BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 19, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2008

¨ 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 001-31361

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

801 Corporate Center Drive, Suite #210

Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number (including area code): 919-582-9050

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

(Do not check if a smaller reporting company)

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

As of November 14, 2008, there were 19,179,029 shares of company common stock issued and 19,163,538 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

Form 10-Q

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash	$ 1,961,647	$ 13,797,093
Investments	361,884	
Certificate of deposit		2,800,000
Accounts receivable	319,209	305,497
Due from related party		14,414
Prepaid expenses and other current assets	233,722	160,704
Deferred income tax asset	4,000,000	
Total current assets	6,876,462	17,077,708
Equipment, net	143,381	222,806
Goodwill	2,715,000	2,715,000
Intangible assets:		
Patents and trademarks	5,674,171	6,124,806
Acquired product rights	313,000	343,157
Total intangible assets	5,987,171	6,467,963
Deposits on equipment	2,489,985	1,344,311
Other assets	13,867	15,937
Restricted cash	144,000	144,000
Total assets	$ 18,369,866	$ 27,987,725
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Note payable, related party	$	$ 1,296,164
Notes payable	134,165	90,834
Income taxes payable	240,000	
Accounts payable and accrued liabilities, other	1,785,363	1,535,077
Accounts payable and accrued liabilities, related party	237,971	166,219
Clinical trial payables and accrued liabilities, other	144,910	2,568,564
Clinical trial payables and accrued liabilities, related party		1,922,708
Deferred revenue, current	29,499,837	120,121
Derivative liabilities (Note 7)	4,754,712	6,543,571
Total current liabilities	36,796,958	14,243,258
Deferred revenue, long-term	7,471,183	32,532,252
Total liabilities	44,268,141	46,775,510
Commitments and contingencies (Notes 6 and 11)		
Stockholders deficit:		
Common stock, $.001 par value; 45,000,000 shares authorized 19,179,029 and 19,101,037 shares issued; 19,163,538 and 19,085,546 shares outstanding in 2008 and 2007, respectively	19,179	19,101
Additional paid-in capital	58,347,516	56,267,563

Treasury stock, at cost, 15,491 shares, 2008 and 2007		(47,183)		(47,183)
Accumulated deficit		(84,217,787)		(75,027,266)
Total stockholders deficit		(25,898,275)		(18,787,785)
Total liabilities and stockholders deficit	$	18,369,866	$	27,987,725

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Royalties, related parties	$ 4,493	$ 19,345	$ 39,730	$ 57,015
Research fees/consulting	12,500		129,499	25,000
	16,993	19,345	169,229	82,015
Expenses:				
Research and development:				
Related party	54,000	1,004,359	591,158	4,063,027
Other	2,081,022	2,298,381	7,930,693	5,510,370
General and administrative:				
Related party	16,100	26,500	46,400	34,802
Other	1,810,044	2,405,121	5,865,768	4,616,244
Total expenses	3,961,166	5,734,361	14,434,019	14,224,443
Loss from operations	(3,944,173)	(5,715,016)	(14,264,790)	(14,142,428)
Interest income (expense), net	8,062	(270,182)	(474,590)	(1,606,640)
Financing expense, related party		(584,108)		(584,108)
Derivative gain (loss)	(494,715)	2,687,233	1,788,859	(990,268)
Loss on extinguishment of debt				(3,595,169)
Loss before income taxes	(4,430,826)	(3,882,073)	(12,950,521)	(20,918,613)
Income tax (expense) benefit:				
Current	(240,000)		(240,000)	
Deferred	2,000,000		4,000,000	
Total income taxes (expense) benefit	1,760,000		3,760,000	
Net loss	(2,670,826)	(3,882,073)	(9,190,521)	(20,918,613)
Constructive dividends				(3,870,588)
Loss attributable to common stockholders	($ 2,670,826)	($ 3,882,073)	($ 9,190,521)	($ 24,789,201)
Per share amounts, basic and diluted:				
Loss attributable to common stockholders	($ 0.14)	($ 0.20)	($ 0.48)	($ 1.50)
Weighted average common stock shares outstanding basic and diluted	19,157,183	19,061,503	19,144,873	16,542,222

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS DEFICIT

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008

(Unaudited)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount				
Balances, January 1, 2008	19,101,037	$ 19,101	$ 56,267,563	$ (47,183)	$ (75,027,266)	$ (18,787,785)
Stock-based compensation			1,971,968			1,971,968
Stock option exercises	65,000	65	107,985			108,050
Warrants exercised for cash	12,992	13				13
Net loss					(9,190,521)	(9,190,521)
Balances, September 30, 2008	19,179,029	$ 19,179	$ 58,347,516	$ (47,183)	$ (84,217,787)	$ (25,898,275)

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended	
	September 30, 2008	**September 30, 2007**
Operating activities:		
Net loss	$ (9,190,521)	$ (20,918,613)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of common stock		209,155
Expenses paid through the issuance of warrants		584,108
Depreciation and amortization	588,871	473,344
Derivative (gain) loss	(1,788,859)	990,268
Unrealized loss on investments	13,160	
Loss on extinguishment of debt		3,595,169
Accretion of discount on note payable, related party	603,836	
Accretion of discount on convertible debentures		1,155,644
Stock-based compensation	1,971,968	878,458
Changes in assets and liabilities:		
Accounts receivable	(13,712)	(27,362)
Prepaid expenses and other current assets	120,436	157,752
Accounts payable and accrued expenses	(1,663,913)	891,261
Income tax payable	240,000	
Deferred revenue	4,318,651	30,000,000
Deferred income tax asset	(4,000,000)	
Net cash flows from operating activities	(8,800,083)	17,989,184
Investing activities:		
Purchase of equipment	(28,564)	(37,932)
Deposits on equipment	(1,660,700)	(711,650)
Purchase of investments	(375,044)	
Proceeds from certificates of deposit	2,800,000	
Purchase of intangible assets		(3,000,000)
Net cash flows from investing activities	735,692	(3,749,582)
Financing activities:		
Proceeds from issuance of common stock		250,000
Proceeds from exercise of stock options	108,050	674,367
Proceeds from notes payable		4,000,000
Payment on notes payable, related parties	(1,900,000)	(3,912,347)
Payment of other notes payable	(148,332)	(181,664)
Proceeds from exercise of common stock warrants	13	3,235,437
(Repayment of) proceeds from related party advances, net	(1,830,786)	273,503
Net cash flows from financing activities	(3,771,055)	4,339,296
Net change in cash	(11,835,446)	18,578,898
Cash at beginning of period	13,797,093	2,172,104
Cash at end of period	$ 1,961,647	$ 20,751,002

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Non-cash investing and financing activities:

The Company financed an insurance policy through the issuance of a note payable in the amount of $191,664 and $254,300 during the nine months ended September 30, 2008 and 2007, respectively.

The Company converted $4,057,401 of convertible notes payable through the issuance of 1,757,454 shares of common stock during the nine months ended September 30, 2007.

The Company converted $201,154 of interest payable through the issuance of common stock to Laurus Master Fund Ltd. during the nine months ended September 30, 2007.

The Company reclassified derivative liabilities of $5,175,701 from debt to equity during the nine months ended September 30, 2007, as a result of the conversions of notes payable to which the derivative related.

The Company paid $152,803 of accrued dividends payable through the issuance of 59,226 shares of common stock with a fair value of $152,803 during the nine months ended September 30, 2007.

The Company recorded a constructive dividend of $3,870,588 related to the redemption of Series A Non-Voting Convertible Preferred Stock during the nine months ended September 30, 2007.

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation:

Overview

The accompanying unaudited condensed consolidated financial statements of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. (Arius One) and Arius Two, Inc. (Arius Two) and its majority-owned inactive subsidiary, Bioral Nutrient Delivery, LLC (BND) (collectively, the Company or we , us or similar terminology) have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at September 30, 2008 and for all periods presented, have been made. All intercompany accounts and transactions have been eliminated.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2007, included in the Company s 2007 Annual Report on Form 10-K, filed with the SEC on March 7, 2008 (as amended, the 2007 Annual Report). The accompanying condensed consolidated balance sheet at December 31, 2007 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements. As used herein, the term Common Stock means the Company s common stock, par value $.001 per share.

The results of operations for the nine months ended September 30, 2008 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this report are encouraged to review the risk factors relating to the Company which are set forth in the 2007 Annual Report.

The Company currently generates revenue or deferred revenue from licensing, milestone payments, research and development services and royalties. Ultimately, if approval of the Company s owned or licensed products is secured from the U.S. Food and Drug Administration (FDA), the Company s goal is to augment revenues or deferred revenues from sales of such approved products, on which royalties will be paid to licensors as applicable. The Company is also required to make certain license, royalty or similar payments (as the case may be) to such licensors or other third parties in accordance with applicable agreements.

Significant Accounting Policies

Revenue Recognition:

Meda License, Development and Supply Agreement Revenue

General

The Company entered into license, development and supply agreements (collectively, the Meda Agreements) with Meda AB (Meda) in September 2007 (covering the United States, Canada and Mexico) and August 2006 (covering certain countries in Europe) to develop and commercialize the Company s lead product, Onsolis (formally known as BEMA Fentanyl), a treatment with an initial indication for

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Significant Accounting Policies (continued):

Revenue Recognition (continued):

Meda License, Development and Supply Agreement Revenue (continued):

breakthrough cancer pain. Onsolis is a product consisting of the narcotic fentanyl formulated with the Company s patented BEMA drug delivery technology (BEMA). The Company recognizes revenue associated with the Meda Agreements in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104), Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), and EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). The Company s deliverables under the Meda Agreements, including the Company s related rights and obligations, contractual cash flows the Meda arrangements, including the Company s related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 6.

License and Product Development Research and Development Services Revenue

Based on the Company s assessment upon inception of each arrangement, all deliverables under the Meda Agreements have been accounted for as one combined unit of accounting and, as such, all cash payments from Meda (upfront payments and product development research and development services revenue) related to these deliverables have been recorded as deferred revenue. Upon delivery of the license rights to Meda (date of first commercial sale in each territory), the Company will recognize revenue associated with the license and the research and development services rendered related to development of the Onsolis product through the date of FDA and other governmental approval delivered to Meda. A portion of the upfront payments will be attributed to the Company s continuing obligation to participate in joint committees with Meda and to provide certain other specified services and this revenue will be recognized as services are provided through expiration of the license agreements.

Non-Cancer Indication and Other Research and Development Services Revenue

Research and development services revenue associated with the non-cancer indication of the Onsolis product and further development of the first indication of the Onsolis product which have been performed prior to the commencement of the license term, has been deferred and will be recognized upon delivery of the license rights to Meda. Services provided subsequent to commencement of the license term will be recognized when the services are performed, if all other revenue recognition criteria are met. Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal under the Meda Agreements and, as such, will record these amounts on a gross basis as research and development services revenue.

Onsolis Product Supply

Revenue associated with product sold to Meda prior to the commencement of the license term has been deferred and will be recognized upon delivery of the license rights to Meda. Subsequent to the commencement of the license term, the Company will recognize revenue for product supplied to Meda when title and risk of loss have passed to Meda and the remaining criteria in SAB 104 have been met. Based on the guidance of EITF 99-19, the Company has determined that it is acting as a principal as it relates to these activities under the product supply agreements and, as such, will record the amounts on a gross basis as product supply revenue.

Royalties

Product royalty revenue is based on third-party sales of the Onsolis product. The Company will recognize product royalty revenues from Meda on the accrual basis in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Significant Accounting Policies (continued):

Revenue Recognition (continued):

Other Research and Development Services Revenue:

The Company provides other research and development services based on various fixed-price and time and materials contracts. Revenues earned from fixed-price contracts are recognized based on the percentage of completion of the contract terms. Revenues from time and materials contracts are generally recognized as revenue when the services are performed, if all other revenue recognition criteria are met.

Reimbursement of Direct Out-of-Pocket Costs:

The Company pays fees to regulatory agencies and other out-of-pocket costs for which they are reimbursed at cost, without mark-up or profit. Revenues derived from reimbursement of these direct out-of-pocket costs associated with research and development services are presented in the accompanying condensed consolidated financial statements based on guidance under EITF Issue 01-14, Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses Incurred (EITF 01-14). According to the criteria established by EITF 0-14, in transactions where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and may perform part of the services required in the transactions, revenue is presented at the gross amount of the reimbursement. The Company will include the revenue associated with these reimbursed costs in Research and Development Services revenue in the accompanying condensed consolidated statements of operations. The expense associated with these reimbursements is reflected as a component of research and development expense in the accompanying condensed consolidated statements of operations.

Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses from third parties who conduct research and development activities on behalf of the Company pursuant to the Meda Agreements.

Certain Risks, Concentrations and Uncertainties

The Company s product candidates under development require approval from the FDA or other international regulatory agencies prior to commercial sales. For those product candidates that have not yet been approved by the FDA, or international regulatory agencies, there can be no assurance the products will receive the necessary approval. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company.

The Company s products compete in rapidly changing, highly competitive markets which are characterized by advances in scientific discovery, changes in customer requirements, evolving regulatory requirements and developing industry standards. Any failure by the Company to

anticipate or to respond adequately to scientific developments in its industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services could have a material adverse effect on the Company s business, operating results and future cash flows.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Significant Accounting Policies (continued):

Certain Risks, Concentrations and Uncertainties (continued)

Accounts receivable from Meda accounted for 100% and 50% of the Company s accounts receivable at September 30, 2008 and December 31 2007, respectively. Substantially all of the deferred revenue balances relate to the Meda Agreements as of September 30, 2008 and December 31, 2007. The Company depends significantly upon the collaboration with Meda, and its activities may be impacted if this relationship is disrupted.

Key components used in the manufacture of Onsolis are currently provided by sole or limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs. The reliance on a sole or limited number of suppliers could potentially result in the Company s inability to timely obtain an adequate supply of required components and could result in reduced control over pricing, quality and timely delivery. Except for the Company s agreements with Aveva Drug Delivery Systems, Inc. (Aveva) and with LTS Lohmann Therapie-Systeme AG (LTS) the manufacturers of the Onsolis product, for distribution in the United States, Mexico and Canada and in certain countries in Europe, respectively, under the Meda Agreements, the Company does not have long-term agreements with any other suppliers and, therefore, the supply of a particular component could be terminated without penalty to the supplier. Any interruption in the supply of components from Aveva, LTS, or other third party suppliers could cause the Company to seek alternative sources of supply. If the supply of any components is interrupted, components from alternative suppliers may not be available in sufficient volumes within required time frames, if at all, to meet the Company s obligations under the Meda supply agreements. This could delay Aveva s or LTS s ability to timely produce supplies for commercial sale, which could delay commercialization or decrease sales by Meda and therefore could cause the Company to lose royalty revenues or incur additional costs, affect the royalty rates payable by Meda, or potentially harm the Company s reputation.

Deferred Revenue

Consistent with the Company s revenue recognition policy, deferred revenue represents cash received in advance for licensing fees, consulting, research and development services and related supply agreements. Such payments are reflected as deferred revenue until revenue can be recognized under the Company s revenue recognition policy. Deferred revenue is classified as current if management believes the Company will be able to recognize the deferred amount as revenue within 12 months of the balance sheet date.

Investments

Investments include preferred stocks and mutual funds classified as trading in accordance with Statement of Financial Accounting Standards No. 115 (SFAS No 115), Accounting for Certain Investments in Debt and Equity Securities. Available-for-sale investments are stated at fair value, based on quoted market prices (classified as a Level 1 input, see Fair Value of Financial Assets and Liabilities below). The Company has decided to report all unrealized gains or losses on the investments in net income in accordance with SFAS No 159.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Significant Accounting Policies (continued):

Investments (continued)

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 159, The Fair Value for Financial Assets and Financial Liabilities-Including an Amendment of FASB No. 115 (SFAS 159). SFAS 159 allows companies the option to irrevocably elect, on a contract by contract basis, fair value as the initial and subsequent measurement for certain financial assets and financial liabilities. The Company did not have any financial assets or financial liabilities that required election upon adoption that were not previously recognized as fair market value.

Reclassification

The Company reclassified the December 31, 2007 balances of clinical trial payables, other and clinical trial payables, related party of $2.57 million and $1.9 million, respectively, from accrued liabilities to conform to the September 30, 2008 presentation.

The Company reclassified the December 31, 2007 balances related to the BEMA technology patents and trademarks owned by the Company from acquired product rights to conform to the September 30, 2008 presentation which provides further description of the intangible assets owned by the Company.

Fair Value of Financial Assets and Liabilities

The Company measures the fair value of financial assets and liabilities based on the guidance of Statement of Financial Accounting Standards No. 157, Fair Value Measurements (Statement No. 157) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

Effective January 1, 2008, the Company adopted the provisions of Statement No. 157 for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis. The adoption of the provisions of Statement No. 157 did not materially impact the Company s consolidated financial position and results of operations.

Statement No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Statement No. 157 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Statement No. 157 describes three levels of inputs that may be used to measure fair value:

Level 1 quoted prices in active markets for identical assets or liabilities

Level 2 quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

Significant Accounting Policies (continued):

Fair Value of Financial Assets and Liabilities (continued)

The following table summarizes liabilities measured at fair value on a recurring basis at September 30, 2008, as required by Statement No. 157:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Assets				
Investments	$ 361,884	$	$	$ 361,884
Liabilities				
Derivative liabilities	$	$ 4,754,712	$	$ 4,754,712

New accounting pronouncements

In March 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities (Statement No. 161), an amendment of SFAS No. 133 Accounting for Derivative Instruments and Hedging (Statement No. 133). Statement No. 161 requires companies with derivative instruments to disclose information about how and why a company uses derivative instruments, how derivative instruments and related hedged items are accounted for under Statement No. 133, and how derivative instruments and related hedged items affect a company s financial position, financial performance, and cash flows. The required disclosures include the fair value of derivative instruments and their gains or losses in tabular format, information about credit-risk-related contingent features in derivative agreements, counterparty credit risk, and the company s strategies and objectives for using derivative instruments. Statement No. 161 expands the current disclosure framework in Statement No. 133. Statement 161 is effective prospectively for periods beginning on or after November 15, 2008. The Company plans to provide these additional disclosures in the first quarter of 2009.

In April 2008, FASB Staff Position No. 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3) was issued. This standard amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company has not determined the impact on its financial statements of the adoption of FSP 142-3.

In May 2008, the FASB issued Financial Accounting Standard (FAS) No. 162, The Hierarchy of Generally Accepted Accounting Principles. The statement is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are prepared in conformance with GAAP. Unlike Statement on Auditing Standards (SAS) No. 69, The Meaning of Present in Conformity With GAAP, FAS No. 162 is directed to the entity rather than the auditor. The statement is effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board (PCAOB) amendments to AU Section 411, The Meaning of Present Fairly in Conformity with GAAP, and is not expected to have any impact on the Company s results of operations, financial condition or liquidity.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

(Unaudited)

1. Basis of presentation (continued):

New accounting pronouncements (continued):

In February 2008, the FASB issued FASB Staff Position 157-2, which provides for a one-year deferral of the provisions of Statement No. 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a non-recurring basis. The Company is currently evaluating the impact of adopting the provisions of Statement No. 157 for non-financial assets and liabilities that are recognized or disclosed on a non-recurring basis.

2. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, and from funded research arrangements and milestone payments. The Company has not generated revenue from the sale of any product, but has generated revenue and deferred revenues from licensing arrangements, including research and development services, and sponsored research in 2008 and 2007. The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock purchase warrants.

Significant financing or commitments in 2007 consisted of:

$1.9 million loan from CDC IV, LLC, a material stockholder of the Company (CDC) (which was repaid in March 2008, see Note 4);

$1.0 million loan from Hopkins Capital Group II, LLC, a material stockholder of the Company controlled by the Company s Chairman of the Board (HCG II) (which was repaid in September 2007);

$0.250 million received from the sale of Common Stock to Sigma Tau Industrie Farmaceutiche Riunite S.p.A (Sigma-Tau) in January 2007 pursuant to a previously executed Stock Purchase Agreement;

Approximately $0.693 million from the exercise of Common Stock options;

Approximately $3.2 million from the exercise of Common Stock warrants held by Laurus Master Fund, Ltd. (Laurus);

$3.0 million loan from Southwest Bank of St. Louis (which was repaid in September 2007); and

$30.0 million up-front, non-refundable payment received in September 2007 under a License and Development Agreement (the Meda U.S. License) with Meda relating to the licensing rights for Onsolis in the U.S., Mexico and Canada (see Note 6).

Significant financing or commitments during the nine months ended September 30, 2008 consisted of;

Approximately $0.11 million from the exercise of Common Stock options; and

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2. Liquidity and management s plans (continued):

$2.5 million milestone payment received in March 2008, under a License and Development Agreement (the Meda European License) with Meda relating to the licensing rights for the Onsolis product in Europe (see Note 6).

Company management believes that the Company s existing cash and cash equivalents are sufficient to finance planned basic operations (minimal research and development activities beyond those covered under the Company s Meda and related agreements) only through the fourth quarter of 2008.

While the Company expects that significant additional payments (aggregating an additional $35.0 million) will be received in 2009 under the Meda U.S. and EU License agreements, the receipt of such payments is conditional upon, among other things, FDA approval of the Company s FDA new drug application (NDA) for Onsolis and the subsequent 2009 approval in Europe. As such, no assurance can be given that such payments will be received in 2009, if at all. Accordingly, and especially if such payments are not received, additional outside capital will be required in order to support the Company s 2009 operations, as well as future development activities around the Company s current pipeline of products in development or other initiatives that the Company may elect to pursue. In addition, the Company is currently negotiating an equipment loan financing, which the Company expects will be secured for specialized equipment manufactured for the Company by Doyen Medipharm Inc. and which will be used by our third-party manufacturer of the Onsolis product. The Company believes that it will be able to secure such outside funding or loans at levels sufficient to support planned operations. There can, however, be no assurance that additional capital or loans will be available on favorable terms, if at all. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company s financial condition and viability.

In addition, the recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when the Company requires additional financial investment. If we are unable to attract additional funds it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

The condensed consolidated financial statements included in this Quarterly Report do not include any adjustment that may arise as a result of these uncertainties.

3. Intangible assets:

Intangible assets consist of the costs associated with the purchase of the patents and trademarks for the BEMA drug delivery technology and the Onsolis product and the purchased product rights relating to the Company s second drug delivery technology, Bioral®

On September 5, 2007, the Company purchased from QLT USA, Inc. (QLT) the patents and trademarks related to the BEMA drug delivery technology. Prior to September 2007, the Company had previously licensed the rights to the BEMA technology from QLT. In consideration for the BEMA patents and trademark, the Company agreed to pay QLT $7.0 million, consisting of $3.0 million in cash and a promissory note, secured by the purchased assets, in the principal amount of $4.0 million. Payments

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3. Intangible assets (continued):

under such note are due as follows: (i) $2.0 million within ten (10) business days of FDA approval of a product based on the BEMA technology and (ii) $2.0 million within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA -based products reach $30.0 million. The Company recorded the $3.0 million cash payment as patents and trademark in the accompanying condensed consolidated balance sheets. Management deems the $4.0 million balance a contingent liability and, therefore, will not record the $4.0 million (or parts thereof) as a liability or intangible asset until such time as the conditions which trigger the payment obligation have been satisfied.

4. Note payable, related parties:

Note payable, related party consists of the following:

	September 30, 2008 (unaudited)	December 31, 2007
Note payable, CDC (stockholder)	$	$ 1,900,000
Less unamortized discount		(603,836)
Total fair value of note payable, related party	$	$ 1,296,164

On March 12, 2007, the Company closed on a one-year, unsecured loan from CDC for $1.9 million, at 10.25% per annum due March 12, 2008 and a warrant to purchase 1 million shares of Common Stock with an exercise price of $3.80 per share. The Company repaid this loan plus accrued interest in March 2008 and the warrant remains outstanding.

5. Notes payable:

Notes payable at September 30, 2008 consist of insurance premium financing. Such short-term financing from First Insurance Funding Corp., is at 5.95% per annum and is payable monthly through April 2009.

6. Meda License, Development and Supply Agreements:

In August 2006 and September 2007, the Company entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda AB (Meda) to develop and commercialize the Onsolis product (formally referred to as BEMA Fentanyl), a drug treatment for breakthrough cancer pain delivered through a patented transmucosal drug delivery technology, BEMA (applied to the inner cheek mucosa) in the United States, Mexico and Canada (Meda U.S. Agreements) and in certain countries in Europe (Meda EU Agreements). These arrangements have license terms which commence on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of the patents, which begin to expire in January 2017.

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6. Meda License, Development and Supply Arrangements (continued):

The Company s rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

	Contractual Cash Flow Nonrefundable Upfront and Milestone Payments			Cash Flows Received and Revenue Deferred	
Contractual Rights and Obligations	**U.S. Arrangement**	**EU Arrangement**	**As Delivered**	**September 30, 2008**	**December 31, 2007**
License rights to Onsolis (BEMA Fentanyl) patents and trademarks	$ 30,000,000	$ 2,500,000		$ 32,500,000	$ 32,500,000
Milestones:					
FDA approval	$ 15,000,000	n/a			
Completion of Phase III clinical trials	n/a	$ 2,500,000		$ 2,500,000	
Governmental Approval in an EU country	n/a	$ 2,500,000			
Earlier of date of first commercial sale or availability of launch supply product inventory	$ 15,000,000	n/a			
Date of first commercial sale in an EU country	n/a	$ 2,500,000			
Research and Development Services for:					
Onsolis product through FDA approval			None		
Onsolis product through governmental approval in a EU country			Contract Hourly Rates	$ 816,357	
Non-Cancer subsequent indication of product and further development of initial product			Contract Hourly Rates	$ 1,039,788	
Other services:					
Participation on Steering, Development, and Commercialization Committees			None		
Other contractual services			None		
Product supply			Company s Fully-burdened Cost		
Royalties			Contract percentage of product net sales revenue		
Commercialization bonuses			Up to $30,000,000		

The Company has assessed the arrangement deliverables under the guidance of Emerging Issues Task Force Issue No. 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) to determine which deliverables to these arrangements are considered separate units of accounting at the inception of the arrangement and upon delivery of the items required in the arrangements. The application of EITF 00-21 requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

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6. Meda License, Development and Supply Arrangements (continued):

The Company determined that upon inception of each arrangement, all deliverables of each arrangement are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable and the research and development efforts provided do not have standalone value apart from the license. As such, all cash payments from Meda related to these deliverables have been recorded as deferred revenue. All cash payments from Meda for upfront and milestone payments and research and development services provided are nonrefundable. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain research and development services deliverables will have been delivered to Meda and based on the residual method an estimated $59.5 million (U.S. arrangement) and $10.5 million (EU arrangement) of the aggregate upfront, product development milestone, and research and development services revenue earned will be recognized. In the third quarter of 2008, the Company reclassified approximately $29.5 million of deferred revenue from long-term to current based on management s estimate that this deferred amount will be recognized within 12 months of September 30, 2008.

Upon delivery of the license to Meda, the Company has determined that each of the undelivered obligations have stand-alone value to Meda since these post-commercialization services encompass additional clinical trials on different patient groups and but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. The Company also obtained third-party evidence of fair value for the non-cancer and other research and development services and other service obligations, based on hourly rates billed by unrelated third-party providers for similar services contracted for by the Company. The Company obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged the Company from the third-party supplier of the product. The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication of the Onsolis product and (3) the combined requirements related to the remaining other service-related obligations due Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.8 million (under the Meda U.S. Agreements) and $0.3 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided over the performance period through expiration of the license terms, as defined above.

Based on Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), the Company has determined that it is acting as a principal under the Meda Agreements and, as such, will record product supply revenue, research and development services revenue and other services revenue amounts on a gross basis in the Company s consolidated financial statements.

The Company will earn royalties based on a percentage of net sales revenue of the Onsolis product. Product royalty revenues are computed on a quarterly basis when Meda s third-party sales revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met. Commercialization bonuses represent additional nonrefundable royalties due if commercial sales exceed certain predefined thresholds. They will be recognized as revenue if and when they are earned.

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7. 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 Company s Common Stock, are classified as liabilities when either (a) the holder possesses rights to net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. 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 estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

The following tabular presentation reflects the components of derivative liabilities as of September 30, 2008 and December 31, 2007:

	September 30, 2008 (unaudited)	December 31, 2007
Free standing warrants	$ 4,754,712	$ 6,543,571

	September 30, 2008 (unaudited)	December 31, 2007
Shares into which derivative liabilities can be settled:		
Free standing warrants	4,622,265	4,622,265

The following tabular presentation reflects the components of derivative financial instruments for the three and nine months ended September 30, 2008 and 2007;

	3 months ending Sep 30, 2008	3 months ending Sep 30, 2007	9 months ending Sep 30, 2008	9 months ending Sep 30, 2007
Derivative income (expense) in the accompanying statement of operations is related to the individual derivatives as follows:				
Embedded derivative instruments	$	$	$	($ 3,430,698)
Free standing derivatives (warrants)	(494,715)	2,687,233	1,788,859	2,440,430
Total	($ 494,715)	$ 2,687,233	$ 1,788,859	($ 990,268)

8. Stockholders equity:

Stock-based compensation:

During the nine months ended September 30, 2008, options were granted to certain employees at prices equal to the market value of the Common Stock on the dates the options were granted. A total of 962,561 options have been granted at a fair market value of approximately $2.2 million. The options granted have a term of 10 years from the grant date and vest either immediately or ratably over a three year period, depending on the terms. The fair value of each option is amortized as compensation expense evenly

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8. Stockholders equity (continued):

through the vesting period. The fair value of each option award is estimated on the date of grant 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 historical volatility of the Common 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. The weighted average for key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2008 follows:

Expected price volatility	54.41%-87.13%
Risk-free interest rate	2.67%-3.88%
Weighted average expected life in years	6-10 years
Dividend yield	

Option activity during the nine months ended September 30, 2008 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2008	2,695,904	$ 3.95	
Granted	962,561	2.31	
Exercised	(65,000)	1.66	
Forfeitures	(90,391)	3.61	
Outstanding at September 30, 2008	3,503,074	$ 3.88	$ 500,208

Options outstanding at September 30, 2008 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	2,739,329	8.24	$ 3.24	
$ 5.01 10.00	763,745	7.56	$ 6.48	
	3,503,074			$ 500,208

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8. Stockholders equity (continued):

Options exercisable at September 30, 2008 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	1,827,115	7.67	$ 2.86	
$ 5.01 10.00	287,916	7.33	$ 6.33	
	2,115,031			$ 297,320

The weighted average grant date fair value of options granted during the nine months ended September 30, 2008 whose exercise price is equal to the market price of the stock at the grant date was $2.31. There were no options granted during the nine months ended September 30, 2008 whose exercise price is greater or lower than the estimated market price of the stock at the grant date.

A summary of the status of the Company s nonvested stock options as of January 1, 2008, and changes during the nine months ended September 30, 2008 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Intrinsic Value
Nonvested at January 1, 2008	1,178,696		
Granted	962,561		
Vested	(662,823)		
Forfeited	(90,391)		
Nonvested at September 30, 2008	1,388,043	$ 3.90	$ 202,888

As of September 30, 2008, there was approximately $2.3 million of unrecognized compensation cost related to unvested shares-based compensation awards granted. These costs will be expensed over the next two years.

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at September 30, 2008, all of which are exercisable are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 5.00	5,148,765	4.84	$ 3.45	
$ 5.01 10.00	700,000	3.04	$ 5.45	
	5,848,765			$ 173,878

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9. Net loss per common share:

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

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Loss attributable to common stockholders	$ (2,670,826)	$ (3,882,073)	$ (9,190,521)	$ (24,789,201)
Basic:				
Weighted average shares outstanding (denominator)	19,157,183	19,061,503	19,144,873	16,542,222
Net loss per common share basic	$ (0.14)	$ (0.20)	$ (0.48)	$ (1.50)
Diluted:				
Weighted average shares outstanding	19,157,183	19,061,503	19,144,873	16,542,222
Net loss per common share diluted	$ (0.14)	$ (0.20)	$ (0.48)	$ (1.50)

The effects of all stock options and warrants outstanding have been excluded from Common Stock equivalents because their effect would be anti-dilutive.

10. Income taxes:

The Company has recognized a $4.0 million deferred tax benefit related to the loss incurred for the nine months ended September 30, 2008. This is based upon the expectation that it is more likely than not that there will be taxable income for the year ended December 31, 2008 because approximately $30.0 million of revenues which are currently deferred for financial reporting purpose will become taxable in 2008, notwithstanding the Company s financial accounting with regard to this item. Therefore since the 2008 loss to date is expected to offset, in part, the taxable income, a deferred tax asset is being recorded for the tax benefit of the current loss.

Based on anticipated taxable income for the year ending December 31, 2008, $0.2 million of alternative minimum tax expense has been accrued and included in current income tax expense and taxes payable as of September 30, 2008 in the accompanying condensed consolidated financial statements. Following is a reconciliation of the expected income tax rate to the effective rate recognized in the accompanying condensed consolidated financial statements for the periods ended September 30, 2008.

	Three months ended September 30, 2008	Nine months ended September 30, 2008
Expected rate (tax benefit)	(34.00)%	(34.00)%
State taxes, net	(3.45)	(3.45)
Permanent difference	4.20	4.20

Change in expected rate (tax benefit)	(14.30)	
Other	2.42	2.42
Effective rate (tax benefit)	(45.13)%	(30.83)%

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11. Commitments and Contingencies:

Litigation

On or about April 19, 2004, the Company was named as the defendant in an action commenced by MAS Capital in the Vanderburgh Circuit Court in the State of Indiana (Case No. 82C01-0404 PL 280). In the lawsuit, the plaintiff sought 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. In 2008, the final resolution of the case resulted in no liability by the Company and a judgment in favor of the Company of $0.021 million related to recovery of legal fees incurred during the appeal process, which was paid in October 2008.

Certain Rights of CDC

The Company and CDC are parties to a Clinical Development and License Agreement, dated July 15, 2005 (as amended, the CDLA) pursuant to which CDC has previously provided funds to the Company for the development of BEMA Fentanyl. Pursuant to the CDLA, in February 2006 the Company entered into a Security Agreement (the Security Agreement) under which it granted CDC a security interest in the Company s assets related to BEMA Fentanyl. The Security Agreement terminates at the time of FDA approval of BEMA Fentanyl. As such, until such approval, CDC retains the right to reclaim the BEMA Fentanyl-related assets in the event of a default by the Company under the CDLA. Events of default include: (i) failure to pay royalties, (ii) acceleration of a debt in excess of $1.0 million and the Company s failure to pay such debt, (iii) judgment of $0.5 million and the Company s failure to satisfy such judgments, or (iv) the Company s insolvency, among other things.

In September 2007, in connection with CDC s consent to the Meda transaction discussed in Note 6, the Company, among other transactions with CDC, granted CDC a 1% royalty on sales of the next BEMA product, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval (the Next BEMA Product). In connection with the 1% royalty grant: (i) CDC shall have the option to exchange its royalty rights to the Next BEMA Product in favor of royalty rights to a substitute BEMA product, (ii) the Company shall have the right, no earlier than six (6) months prior to the initial commercial launch of the Next BEMA Product, to propose in writing and negotiate the key terms pursuant to which it would repurchase the royalty from CDC, (iii) CDC s right to the royalty shall immediately terminate at any time if annual net sales of the Next BEMA Product equal less than seven $7.5 million in any calendar year following the third (3rd) anniversary of initial launch of the product and CDC receives $18,750 in three (3) consecutive quarters as payment for CDC s one percent (1%) royalty during such calendar year and (iv) CDC shall have certain information rights with respect to the Next BEMA Product.

The amount of royalties which the Company may be required to pay for the Next BEMA Product (including estimates of the minimum royalties) is not presently determinable because product sales estimates cannot be reasonably determined and the regulatory approvals of the product for sale is not possible to predict. As such, the Company expects to record such royalties, if any, as cost of sales when and if such sales occur.

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11. Commitments and Contingencies (continued):

Equipment purchase commitment

On August 28, 2007, the Company agreed with Doyen Medipharm Inc. to purchase a BEMA related pharmaceutical device production machine. The Company has made payments or has accrued approximately $2.5 million pursuant to a purchase order (included in deposits on equipment in the accompanying condensed consolidated balance sheet) toward the total cost, which is approximately $3.0 million. Payments are being made in separate increments during the production of the equipment.

12. Restatement:

The Company incorrectly recognized Research and Development Services revenue of approximately $0.6 million and $0.8 million during the quarters ended March 31 and June 30, 2008, respectively. These revenue amounts relate to services provided by the Company to Meda pursuant to the Meda Agreements (Note 6) and should have been deferred since these deliverables do not meet the criteria for separation as a separate unit of accounting based on guidance under EITF 00-21 until commencement of the respective license terms. Following is the impact of this restatement to the condensed consolidated balance sheets and statements of operations as of and for the three months ended March 31, 2008 and as of and for the three and six months ended June 30, 2008.

	March 31, 2008			June 30, 2008		
	As previously reported	Adjustment	As Restated	As previously reported	Adjustment	As Restated
Balance Sheet:						
Total assets	$ 21,147,255	$	$ 21,147,255	$ 19,689,497	$	$ 19,689,497
Deferred revenue, long term	35,050,559	618,274	35,668,833	35,032,052	1,448,269	36,480,321
Total liabilities	42,328,799	618,274	42,947,073	42,084,628	1,448,269	43,532,897
Accumulated deficit	(77,669,614)	(618,274)	(78,287,888)	(80,098,692)	(1,448,269)	(81,546,961)
Total stockholders deficit	(21,181,544)	(618,274)	(21,799,818)	(22,395,131)	(1,448,269)	(23,843,400)
Total liabilities and stockholders deficit	$ 21,147,255	$	$ 21,147,255	$ 19,689,497	$	$ 19,689,497

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	Three Months Ended March 31, 2008			Three Months Ended June 30, 2008			Six Months Ended June 30, 2008		
	As previously reported	Adjustment	As Restated	As previously reported	Adjustment	As Restated	As previously reported	Adjustment	As Restated
Statement of Operations:									
Revenues:									
Royalty revenue, related party	$ 19,748	$	$ 19,748	$ 15,488	$	$ 15,488	$ 35,236	$	$ 35,236
Research fees/consulting	104,500		104,500	12,500		12,500	117,000		117,000
Research and development services	618,274	(618,274)		829,995	(829,995)		1,448,269	(1,448,269)	
	742,522	(618,274)	124,248	857,983	(829,995)	27,988	1,600,505	(1,448,269)	152,236
Total expenses	5,104,466		5,104,466	5,368,388		5,368,388	10,472,854		10,472,854
Loss from operations	(4,361,944)	(618,274)	(4,980,218)	(4,510,405)	(829,995)	(5,340,400)	(8,872,349)	(1,448,269)	(10,320,618)
Net loss	$ (2,642,347)	$ (618,274)	(3,260,621)	$ (2,429,079)	$ (829,995)	(3,259,074)	$ (5,071,426)	$ (1,448,269)	$ (6,519,695)
Per share amounts, basic and diluted: Loss attributable to common stockholders	$ (0.13)	$ (0.02)	$ (0.15)	$ (0.13)	$ (0.01)	(0.14)	$ (0.26)	$ (0.08)	$ (0.34)

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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-Q. 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-Q.

For the three months ended September 30, 2008 compared to the three months ended September 30, 2007

Royalty Revenues. For the three-month periods ended September 30, 2008 and 2007, we reported $0.005 million and $0.02 million, respectively, in royalty revenue from a related company.

Research and consulting Revenues. For the three-month periods ended September 30, 2008 and 2007, we reported $0.01 million and $0.0, respectively, in research and consulting revenues from third-party sources.

Research and Development. Research and development expenses of approximately $2.1 million and $3.3 million were incurred during the three-month periods ended September 30, 2008 and 2007, respectively. These aforementioned amounts included $0.05 million and $1.0 million, respectively, paid to a contract research organization, which was a shareholder. Our 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. The decrease in expense during the three months ended September 30, 2008 compared to September 30, 2007 is primarily due to the higher level of work involved in the Onsolis™ product development in the prior year prior to submission of our Onsolis™ NDA in October 2007.

General and Administrative Expenses. General and administrative expenses of approximately $1.8 million and $2.4 million were incurred in the three-month periods ended September 30, 2008 and 2007, 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. We recorded stock based compensation of $0.6 million and $0.7 million during the three-months ended September 30, 2008 and 2007, respectively. The decrease in the three-month period ended September 30, 2008 is primarily due to lower Bema Fentanyl Marketing costs, which are the responsibility of Meda, and lower Legal fees.

Interest Income (expense). Interest expense for the periods ended September 30, 2008 and 2007 was principally related to amortization of deferred loan costs and notes payable discount amortization, net of interest earnings on invested cash.

Financing Expense, ***related party.*** Financing expense for the three-month period ended September 30, 2007 was warrant expense associated with the termination of a royalty rights agreement previously granted as part of a financing transaction whereby the Company issued a warrant to HCG II to purchase 475,000 shares of Common Stock at $5.55 per share. No such financing expense occurred during the same period in 2008.

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Derivative Gain (Loss). Derivative gain (loss) during 2008 and 2007 is related to the adjustment of related derivative liabilities to fair value. Fair value adjustments relate primarily to fluctuations in our stock price. These derivatives relate to warrants and certain embedded instruments associated with previous financings (see Note 7 to the condensed consolidated financial statements).

***Income Taxes*.** We have recognized a $2.0 million deferred tax benefit related to the loss incurred for the three months ended September 30, 2008. This is based upon the expectation that it is more likely than not that we will have taxable income for the year ended December 31, 2008 primarily due to approximately $30.0 million of revenues which are currently deferred for financial reporting purpose will become taxable in 2008, notwithstanding our financial accounting with regard to this item. Therefore since the 2008 loss to date is not expected to offset the taxable income, a deferred tax asset is being recorded for the tax benefit of the current loss.

For the Nine Months Ended September 30, 2008 Compared to the Nine Months Ended September 30, 2007

Royalty Revenues. For the nine-month periods ending September 30, 2008 and 2007, we reported $0.04 million and $0.06 million, respectively, of royalty revenue from a related company.

Research and consulting Revenues. For the nine-month periods ended September 30, 2008 and 2007, we reported $0.1 million and $0.03, respectively, in research and consulting revenues from third-party sources.

Research and Development. Research and development expenses of approximately $8.5 million and $9.6 million were incurred during the respective nine-month periods ended September 30, 2008 and 2007. These aforementioned amounts included $0.6 million and $4.1 million, respectively, paid to a contract research organization that was a stockholder of the Company. Our 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. The decrease in expense during the nine-months ended September 30, 2008 compared to September 30, 2007 is primarily due to the higher level of work involved in the Onsolis™ product development in the prior year prior to submission of our Onsolis™ NDA in October 2007.

General and Administrative Expenses. General and administrative expenses of approximately $5.9 million and $4.7 million were incurred in the nine-month periods ended September 30, 2008 and 2007, 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. We recorded stock based compensation of $1.98 million and $0.9 million during the nine months ended September 30, 2008 and 2007, respectively. The increase in the three-month period ended September 30, 2008 is primarily due to stock compensation.

Interest Expense, Net. Interest expense for the periods ended September 30, 2008 and 2007 was principally related to amortization of deferred loan costs and notes payable discount amortization, net of interest earnings on invested cash. The relatively high level of expense in 2007 resulted from the write-off of deferred loan costs associated with the principal reduction on the Laurus debt conversions, as Laurus exercised its right to convert the debt to Common Stock.

Financing Expense, ***related party.*** Financing expense for the nine-month period ended September 30, 2007 was warrant expense associated with the termination of a royalty rights agreement

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previously granted as part of a financing transaction whereby we issued a warrant to HCG II to purchase 475,000 shares of Common Stock at $5.55 per share. No such financing expense occurred during the same period in 2008.

Derivative Gain (Loss). Derivative gain (loss) during 2008 and 2007 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to warrants and certain embedded instruments associated with previous financings (see Note 7 to the financial statements).

Income Taxes. We have recognized a $4.0 million deferred tax benefit related to the loss incurred for the nine months ended September 30, 2008. This is based upon the expectation that it is more likely than not that we will have taxable income for the year ended December 31, 2008 due to approximately $30.0 million of revenues which are currently deferred for financial reporting purpose will become taxable in 2008, notwithstanding our financial accounting with regard to this item. Therefore since the 2008 loss to date is not expected to offset the taxable income, a deferred tax asset is being recorded for the tax benefit of the current loss.

Financial Terms of our License, Development and Supply Agreements with Meda AB

We entered into license, development and supply agreements with Meda in September 2007 and August 2006 to develop and commercialize Onsolis in the United States, Mexico and Canada (memorialized in the Meda U.S. Agreements) and in certain countries in Europe (memorialized in the Meda EU Agreements), respectively. The Meda Agreements have license terms which commence on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of the patents, which begin to expire in January 2017.

Up-front and Product Development Milestone Payments

Upon signing the Meda U.S. Agreements, we received a non-refundable up-front payment of $30.0 million. We will also receive the following non-refundable payments from Meda when and if we achieve the specific product development milestones:

- $15.0 million upon the receipt of approval from the FDA for Onsolis .
- $15.0 million upon the earlier of the first commercial sale of Onsolis in the United States, Mexico or Canada or when we have made available the launch supply product inventory of Onsolis .

Upon signing the Meda EU Agreements, we received a non-refundable up-front payment of $2.5 million. In March 2008 we received an additional $2.5 million upon completion of the initial Phase III clinical trials of Onsolis . We will also receive the following non-refundable payments from Meda when and if we achieve the specific product development milestones:

- $2.5 million upon the initial Governmental Approval of the product in an EU country included in the Meda EU agreements.
- $2.5 million upon the first commercial sale of Onsolis in the EU Territory.

We deferred the $35.0 million of up-front payments and first product development milestone payment related to the Meda EU Agreements. We will also defer recognition of the $35.0 million of product development milestone payments, when and if received, until the commencement of the license

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term which occurs on the date of the first commercial sale of Onsolis in the respective territories. Assuming we achieve the remaining product development milestones, we will recognize approximately $58.2 million and $9.7 million of the up-front and milestone payments on the dates of first commercial sale in the United States, Mexico and Canada and in certain countries in Europe, respectively. The remaining deferred revenue of approximately $2.1 million, which is associated with our obligation to participate in joint committees with Meda and perform certain other services, will be recognized as the services are rendered over the remaining terms of the agreements.

Research and Development Services to be provided to Meda

The Meda U.S. Agreements provide that we will perform research and development activities for the Onsolis product to be sold in the United States, Mexico and Canada as follows:

- We are responsible for all research and development expenses related to the development of Onsolis for the use on cancer patients through the date the product is approved by the FDA. We have incurred total product development expense associated with this product of approximately $34.0 million from January 2005 through September 30, 2008.

- We will provide, if requested, research and development services relating to changing or expanding the labeling of Onsolis for the treatment of breakthrough cancer pain and Meda is responsible for these expense associated with these services. We will not provide any services of this nature until after we have received product approval from the FDA.

- We will provide research and development services related to Phase IV clinical trials of Onsolis for the treatment of breakthrough cancer pain in alternate types of cancer patients and the expense will be borne by Meda in full. We will not provide any services of this nature until we have received product approval from the FDA.

- We will provide, if necessary, services in connection with additional clinical trials required by regulatory authorities relating to Onsolis for treatment of breakthrough cancer pain and Meda is responsible for full reimbursement of these expenses. We will not incur any expenses of this nature until after we have received product approval from the FDA.

- Meda is responsible for all expenses we incur related to the development of Onsolis for the non-cancer indication. At this time, we have not initiated any clinical trials of Onsolis for the treatment of breakthrough pain in non-cancer patients. We began incurring expenses related to the initial administration of these trials in the first quarter of 2008. We have provided services of approximately $1.0 million through September 30, 2008, all of which have been or will be paid by Meda. The non-cancer research and development revenues to-date have been deferred and will be recognized on the date of first commercial sale of the product in the United States, Mexico and Canada.

The Meda EU Agreements provide that we will perform research and development activities for the Onsolis product to be sold in certain countries in Europe. Meda is responsible for all research and development expenses related to the development of Onsolis for the use on cancer patients through the date the product is approved by regulatory authorities in a country in the Europe territory. We have provided services of approximately $0.8 million through September 30, 2008, all of which have been or will be paid by Meda. The EU research and development revenues to-date have been deferred and will be recognized on the date of first commercial sale of the product in a country in the Europe territory.

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Product Supply Revenue

The Meda Agreements provide that we will be the exclusive supplier of the Onsolis product to Meda for sales in the United States, Mexico, Canada and certain countries in Europe. Per the agreements, we can manufacture or have manufactured the product supply and Meda is required to pay us our fully-burdened cost of the product.

Product Royalty Revenue and Commercialization Milestone Payments

Meda is obligated to pay us a royalty based on a percentage of the net sales revenue from the sale of Onsolis in the United States, Mexico, Canada and certain countries in Europe, net of the product supply price. We expect to begin recognizing product royalty revenue in the second quarter ended June 30, 2009, reflecting the commencement of commercial sales of Onsolis in the United States, Mexico and Canada.

The Meda Agreements also require Meda to pay us up to an additional aggregate of $30.0 million of commercialization milestone payments conditioned upon the achievement of specified targets for annual net sales revenue from Onsolis in the United States and Canada.

Liquidity and Capital Resources

From inception through November 2008, we financed our operations primarily from the private sales of our convertible preferred stock, convertible debt and common stock, our public offering in 2002 and follow-on public offering in 2005, exercise of options, various strategic and licensing agreements (including the CDLA and our Meda Agreements), NIH grants, bank financing, and through the sale of a royalty stream asset.

In January 2005, we signed a definitive licensing agreement with Sigma-Tau Pharma for the application of our Bioral® nanocochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of $0.25 million from another Sigma Tau-related entity. This upfront payment was made in consideration of unregistered shares of our common stock priced at $4.25 a share. The stock purchase agreement with Sigma-Tau provides for the acquisition by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of our common stock, up to an aggregate potential of $1.5 million worth of such shares. Such additional unregistered shares will be issued at the lesser of: (i) $4.25 and (ii) the average of the closing trade price of our Common Stock for the ten (10) trading days through and including the applicable payment date, with an absolute floor $3.38 per share. In January 2007, under our development agreement with Sigma Tau, we were paid a milestone payment of $0.25 million for which we issued 73,964 shares of Common Stock at $3.38. Sigma-Tau, through other holding entities, is currently a stockholder of our Company. In addition to the milestone payments, we will receive a royalty on future sales of each of the four products which may arise from the encochleated compounds.

In March 2007, we entered into a $1.9 million financing with CDC. This financing involved a one-year, 10.25% loan from CDC and a warrant to purchase 1 million shares of our common stock with an exercise price of $3.80. On March 12, 2008, we repaid the loan in full plus interest due to CDC.

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In August 2006 and September 2007, we received up-front non-refundable payments in connection with our license, development and supply agreements with Meda of $2.5 million and $30.0 million, respectively.

At September 30, 2008, we had cash of approximately $2.0 million and investments of an additional $0.4 million. The adequacy of cash for our operations and continued research is dependent on, among other things, licensing and milestone payments from Meda of approximately $35.0 million expected to be received by the Company in 2009, and additional equity or debt financing opportunities that we are able to negotiate in the coming year. We used $8.8 million of cash for operations for the nine months ended September 30, 2008. This resulted from a net loss of $9.2 million (which included a derivative gain of $1.8 million), offset by stock-based compensation of $1.97 million, a decrease in our related party accounts receivable (primarily Meda) of $0.01 million and a decrease in our accounts payable and accrued liabilities of $1.7 million. We received a $2.5 million additional up-front payment from Meda in connection with our EU license in March 2008, which was recorded as deferred revenue, and received research and development services reimbursements from Meda of $1.4 million which is recorded as deferred revenue.

We have incurred significant net losses and negative cash flows from operations since our inception. As of September 30, 2008, we had a stockholders deficit of $25.9 million, versus $18.8 million at December 31, 2007.

We anticipate that cash used in operations and our investment in facilities will continue beyond our BEMA Fentanyl agreements with Meda, as we research, develop, and, potentially, manufacture and commercialize additional drug formulations with our BEMA and Bioral® technologies. While we believe further application of our BEMA and Bioral® cochleate technologies to other drugs will result in license agreements with additional pharmaceutical manufacturers, our plan of operations for the foreseeable future will be to develop additional products with our BEMA technology and further develop our Bioral® cochleate technology for use in a limited number of applications. Such focus will not be on the marketing, production or sale of FDA approved products.

Until FDA approval, we are required under our Meda Agreements to pay certain chemistry, manufacturing and control and clinical and regulatory costs associated with the BEMA Fentanyl NDA, as well as manufacturing and packaging equipment costs for Onsolis . The Meda Agreements require all pre-launch marketing and commercialization costs for Onsolis to be paid by Meda, as well as all required clinical costs associated with Onsolis after FDA approval. Meda will pay for costs of Phase III-b and Phase IV studies which, although not required as part of our Onsolis NDA, may be done to support the program with additional market data. In addition, Meda is paying for the development costs for BEMA Fentanyl in non-cancer breakthrough pain.

The recent worldwide financial and credit crisis has strained investor liquidity and contracted credit markets. If this environment continues or worsens, it may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable at a time when the Company requires additional financial investment. If we are unable to attract additional funds it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned basic operations (minimal research and development activities beyond those covered under our Meda and other related agreements), debt repayment obligations and capital expenditures through the fourth quarter of 2008.

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Under the Meda Agreements, we expect to receive additional payments aggregating $30.0 million upon FDA approval and launch of Onsolis , for which we had a Prescription Drug User Fee Act (PDUFA) date of August 31, 2008. On August 28, 2008 we announced receipt of a Complete Response letter from the FDA regarding our NDA for Onsolis . The FDA has requested that the Company make modifications to the submitted risk management program. All aspects of the review were complete and no deficiencies were noted in chemistry, manufacturing and controls, nonclinical, or clinical efficacy/safety. We will submit the requested information in the fourth quarter of 2008 and anticipate a first half of 2009 FDA approval. The FDA requested conversion of the risk minimization action plan (RiskMAP) submitted as part of the NDA for ONSOLIS into a Risk Evaluation and Mitigation Strategy (REMS). REMS is a new term for a strategy and plan aimed at ensuring the benefits of a drug outweigh its risks. The REMS requested of us is believed to be the result of the FDA s recent experience with other high-potency opioid products and the new authority granted under the Food and Drug Administration Amendment Act (FDAAA) enacted in March of 2008. This followed our submission of our Onsolis NDA in October 2007. We expect to incur minimal additional research and development expense in order to complete the FDA REMS requirements.

However, there can be no assurances that we will receive FDA approval or the timing of such approval, if received. Additional capital will be required in order to proceed with our support of the commercial launch of Onsolis , clinical development programs for other products in our pipeline, such as BEMA Buprenorphine and Biora® Amphotericin B (the scale of which is dependent in part on the success of Onsolis and on the results from our Phase I studies for each of these products), and for general working capital. Based on 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;

private equity financings;

collaborative arrangements;

grants and new license revenues;

bank loans;

equipment financing

public or private debt; and

exercise of existing 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 in 2008 and beyond. 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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Critical Accounting Policies

Revenue Recognition

Meda License, Development and Supply Agreements:

We recognize revenue associated with the Meda Agreements in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104), Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), and EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Our deliverables under the Meda Agreements, including our related rights and obligations, contractual cash flows and performance periods, are more fully described in Note 6 to the accompanying financial statements.

Based on our assessment upon inception of each arrangement, all deliverables of the Meda Agreements have been accounted for as one combined unit of accounting and as such, all cash payments from Meda (upfront payments and product development research and development services revenue) related to these deliverables have been recorded as deferred revenue.

Upon delivery of the license rights to Meda (date of first commercial sale in each territory), we will recognize revenue associated with the license and the research and development services rendered related to development of the Onsolis product through the date of FDA and other governmental approval delivered to Meda. A portion of the upfront payments will be attributed to our continuing obligation to participate in joint committees with Meda and to provide certain other specified services and this revenue will be recognized as services are provided through expiration of the license agreements.

Research and development services revenue associated with the non-cancer indication and further development of the first indication for treatment of breakthrough cancer pain of the Onsolis product which have been performed prior to the commencement of the license term has been deferred and will be recognized upon delivery of the license rights to Meda. Services provided subsequent to commencement of the license term will be recognized when the services are performed, if all other revenue recognition criteria are met. Based on the guidance of EITF 99-19, we have determined that it is acting as a principal under the Meda Agreements and, as such, will record these amounts on a gross basis as research and development services revenue.

Revenue associated with product sold to Meda prior to the commencement of the license term has been deferred and will be recognized upon delivery of the license rights to Meda. Subsequent to the commencement of the license term, we will recognize revenue for product supplied to Meda when title and risk of loss have passed to Meda and the remaining criteria in SAB 104 have been met. Based on the guidance of EITF 99-19, we have determined that we are acting as a principal as it relates to these activities under the product supply agreements and, as such, will record the amounts on a gross basis as product supply revenue.

Product royalty revenue is based on third-party sales of the Onsolis product. We will recognize product royalty revenues from Meda on the accrual basis in accordance with contractual terms when third-party results are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met.

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Accounting for Meda License, Development and Supply Agreements:

In August 2006 and September 2007, we entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda to develop and commercialize Onsolis , a drug treatment for breakthrough cancer pain delivered through our patented BEMA technology (applied to the inner cheek mucosa) in the United States, Mexico and Canada and in certain countries in Europe. These arrangements have license terms which commence on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of the patents, which begin to expire in January 2017.

Our rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

	Contractual Cash Flow				
	Upfront and Milestone Payments			Cash Flows Received and Revenue Deferred	
Contractual Rights and Obligations	U.S. Arrangement	EU Arrangement	As Delivered	September 30, 2008	December 31, 2007
License rights to Onsolis (BEMA Fentanyl) patents and trademarks	$ 30,000,000	$ 2,500,000		$ 32,500,000	$ 32,500,000
Milestones:					
FDA approval	$ 15,000,000	n/a			
Completion of Phase III clinical trials	n/a	$ 2,500,000		$ 2,500,000	
Governmental Approval in an EU country	n/a	$ 2,500,000			
Earlier of date of first commercial sale or availability of launch supply product inventory	$ 15,000,000	n/a			
Date of first commercial sale in an EU country	n/a	$ 2,500,000			
Research and Development Services for:					
Onsolis product through FDA approval			None		
Onsolis product through governmental approval in a EU country			Contract Hourly Rates	$ 816,357	
Non-cancer subsequent indication of product and further development of initial of product			Contract Hourly Rates	$ 1,039,788	
Other services:					
Participation on Steering, Development, and Commercialization Committees			None		
Other contractual services			None		
Product supply			Company s Fully-burdened Cost		
Royalties			Contract percentage of product net sales revenue		
Commercialization bonuses			Up to $30,000,000		

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We have assessed the arrangement deliverables under the guidance of Emerging Issues Task Force Issue No. 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) to determine which deliverables to these arrangements are considered separate units of accounting at the inception of the arrangement and upon delivery of the items required in the arrangements. The application of EITF 00-21 requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable from the other aspects of the contractual arrangement into separate units of accounting and, if so, to determine the fair value to be allocated to each unit of accounting.

We have determined that upon inception of each arrangement, all deliverables of each arrangement are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable. As such, all cash payments from Meda related to these deliverables have been recorded as deferred revenue. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain research and development services deliverables will have been delivered to Meda and an estimated $59.5 million (under Meda U.S. Agreements) and $10.5 million (under the Meda EU Agreements) of the aggregate upfront and product development milestones payments will be recognized as revenue using the residual method. In the third quarter of 2008, the Company reclassified approximately $29.5 million of deferred revenue from long-term to current based on management s estimate that this deferred amount will be recognized within 12 months of the September 30, 2008.

Upon delivery of the license to Meda, we have determined that each of the undelivered obligations have stand-alone value to Meda since these post-commercialization services encompass additional clinical trials on different patient groups and but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. We also obtained third-party evidence of fair value for the non-cancer and other research and development services and other service obligations, based on hourly rates billed by unrelated third-party providers for similar services contracted for by us. We obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged to us from the third-party supplier of the product. The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication for treatment of breakthrough cancer pain of the Onsolis product and (3) the combined requirements related to the remaining other service-related obligations due Meda to include participation in committees and certain other specified services. The estimated portion of the upfront payments of approximately $1.8 million (under the Meda U.S. Agreements) and $0.3 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided over the performance period through expiration of the license terms, as defined above.

Based on Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF 99-19), we have determined that it is acting as a principal under the Meda Agreements and, as such, will record product supply revenue, research and development services revenue and other services revenue amounts on a gross basis in our consolidated financial statements.

We will earn royalties based on a percentage of net sales revenue of the Onsolis product. Product royalty revenues are computed on a quarterly basis when Meda s third-party sales revenues are reliably measurable, collectability is reasonably assured and all other revenue recognition criteria are met.

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Valuation of Goodwill and Intangible Assets

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for based on Financial Accounting Standard Statement No. 142 Goodwill and Other Intangible Assets (FAS 142). As described below, goodwill is not amortized but is tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated period of benefit, ranging from eleven to thirteen years.

Our carrying value of goodwill at September 30, 2008 was $2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other, amortizing intangible assets at September 30, 2008 was $6.0 million, net of accumulated amortization of $1.4 million. We begin amortizing capitalized intangibles on their date of acquisition.

Impairment Testing

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test has two steps. The first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired and the second step is not necessary. If the carrying value exceeds the fair value, the second step calculates the possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded. No goodwill impairment charges have resulted from this analysis for 2008 or 2007.

In accordance with SFAS 144, which relates to impairment of long-lived assets other than goodwill (our other amortizing intangibles), impairment exists if the sum of the future estimated undiscounted cash flows related to the asset is less than the carrying amount of the intangible asset or to its related group of assets. In that circumstance, then an impairment charge is recorded for the excess of the carrying amount of the intangible over the estimated discounted future cash flows related to the asset.

In making this assessment, we predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our impairment testing. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In addition, selection of a risk-adjusted discount rate on the estimated undiscounted cash flows is susceptible to future changes in market conditions, and when unfavorable, can adversely affect our original estimates of fair values. In the event that our management determines that the value of intangible assets have become impaired using this approach, we will record an accounting charge for the amount of the impairment. No impairment charges have been recorded to other amortizing intangibles in either 2008 or 2007.

Stock-Based Compensation and other stock based valuation issues (derivative accounting)

We account for stock-based awards to employees and non-employees using the accounting provisions of SFAS 123R Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our Common Stock. The values of

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these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide the service in exchange for the award. We use the Black-Scholes options-pricing model to determine the fair value of stock option and warrant grants. We also use the Black Scholes option pricing model as the primary basis for valuing our derivative liabilities at each reporting date (both embedded and free-standing derivatives). The underlying assumptions used in this determination are primarily the same as are used in the determination of stock-based compensation except contractual lives of the derivative instruments are utilized rather than expected option terms as discussed in the previous paragraph.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4T. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, the Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer (the Certifying Officers), conducted evaluations of the Company s disclosure controls and procedures. As defined under Sections 13a 15(e) and 15d 15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), the term disclosure controls and procedures means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission s rules and forms. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer s management, included the Certifying Officers, to allow timely decisions regarding required disclosures.

Based on this evaluation, the Certifying Officers have concluded that the Company s disclosure controls and procedures were effective to ensure that material information is recorded, processed, summarized and reported by management of the Company on a timely basis in order to comply with the Company s disclosure obligations under the Exchange Act and the rules and regulations promulgated thereunder.

This Report does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by the Company s registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only management s report in this report.

Changes in Internal Control Over Financial Reporting

Pursuant to the Company s internal controls over financial reporting, during the quarter ended September 30, 2008, the Company performed a comprehensive analysis of the accounting and disclosure required for certain license, development and supply arrangements (revenue arrangements with multiple deliverables), specifically the Meda Agreements as further described in Note 6 to the condensed consolidated financial statements included as part of this Report. The application of the required generally accepted accounting principles is complex and requires extensive subjective analysis on the part of management and for management to make significant estimates and assumptions. In conjunction with the analysis, the Company identified certain errors related to the recognition of certain revenues associated with the arrangements. The Company has determined these errors to be immaterial to its previously reported financial statements and has corrected the errors in the condensed consolidated financial statements and footnotes included in this Report (see Notes 6 and 12 to the condensed consolidated financial statements). As such, the Company has revised certain entity-level controls and specific internal controls related to revenue recognition, management estimates, and financial reporting in order to ensure accurate and comprehensive accounting for these and future multiple deliverable revenue arrangements.

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Limitations on the Effectiveness of Internal Controls

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

NOTE ON FORWARD-LOOKING STATEMENTS

The information set forth in this Quarterly Report on Form 10-Q 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. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company s plans, objectives, projections, expectations and intentions and other statements identified by words such as projects , may , could , would , should , believes , anticipates , estimates , intends , plans or similar expressions. These statements are based upon the current beliefs and expectations of the Company s management and are subject to significant risks and uncertainties, including those detailed in the Company s filings with the Securities and Exchange Commission. Actual results, including, without limitation: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and the Company s need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial launch of the Company s formulations and products and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve 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 2007 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.

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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 in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff sought 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. In 2008 the final resolution of the case resulted in no liability by the Company and a judgment of $21,000 related to legal fees in the appeal process was awarded by the courts to the Company based on the frivolous nature of the lawsuit, which was paid in October 2008.

Item 4. Submission of Matters to a Vote of Security Holders

On July 24, 2008, the Company held its 2008 annual meeting of stockholders (the Annual Meeting). At the Annual Meeting, all proposals presented were approved by the Company s stockholders. The following is a tabulation of the voting on the proposals presented at the Annual Meeting:

Proposal 1: The following nominees were elected as directors of the Company, to serve until the 2009 Annual Meeting of Stockholders and until his successor has been duly elected and qualified.

Name	Shares Voted For	Shares Withheld
Francis E. O Donnell, Jr.	16,854,170	68,316
Mark A. Sirgo	16,859,532	62,954
John J. Shea	16,855,932	66,554
William B. Stone	16,864,132	58,354
William S. Poole	16,862,983	59,503

Proposal 2: A proposal to adopt an amendment to the Company s Certificate of Incorporation to create a classified board of directors comprised of three classes with staggered terms was approved as follows:

Shares Voted For	Shares Withheld	Shares Abstaining
8,098,089	2,234,625	21,880

Proposal 3: A proposal to ratify the appointment by the Audit Committee of the Company s Board of Directors of Cherry, Bekaert & Holland, L.L.P. (as the successor to Aidman Piser & Company, P.A. s practice as a result of the acquisition of such practice on May 1, 2008) as the Company s independent auditors for the fiscal year ending December 31, 2008 was approved as follows:

Shares Voted For	Shares Withheld	Shares Abstaining
16,902,804	8,895	10,786

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Item 6. Exhibits.

Number	Description
31.1	Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302
31.2	Certification of Chief Financial Officer 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.

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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 19, 2008

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

Date: November 19, 2008

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