

BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
November 14, 2006
Table of Contents

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, 2006

.. 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)

2501 Aerial Center Parkway Suite 205

Morrisville, NC 27560

(Address of principal executive offices)

35-2089858
(I.R.S. Employer
Identification No.)

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 10QSB

(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 13,953,637 shares of common stock issued and 13,938,146 shares of common stock outstanding as of September 30, 2006.

Transitional Small Business Disclosure Format (Check one): Yes No

Table of Contents

BioDelivery Sciences International, Inc. and Subsidiaries

Form 10-QSB

for the period ended September 30, 2006

Index

	Page
Part I. Financial Information	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets as of September 30, 2006 (unaudited) and December 31, 2005 (audited)</u>	1
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2006 and 2005 (unaudited)</u>	2
<u>Condensed Consolidated Statement of Stockholders' Equity for the nine months ended September 30, 2006 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2006 and 2005 (unaudited)</u>	4
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis or Plan of Operation</u>	20
Item 3. <u>Controls and Procedures</u>	25
<u>Note on Forward Looking Statements</u>	25
Part II. Other Information	
Item 1. <u>Legal Proceedings</u>	26
Item 5. <u>Other Information</u>	27
Item 6. <u>Exhibits</u>	27
<u>Signatures</u>	S-1
Certifications	

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2006 (Unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,086,301	\$ 4,914,735
Accounts Receivable	75,000	
Due from related party	112,876	59,038
Prepaid expenses and other current assets	216,270	211,445
Total current assets	4,490,447	5,185,218
Equipment, net	447,908	647,677
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	2,442,171	2,442,171
Acquired product rights	2,000,000	
Non-compete agreements	500,000	500,000
Accumulated amortization	(953,741)	(647,608)
Total other intangible assets	3,988,430	2,294,563
Other assets	558,986	844,430
Total assets	\$ 12,200,771	\$ 11,686,888
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current maturities of convertible notes payable	\$ 3,194,523	\$ 1,609,144
Current maturity of note payable	1,000,000	
Accounts payable and accrued liabilities	1,461,397	1,194,797
Due to related parties	819,229	37,668
Deferred revenue	145,360	70,360
Dividends payable	136,356	87,553
Derivative liability	618,286	1,687,026
Total current liabilities	7,375,151	4,686,548
Convertible notes payable, less current maturities	553,507	1,623,144
Total liabilities	7,928,658	6,309,692
Contingency (Note 10)		
Stockholders equity:		
Series A Preferred stock, \$.001 par value; 1,647,059 shares designated, 1,647,059 issued and outstanding	3,705,883	3,705,883
Series B Preferred stock, \$.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000	1,450,000
Common stock, \$.001 par value; 45,000,000 shares authorized, 13,953,637 and 11,828,637 shares issued; 13,938,146 and 11,813,146 shares outstanding in 2006 and 2005, respectively	13,954	11,829
Additional paid-in capital	32,788,888	23,831,168
Treasury stock, at cost, 15,491 shares, 2006 and 2005	(47,183)	(47,183)

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 10QSB

Accumulated deficit	(33,639,429)	(23,574,501)
Total stockholders' equity	4,272,113	5,377,196
Total liabilities and stockholders' equity	\$ 12,200,771	\$ 11,686,888

See notes to condensed consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005 (Restated)	2006	2005 (Restated)
Revenues:				
Sponsored research revenues	\$ 51,368	\$ 16,415	\$ 75,717	\$ 206,031
License fees and royalties, related parties	12,973	17,827	51,578	401,680
License fees, European	2,500,000		2,500,000	
Research fees		25,000	10,000	49,995
	2,564,341	59,242	2,637,295	657,706
Expenses:				
Research and development	1,584,362	1,533,756	5,750,394	3,986,549
Related party research and development	758,770	29,234	2,208,471	452,679
Product development costs			746,591	
General and administrative	1,501,581	853,851	3,135,163	2,987,163
Related party general and administrative	60,459	44,243	105,748	55,832
Total expenses	3,905,172	2,461,084	11,946,367	7,482,223
Loss from operations	(1,340,831)	(2,401,842)	(9,309,072)	(6,824,517)
Other income, net			7,663	
Interest expense, net	(448,450)	(393,064)	(1,531,597)	(789,599)
Derivative gain	386,333		768,078	917,548
Loss before income taxes	(1,402,948)	(2,794,906)	(10,064,928)	(6,696,568)
Income tax benefit (expense)				
Net loss	(1,402,948)	(2,794,906)	(10,064,928)	(6,696,568)
Preferred stock dividends	(16,447)	(16,447)	(48,803)	(48,803)
Loss attributable to common stockholders	\$ (1,419,395)	\$ (2,811,353)	\$ (10,113,731)	\$ (6,745,371)
Per share amounts, basic and diluted:				
Loss attributable to common stockholders	\$ (0.10)	\$ (0.38)	\$ (0.76)	\$ (0.93)
Weighted average common stock shares outstanding basic and diluted	13,938,146	7,348,209	13,259,684	7,274,500

See notes to condensed consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2006

(Unaudited)

	Series A		Series B		Common Stock		Additional	Treasury	Accumulated	Total
	Preferred Stock Shares	Amount	Preferred stock Shares	Amount	Shares	Amount	Paid-In Capital	Stock	Deficit	Stockholders Equity
Balances, January 1, 2006	1,647,059	\$ 3,705,883	341,176	\$ 1,450,000	11,828,637	\$ 11,829	\$ 23,831,168	\$ (47,183)	\$ (23,574,501)	\$ 5,377,196
Stock-based compensation							428,354			428,354
Issuance of common stock and warrants, net of offering costs					2,000,000	2,000	6,973,900			6,975,900
Issuance of warrants for product development costs							797,796			797,796
Issuance of warrants for financing costs							199,686			199,686
Conversion of notes payable to common stock					118,363	118	289,870			289,988
Payment of interest with common stock					6,637	7	16,254			16,261
Reclassification of derivative liability to equity							300,663			300,663
Series B Preferred Dividends							(48,803)			(48,803)
Net loss									(10,064,928)	(10,064,928)
Balances, September 30, 2006	1,647,059	\$ 3,705,883	341,176	\$ 1,450,000	13,953,637	\$ 13,954	\$ 32,788,888	\$ (47,183)	\$ (33,639,429)	\$ 4,272,113

See notes to condensed consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30, (restated)	
	2006	2005
Operating activities:		
Net loss	\$ (10,064,928)	\$ (6,696,568)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of treasury stock		20,000
Expenses paid through the issuance of common stock	16,261	
Expenses paid through the issuance of warrants	997,482	84,573
Depreciation	209,316	212,238
Amortization of deferred finance costs and intangible assets	591,577	479,931
Derivative gain	(768,078)	(917,548)
Accretion of interest on convertible debentures	805,731	485,614
Stock-based compensation	428,354	10,450
Changes in assets and liabilities:		
Accounts receivable	(75,000)	(4,987)
Prepaid expenses	(4,826)	(138,047)
Accounts payable and accrued liabilities	266,600	1,800,867
Deferred revenue	75,000	(52,950)
Net cash flows used in operating activities	(7,522,511)	(4,716,427)
Investing activities:		
Purchase of equipment	(9,546)	(14,750)
Purchase of intangible assets	(1,000,000)	
Net cash flows from investing activities	(1,009,546)	(14,750)
Financing activities:		
Proceeds from sale of common stock and warrants	6,975,900	250,000
Proceeds from convertible debentures		5,000,000
Change in amounts due to related parties	727,723	(209,934)
Payment on notes payable		(333,333)
Cash paid for loan costs		(595,000)
Net cash flows from financing activities	7,703,623	4,111,733
Net change in cash and cash equivalents	(828,434)	(619,444)
Cash and cash equivalents at beginning of period	4,914,735	749,932
Cash and cash equivalents at end of period	\$ 4,086,301	\$ 130,488

See notes to condensed consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

The Company paid cash for interest expense in the amounts of \$330,020 and \$194,271 during the nine months ended September 30, 2006 and 2005, respectively.

Non-cash investing and financing activities:

The Company accrued \$48,803 in annual cumulative dividends in connection with its Series B Preferred stock during each of the nine months ended September 30, 2006 and 2005, respectively.

The Company converted \$289,988 of its convertible note payable to 118,363 shares of common stock in the nine months ended September 30, 2006.

The Company reclassified derivative liabilities of \$300,663 in the nine months ended September 30, 2006, from debt to equity as a result of the conversion to common stock of a portion of notes payable to which the derivative related.

The Company purchased certain intangible assets for \$2,000,000, including a \$1,000,000 promissory note during the nine months ended September 30, 2006.

See notes to condensed consolidated financial statements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheet of BioDelivery Sciences International, Inc. (BDSI), together with its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. (Arius One) and Arius Two, Inc. (Arius Two), and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND), which, collectively with BDSI, Arius One and Arius Two, is referred to herein as the Company or we , us or similar terminology) as of September 30, 2006, and the condensed consolidated statements of operations for the nine and three months ended September 30, 2006 and 2005 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, 2006 and for all periods presented, have been made.

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, 2005, included in the Company s 2005 Annual Report on Form 10-KSB, filed with the SEC on April 1, 2006 (2005 Annual Report).

The results of operations for the nine months ended September 30, 2006, are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

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

The common stock, par value \$.001 per share, of the Company is referred to herein as the Common Stock .

2. Summary of certain significant accounting policies:

General:

The Company currently generates revenue from licensing, milestone and royalty payments, and has generated revenue from grants. Ultimately, if regulatory approval of licensed or proprietary products and formulations is secured (from, among other agencies, the U.S. Food and Drug Administration (FDA)), the Company s goal is to augment its revenues from sales of such products and formulations, on which royalties will be paid to licensors. The Company is also and may in the future be required to make certain license or other payments to such licensors and other third parties in accordance with applicable agreements.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

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

Revenue Recognition:

Royalties are recognized as earned.

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, and there are otherwise no continuing obligations to the licensee, the Company recognizes revenues upon delivery of the technology. In July 2006, the Company licensed to Meda AB, a Swedish corporation (Meda), the European rights to BEMFentanyl, as further described in Note 3. The initial non-refundable payment was \$2.5 million, which is recognized as license revenue in the period ended September 30, 2006.

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 or other 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.

Stock-based compensation:

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (FAS 123(R)) using the modified-prospective-transition method. Under this transition method, compensation cost in 2006 includes cost for options granted prior to but not vested as of December 31, 2005, and options vested in 2006. Therefore, results for prior periods have not been restated.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

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

The adoption of SFAS No. 123(R) lowered net income by approximately \$0.5 million for the nine months ended September 30, 2006, compared to continued accounting for share-based compensation using the intrinsic value method under APB No. 25, Accounting for Stock Issued to Employees.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 during the three and nine months ended September 30, 2005. For the purposes of this pro forma disclosure, the value of the options is estimated using a Black-Scholes option-pricing model and amortized to expense over the options vesting periods.

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Loss-attributable to common stockholders, as reported	\$ (2,811,353)	\$ (6,745,371)
Stock-based employee compensation, as reported	\$ 1,735	\$ 10,450
Stock-based employee compensation under fair value method	\$ 534,897	\$ 659,224
Pro forma loss attributable to common stockholders under fair value method	\$ (3,344,515)	\$ (7,394,145)
Loss per share attributable to common stockholders basic and diluted:		
As reported	\$ (0.38)	\$ (0.93)
Pro forma under fair value method	\$ (0.46)	\$ (1.02)

As of September 30, 2006, there was approximately \$955,000 of unrecognized compensation cost related to unvested share-based compensation awards granted. That cost is expected to be recognized over the next four years.

Options were granted to certain employees during July 2006 at prices equal to the market value of the stock on the dates the options were granted. The options granted have a term of 10 years from the grant date and granted options for employees vest ratably over a three year period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the option and each vesting date. The Company has estimated the fair value of all stock option awards as of the date of the grant by applying the Black-Scholes pricing valuation model. The application of this valuation model involves assumptions that are judgmental and sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted during the period ended September 30, 2006 follows:

Expected price volatility	64.86%
Risk-free interest rate	5.00%
Weighted average expected life in years	6 years
Dividend yield	0

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

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

Option activity during the period ending September 30, 2006 was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Yrs)
Outstanding at January 1, 2006	2,198,562	\$ 4.44	4.29
Forfeited	(81,174)	\$ 3.00	
Exercised			
Granted	448,453	\$ 2.20	9.70
Outstanding at September 30, 2006	2,565,841	\$ 4.05	5.23
Exercisable at September 30, 2006	2,105,647	\$ 4.33	5.23

The fair value of each option award is estimated on the date of grant issue using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from traded options on the Company's stock, historical volatility of the Company's stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term.

Options outstanding at September 30, 2006 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 1.00 - 5.00	2,157,976	6.14	\$ 2.77	
\$ 5.01 - 10.00	177,889	0.86	\$ 5.85	
\$10.01 - 15.00	114,988	0.09	\$ 11.80	
\$15.01 - 20.00	114,988	0.09	\$ 17.48	
	2,565,841			\$ 46,200

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

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

Options exercisable at September 30, 2006 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 1.00 5.00	1,703,782	6.14	\$ 2.79	
\$ 5.01 10.00	171,889	0.86	\$ 5.86	
\$10.01 15.00	114,988	0.09	\$ 11.80	
\$15.01 20.00	114,988	0.09	\$ 17.48	
	2,105,647			\$ 46,200

The fair market value of options granted during the period ended September 30, 2006 was \$428,354.

Warrants outstanding at September 30, 2006 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 1.00 5.00	2,770,765	6.38	\$ 3.14	
\$ 5.01 10.00	2,310,000	0.93	\$ 6.20	
	5,080,765			\$ 220,762

Warrants exercisable at September 30, 2006 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 1.00 \$ 5.00	2,635,765	6.38	\$ 3.15	
\$ 5.01 \$10.00	1,703,782	0.93	\$ 6.20	
	4,339,547			\$ 215,012

Edgar Filing: BIODELIVERY SCIENCES INTERNATIONAL INC - Form 10QSB

New accounting pronouncements:

In February 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 155 (SFAS No. 155), Accounting for Certain Hybrid Financial Instruments An Amendment Of FASB Statements No. 133 and 140 , to simplify and make more consistent the accounting for certain financial instruments. Specifically, SFAS No. 155 amends SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities , to permit fair value re-measurement for any hybrid financial instrument with an embedded derivative that otherwise would require bifurcation provided that the whole instrument is accounted for on

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

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

a fair value basis. Prior to fair value measurement, however, interests in securitized financial assets must be evaluated to identify interests containing embedded derivatives requiring bifurcation. The amendments to SFAS No. 133 also clarify that interest-only and principal-only strips are not subject to the requirements of the SFAS, and that concentrations of credit risk in the form of subordination are not embedded derivatives. Finally, SFAS No. 155 amends SFAS No. 140, *Accounting for the Impairment or Disposal of Long-Lived Assets*, to allow a qualifying special-purpose entity (SPE) to hold a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. SFAS No. 155 applies to all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006, with earlier application allowed. The Company does not anticipate that the adoption of this statement will have a material impact on its consolidated financial statements.

FASB has recently announced a new interpretation, FASB Interpretation no. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), which will be effective for fiscal years beginning after December 15, 2006, FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB statement No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company has not determined the impact of the adoption of FIN 48 on its consolidated financial statements.

Reclassifications

Certain prior period amounts have been reclassified to conform to current period presentation.

3. Liquidity and management's plans:

The Company has financed operations primarily from the sale of securities and loans from third parties. From inception through September 30, 2006, the Company raised approximately \$40.6 million, net of issuance costs, through these avenues. At September 30, 2006, the Company had \$4.1 million in cash and at December 31, 2005, the Company had cash totaling approximately \$4.9 million. The adequacy of cash for operations and continued research and development of the Company's technologies, is dependent on, among other things, licensing and other strategic and/or financing opportunities in the coming year, as well as the funding of its equity line of credit, which had an available balance remaining of \$2.6 million at September 30, 2006.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

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

The Company's working capital deficit was \$2.9 million at September 30, 2006 and working capital was \$0.5 million at December 31, 2005. The Company has incurred significant net losses and negative cash flows from operations since inception. As of September 30, 2006, the Company had an accumulated deficit of \$33.6 million and total stockholders' equity of \$4.2 million. At December 31, 2005, the corresponding amounts were \$23.6 million and \$5.4 million, respectively.

On May 16, 2006, the Company closed a transaction with Clinical Development Capital, LLC and its affiliates (CDC) pursuant to which \$7.0 million in funds previously committed by CDC to fund the clinical development of the Company's BEMA/Fentanyl product under a Clinical Development and License Agreement, dated July 14, 2005, between BDSI, Arius One and CDC (as amended, the CDLA) were converted into shares of Common Stock at premium to the market price of the Common Stock. Pursuant to this transaction, \$2.8 million of funds previously received by the Company in calendar 2006 and recorded as a deposit liability under the July 2005 CDC agreement and approximately \$4.2 million in cash received by the Company were in consideration for shares of Common Stock at \$3.50 per share. As a result, the Company's equity was increased by \$7.0 million. Pursuant to this transaction, the Company has also: (i) issued CDC an additional warrant to purchase 904,000 shares of Common Stock at \$3.00 and (ii) made certain amendments with CDC to the July 2005 agreements.

The Company anticipates that cash used in operations will continue to increase significantly in the future as it researches, develops, and, potentially, manufactures, distributes and/or sells its proposed drug products. While the Company believes further application of their 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 their BEMA and Bioral® technologies, and the application of such technologies to a limited number of pharmaceutical products. The Company has several small third-party contracts ongoing with respect to the development of the Bioral® technology. However, the Company expects to spend a significant majority of its corporate resources over the next 6-9 months on the Phase III program and subsequent New Drug Application (NDA) submission to the FDA for BEMA Fentanyl. Marketing, production or sale of FDA approved products will receive limited emphasis, as the Company is currently and will continue to seek to enter into a partnering arrangements that will provide resources needed to address substantially all commercialization costs for products currently in development.

Existing cash and cash equivalents, together with available financing, including the remaining balance of the Company's existing equity line of credit, as described above, are considered by management to be sufficient to finance planned operations and capital expenditures through first quarter of 2007. Further, management believes that potential licensing opportunities, if consummated, will be sufficient to finance operations significantly beyond such period. The Company does not expect any material capital expenditures in the next 18 to 24 months. Product development timelines and agreements with development partners, the ability to scale up or reduce personnel and associated costs are factors

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

3. Liquidity and management s plans (continued):

considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, the Company anticipates that it may be required to raise additional capital through a variety of sources, including:

public equity markets;

private equity financings;

collaborative arrangements, partnering and other strategic and/or financing transactions;

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 their operations or to obtain funds through arrangements that may require them to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company, their financial condition and their results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

4. Intangible assets, notes payable and license revenue:

On August 2, 2006, Arius Two, a newly formed, wholly-owned subsidiary of the Company, entered into an Intellectual Property Assignment Agreement and related agreements with QLT USA, Inc. (QLT) pursuant to which Arius Two purchased intellectual property rights owned by QLT related to its BEMA technology for territories located outside of the United States. The Company, through its Arius One subsidiary, previously licensed exclusive rights to the BEMA technology for such territories. Arius Two paid \$3.0 million for the acquired intellectual property rights, consisting of \$1.0 million in cash and a promissory note, secured by the purchased assets, for \$2.0 million. Payments under such note are due as follows: (i) \$1.0 million on March 31, 2007 and (ii) \$1.0 million within 10 business days of initial non-U.S. approval of any BEMA product.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

4. Intangible assets, notes payable and license revenue (continued):

Management deems this payment a contingent liability and therefore will not record the \$1.0 million as a liability or intangible asset as of September 30, 2006. In addition to the purchased BEMA intellectual property rights, QLT granted to the Company the option, for a period of 12 months, to purchase the intellectual property rights owned by QLT related to its BEMA technology for the United States territory. If such option is exercised, the purchase price for the United States territory would be \$7.0 million, which would be paid over time.

On August 2, 2006, the Company, Arius One and Meda entered into a License and Development Agreement pursuant to which the Company and Arius One granted Meda an exclusive license to develop and sell the Company's BEMA Fentanyl product in Europe in exchange for an upfront payment of \$2.5 million, milestone payments, and a royalty on sales. Milestone payments, totaling an additional \$7.5 million, shall be received by the Company upon the achievement of certain future milestones. As part of this transaction, Meda, the Company and Arius One have also entered into a BEMA Fentanyl Supply Agreement pursuant to which Meda shall acquire, and the Company and Arius One shall supply (directly or indirectly through third party contractors), all of Meda's requirements of BEMA Fentanyl product.

5. Convertible notes payable:

On February 22 and May 31, 2005, the Company entered into two separate \$2.5 million convertible note and warrant financings with Laurus Master Fund Ltd. (Laurus). The notes have 3-year terms and are each payable in monthly installments of \$75,758 plus interest at prime plus 2%, with a floor of 7.5%. The notes are convertible, under certain conditions, into shares of Common Stock at a price equal to \$2.45 per share (originally \$3.10 per share, which conversion price was adjusted downward as a result of the pricing of the Company's October 2005 public offering).

In connection with these financings, the Company also issued Laurus two Common Stock purchase warrants to purchase up to an aggregate of 833,871 shares of Common Stock at a price equal to \$3.88 per share. Registration statements were filed with the SEC to register the shares of Common Stock underlying the Laurus notes and warrants.

In addition, on June 29, 2005 and December 30, 2005 the Company entered into amendments to the February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by the Company of principal under the Laurus notes until July 1, 2006. In consideration of these amendments, the Company issued to Laurus four warrants to purchase an aggregate of 99,274 shares of Common Stock at an exercise price of \$.001 per share, with the last warrant expiring on December 28, 2012. The shares of Common Stock underlying all of such warrants have been registered with the SEC.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

5. Convertible notes payable (continued):

On July 31, 2006, the Company entered into two separate third amendments to the Company's February and May 2005 financing agreements with Laurus. Under the third amendments, Laurus has agreed to defer payments by the Company of certain monthly principal amounts under the Company's February and May 2005 Convertible Notes with Laurus (\$909,096 in the aggregate), as well as certain other previously postponed principal amounts due under such notes (\$1,280,945 in the aggregate), until the first business day of January 2007.

In consideration of Laurus' agreement to enter into the third amendments, the Company issued the July 2006 Warrants. The July 2006 Warrants are exercisable into 110,000 shares of Common Stock at an exercise price of \$3.00 per share and expire on July 31, 2013. Except for the exercise price of the warrants, the July 2006 Warrants are substantially similar to the warrants previously issued to Laurus.

The following tabular presentation reflects the allocation of the proceeds of Laurus financings:

Principal balance of notes	\$ 5,000,000
Less reduction for:	
Fair value of beneficial conversion option	(1,450,404)
Fair value of warrants	(993,501)
Recorded at closing	2,556,095
Accretion of discount (interest expense) through September 30, 2006 using effective interest method	1,653,424
Conversion of debt to equity	(461,489)
Carrying value at September 30, 2006	\$ 3,748,030
As presented on balance sheet:	
Current maturities of convertible notes payable	\$ 3,194,523
Convertible notes payable, less current maturities	553,507
	\$ 3,748,030

The discount to the debt instruments resulting from the aforementioned allocation is being amortized through periodic charges to interest expense using the effective interest method. Effective interest rates used to amortize the Laurus financing discounts amounted to 33.3%, and 46.6% for the February and May financings, respectively.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

5. Convertible notes payable (continued):

Future maturities of convertible note payable are as follows:

Year Ended September 30,	
2007	\$ 3,843,282
2008	695,229
	4,538,511
Less unamortized discount	(790,481)
	\$ 3,748,030

6. Derivative Financial Instruments:

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Common Stock, are classified as liabilities when either: (a) the holder possesses rights to net-cash settlement (assumed under the Laurus registration rights obligations) or (b) physical or net-share settlement is not within the control of the Company (assumed when and if the Company sells Common Stock for amounts less than Laurus conversion price). In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value and subsequently adjusted to fair value at the close of each reporting period.

As of September 30, 2006, the derivative liability is composed of the following:

	Amount	Number of shares into which derivative liability can be settled
Embedded beneficial conversion option	\$ 618,286	1,852,453

Derivative gain in the accompanying condensed consolidated statements of operation is related to the individual derivatives as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Free standing warrants	\$	\$	\$ 693	\$ 309,161
Embedded beneficial conversion option		386,333	767,385	608,387

\$ 386,333 \$ 768,078 \$ 917,548

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

7. Stockholders equity:

Stock options:

The Company's Amended and Restated 2001 Stock Incentive Plan (the "Plan") covers a total of 3,500,000 shares of Common Stock (amended from 2,100,000 and approved by the Company stockholders at the Company's 2006 annual meeting in July 2006). Options may be awarded during the ten-year term of the Plan to Company employees, directors, consultants and other affiliates.

Common stock:

During the nine months ended September 30, 2006, under its convertible debt arrangements with Laurus, the Company issued 118,363 shares of Common Stock with a share price of \$2.45 for payment of \$289,988 of principal.

Warrants:

See Note 3 regarding warrants issued in connection with the CDC transaction.

See Note 5 regarding warrants issued in connection with modification of convertible note terms.

The Company issued warrants to purchase 33,000 shares of Common Stock at a price of \$3.50, for financing costs. The warrants had a fair value of \$32,485 at the date of the grant.

8. Net loss per common share:

The following table reconciles the numerators and denominators of the basic and diluted income per share computations.

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2006	2005	2006	2005
Loss attributable to common stockholders	\$ (1,419,394)	\$ (2,811,353)	\$ (10,113,732)	\$ (6,745,371)
Basic:				
Weighted average shares outstanding (denominator)	13,938,146	7,348,209	13,259,684	7,274,500
Net loss per common share - basic	\$ (0.10)	\$ (0.38)	\$ (0.76)	\$ (0.93)
Diluted:				
Weighted average shares outstanding	13,938,146	7,348,209	13,259,684	7,274,500
Net loss per common share - diluted	\$ (0.10)	\$ (0.38)	\$ (0.76)	\$ (0.93)

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

8. Net loss per common share (continued):

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, 2006 and 2005:

	2006	2005
Options and warrants to purchase common stock	7,646,606	5,814,424
Preferred stock (convertible to common stock)	1,988,235	1,988,235
Shares issuable for convertible debt	1,852,453	2,094,680

9. Restatement of previously reported September 30, 2005 quarterly information:

During the fourth quarter of 2005, the Company reevaluated its accounting for the convertible note financing transaction with Laurus discussed in Note 4. During the nine months ended September 30, 2005, the Company accounted for its freestanding warrants and embedded beneficial conversion option associated with the convertible notes as equity. During the fourth quarter of 2005, management determined that these derivatives should be recorded as liabilities at fair value and thereafter adjusted to fair value at each subsequent reporting period until certain conditions are met, at which time such derivative liabilities will be reclassified into equity. As such, the unaudited quarterly financial information as previously reported for September 30, 2005, has been restated. More information can be found regarding such restatement in Note 14 to the audited financial statements appearing in the 2005 Annual Report.

10. Contingencies:

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 June 9, 2005 and on August 25, 2006, the U.S. District Court granted the Company's motion for summary judgment on all of MAS Capital's claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on the Company's claim for attorneys' fees and costs, but were unable to resolve in light of MAS Capital's intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 2006 AND 2005

(Unaudited)

10. Contingencies (continued):

Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the Motion. Accordingly, the parties are to proceed until resolution of the Company's counterclaim for attorneys' fees and costs and either party could appeal at that point in time. The parties, by counsel, are to appear before the Judge for a scheduling conference on November 13, 2006. We believe that the plaintiff's claims are without merit and we intend to continue to vigorously defend the lawsuit.

On August 30, 2006, the Company delivered to CDC a Notice of Breach and Demand for Dispute Resolution (the "BDSI Notice") pursuant to the CDLA. Pursuant to the CDLA and related agreements, CDC has provided funding to the Company in support of the Company's BEMATM Fentanyl clinical program. In the BDSI Notice, the Company claimed that CDC breached the CDLA and damaged the Company when it acted or failed to act in accordance with or in contravention of the terms of the CDLA. In the BDSI Notice, the Company reserved the right to make additional claims against CDC. Also on August 30, 2006, the Company received written notice from CDC of CDC's claim of termination of the CDLA. In its notice, CDC alleged that the Company undertook certain actions which materially breached the CDLA, which breaches, CDC alleged, require the Company to transfer certain specified rights and assets relating to BEMATM Fentanyl to CDC. Pursuant to the CDLA, any claim of breach of material terms is subject to the dispute resolutions procedures, including arbitration, contained within the CDLA. As of the date of this Report, the Company's attempts at pre-arbitration dispute resolution are ongoing. The Company has rejected CDC's claims in their entirety, believes such claims are without merit and is presently and will continue to vigorously defend its position and enforce its rights against CDC.

Table of Contents

ITEM 2. Management's Discussion and Analysis or Plan of Operation.

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, 2006 compared to the three months ended September 30, 2005

Sponsored Research Revenue. For the three-months ended September 30, 2006, the Company reported \$0.05 million of sponsored research revenues from a grant from the National Institutes of Health, compared to such revenue aggregating \$0.02 million during the same period in 2005.

License Fees and Milestone Revenues. During the three-months ended September 30, 2006 the Company closed a license transaction and reported as license revenue, a non-refundable payment of \$2.5 million for the European rights to its BEMA Fentanyl product in development. The Company had no continuing obligations to the licensee with respect to this fee. The Company reported zero license or milestone revenue in the previous year.

Royalty Revenues. For the three-month periods ended September 30, 2006 and 2005, the Company reported \$0.01 million and \$0.02 million, respectively, in royalty revenue from a related company.

Research Fee Revenues. From time to time the company earns fees from collaborative research projects with third parties. There were no such revenues during the three-months ended September 30, 2006 or 2005.

Research and Development. Research and development expenses of approximately \$2.3 million and \$1.6 million were incurred during the respective three-month periods ended September 30, 2006 and 2005. These aforementioned amounts included \$0.8 million and \$0.03 million, respectively, paid to a contract research organization, which is a shareholder. The Company's scientific staff continued to work toward increased development and application of our BEMA and Bioral technologies and other drug-related areas. 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 and Stock-based Compensation. General and administrative expenses of approximately \$1.6 million and \$0.9 million were incurred in the three-month periods ended September 30, 2006 and 2005, respectively. These expenses are principally composed 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, 2005. The Company has adopted

Table of Contents

FAS 123R on January 1, 2006 for new options granted to employees, resulting in stock based compensation of \$0.5 million during the three months ended September 30, 2006. Such adoption accounts for the large current period expense increase.

Interest Expense (net). Interest expense (net) for the periods ended September 30, 2006 and 2005 was composed of interest expense on notes payable, including deferred loan costs and notes payable discount amortization, offset by minimal earnings from invested cash.

Derivative Gain. Derivative gain during 2006 and 2005 is related to the adjustment of related derivative liabilities to fair value. These derivatives relate to the Laurus financing (see Note 6 to the condensed consolidated financial statements).

Income Taxes. While net operating losses were generated during the three month periods ended September 30, 2006 and 2005, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

For the nine months ended September 30, 2006 compared to the nine months ended September 30, 2005

Sponsored Research Revenue. During the nine-months ended September 30, 2006, the Company reported \$0.08 million of sponsored research revenues from a grant from the National Institutes of Health. In the corresponding prior year period, revenue aggregating \$0.2 million was recognized from an SBIR grant.

License Fee and Milestone Revenues. In July 2006, the Company closed a license transaction for the European rights to its BEMA Fentanyl product in development, which included a non-refundable payment of \$2.5 million. The Company had no continuing obligations to the licensee with respect to this fee. The Company reported \$0.4 million in milestone revenue in the previous year.

Royalty Revenues. For the nine-month periods ended September 30, 2006 and 2005, the Company reported \$0.05 million and \$0.04 million, respectively, of royalty revenue from a related company.

Research Fee Revenues. From time to time the company earns fees from collaborative research projects with third parties. During the nine-months ended September 30, 2006, the Company reported \$0.01 million, compared to a corresponding prior year amount of \$0.05 million.

Research and Development. Research and development expenses of approximately \$8.7 million and \$4.4 million were incurred during the nine-months ended September 30, 2006 and 2005, respectively. Included in the before-described amounts were \$2.2 million and \$0.5 million, respectively, paid to a contract research organization which is a stockholder. The Company's scientific staff continued to work toward increased development and application of our BEMA and

Table of Contents

Bioral® technologies and other drug-related areas. 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 and Stock-based Compensation. General and administrative expenses of approximately \$3.2 million and \$3.0 million, including \$0.1 million and \$0.06 million to a related party, were incurred in the nine-months ended September 30, 2006 and 2005, respectively. These expenses are principally composed of legal and professional fees, patent costs, and other costs including office supplies, conferences, travel costs, salaries and benefits for executive management, and other business development costs. Stock-based compensation costs of \$0.5 million in 2006 were associated with employee vested options during the period. Employees' stock option grants were treated under APB 25 through December 31, 2005. The Company has adopted FAS 123R on January 1, 2006 for new options granted to employees.

Interest Expense (net). Interest expense (net) for the periods ended September 30, 2006 and 2005 was composed of interest expense on notes payable, including deferred loan costs and notes payable discount amortization, reduced by minimal earnings from invested cash.

Income Taxes. While net operating losses were generated during the nine month period ended September 30, 2006, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Liquidity and Capital Resources

We have financed our operations primarily from the sale of our securities and loans from third parties. From inception through September 30, 2006, we raised approximately \$40.6 million, net of issuance costs, through these avenues. At September 30, 2006, we had \$4.1 million in cash and at December 31, 2005, we had cash totaling approximately \$4.9 million. The adequacy of cash for our operations and continued research and development of our technologies, is dependent on, among other things, licensing and other strategic and/or financing opportunities in the coming year, as well as the funding of our equity line of credit, which had a balance remaining of \$2.6 million at September 30, 2006.

Our working capital deficit was \$2.9 million at September 30, 2006 and working capital was \$0.5 million at December 31, 2005. We have incurred significant net losses and negative cash flows from operations since our inception. As of September 30, 2006, we had an accumulated deficit of \$33.6 million and total stockholders' equity of \$4.2 million. At December 31, 2005, the corresponding amounts were \$23.6 million and approximately \$5.4 million, respectively.

On May 16, 2006, we closed a transaction with CDC pursuant to which \$7.0 million in funds previously committed by CDC under the CDLA to fund the clinical development of our BEMA Fentanyl product were converted into shares of Common Stock at premium to the market price of the Common Stock. Pursuant to this transaction, \$2.8 million of funds previously received by the Company in calendar

Table of Contents

2006 and recorded as a deposit liability under the July 2005 CDC agreement and approximately \$4.2 million in cash received by the Company were in consideration for shares of Common Stock at \$3.50 per share. As a result, the Company's equity was increased by \$7.0 million. Pursuant to this transaction, the Company has also: (i) issued CDC an additional warrant to purchase 904,000 shares of Common Stock at \$3.00 and (ii) made certain amendments with CDC to the July 2005 agreements.

On August 2, 2006, BDSI, Arius One and Meda entered into a License and Development Agreement pursuant to which BDSI and Arius One granted Meda an exclusive license to develop and sell the BEMA Fentanyl product in Europe in exchange for an upfront payment of \$2.5 million, milestone payments, and a royalty on sales. Milestone payments, totaling an additional \$7.5 million, shall be received by us upon the achievement of certain future milestones.

We account for our spending on BEMA Fentanyl in a segregated account. Funds for BEMA Fentanyl development were in part provided by our transactions with CDC, as described earlier. Budgeted spending, prior to anticipated filing of the NDA on BEMA Fentanyl in the second quarter of 2007, is substantially covered by above-mentioned segregated funds currently on hand, including funds from CDC. Our remaining equity line of credit of \$2.6 million may be drawn during the fourth quarter of 2006, depending on the results of ongoing and potential licensing and partnering arrangements, such as the earlier-described July 2006 transaction with Meda.

We anticipate that cash used in operations will continue to increase significantly in the future as we research, develop, and, potentially, manufacture, distribute and/or sell our proposed drug products. While we believe further application of our BEMA and Bioral[®] cochleate technologies to other drugs will result in license agreements with manufacturers of generic and over-the-counter drugs, our plan of operations for the next 24 months will be focused primarily on the further development of our BEMA and Bioral[®] technologies, and the application of such technologies to a limited number of pharmaceutical products. We have several small third-party contracts ongoing with respect to the development of the Bioral[®] technology. However, we expect to spend a significant majority of our corporate resources over the next 6-9 months on the Phase III program and subsequent NDA submission for BEMA Fentanyl. Marketing, production or sale of FDA approved products will receive limited emphasis, as we currently are and will continue to seek partnering arrangements that will provide resources needed to address substantially all commercialization costs for products currently in development.

Existing cash and cash equivalents, together with available financing, including the remaining balance of our existing equity line of credit, as described above, are considered by our management to be sufficient to finance planned operations and capital expenditures through first quarter of 2007. Further, our management believes that potential licensing opportunities, if consummated will be sufficient to finance operations significantly beyond such period. We do not expect any material capital expenditures in the next 18 to 24 months. Product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

public equity markets;

Table of Contents

private equity financings;

collaborative arrangements, partnering and other strategic and/or financing transactions;

grants and new license revenues;

bank loans;

public or private debt; and

redemption and/or exercise of existing public warrants.

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

Critical Accounting Policies and Estimates

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

Revenue recognition:

License fee revenue is recognized over the life of the respective agreements, except when a non-refundable up-front payment is made, and in that case it is recognized upon receipt if we have no continuing obligations associated with the license. Royalties are recognized as earned. Milestone payments are recognized as income in the period the payments are earned and received. We have not received any milestone payments through September 30, 2006.

Stock-based compensation:

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (FAS 123(R)) using the modified-prospective-transition method. Under this transition method, compensation cost in 2006 includes cost for options granted prior to but not vested as of December 31, 2005, and options vested in 2006. Therefore results for prior periods have not been restated.

Table of Contents

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.

NOTE ON FORWARD-LOOKING STATEMENTS

The information set forth in this Report on Form 10-QSB under the Section Management's Discussion and Analysis or Plan of Operation 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, expects, 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 2005 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 June 9, 2005 and on August 25, 2006, the U.S. District Court granted the Company's motion for summary judgment on all of MAS Capital's claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on the Company's claim for attorneys' fees and costs, but were unable to resolve in light of MAS Capital's intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the Motion. Accordingly, the parties are to proceed until resolution of the Company's counterclaim for attorneys' fees and costs and either party could appeal at that point in time. The parties, by counsel, are to appear before the Judge for a scheduling conference on November 13, 2006. We believe that the plaintiff's claims are without merit and we intend to continue to vigorously defend the lawsuit.

On August 21, 2006, the Company filed an action in New York State Supreme Court against CDC seeking: (i) to enjoin CDC from filing a Schedule 13D filing with the Securities and Exchange Commission without first giving the Company an opportunity to review the proposed Schedule 13D filing for potential disclosures of Company confidential information in violation of the CDLA and (ii) to compel CDC to adhere to the dispute resolution mechanisms set forth in the CDLA. The Company's motion for a preliminary injunction enjoining the filing of CDC of the Schedule 13D was denied on August 22, 2006. As of the date of this Report, there is no present activity relating to this matter, although it has not technically been dismissed and therefore remains pending.

On August 30, 2006, the Company delivered to CDC the BDSI Notice pursuant to the CDLA. In the BDSI Notice, the Company claimed that CDC breached the CDLA and damaged the Company when it acted or failed to act in accordance with or in contravention of the terms of the CDLA. In the BDSI Notice, the Company reserved the right to make additional claims against CDC. Also on August 30, 2006, the Company received written notice from CDC of CDC's claim of termination of the CDLA. In its notice, CDC alleged that the Company undertook certain actions which materially breached the CDLA, which breaches, CDC alleged, require the Company to transfer certain specified rights and assets relating to BEMA™ Fentanyl to CDC. Pursuant to the CDLA, any claim of breach of material terms is subject to the dispute resolutions procedures, including arbitration, contained within the CDLA. As of the date of this Report, the Company's attempts at pre-arbitration dispute resolution are ongoing. The Company has rejected CDC's claims in their entirety, believes such claims are without merit and is presently and will continue to vigorously defend its position and enforce its rights against CDC.

The Company may, from time to time, be involved in actual or potential routine 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.

Table of Contents

Item 5. Other Information.

On October 17, 2006, CDC filed an action in New York State Supreme Court against the Company seeking to enjoin the Company from entering into a financing transaction with a third party pursuant to a purported right of first negotiation provision granted to CDC under the Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC. On October 26, 2006, the Company and CDC entered into a stipulation to settle this case without prejudice pursuant to which the Company and CDC agreed to follow a procedure regarding the right of first negotiation as modified by the stipulation.

Item 6. Exhibits.

Number	Description
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 (*)

* 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.

Table of Contents

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 14, 2006

By: /s/ Mark A. Sirgo
Mark A. Sirgo, President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2006

By: /s/ James A. McNulty
James A. McNulty, Secretary, Treasurer and
Chief Financial Officer
(Principal Financial Officer)

S-1