BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10QSB
November 14, 2007
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-QSB

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2007

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 0-28931

BioDelivery Sciences International, Inc.

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

Delaware	**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)

(919) 582-9050

(Issuer s telephone number)

2501 Aerial Center Parkway Suite 205

Morrisville, NC 27560

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

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

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

State the number of shares outstanding of each of the issuer s classes of common equity, as of the latest practicable date: The Issuer had 19,095,095 shares of common stock issued and 19,079,604 shares of common stock outstanding as of November 14, 2007.

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

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Table of Contents

BioDelivery Sciences International, Inc. and Subsidiaries

Form 10-QSB

Index

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2007 (Unaudited)	December 31, 2006 (Restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,751,002	2,172,104
Accounts receivable	14,756	42,118
Due from related party	35,386	8,523
Prepaid expenses and other current assets	263,654	180,863
Total current assets	21,064,798	2,403,608
Equipment, net	218,959	379,654
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,802,467	1,941,942
Acquired product rights	4,803,220	1,938,462
Total other intangible assets	6,605,687	3,880,404
Other assets	858,724	463,268
Total assets	$ 31,463,168	$ 9,841,934
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Notes payable	$ 160,289	$ 1,000,000
Notes payable, related parties	728,636	
Accounts payable and accrued liabilities	2,904,370	2,032,765
Due to related parties	257,884	1,001,177
Deferred revenue, current	70,360	70,360
Dividends payable		152,803
Derivative liability (Note 7)	9,841,272	7,795,931
Total current liabilities	13,962,811	12,053,036
Convertible notes payable, less current maturities		4,003,250
Deferred revenue, long-term	32,500,000	2,500,000
Total liabilities	46,462,811	18,556,286
Commitments and contingencies (Notes 6 and 11)		
Stockholders deficit:		
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 0 and 1,647,059 shares issued and outstanding in 2007 and 2006, respectively		3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 0 and 341,176 shares issued and outstanding in 2007 and 2006, respectively		1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized, 19,095,096 and 14,048,637 shares issued; 19,079,605 and 14,033,146 shares outstanding in 2007 and 2006, respectively	19,096	14,049

Additional paid-in capital	55,787,353	32,132,609
Treasury stock, at cost, 15,491 shares, 2007 and 2006	(47,183)	(47,183)
Accumulated deficit	(70,758,911)	(45,969,710)
Total stockholders deficit	(14,999,644)	(6,714,352)
Total liabilities and stockholders deficit	$ 31,463,168	$ 9,841,934

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006 (Restated)	2007	2006 (Restated)
Sponsored research revenues	$	$ 51,368	$	$ 75,717
Royalties, related parties	19,345	12,973	57,015	51,578
Research fees/consulting			25,000	10,000
	19,345	64,341	82,015	137,295
Expenses:				
Research and development	2,298,381	1,584,362	5,510,370	5,750,394
Related party research and development	1,004,359	758,770	4,063,027	2,208,471
Product development costs				746,591
General and administrative	2,405,121	1,501,581	4,616,244	3,135,163
Related party general and administrative	26,500	60,459	34,802	105,748
Total expenses	5,743,361	3,905,172	14,224,443	11,946,367
Loss from operations	(5,724,016)	(3,840,831)	(14,142,428)	(11,809,072)
Other income, net				7,663
Interest expense, net	(270,182)	(448,450)	(1,606,640)	(1,531,597)
Financing expense, related party	(584,108)		(584, 108)	
Derivative gain (loss)	2,687,233	386,333	(990,268)	768,078
Loss on extinguishment of debt			(3,595,169)	
Loss before income taxes	(3,891,073)	(3,902,948)	(20,918,613)	(12,564,928)
Income tax benefit (expense)				
Net loss	(3,891,073)	(3,902,948)	(20,918,613)	(12,564,928)
Preferred stock dividends		(16,447)		(48,803)
Constructive dividends			(3,870,588)	
Loss attributable to common stockholders	$ (3,891,073)	$ (3,919,395)	$ (24,789,201)	$ (12,613,731)
Per share amounts, basic and diluted:				
Loss attributable to common stockholders	$ (0.20)	$ (0.28)	$ (1.50)	$ (0.95)
Weighted average common stock shares outstanding basic and diluted	19,061,503	13,938,146	16,542,222	13,259,684

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS DEFICIT

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2007

(Unaudited)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred stock		Common Stock		Additional Paid-In	Treasury	Accumulated	T Stock
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	De
,												
, 2007	1,647,059	$ 3,705,883	341,176	$ 1,450,000			14,048,637	$ 14,049	$ 32,132,609	($ 47,183)	($ 45,969,710)	($ 8,
sed ation									878,458			
tion							262,176	262	674,105			
sued							73,964	74	249,926			
paid mon							1,985	2	7,998			
							850,879	851	3,234,586			3,
on of able on							1,757,454	1,758	4,055,643			4,
of with stock							52,539	53	201,102			
ication tive o									5,175,700			5,
on of to												
stock	(1,647,059)	(3,705,883)			1,647,059	7,576,471						3,
on of stock on			(341,176)	(1,450,000)			341,176	341	1,449,659			
on of												
stock					(1,647,059)	(7,576,471)	1,647,059	1,647	7,574,824			
of							59,227	59	152,743			
s with												

stock																
tive																
s															(3,870,588)	(3,
															(20,918,613)	(20,
,																
er 30,																
	0	$	0	0	$	0	0	$	0	19,095,096	$ 19,096	$ 55,787,353	$ (47,183)	$	(70,758,911)	$ (14,

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited)

	Nine Months Ended	
	September 30, 2007	**September 30, 2006 (Restated)**
Operating activities:		
Net loss	$ (20,918,613)	$ (12,564,928)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of common stock	209,155	16,261
Expenses paid through the issuance of warrants	584,108	997,482
Depreciation and amortization	473,344	800,893
Derivative loss (gain)	990,268	(768,078)
Loss on extinguishment of debt	3,595,169	
Accretion of interest on convertible debentures	1,155,644	805,731
Stock-based compensation	878,458	428,354
Changes in assets and liabilities:		
Accounts receivable	(27,362)	(75,000)
Prepaid expenses and other current assets	157,752	(4,826)
Accounts payable and accrued expenses	891,261	266,600
Deferred revenue	30,000,000	2,575,000
Net cash flows from operating activities	17,989,184	(7,522,511)
Investing activities:		
Purchase of equipment	(37,932)	(9,546)
Deposits paid on equipment	(711,650)	
Purchase of intangible assets	(3,000,000)	(1,000,000)
Net cash flows from investing activities	(3,749,582)	(1,009,546)
Financing activities:		
Proceeds from issuance of common stock	250,000	6,975,900
Proceeds from exercise of stock options	674,367	
Change in amounts due to related parties	273,503	727,723
Payments on notes payable	(4,094,011)	
Proceeds from notes payable	4,000,000	
Proceeds from exercise of common stock warrants	3,235,437	
Net cash flows from financing activities	4,339,296	7,703,623
Net change in cash and cash equivalents	18,578,898	(828,434)
Cash and cash equivalents at beginning of period	2,172,104	4,914,735
Cash and cash equivalents at end of period	$ 20,751,002	$ 4,086,301

See notes to condensed consolidated financial statements

4

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited)

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Non-cash investing and financing activities:

The Company converted $4,057,401 and $289,988 of convertible notes payable through the issuance of 1,757,454 and 118,363 shares of common stock to Laurus Master Fund Ltd. during the nine months ended September 30, 2007 and 2006, respectively.

The Company converted $201,155 and $16,261 of interest payable through the issuance of 52,539 and 6,637 shares of common stock to Laurus Master Fund Ltd. during the nine months ended September 30, 2007 and 2006, respectively.

The Company reclassified derivative liabilities of $5,175,701 and $300,664 from debt to equity during the nine months ended September 30, 2007 and 2006, respectively, as a result of the conversions of notes payable and interest to which the derivative related.

The Company paid $152,802 of accrued dividends payable through the issuance of 59,226 shares of common stock with a fair value of $152,802 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.

The Company purchased directors and officers and employee practices insurance policies with proceeds from notes payable in the aggregate amount of $254,300 during the nine months ended September 30, 2007.

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

1. Basis of presentation:

The condensed consolidated balance sheet 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 subsidiary, Bioral Nutrient Delivery, LLC (BND and, collectively with Arius and Arius Two, the Company or we , us or similar terminology) as of September 30, 2007, and the condensed consolidated statements of operations for the three and nine months ended September 30, 2007 and 2006 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, 2007 and for all periods presented, have been made. The accompanying consolidated financial statements include the accounts of BioDelivery Sciences International, Inc. and its subsidiaries, Arius One, Arius Two and BND. All intercompany accounts and transactions have been eliminated. BND became substantially inactive as of September 30, 2005.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2006, included in the Company s 2006 Annual Report on Form 10-KSB, filed with the SEC on April 17, 2007 (as amended, the 2006 Annual Report). As used herein, the term Common Stock means the Company s common stock, par value $.001 per share.

The results of operations for the three and nine months ended September 30, 2007 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 2006 Annual Report.

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

Revenue Recognition

The Company recognizes revenue in accordance with the SEC s Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements. When evaluating multiple element arrangements, the company considers whether the components of the arrangement represents separate units of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21). Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether it is separable from the other aspects of the contractual relationship.

License Arrangements

License arrangements may consist of non-refundable upfront license fees, data transfer fees, exclusive licensed rights to manufacture patented or patent pending products, technology access fees, various performance or sales milestones and future product royalty payments.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

1. Basis of presentation (continued):

Non-refundable, upfront fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue over the established or estimated term of the license when the license arrangement commences and the licensed data, technology and/or product or supplies to manufacture the product is delivered. Such deliverables may include physical quantities of products, supplies, or design of the products, the conceptual framework and mechanism of actions taken by a third party, and rights to the patents or patents pending for such products.

We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology, know-how, rights, products or services conveyed in conjunction with the non-refundable fees have no utility to the licensee that could be considered separate and independent of our performance under other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such upfront fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in research and development arrangements are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process. This includes the acceptance by the customer; no requirement by us for continued performance of future research and development services related to the milestone; the milestone payments are non-refundable, and substantive effort is involved in achieving the milestone. If any of these conditions are not met, the Company defers the milestone payments and recognizes them as revenue over the estimated period of performance under the contract as the Company completes its performance obligations.

Payment related to sales targets, whether or not referred to as milestones, specified in underlying sales and manufacturing agreements are recognized upon achievement of those targets as a performance bonus.

Sponsored Research

Sponsored research amounts are recognized as revenue when the research underlying such funding has been performed or when the grant funds have otherwise been properly utilized, such as for the purchase of operating assets. Grant revenue is recognized to the extent provided for under the related grant or collaborative research agreement. This is shown as sponsored research revenue on the accompanying consolidated statements of operations.

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. The Company has not generated revenue from the sale of any product, but has generated deferred revenues from licensing arrangements, research fees and sponsored research in 2007 and 2006. 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 funding in 2005 and 2006 consisted of:

7

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

2. Liquidity and management s plans (continued):

Proceeds from an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC (HCG), a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman. Pursuant to the Equity Line Agreement as amended, HCG, at the Company s request, was to invest up to $4.0 million in the Company from August 23, 2004 through December 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock (Series B Preferred). As of December 31, 2006, the Equity Line Agreement terminated with $1.45 million having been drawn thereunder. On January 10, 2007, HCG converted 341,176 shares of Series B Preferred (consisting of all said Series B Preferred then outstanding) into 341,176 shares of Common Stock. No other consideration was paid. HCG also acquired 59,226 shares of Common Stock pursuant to the payment of $152,802 accrued and unpaid dividends on the Series B Preferred;

$5,000,000 secured convertible debt financings with Laurus Master Fund, Ltd. (Laurus) (see Note 5); and

$7,000,000 sale of Common Stock in 2006, consisting of 2 million shares of Common Stock issued to CDC IV, LLC, as successor in interest to Clinical Development Capital, LLC (collectively CDC), $2,416,667 of which had been received and recorded as a deposit during the first quarter of 2006 pursuant to a Clinical Development and License Agreement, dated July 15, 2005, between the Company and CDC (the CDLA) relating to the development of the Company s BEMA™ Fentanyl product.

Significant financing or commitments during the nine months ended September 30, 2007 consisted of:

$1,900,000 loan from CDC (see Note 4);

$1,000,000 loan from HCG (see Note 4);

$250,000 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 $675,000 from the exercise of Common Stock options;

Approximately $3,200,000 from the exercise of Common Stock warrants held by Laurus;

$3,000,000 loan from Southwest Bank of St. Louis (SWB) (see Note 5);

Received $30,000,000 from up-front payment under a license agreement with Meda AB, a Swedish company (Meda) (see Note 6); Additionally, Laurus converted all debt remaining ($4,057,401) under its February and May 2005 convertible notes with the Company to Common Stock during this period.

The Company s existing cash and cash equivalents are considered by management to be sufficient to finance the Company s basic operations, capital expenditures and debt obligations through the end of the third quarter 2008.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

2. Liquidity and management s plans (continued):

Although the $30 million payment received in September 2007 and expected future payments from Meda will make the Company s cash flow positive in 2007 and enhance its prospects for positive cash flow in 2008, it is possible that additional outside capital may be required in order to support the Company s planned expanded, 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. The Company believes that it will be able to secure such funding at levels sufficient to support planned expanded operations. However, there can be no assurance that additional capital will be available on favorable terms, if at all, or that such expanded operations will be initiated or maintained. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned expanded 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 their financial condition.

3. New accounting pronouncements:

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities . SFAS 159 permits entities to choose to measure financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The decision to elect the fair value option may be applied instrument by instrument, is irrevocable, and is applied to the entire instrument and not to only specified risks, specific cash flows or portions of that instrument. An entity is restricted in choosing the dates to elect the fair value option for an eligible item. Adoption of SFAS 159 is effective for the Company on January 1, 2008. Early adoption is permitted, provided the entity also elects to apply the provisions of SFAS 157, Fair Value Measurements . Management of the Company is currently evaluating the potential impact of SFAS 159 on the Company s financial condition, results of operations, and liquidity.

4. Notes payable, related parties:

Notes payable, related parties at September 30, 2007 consist of the following:

Note payables. HCG (1)	
Note payable, CDC (stockholder) (2)	1,900,000
Less unamortized discount	(1,171,364)
Total at September 30, 2007	$ 728,636

(1) On March 30, 2007, HCG funded a $1.0 million unsecured, non-interest bearing note, due September 30, 2007. As consideration for the loan made by HCG, the Company granted HCG the right, for a period of six months, to participate in and enter into a royalty purchase agreement. The consideration to be paid upon exercise of the right, which could have been demanded by either the Company or HCG at any time before September 30, 2007, was $5.0 million. The royalty was to be paid based on a low, single digit tiered percentage of net sales of the BEMA Fentanyl once the product is approved and commercial sales begin. On September 5, 2007, the Company and HCG entered into an agreement to terminate HCG s royalty purchase rights and, as consideration, the Company issued a warrant to HCG to purchase 475,000 shares of Common Stock at $5.55 per share (the closing price on April 2, 2007). On September 14, 2007, the Company

paid the note in full to HCG.

(2) On March 12, 2007, the Company closed a one-year, unsecured loan from CDC for $1.9 million, at 10.25% per annum due March 12, 2008 and a warrant (the New CDC Warrant) to purchase 1 million shares of Common Stock with an exercise price of $3.80 per share. The Company is not required to file a

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

4. Notes payable, related parties (continued):

registration statement with the SEC to register the shares of Common Stock underlying the New CDC Warrant for a period of one year from loan closing (i.e., a registration statement must be filed by March 12, 2008). CDC was also granted piggyback registration rights with respect to such shares of Common Stock which come into effect only after March 12, 2008. The New CDC Warrant contains weighted average anti-dilution protection.

5. Notes payable:

Notes payable at September 30, 2007, consist of insurance premium financing. The short-term financing from First Insurance Funding Corp., at 7.7% per annum is payable monthly through May 25, 2008.

On September 4, 2007, the Company closed a short-term loan (promissory note) from SWB for $3.0 million, at 1% per annum due October 31, 2007. The Company paid the loan in full plus accrued interest on September 14, 2007.

6. Acquired product rights and license agreement:

Acquired product rights

On September 5, 2007, the Company exercised a previously granted option and purchased from QLT USA, Inc. (QLT) the BEMA drug delivery technology and intellectual property assets specifically related to the development and commercialization of BEMA in the United States (the BEMA U.S. Rights). The Company had previously licensed the BEMA U.S. Rights from QLT.

In consideration for the BEMA U.S. Rights, the Company agreed to pay QLT $7 million, consisting of $3 million in cash and a promissory note, secured by the purchased assets, in the principal amount of $4 million. Payments under such note are due as follows: (i) $2 million within ten (10) business days of FDA approval of a product based on the BEMA technology and (ii) $2 million within thirty (30) days of the end of the calendar quarter during which cumulative net sales of BEMA -based products reach $30 million.

The Company has recorded the $3 million payment as additional acquired product rights in the accompanying September 30, 2007 consolidated balance sheet. Management deems the $4 million balance a contingent liability and, therefore, will not record the $4 million (or parts thereof) as a liability or intangible asset until such time as the conditions which trigger the payment obligation have been satisfied.

Meda license agreement

On September 5, 2007, the Company entered into a definitive License and Development Agreement (the License Agreement) with Meda and the Company s Arius subsidiary pursuant to which the Company and Arius agreed to grant to Meda an exclusive commercial license to manufacture, market, sell, and, following regulatory approval, continue development of the Company s BEMA Fentanyl product in the United States, Mexico and Canada.

Pursuant to the License Agreement, the Company did or will receive:

$30 million milestone payment upon closing (which was received on September 14, 2007).

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

6. Acquired product rights and license agreement (continued):

An additional $30 million milestone payment concurrently with receipt of approval of BEMA Fentanyl by the FDA, unless the Company has not, at such time, manufactured stocks of BEMA Fentanyl, in bulk or finished form, sufficient for commercial launch of BEMA Fentanyl in the U.S., in which case $15 million will be paid upon FDA approval and $15 million will be paid upon the earlier of: (A) the date that such sufficient launch stocks are manufactured or (B) the first commercial sale of BEMA Fentanyl. The Company anticipates that it will have sufficient launch stocks of BEMA Fentanyl product concurrently with FDA approval of BEMA Fentanyl.

A significant double digit royalty on net sales of BEMA Fentanyl in the covered territories, subject to certain third party royalty adjustments and other adjustments in the event of certain specific supply disruptions. The License Agreement provides for certain guaranteed minimum annual royalties to the Company during the second through seventh years following the product s first commercial sale.

Sales milestones: A total of $30 million payable at:

$10 million when and if annual sales exceeds $75 million;

$10 million when and if annual sales exceeds $125 million; and

$10 million when and if annual sales exceeds $175 million

Also, pursuant to the License Agreement, the Company has been granted certain rights to co-promote BEMA Fentanyl using its own sales force, with financial support by Meda of such efforts for a period of 3 years. In addition, Meda is subject to certain minimum sales call and advertising and promotional expenditure requirements under the License Agreement, and has agreed to support costs of clinical development undertaken following FDA approval to pursue approval of additional indications for BEMA Fentanyl.

The Company has recorded the $30 million payment received as deferred revenue (see Note 1 for revenue recognition policy).

7. Convertible notes payable:

On April 10, 2007, the Company entered into a fifth amendment to the May 2005 convertible note with Laurus. Pursuant to the Fifth Amendment, Laurus agreed: (i) to exercise an aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of Common Stock, resulting in cash proceeds of approximately $3.2 million to the Company and (ii) to defer all principal payments under the Company s May 2005 note with Laurus to July 1, 2008. In consideration of these agreements, the Company issued to Laurus a new warrant to purchase 833,871 shares of Common Stock at $5.00 per share. The Company agreed to file by May 25, 2007 a registration statement registering the shares underlying such warrant, together with certain other shares of Common Stock beneficially held by Laurus (such statement was filed on May 24, 2007 and declared effective by the SEC on June 29, 2007). Subsequently, Laurus converted all outstanding principal and interest

under its May 2005 note into shares of Common Stock. As a result, all principal and interest under the Company s February and May 2005 convertible notes with Laurus has been either paid or fully converted into shares of Common Stock.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

7. Convertible notes payable (continued):

The Company applied the provisions of EITF 06-06 Debtor s Accounting for Modification (or exchange) of Convertible Debt Instruments to the above amendment dated April 10, 2007. Since the post-modification present value of the cash flows to the lender, including the $3,746,666 fair value of the new warrants, exceeded the fair value of such cash flows before the modification by more than 10%, the debt modification was accounted for as a debt extinguishment. As such, the debt was adjusted to its fair value; the $151,497 excess of the carrying value of the debt over its fair value (gain) net of the $3,746,666 fair value of the warrants was recorded as a loss on extinguishment of debt.

Activity with respect to the Company s February and May 2005 convertible notes payable with Laurus during the nine months ended September 30, 2007 was as follows:

Carrying value at January 1, 2007	$ 4,003,250
Conversion of debt to equity	(4,057,401)
Extinguishment of debt	(151,497)
Accretion of discount	205,648
Carrying value at September 30, 2007	$

During the nine months ended September 30, 2007, the Company wrote off approximately $463,000 in deferred loan costs associated with the Laurus February and May convertible notes.

8. 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 and subsequently adjusted to fair value at the close of each reporting period.

Significant new derivatives instruments (liabilities) issued during the nine months ended September 30, 2007 consisted of Common Stock warrants issued to CDC in connection with the March 12, 2007 note payable to CDC (see Note 4), warrants issued to Laurus in connection with the April 10, 2007 debt modification (see Note 7) and warrants issued to HCG in connection with the termination of a royalty rights purchase agreement (see Note 4).

The derivative liability is composed of the following:

	September 30, 2007	December 31, 2006
Embedded beneficial conversion option in the Laurus convertible debt	$	$ 1,993,655
Free standing warrants	9,841,272	5,802,276
Total	$ 9,841,272	$ 7,795,931

Shares into which derivative liability can be settled:

	September 30, 2007	December 31, 2006
Embedded beneficial conversion option		1,757,816
Free standing warrants	4,622,265	2,313,031
Total	4,622,265	4,070,847

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

8. Derivative Financial Instruments (continued):

Derivative gain (loss) in the accompanying statement of operations is related to the individual derivatives as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Embedded beneficial conversion option		$ 386,333	$ (3,430,698)	$ 767,385
Free standing warrants	2,687,233		2,440,430	693
Total	$ 2,687,233	$ 386,333	$ (990,268)	$ 768,078

9. Stockholders equity:

Common stock:

During the nine months ended September 30, 2007, under its convertible debt arrangements with Laurus, the debt holder opted to convert $4,057,401 of debt into 1,757,454 shares of Common Stock and further opted to be paid accrued interest of $201,155 in the form of 52,539 shares of Common Stock.

On January 24, 2007, Sigma Tau acquired 73,964 shares of Common Stock at a price of $3.38 per share for aggregate proceeds to the Company of $0.25 million in accordance with their Stock Purchase Agreement. The Stock Purchase Agreement dated January 20, 2005 provides for certain development milestones and purchases of stock thereof. No other consideration was paid.

On February 22, 2007, all 1,647,059 shares of the Company s Series A Preferred (which were issued to the former stockholders of Arius One upon the Company s acquisition of Arius One in August 2004) were exchanged with the holders thereof via redemption for an identical number of shares of newly designated Series C Non-Voting Convertible Preferred Stock (Series C Preferred). The rights associated with the Series C Preferred Stock were identical to those associated with the Series A Preferred in all material respects except that the Series C Preferred had different terms of conversion into shares of Common Stock.

The Company recorded the excess of the fair value of the Series C Preferred (based upon the fair value of the underlying Common shares into which the Series C Preferred was deemed likely to be convertible in the near term) over the carrying value of the Series A Preferred Stock redeemed as a preferred Stock constructive dividend. As of September 30, 2007, all 1,647,059 shares of Series C Preferred had been converted into a like number of shares of Common Stock.

Stock-based compensation:

As of September 30, 2007, there was approximately $3,400,000 of unrecognized compensation cost related to unvested share-based compensation awards granted. That cost is expected to be recognized over the next three years.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

9. Stockholders equity (continued):

During the nine months ended September 30, 2007, options were granted to certain employees and board members at prices equal to or above the market value of the Company s Common Stock on the dates the options were granted. A total of 1,364,446 options have been granted at a fair market value of $6,905,232. The options granted have a term of 10 years from the grant date and vest ratably either immediately or over a two or three year period, depending on the terms. The fair value of each option is amortized into compensation expense as vesting milestones are achieved. 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 traded options on the Company s Common Stock, historical volatility of the Company s 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, 2007 follows:

Expected price volatility	50.23%-65.78%
Risk-free interest rate	4.26%-5.06%
Weighted average expected life in years	5-6 years
Dividend yield	0

Option activity during the nine months ended September 30, 2007 was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Yrs)
Outstanding at January 1, 2007	2,023,704	$ 3.04	6.51
Forfeited	(242,093)	$ 4.40	
Exercised	(262,176)	$ 4.56	
Granted	1,364,446	$ 5.11	9.56
Outstanding at September 30, 2007	2,883,881	$ 3.93	7.71
Exercisable at September 30, 2007	1,654,532	$ 3.09	7.71

The fair market value of options granted in the nine months ended September 30, 2007 was $6,900,000.

14

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

9. Stockholders equity (continued):

Options outstanding at September 30, 2007 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	2,072,974	7.21	$ 2.89	
$ 5.01 10.0	793,745	9.19	$ 6.44	
$10.01 15.00	8,581	0.13	$ 11.80	
$15.01 20.00	8,581	0.13	$ 17.48	
	2,883,881			$ 2,166,784

Options exercisable at September 30, 2007 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	1,613,370	7.21	$ 2.89	
$ 5.01 10.00	24,000	9.19	$ 6.44	
$10.01 15.00	8,581	0.13	$ 11.80	
$15.01 20.00	8,581	0.13	$ 17.48	
	1,654,532			$ 1,617,701

Warrants outstanding at September 30, 2007 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.01 5.00	5,240,765	5.77	$ 3.44	
$ 5.01 10.00	700,000	4.04	$ 5.45	

	5,940,765	$ 3,365,077

Warrants exercisable at September 30, 2007 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.01 $ 5.00	5,215,774	5.77	$ 3.45	
$ 5.01 $ 10.00	700,000	4.04	$ 5.45	
	5,915,774			$ 3,313,086

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

10. 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,	
	2007	2006	2007	2006
Loss attributable to common stockholders	$ (3,891,073)	$ (3,919,395)	$ (24,789,200)	$ (12,613,731)
Basic and diluted:				
Weighted average shares outstanding (denominator)	19,061,503	13,938,146	16,542,222	13,259,684
Net loss per common share basic	$ (0.20)	$ (0.28)	$ (1.50)	$ (0.95)

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

11. Commitments and Contingencies:

MAS Capital Litigation

On or about April 19, 2004, the Company was named as the defendant in an action commenced by MAS Capital Inc. (MAS Capital) in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company has provided MAS Capital s counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleges fully release the Company. Upon MAS Capital s refusal to dismiss the action, notwithstanding the documents that fully release the Company, the Company filed an Amended Answer asserting a claim for attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital s claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on the Company s claim for attorneys fees and costs, but were unable to resolve in light of MAS Capital s intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the motion. Accordingly, the parties proceeded until resolution of the Company s counterclaim for attorneys fees and costs and either party could appeal at that point in time. On August 6, 2007, the U.S. District Court entered a final judgment on the Company s counterclaim pursuant to the parties stipulation of dismissal. MAS Capital was required to initiate any appeal within thirty days of the entry of final judgment. MAS Capital has now filed its appeal with the Seventh Circuit Court of Appeals. The parties are now in the briefing stage of the appeal. The Company strongly believes that the District Judge s order will be upheld on appeal and, accordingly, no potential liability has been recorded.

16

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

11. Commitments and Contingencies (continued):

CDC Matters

On October 17, 2006, CDC filed an action in New York State Supreme Court against the Company seeking to enjoin the Company from entering into a financing transaction with a third party pursuant to a purported right of first negotiation provision (the ROFN) granted to CDC under a Securities Purchase Agreement, dated May 16, 2006, between the Company and CDC (the SPA). On October 26, 2006, the Company entered into a Stipulation, Index no. 06/603626 (the Stipulation), with CDC to settle this case without prejudice pursuant to which the Company and CDC agreed to follow a procedure regarding the ROFN as modified by the Stipulation.

On March 12, 2007, the Company entered into a Dispute Resolution Agreement (the DRA) with CDC. Pursuant to the DRA, the Company and CDC have terminated the previously instituted dispute resolution procedures between the parties relating to the allegations and demands made by the parties against each other in August 2006 (the Disputed Matters). The effect of the DRA is that CDC has withdrawn its August 2006 claims to ownership of the Company s BEMA Fentanyl asset, which had been asserted by CDC as part of the Disputed Matters, and the Company has withdrawn its claims against CDC. The Company had previously rejected CDC s August 2006 allegations and demands. The resolution of the disputes under the DRA was without prejudice to the Disputed Matters of both the Company and CDC. Simultaneously with the Company and CDC s entry into the DRA, the Company and CDC entered into an amendment to the CDLA. The purpose of the amendment to the CDLA is to clarify certain reporting and other obligations between the parties regarding the development and commercialization of BEMA Fentanyl.

Concurrently with the parties negotiation of the DRA, CDC alleged that the Company had violated the ROFN. Specifically, in January 2007, CDC alleged by written notice that the Company s December 2006 note deferral agreements with Laurus Master Fund Ltd. (the Laurus Deferral Transaction) triggered the ROFN provisions. In order for the Company to avoid CDC s continued assertion of its alleged ROFN with respect to the Laurus Deferral Transaction, and in order to enter into the DRA with the resulting resolution of the August 2006 disputes, CDC required that, simultaneously with the entry into the DRA, the Company enter into to a $1.9 million financing with CDC (See Note 4) (the New CDC Financing). The New CDC Financing is intended to resolve CDC s January 2007 ROFN claims, notwithstanding the Company s rejection of CDC s assertion that the ROFN was triggered by the Laurus Deferral Transaction.

On September 5, 2007, in connection with CDC s consent to the Meda transaction discussed in Note 6, the Company and CDC entered into a second Dispute Resolution Agreement (DRA II) pursuant to which the Company and CDC agreed to waive and dismiss with prejudice all current disputes between the Company and CDC concerning each of the CDLA and the SPA.

As a condition to CDC s entrance into DRA II and its consent to the Meda transaction, the Company and CDC entered into a Royalty Purchase and Amendment Agreement, dated September 5, 2007 (the RPAA) pursuant to which: (i) the right of first negotiation on Company financings as set forth in the Stipulation was amended to covert such right into a right of first refusal on Company financings (the ROFR) and (ii) the Company 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).

Pursuant to the ROFR, if the Company desires to enter into a transaction with any third party to offer and sell its debt and/or equity securities for cash other than in connection with: (i) a bona fide commercial partnering transaction relating to BEMA™ Fentanyl product or (ii) any debt financing from a federal or state accredited

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

11. Commitments and Contingencies (continued):

bank, provided the annualized interest rate thereunder will not exceed 18% (a Financing Transaction), the Company shall first provide CDC a written notice containing all of the terms and conditions pursuant to which the Company would enter the Financing Transaction (the Definitive Terms). For a period of ten (10) days following CDC s receipt of the Definitive Terms (the Acceptance Period), CDC shall have the right, but not the obligation (the Acceptance Right), to elect in writing to engage in the Financing Transaction on the Definitive Terms. If, during the Acceptance Period, CDC elects to exercise its Acceptance Right, the Company and CDC agree to then exclusively negotiate definitive documentation relating to the Financing Transaction for a period not to exceed thirty (30) days from the date of CDC s exercise of its Acceptance Right. The definitive documentation shall be based upon, and shall be consistent in all material respects with, the Definitive Terms, without modification. If, during the Acceptance Period, CDC does not elect to exercise its Acceptance Right, or, in the event the Acceptance Right is exercised but a closing of the Financing Transaction does not occur within the thirty (30) day period referred to above, then the Company shall have sixty (60) days in which to consummate a Financing Transaction with any third party with no further action or approval required by the CDC; provided, however, that the terms and conditions of such transaction shall be not less favorable to the Company than the terms and conditions set forth in the Definitive Terms.

The ROFR will cease at any time the Company maintain a volume weighted average stock price of $9.00 per share (as adjusted for stock splits, reverse stock splits, stock dividends and such similar transactions) for ten (10) trading days during any twenty (20) consecutive trading day period.

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 (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 product sales, if any, occur.

In connection with the RPAA, the Company and CDC amended the promissory note dated March 12, 2007 (the March Note) (See Note 4) in the amount of $1,900,000, executed by the Company in favor of CDC so that any breach or default under the RPAA shall also be considered an event of default under the March Note.

Doyen Medipharm

On August 28, 2007, the Company agreed with Doyen Medipharm Inc. to purchase a BEMA™-related pharmaceutical device production machine. The Company made an initial payment in September 2007 of $711,650 pursuant to a purchase order (included in other assets in the accompanying financial statements) toward the total cost, which is $2,372,165. Payments will be made in separate increments during the production of the equipment.

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

11. Commitments and Contingencies (continued):

New Office Lease

On November 1, 2007, the Company relocated its corporate offices to a new location and executed a lease with Highwoods Realty Limited Partnership. The lease term is for approximately 63 months and base rent for this term is $589,455, payable in monthly installments.

12. Restatement of Previously Reported Financial Information:

During the three months ended September 30, 2006, the Company licensed the European manufacturing and distribution rights for BEMA™ Fentanyl (BEMA Fentanyl) to Meda. In connection with this agreement, the Company received a $2,500,000 initial non-refundable payment for delivery of the licensed technology and recognized that amount as revenue during the quarter ended September 30, 2006 since the Company and its independent registered public accounting firm believed that it had no significant continuing obligations with respect to the license delivery. The agreement provides for additional payments to the Company upon the achievement of certain milestones as well as payments for the Company s possible future manufacture of BEMA Fentanyl for Meda.

The Company and its independent registered public accounting firm have reevaluated the accounting for the $2,500,000 payment based on the criteria of both SEC Staff Accounting Bulletin No. 104 and EITF 00-21 (see Note 1 - Revenue recognition) and determined that revenue recognition should have been deferred and recognized over the estimated term of the license (the term is expected to commence upon regulatory approval of BEMA Fentanyl in various European jurisdictions and generally terminates with the expiration of the patents underlying the licensed technology in the various European jurisdictions). As such, the unaudited quarterly financial information as previously reported as of and for the periods ended September 30, 2006 has been restated as follows:

	Balance Sheet September 30, 2006		
	As previously reported (1) (Unaudited)	restatement adjustment (2)	Restated
ASSETS			
Current assets:			
Cash and cash equivalents	$ 4,086,301	$	$ 4,086,301
Accounts Receivable	75,000		75,000
Due from related party	112,876		112,876
Prepaid expenses and other current assets	216,270		216,270
Total current assets	4,490,447		4,490,447
Equipment, net	447,908		447,908
Goodwill	2,715,000		2,715,000
Other intangible assets:			
Licenses	2,442,171		2,442,171

Acquired product rights	2,000,000		2,000,000
Non-compete agreements	500,000		500,000
Accumulated amortization	(953,741)		(953,741)
Total other intangible assets	3,988,430		3,988,430
Other assets	558,986		558,986
Total assets	$ 12,200,771	$	$ 12,200,771

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

12. Restatement of Previously Reported Financial Information (continued):

LIABILITIES AND STOCKHOLDERS EQUITY			
Current liabilities:			
Current maturities of convertible notes payable	$ 3,194,523	$	$ 3,194,523
Current maturity of note payable	1,000,000		1,000,000
Accounts payable and accrued liabilities	1,461,397		1,461,397
Due to related parties	819,229		819,229
Deferred revenue	145,360		145,360
Dividends payable	136,356		136,356
Derivative liability	618,286		618,286
Total current liabilities	7,375,151		7,375,151
Convertible notes payable, less current maturities	553,507		553,507
Deferred revenue		2,500,000	2,500,000
Total liabilities	7,928,658	2,500,000	10,428,658
Stockholders equity:			
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 1,647,059 issued and outstanding	3,705,883		3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000		1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized, 13,953,637 and 11,828,637 shares issued; 13,938,146 and 11,813,146 shares outstanding in 2006 and 2005, respectively	13,954		13,954
Additional paid-in capital	32,788,888		32,788,888
Treasury stock, at cost, 15,491 shares, 2006 and 2005	(47,183)		(47,183)
Accumulated deficit	(33,639,429)	(2,500,000)	(36,139,429)
Total stockholders equity	4,272,113	(2,500,000)	1,772,113
Total liabilities and stockholders equity	$ 12,200,771	$	$ 12,200,771

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

12. Restatement of Previously Reported Financial Information (continued):

	Statement of Operations					
	Three Months Ended September 30, 2006			Nine Months Ended September 30, 2006		
	As previously reported (1)	Restatement Adjustment (2)	Restated	As previously reported (1)	Restatement Adjustment (2)	Restated
Revenues:						
Sponsored research revenues	$ 51,368	$	$ 51,368	$ 75,717	$	$ 75,717
License fees and royalties, related parties	12,973		12,973	51,578		51,578
License fees, European	2,500,000	(2,500,000)		2,500,000	(2,500,000)	
Research fees				10,000		
Total revenues	2,564,341	(2,500,000)	64,341	2,637,295	(2,500,000)	137,295
Expenses:						
Research and development	1,584,362		1,584,362	5,750,394		5,750,394
Related party research and development	758,770		758,770	2,208,471		2,208,471
Product development costs				746,591		746,591
General and administrative	1,501,581		1,501,581	3,135,163		3,135,163
Related party general and administrative	60,459		60,459	105,748		105,748
Total expenses	3,905,172		3,905,172	11,946,367		11,946,367
Loss from operations	(1,340,831)	(2,500,000)	(3,840,831)	(9,309,072)	(2,500,000)	(11,809,072)
Other income, net				7,663		7,663
Interest expense, net	(448,450)		(448,450)	(1,531,597)		(1,531,597)
Derivative gain	386,333		386,333	768,078		768,078
Loss before income taxes	(1,402,948)	(2,500,000)	(3,902,948)	(10,064,928)	(2,500,000)	(12,564,928)
Income tax benefit (expense)						
Net loss	(1,402,948)	(2,500,000)	(3,902,948)	(10,064,928)	(2,500,000)	(12,564,928)
Preferred stock dividends	(16,447)		(16,447)	(48,803)		(48,803)
Loss attributable to common stockholders	$ (1,419,395)	(2,500,000)	$ (3,919,395)	$ (10,113,731)	(2,500,000)	$ (12,613,731)
Per share amounts, basic and diluted:						
Loss attributable to common stockholders	$ (0.10)		$ (0.28)	$ (0.76)		$ (0.95)

Weighted average common stock shares outstanding - basic and diluted	13,938,146	13,938,146	13,259,684	13,259,684

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

12. Restatement of Previously Reported Financial Information (continued):

Additionally, the balance sheet information as of December 31, 2006 as previously reported in the Company s 2006 annual report on Form 10KSB and also included herein has also been restated as the result of this matter as follows:

	As previously reported (3)	Balance Sheet December 31, 2006 Restatement Adjustment (1)	Restated
ASSETS			
Current assets:			
Cash and cash equivalents	$ 2,172,104	$	$ 2,172,104
Accounts receivable	42,118		42,118
Due from related party	8,523		8,523
Prepaid expenses and other current assets	180,863		180,863
Total current assets	2,403,608		2,403,608
Equipment, net	379,654		379,654
Goodwill	2,715,000		2,715,000
Other intangible assets:			
Licenses	1,941,942		1,941,942
Acquired product rights	1,938,462		1,938,462
Total other intangible assets	3,880,404		3,880,404
Deferred loan costs	463,268		463,268
Total assets	$ 9,841,934	$	$ 9,841,934

	As previously reported (3)	December 31, 2006 Restatement adjustment (1)	Restated
LIABILITIES AND STOCKHOLDERS DEFICIT			
Current liabilities:			
Notes payable	$ 1,000,000	$	$ 1,000,000
Notes payable, related parties			
Accounts payable and accrued liabilities	2,032,765		2,032,765
Due to related parties	1,001,177		1,001,177
Deferred revenue	70,360		70,360
Dividends payable	152,803		152,803
Derivative liability (Note 6)	7,795,931		7,795,931

Total current liabilities	12,053,036		12,053,036
Convertible notes payable, less current maturities	4,003,250		4,003,250
Deferred revenue		2,500,000	2,500,000
Total liabilities	16,056,286	2,500,000	18,556,286

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006 (RESTATED)

(Unaudited)

Commitments and contingencies (Note 9)			
Stockholders deficit:			
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, 0 and 1,647,059 shares issued and outstanding in 2007 and 2006, respectively	3,705,883		3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 0 and 341,176 shares issued and outstanding in 2007 and 2006, respectively	1,450,000		1,450,000
Series C Preferred stock, $.001 par value; 1,647,059 shares designated, 9,570 and 0 issued and outstanding in 2007 and 2006, respectively			
Common stock, $.001 par value; 45,000,000 shares authorized, 19,016,532 and 14,048,637 shares issued; 19,001,041 and 14,033,146 shares outstanding in 2007 and 2006, respectively	14,049		14,049
Additional paid-in capital	32,132,609		32,132,609
Treasury stock, at cost, 15,491 shares	(47,183)		(47,183)
Accumulated deficit	(43,469,710)	(2,500,000.00)	(45,969,710)
Total stockholders deficit	(6,214,352)	(2,500,000.00)	(8,714,352)
Total liabilities and stockholders deficit	$ 9,841,934		$ 9,841,934

(1) Source Financial statements included in September 30, 2006 Form 10-QSB
(2) Adjustment to defer revenue associated with upfront, non-refundable payment received associated with the European licensing rights to BEMA.
(3) Source-Financial statements included in December 31, 2006 Form 10KSB.

Table of Contents

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

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

For the three months ended September 30, 2007 compared to the three months ended September 30, 2006 (restated)

Sponsored Research Revenue. For the three-month periods ended September 30, 2007 and 2006, the Company reported $0.00 million and $0.05 million, respectively, from a grant from the National Institutes of Health. The grant expired in 2006 and currently no additional revenue is being earned.

Royalty Revenues. For the three-month periods ended September 30, 2007 and 2006, the Company reported $0.02 million and $0.01 million, respectively, in royalty revenue from a related company.

Research and Development. Research and development expenses of approximately $3.3 million and $2.3 million were incurred during the three-month periods ended September 30, 2007 and 2006. These aforementioned amounts included $1.0 million and $0.8 million, respectively, paid to a contract research organization, which is a shareholder. The Company s scientific staff continued to work toward increased development and application of our BEMA® and Bioral® technologies and other drug-related areas. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA® and Bioral® drug delivery technologies.

General and Administrative Expenses. General and administrative expenses of approximately $2.4 million and $1.5 million were incurred in the three-month periods ended September 30, 2007 and 2006, 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. The Company granted employees and board members stock based compensation valued at $0.7 million and $0.4 million during the three months ended September 30, 2007 and 2006 respectively, which is included in the aforementioned general and administrative amounts.

Interest Expense. Interest expense for the periods ended September 30, 2007 and 2006 was principally composed of interest expense for deferred loan costs and notes payable discount amortization, net of interest earnings on invested cash.

Financing Expense, ***related party.*** Financing expense for the 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 to purchase 475,000 shares of Common Stock at $5.55 per share. No such financing expense occurred during the same period in 2006.

Derivative Gain. Derivative gain during 2007 and 2006 is related to the adjustment of related derivative liabilities to fair value. These derivatives relate to the Laurus and CDC financings (see Notes 4, 5 and 6 to the condensed consolidated financial statements).

***Income Taxes*.** While net operating losses were generated during the three month period ended September 30, 2007 and 2006, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes our historical operating performance and our reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Table of Contents

For the Nine Months Ended September 30, 2007 Compared to the Nine Months Ended September 30, 2006 (restated)

Sponsored Research Revenue. During the nine-month periods ending September 30, 2007 and September 30, 2006, we reported $0.00 million and $0.08, respectively of sponsored research revenues from a grant from the National Institutes of Health. The grant expired in 2006 and currently no additional revenue is being earned.

Research Fee Revenues. During the nine-month periods ending September 30, 2007 and September 30, 2006 we reported research revenues of $0.025 million and $0.01 million respectively.

Royalty Revenues. During the nine-month periods ending September 30, 2007 and September 30, 2006, we reported $0.06 million and $0.05 million of royalty revenue respectively from a related company.

Research and Development. Research and development expenses of approximately $9.6 million and $8.7 million were incurred during the respective nine-month periods ended September 30, 2007 and 2006. These aforementioned amounts included $4.0 million and $2.2 million, respectively, paid to a contract research organization that is 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.

General and Administrative Expenses including Stock-based Compensation. General and administrative expenses of approximately $4.6 million and $3.2 million were incurred in the nine-month periods ended September 30, 2007 and 2006, 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. The Company granted employees and board members stock based compensation of $0.9 million and $0.4 million during the nine months ended September 30, 2007 and 2006 respectively, which are included in the aforementioned general and administrative amounts.

Interest Expense Net. Interest expense for the periods ended September 30, 2007 and 2006 was principally composed of interest expense for 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 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 to purchase 475,000 shares of Common Stock at $5.55 per share. No such financing expense occurred during the same period in 2006.

Derivative Gain (Loss). Derivative gain (loss) during 2007 and 2006 is related to the adjustment of derivative liabilities to fair value. These derivatives relate to the Laurus and CDC financings (see Notes 4, 5, and 6 to the accompanying financial statements).

Income Taxes. While net operating losses were generated during the nine months ended September 30, 2007 and 2006, we did not recognize any benefit associated with these losses, as all related deferred tax assets have been fully reserved. Financial Accounting Standards Board Statement No. 109 provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon available data, which includes historical operating performance and reported cumulative net losses in prior years, we have provided a full valuation allowance against our net deferred tax assets as the future realization of the tax benefit is not sufficiently assured.

Table of Contents

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, and from funded research arrangements. We have not generated revenue from the sale of any product but have generated deferred revenues from licensing arrangements, research fees and sponsored research in 2007 and 2006. We intend to finance our research and development and commercialization efforts and our 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.

We have incurred significant net losses and negative cash flows from operations since our inception. As of September 30, 2007, we had stockholders deficit of $14.9 million, versus a deficit of $6.7 million at December 31, 2006.

We used $18.0 million of cash for operations during the nine months ended September 30, 2007. The net loss for the nine month period ended September 30, 2007 of $20.9 million included non-cash charges of $8.4 million, primarily related to the cost of warrants issued and accounting requirements related to derivatives.

On September 3, 2004, we entered into an Equity Line of Credit Agreement with HCG II, a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman. Pursuant to the Equity Line Agreement as amended, HCG was to, at our request, invest up to $4.0 million in the Company from August 23, 2004 through December 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock, or Series B Preferred. As of December 31, 2006, when the Equity Line expired, $1.45 million had been drawn under the Equity Line Agreement. On January 10, 2007, HCG converted 341,176 shares of the Company s Series B Convertible Preferred Stock (consisting of all said Series B Preferred Shares outstanding) into 341,176 shares of Common Stock. No other consideration was paid. HCG also acquired 59,226 shares of Common Stock pursuant to the conversion of accrued and unpaid dividends on the Series B Convertible Preferred Stock.

In February and May 2005, we consummated two separate $2.5 million secured convertible debt financings from Laurus. Net proceeds from the financing were used primarily to retire a secured equipment loan and were used to support research and development opportunities and for general working capital purposes.

On May 16, 2006, we consummated a transaction with CDC pursuant to which $7 million in funds previously committed by CDC under the CDLA to fund our clinical development of BEMA Fentanyl was converted into shares of our common stock at a value of $3.50 per share. As a result of this transaction, CDC was issued 2 million shares of our common stock and 904,000 common stock warrants at $3.00 each in return for accelerating the funding of the aggregate commitment under the CDLA and for eliminating the $7 million milestone payable to CDC upon the approval by the FDA of BEMA Fentanyl which had been required under the CDLA.

On January 24, 2007, Sigma Tau acquired for $0.25 million 73,964 shares of our Common Stock at a price of $3.38 per share in accordance with their Stock Purchase Agreement. The Stock Purchase Agreement dated January 20, 2005 provides for certain development milestones and purchases of stock thereof. No other consideration was paid.

On February 22, 2007, all 1,647,059 shares of our Series A Preferred Stock were exchanged with the holders thereof for an identical number of shares of newly designated Series C Non-Voting Convertible Preferred Stock. The rights associated with the Series C Preferred Stock are identical to those associated with the Series A Preferred Stock in all material respects except that the Series C Preferred Stock has different terms of conversion into shares of Common Stock.

Table of Contents

On March 12, 2007, we obtained from CDC a one-year, unsecured $1.9 million loan which accrues interest at 10.25%. In connection with this loan, we issued CDC a warrant to purchase 1 million shares of Common Stock with an exercise price of $3.80. We are not required to file a registration statement with the SEC to register the shares of Common Stock underlying such warrant for a period of one year (i.e., a registration statement must be filed by March 12, 2008). CDC was also granted piggyback registration rights with respect to such shares of Common Stock which come into effect only after March 12, 2008. The warrant contains weighted average anti-dilution protection. The proceeds from this loan were used for general corporate purposes and for the continued development of BEMA Fentanyl.

On March 30, 2007, we closed with HCG a $1.0 million unsecured, non-interest bearing note, due June 30, 2007. As consideration for the loan made by HCG, we granted HCG the right, for a period of six months, to participate in and enter into a royalty purchase agreement. The consideration to be paid upon exercise of the right, which could have been demanded by either us or HCG at any time before September 30, 2007, is $5.0 million. The royalty would have been paid based on a low, single digit tiered percentage of net sales of the BEMA Fentanyl once the product is approved and commercial sales begin. In addition, if the royalty purchase agreement is entered into, we would issue a warrant to HCG to purchase 475,000 shares of Common Stock at $5.55 per share (the closing price on April 2, 2007). On September 5, 2007, we entered into a Termination Agreement whereby we and HCG terminated HCG s royalty purchase option and we issued a warrant to HCG to purchase 475,000 shares of our Common Stock at $5.55 per share (the closing price on April 2, 2007). On September 14, 2007, we paid the note in full to HCG.

On April 10, 2007, we entered into a fifth amendment to the May 2005 convertible note with Laurus. Pursuant to the fifth amendment, Laurus agreed: (i) to exercise an aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of Common Stock, resulting in cash proceeds of approximately $3.2 million to us and (ii) to defer all principal payments under our May 2005 note with Laurus (which remaining balance has been converted as of April 25, 2007) to July 1, 2008. In consideration of these agreements, the Company issued to Laurus a new warrant to purchase 833,871 shares of Common Stock at $5.00 per share. We agreed to file a registration statement registering the shares underlying such warrant by July 31, 2007 (subsequently amended to May 25, 2007), which registration statement was filed on May 24, 2007 and declared effective June 29, 2007.

Laurus converted the remaining balance of approximately $4.06 million of principal of its convertible notes and $0.20 million of interest into common stock from January through April 2007.

On September 14, 2007, we received an initial $30 million non-refundable milestone payment from Meda AB under our exclusive license agreement for the commercialization of BEMA Fentanyl in the U.S., Canada and Mexico (see Note 6 to the accompanying financial statements).

Our existing cash and cash equivalents are considered by management to be sufficient to finance our basic operations, capital expenditures and debt obligations through the end of the third quarter 2008.

Although the $30 million payment received in September 2007 and expected future payments from Meda will make us cash flow positive in 2007 and enhance our prospects for positive cash flow in 2008, it is possible that additional outside capital may be required in order to support our planned expanded, as well as future, development activities around our current pipeline of products in development or other initiatives that we may elect to pursue. If required, management believes that we will be able to secure such additional funding at levels sufficient to support planned expanded operations. However, there can be no assurance that additional capital will be available on favorable terms, if at all, or that such expanded operations will be initiated or maintained. If adequate outside funds are not available, we could likely be required to significantly reduce or refocus our planned expanded 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 our financial condition.

Table of Contents

Critical Accounting Policies and Estimates

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

Revenue Recognition

The Company recognizes revenue in accordance with the SEC s Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements. When evaluating multiple element arrangements, the company considers whether the components of the arrangement represents separate units of accounting as EITF 00-21. Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether it is separable from the other aspects of the contractual relationship. See Note 1 to our condensed consolidated financial statements for further discussion regarding revenue recognition. Ultimately, the objective of our analysis of each customer contract based on the aforementioned criteria is to determine the amount and appropriate accounting period in which revenue should be recognized. To date our primary source of revenue has been the issuance of European and U.S. licensing rights to BEMA Fentanyl and related formulations. All amounts received have currently been recorded as deferred revenue in our financial statements.

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, 2007 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. Our carrying value of other, amortizing intangible assets at September 30, 2007 was $6.6 million, net of accumulated amortization of $.8 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 2007 or 2006.

Table of Contents

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 2007 or 2006.

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 the Company s common stock. The values of 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 discussed in the previous paragraph except contractual lives of the derivative instruments are utilized rather than expected option terms as discussed in the previous paragraph.

ITEM 3. Controls and Procedures

The Company s Chief Executive Officer and Chief Financial Officer (collectively, the Certifying Officers) are responsible for establishing and maintaining disclosure controls and procedures for the Company. Such officers have concluded (based on their evaluation of these controls and procedures as of a date within 90 days of the filing of this report) that the Company s disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in this report is accumulated and communicated to the Company s management, including its principal executive officers as appropriate, to allow timely decisions regarding required disclosures. The Certifying Officers also have indicated that there were no significant changes in the Company s internal controls or other factors that could significantly affect such controls subsequent to the date of their evaluation, and there were no corrective actions with regard to significant deficiencies and material weaknesses.

NOTE ON FORWARD-LOOKING STATEMENTS

The information set forth in this Report on Form 10-QSB under the 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

Table of Contents

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 2006 Annual Report and other factors detailed from time to time in the Company s other filings with the Securities and Exchange Commission. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Report.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

MAS Capital

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 seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company has provided MAS Capital s counsel with copies of documents executed by MAS Capital and its affiliates that the Company alleges fully release them. Upon MAS Capital s refusal to dismiss the action, notwithstanding the documents that fully release the Company; the Company filed an Amended Answer asserting a claim for attorneys fees and costs expended to defend the case, pursuant to an Indiana frivolous litigation statute. The Company also filed a motion for summary judgment on June 9, 2005 and on August 25, 2006, the U.S. District Court granted the motion for summary judgment on all of MAS Capital s claims for relief. On September 6, 2006, the parties, by their respective counsel, appeared before the Judge for a settlement conference on the Company s claim for attorneys fees and costs, but were unable to resolve in light of MAS Capital s intent to appeal the summary judgment order. MAS Capital subsequently filed its Motion for Certificate of Appealability of Interlocutory Order requesting the Judge certify the case for interlocutory appeal, which would allow MAS Capital to appeal the summary judgment order at this time rather than once the entire case had yet to be decided on the merits. The Judge denied the Motion. Accordingly, the parties were to proceed until resolution of the Company s counterclaim for attorneys fees and costs and either party could appeal at that point in time. On August 6, 2007, the U.S. District Court entered a final judgment on the Company s counterclaim pursuant to the parties stipulation of dismissal. MAS Capital was required to initiate any appeal within thirty days of the entry of final judgment. MAS Capital has now filed its appeal with the Seventh Circuit Court of Appeals. The parties are now in the briefing stage of the appeal. The Company strongly believes that the District Judge s order will be upheld on appeal and, accordingly, no potential liability has been recorded.

CDC

On October 17, 2006, CDC filed an action in New York State Supreme Court against the Company seeking to enjoin the Company from entering into a financing transaction with a third party pursuant to CDC s purported ROFN granted to CDC under the SPA. On October 26, 2006, the Company entered into the Stipulation to settle this case without prejudice pursuant to which the Company and CDC agreed to follow a procedure regarding the ROFN as modified by the stipulation. On March 12, 2007, the Company entered into the DRA with CDC pursuant to which the Company and CDC have terminated the previously instituted dispute resolution procedures between the parties relating to the Disputed Matters. The effect of the DRA is that CDC has withdrawn its August 2006 claims to ownership of the Company s BEMA Fentanyl asset, which had been asserted by CDC as part of the Disputed Matters, and the Company has withdrawn its claims against CDC. The Company had previously rejected CDC s August 2006 allegations and demands. The resolution of the disputes under the DRA was without prejudice to the Disputed Matters of both the Company and CDC. Simultaneously with the Company and CDC s entry into the DRA, the Company and CDC entered into an amendment to the CDLA. The purpose of the amendment to the CDLA is to clarify certain reporting and other obligations between the parties regarding the development and commercialization of BEMA Fentanyl.

Concurrently with the parties negotiation of the DRA, CDC alleged that the Company had violated the ROFN. Specifically, in January 2007, CDC alleged by written notice that the Laurus Deferral Transaction triggered the ROFN provisions. In order for the Company to avoid CDC s continued assertion of its alleged ROFN with

Table of Contents

respect to the Laurus Deferral Transaction, and in order to enter into the DRA with the resulting resolution of the August 2006 disputes, CDC required that, simultaneously with the entry into the DRA, the Company enter into the New CDC Financing. The New CDC Financing was intended to resolve CDC s January 2007 ROFN claims, notwithstanding the Company s rejection of CDC s assertion that the ROFN was triggered by the Laurus Deferral Transaction.

On September 5, 2007, in connection with CDC s consent to the Meda transaction, the Company and CDC entered into DRA II, pursuant to which the Company and CDC agreed to waive and dismiss with prejudice all current disputes between the Company and CDC concerning each of the CDLA and the SPA. As a condition to CDC s entrance into the DRA II and its consent to the Meda transaction, the Company and CDC entered into the RPAA pursuant to which: (i) the ROFN was amended to covert such right into the ROFR and (ii) the Company granted CDC a 1% royalty on the Next BEMA Product. See Note 11 to the accompanying financial statements for further information.

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

On July 26, 2007, the Company held its 2007 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 2008 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.	13,227,698	11,720
Mark A. Sirgo	13,168,251	71,167
Raphael J. Mannino	13,161,084	78,334
William B. Stone	13,169,051	70,367
John J. Shea	13,163,104	76,314
William S. Poole	13,168,931	70,487
Thomas D Alonzo	13,168,131	71,287

Proposal 2: A proposal to ratify the appointment by the Audit Committee of the Company s Board of Directors of Aidman Piser & Company, P.A. as the Company s independent auditors for the fiscal year ending December 31, 2007 was approved as follows:

Shares Voted For	Shares Withheld	Shares Abstaining
13,216,667	8,453	14,298

Item 6. Exhibits.

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

* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

32

Table of Contents

SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: November 14, 2007

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

Date: November 14, 2007

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

S-1