the proposed funding from CDC.

The Company's working capital deficit was \$4.0 million and \$0.4 million at September 30, 2005 and December 31, 2004, respectively. The working capital deficit was eliminated in October 2005 with the closing of the Company's public offering of Common Stock described above, which provided net proceeds after all offering costs of approximately \$7.9 million after the exercise of a portion of the underwriters over-allotment option.

The Company has incurred significant net losses and negative cash flows from operations since inception. As of September 30, 2005, the Company had an accumulated deficit of \$21.0 million and total stockholders' equity of \$1.7 million. After giving effect on a pro-forma basis to the public offering of Common Stock closed in October 2005, the Company's stockholders' equity was \$9.4 million. At December 31, 2004, the Company's accumulated deficit was \$13.5 million and its stockholders' equity was approximately \$6.0 million.

We anticipate that cash used in operations will increase significantly in the future as the Company researches, develops, and, potentially, manufactures, distributes and/or sells its proposed drug formulations. While the Company believes further application of its licensed BEMA and Bioral® cochleate technologies to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, the Company's plan of operations for the next 24 months will be focused primarily on the further development of the Emezine® formulation and the BEMA and Bioral® technologies, and the application of such technologies to a limited number of pharmaceutical products, and not on the marketing, production or sale of FDA approved products.

The Company's existing cash and cash equivalents, together with the net proceeds from the public offering closed in October 2005, and remaining balances of the Company's existing equity line of credit and grant, and potential new license revenue, is considered by our management to be sufficient to finance the planned operations and capital expenditures through at least June 30, 2006 assuming that the Company does not accelerate the development of other opportunities available to it, engage in an extraordinary transaction or otherwise face unexpected expenses, events or contingencies, any of which could effect the Company's cash requirements. Additionally, available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, the Company anticipates that it will likely be required to raise additional capital through one or more of a variety of potential sources, including:

public equity markets;



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private equity financings;

collaborative arrangements;

grants and new license revenues;

bank loans;

public or private debt; and

redemption and/or exercise of existing public warrants.

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

**Critical Accounting Policies and Estimates**

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

*Revenue recognition:*

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

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



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In addition to license fees, the Company may also generate revenue from time to time in the form of milestone payments. Milestone payments are only received and recognized as revenues if the specified milestone is achieved and accepted by the customer and continued performance of future research and development services related to that milestone are not required. The Company, for arrangements where non-refundable upfront fees exist and there are further payments due upon achieving certain milestones, recognizes such revenue pursuant to Emerging Issues Task Force 00-21, Revenue Arrangements with Multiple Deliverables, whereby multiple deliverables are evaluated to determine whether such deliverables should be considered a single unit of accounting.

### *Recent accounting pronouncements:*

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

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

### **ITEM 3. Controls and Procedures**

The Company's Chief Executive Officer and Chief Financial Officer (collectively, the Certifying Officers ) are responsible for establishing and maintaining disclosure controls and procedures for the Company. Such officers have concluded (based on their evaluation of these controls and procedures as of a date within 90 days of the filing of this report) that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in this report is accumulated and communicated to the Company's management, including its principal executive officers as appropriate, to allow timely decisions regarding required disclosures.

The Certifying Officers also have indicated that there were no significant changes in the Company's internal controls or other factors that could significantly affect such controls subsequent to the date of their evaluation, and there were no corrective actions with regard to significant deficiencies and material weaknesses.

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**NOTE ON FORWARD-LOOKING STATEMENTS**

The information set forth in this Report on Form 10-QSB under the Sections Management's Discussion and Analysis or Plan of Operation, Management's plans regarding liquidity and capital resources and elsewhere relate to future events and expectations and as such constitute Forward-Looking Statement within the meaning of the Private Securities Litigation Act of 1995. The words believes, anticipates, plans, expect and similar expressions in this report are intended to identify forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results, performance or achievements of the Company to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1 of the 2004 Annual Report and other factors detailed from time to time in the Company's other filings with the Securities and Exchange Commission. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this report.

**Table of Contents****PART II. OTHER INFORMATION****Item 1. Legal Proceedings.**

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

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

**Item 5. Other Information.**

Effective October 17, 2005, the Company entered into a supply agreement with Aveva Drug Delivery Systems, Inc. (Aveva) under which Aveva will prepare clinical supplies for the Company's Phase III trials of, and provide commercial manufacturing for, BEMA<sup>TM</sup> Fentanyl. BEMA<sup>TM</sup> Fentanyl is an oral adhesive disc formulation of the narcotic fentanyl. In addition to the consideration to be paid to Aveva as described in the Aveva documents (which documents are filed as exhibits to this Report), the Company has also granted to Aveva a warrant to purchase up to 75,000 shares of Common Stock at \$3.50 per share. The shares underlying the Aveva warrant are subject to vesting in three equal installments of 25,000 shares upon completion of certain specified milestones relating to the BEMA<sup>TM</sup> Fentanyl clinical program.

**Item 6. Exhibits and Reports on Form 8-K.**

## (a) Exhibits

<b>Exhibit Index Number</b>	<b>Description</b>
10.1	Supply Agreement, dated October 17, 2005, between Aveva Drug Delivery Systems, Inc., Arius Pharmaceuticals, Inc. (the Company's wholly-owned subsidiary) and the Company (confidential treatment requested for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2)
10.2	Common Stock Purchase Warrant, dated October 17, 2005, by the Company in favor of Aveva Drug Delivery Systems, Inc.

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31.1	Certification Pursuant To Sarbanes-Oxley Section 302
31.2	Certification Pursuant To Sarbanes-Oxley Section 302
32.1	Certification Pursuant To 18 U.S.C. Section 1350 (*)
32.2	Certification Pursuant To 18 U.S.C. Section 1350 (*)

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\* A signed original of this written statement required by Section 906 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.

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(b) Reports on Form 8-K

On July 21, 2005, the Company filed a Current Report on Form 8-K regarding its clinical development and license agreement with Clinical Development Capital LLC.

On August 1, 2005, the Company filed a Current Report on Form 8-K regarding the approved proposals from the July 28, 2005 Annual Meeting.

On August 24, 2005, the Company filed a Current Report on Form 8-K regarding the departure and appointment of certain directors and amendments to the Company's Bylaws.

On September 16, 2005, the Company filed a Current Report on Form 8-K regarding a listing qualification notice from the Nasdaq Stock Market and the resignation of two directors.

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**SIGNATURES**

Pursuant to the requirements 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: November 10, 2005

By: /s/ Mark A. Sirgo

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Mark A. Sirgo, President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 10, 2005

By: /s/ James A. McNulty

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James A. McNulty, Secretary, Treasurer and Chief Financial Officer  
(Principal Financial Officer)

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