BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB/A
November 21, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB/A

(Amendment No. 2)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

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

Commission file number 0-28931

BioDelivery Sciences International, Inc.

(Name of small business issuer in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
801 Corporate Center Drive, Suite 210	
Raleigh, NC	**27607**

(Address of principal executive offices) **(Zip Code)**

Issuer s telephone number: (919) 582-9050

2501 Aerial Center Parkway Suite 205

Morrisville, NC 27560

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

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 par value; **NASDAQ-Capital Market**

(Title of class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act ¨

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 ¨

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of issuer s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. ¨

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

Issuer s revenues for fiscal year 2006 were $275,778.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of April 13, 2007 was approximately $69,831,096 based on the closing sale price of the company s common stock on such date of U.S. $6.03 per share, as reported by the Nasdaq Capital Market.

As of April 13, 2007, there were 16,666,777 shares of the company s common stock outstanding.

Transitional Small Business Disclosure Format: Yes ¨ No x

EXPLANATORY NOTE

This Amendment No. 2 on Form 10-KSB/A (the Amendment) to the Annual Report on Form 10-KSB of BioDelivery Sciences International, Inc. (the Company) for the year ended December 31, 2006, which was filed with the Securities and Exchange Commission on April 17, 2007 (the Original Filing) and amended on May 31, 2007, is being filed for the limited purpose of amending Item 6. Management s Discussion and Analysis of Financial Condition and Results of Operations (only to modify revenue recognition) and Item 7. Financial Statements (only to show deferred revenue) to the Original Filing to reflect the November 9, 2007 reevaluation by the Company s Audit Committee and the Company s independent registered public accounting firm of the accounting for a $2,500,000 milestone payment received by the Company in September 2006 based on criteria of both SEC Staff Accounting Bulletin No. 104 and EITF 00-21 that revenue recognition should have been deferred and recognized over the estimated term of the license.

As a result of these amendments, the certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as filed as exhibits to the Original Filing, have been re-executed and re-filed as of the date of this Amendment.

Except for the amendments described above, this Amendment does not modify or update other disclosures in, or exhibits to, the Original Filing, as amended. Readers should be aware that certain information contained herein is as of the date of the Original Filing and may therefore not be current as such information is not being amended pursuant to this Amendment. Please see the Company s filings with the Securities and Exchange Commission for more current information.

Item 6. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those which are not within our control.

Limited Operating History; Background of Our Company

Until 2002, we were a development stage company. Our first license agreement was funded in 2003 in the amount of $2 million, and we had an additional license funded in 2004 for $1 million, as part of our acquisition of Arius. We expect to continue research and development of our drug delivery technologies, and while we are seeking additional license agreements, which may include up-front payments, we anticipate nominal royalty revenues from the sale or commercialization of our products under development (other than license fees) during 2007. We anticipate that funding for the next several years will come primarily from the sale of securities, collaborative research agreements, including pharmaceutical companies, grants from public service entities and government entities, and potential exercises of our warrants.

In 2001, the National Institutes of Health awarded us a three-year $2.7 million Small Business Innovation Research Grant, which was fully funded through 2004, and which was utilized in our research and development efforts. We had an additional grant of approximately $0.6 million which was funded through July 2006. No additional funds are available on this grant.

We have a limited history of operations, and while we have received license revenues in 2003, 2004, 2005 and 2006 for licensing our technology, we anticipate that our quarterly results of operations will fluctuate significantly for the foreseeable future. We believe period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies maturing in commercialization of their technologies, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. For the foreseeable future, we must, among other things, seek regulatory approval for and commercialize our proposed drugs, which may not occur. We may not be able to appropriately address these risks and difficulties. We may require additional funds to complete the development of our technology and to fund expected operations in the next several years.

Critical Accounting Policies and Estimates

Revenue Recognition

We recognize revenue in accordance with the SEC s Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements. When evaluating multiple element arrangements, we consider 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 December 31, 2006 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 December 31, 2006 was $3.88 million, net of accumulated amortization of $.6 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 2006 or 2005.

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 intangible in either 2006 or 2005.

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 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. In applying the Black-Scholes options-pricing model during 2006, we assumed no dividend yield, risk-free interest rates ranging from 4.5% to 4.7%, expected option terms ranging from 5 to 6 years (for employee options), a volatility factor range between 54.5% to 89.5%, share prices ranging from $2.05 to $2.69, and option exercise prices ranging from $2.05 to $2.69.

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.

For the Year Ended December 31, 2006 Compared to the Year Ended December 31, 2005

Sponsored Research Revenue. During the year ended December 31, 2006, we recognized sponsored research revenue of $0.08 million, compared to $0.4 million in the prior year.

Milestone and Royalty Revenues. During the year ended December 31, 2005, we recognized milestone revenue of $0.4 million relating to Emezine®. In addition, we recognized $0.07 million and $0.06 million in royalty revenue in 2006 and 2005, respectively, under our license agreement with Accentia relating to CRS.

Research and Development Expenses. During the years ended December 31, 2006 and 2005, research and development expenses totaled $9.3 million and $6.5 million, respectively. Our scientific staff continued to work toward increased development and application of our BEMA and Bioral® cochleate technologies and other drug-related areas. Funding of this research was obtained through sponsored research revenue, exercise of options by directors, sales of securities and funding of an equity line of credit from HCG. Research and development expenses generally include salaries for key scientific personnel, research supplies, facility rent, lab equipment depreciation and a portion of overhead operating expenses and other costs directly related to the development and application of the BEMA and Bioral® drug delivery technologies.

General and Administrative Expenses. During the years ended December 31, 2006 and 2005, general and administrative expenses totaled $5.1 million and $3.6 million, respectively. General and administrative costs include legal and professional fees, office supplies, travel costs, executive personnel costs, consulting fees, and business development costs. Product development cost in 2006 is warrant expense related to a securities purchase agreement. Furthermore, we incurred expenses in 2005 of approximately $0.08 million related to operating activities of our currently inactive Bioral Nutrient Delivery, LLC subsidiary that commenced in 2003. There were no expenses related to this subsidiary in 2006. The increase in general and administrative expenses in 2006 is primarily due to increased professional and legal fees incurred in connection with legal due diligence associated with licensing transactions, increased patent costs, stock-based compensation (related to our adoption of FAS 123R), and investor relations.

Product Development Expense. In 2006, we issued 601,120 warrants valued at $0.7 million in connection with the initial $2.0 million deposit transaction with CDC Clinical Development Licensing Agreement for BEMA Fentanyl. We had no such expense in 2005.

Interest Income (Expense), Net. During the year ended December 31, 2006 we had net interest expense of $1.95 million, compared to $1.35 million in 2005. The increase in net interest expense is primarily due to amortization of debt discount and interest paid to Laurus for the two convertible notes. Interest income for years ending 2006 and 2005 was nominal.

Derivative Gain (loss). Derivative loss in 2006 is related to the adjustment of derivative liabilities to fair value as of December 31, 2005 and subsequent changes in fair value in 2006. These derivatives relate to the Laurus financing (see Notes 1 and 7 to financial statements) and warrants issued to CDC.

Debt extinguishment (loss). During the year ended December 31, 2006, we had a debt extinguishment loss related to the debt modification that arose from the amendments to the Laurus convertible term notes and related deferral warrants.

Income Tax Benefit and sale of state tax loss carryforwards. We incurred net operating losses during both years presented, and we did not recognize any benefit associated with these losses. We had federal net operating loss carryforwards of $33.0 million at December 31, 2006 and $25.5 million of state carryforwards. The federal net operating loss carryforwards expire beginning in 2020, if not utilized. We sold New Jersey state tax credits and net operating losses in 2005 of $4.5 million, which generated cash of $0.5 million in 2005. The state operating loss carryforwards expire beginning in 2008, if not utilized. Financial Accounting Standards Board Statement No.109 provides for the recognition of deferred tax assets if realization 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.

Item 7. Financial Statements.

Our Consolidated Financial Statements and Notes thereto, as amended, and the report of Aidman, Piser & Company, P.A., our independent registered public accounting firm, are set forth on pages F-1 through F-27 of this Report.

Item 13. Exhibits

The following exhibits are filed with this Amendment No. 2.

31.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
31.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.1	Certification of the Company s Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)
32.2	Certification of the Company s Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (*)(**)

* Filed herewith

** A signed original of this written statement 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors

BioDelivery Sciences International, Inc.

We have audited the accompanying consolidated balance sheet of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2006, and the related consolidated statements of operations, stockholders deficit, and cash flows for each of the two years in the period then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioDelivery Sciences International, Inc. and Subsidiaries as of December 31, 2006, and the consolidated results of their operations and their cash flows for each of the two years in the period then ended in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 13 to the consolidated financial statements the accompanying 2006 consolidated financial statements have been restated.

/s/ Aidman, Piser & Company, P.A.

Tampa, Florida

April 16, 2007 except for Notes 1, 8 and 13 as to which the date is November 20, 2007

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

DECEMBER 31, 2006 (Restated)

ASSETS	
Current assets:	
Cash and cash equivalents	$ 2,172,104
Accounts receivable	42,118
Due from related party	8,523
Prepaid expenses and other current assets	180,863
Total current assets	2,403,608
Equipment, net	379,654
Goodwill	2,715,000
Other intangible assets:	
Licenses	2,442,171
Acquired product rights	2,000,000
Accumulated amortization	(561,767)
Total other intangible assets	3,880,404
Other assets	463,268
Total assets	$ 9,841,934
LIABILITIES AND STOCKHOLDERS DEFICIT	
Current liabilities:	
Note payable	1,000,000
Accounts payable and accrued expenses	2,032,765
Due to related party	1,001,177
Deferred revenue	2,570,360
Dividends payable	152,803
Derivative liability	7,795,931
Total current liabilities	14,553,036
Convertible notes payable	4,003,250
Total liabilities	18,556,286
Commitments and contingencies (Notes 6 and 12)	
Stockholders deficit:	
Series A Preferred stock, $.001 par value; 1,647,059 shares designated, issued and outstanding	3,705,883
Series B Preferred stock, $.001 par value, 941,177 shares designated, 341,176 shares issued and outstanding	1,450,000
Common stock, $.001 par value; 45,000,000 shares authorized, 14,048,637 shares issued; 14,033,146 shares outstanding	14,049
Additional paid-in capital	32,132,609
Treasury stock, at cost, 15,491 shares	(47,183)
Accumulated deficit	(45,969,710)

Total stockholders deficit	(8,714,352)
Total liabilities and stockholders deficit	$ 9,841,934

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2006 AND 2005

	2006 (Restated)	2005
Sponsored research revenues	$ 75,717	$ 364,225
Milestone and royalty revenues, related parties	65,061	422,342
Research fees	135,000	62,995
	275,778	849,562
Expenses:		
Research and development	6,718,638	5,526,833
Related party research and development	2,550,058	937,029
Product development	746,591	
General and administrative	4,947,506	3,533,286
Related party general and administrative	124,505	66,835
	15,087,298	10,063,983
Loss from operations	(14,811,520)	(9,214,421)
Other income, net	7,663	
Other expense:		
Sale of tax loss carryforwards		451,590
Interest expense, net	(1,948,264)	(1,345,496)
Derivative gain (loss)	(1,013,142)	28,930
Loss on extinguishment of debt	(4,629,946)	
	(7,591,352)	(864,976)
Net loss	(22,395,209)	(10,079,397)
Preferred stock dividends	(65,250)	(65,250)
Loss attributable to common stockholders	$ (22,460,459)	$ (10,144,647)
Per share amounts, basic and diluted:		
Loss attributable to common stockholders	$ (1.67)	$ (1.21)
Weighted average common stock shares outstanding:		
Basic and diluted	13,435,091	8,353,346

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

YEARS ENDED DECEMBER 31, 2006 (Restated) AND 2005

	Series A Preferred Stock		Series B Preferred stock				Additional			Total
	Shares	Amount	Shares	Amount	Common Stock		Paid-In Capital	Treasury Stock	Accumulated Deficit	Stockholders Equity
Balances, January 1, 2005	1,647,059	$ 3,705,883	341,176	$ 1,450,000	7,245,863	$ 7,246	$ 14,619,701	$ (303,894)	$ (13,495,104)	$ 5,983,832
Stock-based compensation							11,724			11,724
Conversion of notes payable to common stock					70,000	70	171,430			171,500
Issuance of treasury stock							(99,711)	256,711		157,000
Shares issued for cash, net of offering costs					4,512,774	4,513	7,901,253			7,905,766
Reclassification of equity to derivative liability							(624,593)			(624,593)
Reclassification of derivative liability to equity							1,610,929			1,610,929
Issuance of warrants for financing costs							305,685			305,685
Series B Preferred Dividends							(65,250)			(65,250)
Net loss									(10,079,397)	(10,079,397)
Balances, December 31, 2005	1,647,059	$ 3,705,883	341,176	$ 1,450,000	11,828,637	$ 11,829	$ 23,831,168	$ (47,183)	$ (23,574,501)	$ 5,377,196
Stock-based compensation							576,627			576,627
Issuance of stock, net of offering costs					2,000,000	2,000	6,973,900			6,975,900
Issuance of warrants for product development expense							51,205			51,205
Conversion of notes payable to common					213,363	213	522,524			522,737

stock										
Expense paid through the issuance of common stock					6,637	7	20,768			20,775
Reclassification of derivative liability to equity							221,667			221,667
Series B Preferred Dividends							(65,250)			(65,250)
Net loss									(22,395,209)	(22,395,209)
Balances, December 31, 2006	1,647,059	$ 3,705,883	341,176	$ 1,450,000	14,048,637	$ 14,049	$ 32,132,609	$ (47,183)	$ (45,969,710)	$ (8,714,352)

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2006 AND 2005

	2006 (Restated)	2005
Operating activities:		
Net loss	$ (22,395,209)	$ (10,079,397)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Expenses paid through the issuance of treasury stock		57,000
Expenses paid through the issuance of common stock	20,775	
Expenses paid through the issuance of warrants	988,185	
Depreciation	277,569	281,392
Amortization of deferred finance costs and intangible assets	795,321	435,950
Accretion of interest on convertible debentures	1,044,203	1,054,846
Derivative loss (gain)	1,013,142	(28,930)
Loss on extinguishment of debt	4,629,946	
Stock-based compensation expense	576,627	31,725
Changes in assets and liabilities:		
Prepaid expenses and other assets	30,580	31,392
Accounts payable and accrued expenses	837,970	558,883
Deferred revenue	2,500,000	(52,950)
Net cash flows from operating activities	(9,680,891)	(7,710,089)
Investing activities:		
Purchase of equipment	(9,546)	(33,776)
Purchase of intangible assets	(1,000,000)	
Net cash flows from investing activities	(1,009,546)	(33,776)
Financing activities:		
Proceeds from issuance of common stock and sale of warrants	7,000,900	8,163,322
Offering cost paid from issuance of Common Stock and Sale of Warrants	(25,000)	(257,556)
Proceeds from convertible debentures		5,000,000
Proceeds from (repayment of) related party borrowings	971,906	(156,265)
Cash paid for loan costs		(507,500)
Payment on notes payable		(333,333)
Net cash flows from financing activities	7,947,806	11,908,668
Net change in cash and cash equivalents	(2,742,631)	4,164,803
Cash and cash equivalents at beginning of year	4,914,735	749,932
Cash and cash equivalents at end of year	$ 2,172,104	$ 4,914,735

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

SUPPLEMENTAL CASH FLOW INFORMATION

The Company paid interest of $0.5 million and $0.3 million during 2006 and 2005, respectively.

Non-cash Financing and Investing activities

The Company accrued $0.07 million and $0.07 million in annual cumulative dividends in connection with its Series B Preferred stock during 2006 and 2005 respectively.

The Company converted $522,737 and $171,500 of convertible notes payable through the issuance of 213,363 and 70,000 shares of common stock during 2006 and 2005 respectively.

The Company reclassified derivative liabilities of $221,667 and $1,610,929 from debt to equity during 2006 and 2005 respectively.

During 2005, the Company reclassified the $624,593 fair value of a beneficial conversion option from equity to liabilities at the point that the conversion price became variable.

During 2005, the Company issued common stock warrants for $305,685 of deferred financing costs.

During 2006, the Company issued common stock warrants of $51,205 for product development costs.

The Company purchased certain intangible assets for $2,000,000, including a $1,000,000 promissory note during the year ended December 31, 2006.

See notes to consolidated financial statements.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

1. Nature of business and summary of significant accounting policies:

Organization:

BioDelivery Sciences International, Inc. (BDSI or the Company) was incorporated in the State of Indiana on January 6, 1997 and later reincorporated as a Delaware corporation in 2002. BDSI and its subsidiaries are collectively referred herein to as the Company.

BDSI is a specialty biopharmaceutical company that is exploring its licensed and patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, clinically-significant new formulations of proven therapeutics targeted at acute treatment opportunities such as pain, anxiety, nausea and vomiting, and infections. The Company s drug delivery technologies include: (i) the patented BEMA (transmucosal or mouth) drug delivery technology and (ii) the patented Bioral® nanocochleate technology, designed for a potentially broad base of applications.

Principles of consolidation:

The financial statements include the accounts of BDSI and its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. (Arius One) and Arius Two, Inc. (Arius Two) and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC (BND), which is currently an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Cash and cash equivalents:

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. The Company s cash and cash equivalents are placed in high credit quality institutions, but amounts on deposit significantly exceed federally insured limits.

Revenue Recognition:

The Company recognizes revenue in accordance with the SEC 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.

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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

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

License Arrangements (continued):

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.

Equipment:

Office and laboratory equipment are carried at cost less accumulated depreciation, which is computed on a straight-line basis over their estimated useful lives, generally 5 years. Accelerated depreciation methods are utilized for income tax purposes.

Goodwill and other intangible assets:

Other intangible assets include licenses and noncompete agreements, which are accounted for based on Financial Accounting Standard Statement No. 142 Goodwill and Other Intangible Assets (FAS 142).

The Company periodically reviews intangible assets and equipment with finite lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company uses an estimate of the undiscounted cash flows over the remaining life of its long-lived assets, or related group of assets where applicable, in measuring whether the assets to be held and used will be realizable. In the event of impairment, the Company would discount the future cash flows using its then estimated incremental borrowing rate to estimate the amount of the impairment. There were no impairment charges recognized on finite lived intangibles or equipment in 2006 or 2005.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

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

Intangible assets with finite useful lives are amortized over the estimated useful lives as follows:

	Estimated Useful Lives
Licenses	13 years
Product rights	11 years

The Company incurred amortization expense of other intangibles of $414,160 and $435,950 for the years ended 2006 and 2005 respectively. Estimated aggregate future amortization expenses for other intangible assets with finite lives for each of the next five years and thereafter is as follows:

Year ending December 31,	
2007	366,279
2008	366,279
2009	366,279
2010	366,279
2011	366,279
Thereafter	2,049,009
	$ 3,880,404

Goodwill is evaluated for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment analysis involves a two step process. Step one involves the comparison of the fair value of the reporting unit to which goodwill relates to the carrying value of the reporting unit. If the fair value exceeds the carrying value, there is no impairment. If the carrying value exceeds the fair value of the reporting unit, the Company determines the implied fair value of goodwill and records an impairment charge for any excess of the carrying value of goodwill over its implied fair value. There were no goodwill impairment charges in 2006 or 2005.

Other assets

Other assets consist of deferred finance costs.

Deferred finance costs will be amortized over the term of the related financial instrument. Approximate future amortization of deferred finance costs are as follows:

Year ending December 31,	
2007	$ 381,176
2008	82,092
	$ 463,268

Income taxes:

Deferred income tax assets and liabilities are determined based on differences between the financial statement and tax bases of assets and liabilities as measured by the enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

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

Use of estimates in financial statements:

The preparation of the accompanying financial statements conforms with accounting principles generally accepted in the United States of America and requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures 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 and assumptions.

Net loss per common share:

The Company had net losses for all periods presented in which potential common shares were in existence. Diluted loss per share assumes conversion of all potentially dilutive outstanding common stock equivalents. Potential common shares outstanding are excluded from the calculation of diluted loss per share if their effect is anti-dilutive. As such, dilutive loss per share is the same as basic loss per share for all periods presented as the effect of all the following common stock equivalents outstanding is anti-dilutive:

The following table sets forth the calculations of basic and diluted net loss per share:

	2006 (restated)	2005
Numerator:		
Net loss attributable to common stockholders	$ (22,460,459)	$ (10,144,647)
Denominator:		
For basic loss per share weighted average shares	13,435,091	8,353,346
Effect of dilutive securities		
Weighted average shares for dilutive loss per share	13,435,091	8,353,346
Net loss per share attributable to common stockholders, basic and dilutive	$ (1.67)	$ (1.21)

The effect of common stock equivalents are not considered in the calculation of diluted loss per share because the effect would be anti-dilutive. They are as follows:

	2006	2005
Options and warrants to purchase common stock	8,604,469	5,615,740
Preferred stock convertible to common stock	1,988,235	1,988,235
Convertible debt	1,757,453	1,970,694

Stock-based compensation:

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

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

The adoption of SFAS No. 123(R) lowered net income by approximately $0.6 million for the year ended December 31, 2006, compared to continued accounting for share-based employee compensation using the intrinsic value method under APB No. 25, Accounting for Stock Issued to Employees.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 in the year ended December 31, 2005. For the purposes of this pro forma disclosure, the value of the options is estimated using a Black-Scholes option-pricing model and amortized to expense over the options vesting periods.

	Year ended December 31, 2005
Loss-attributable to common stockholders, as reported	$ (10,144,647)
Stock-based employee compensation, as reported	11,724
Stock-based employee compensation under fair value method	(721,244)
Pro forma loss attributable to common stockholders under fair value method	$ (10,854,167)
Loss attributable to common stockholders basic and diluted:	
As reported	$ (1.21)
Pro forma under fair value method	$ (1.30)

As of December 31, 2006, there was approximately $820,000 of unrecognized compensation cost related to unvested share-based compensation awards granted. That cost is expected to be recognized over the next three years. Options were granted to certain employees during July 2006 at prices equal to the market value of the stock on the dates the options were granted. The options granted have a term of 10 years from the grant date and granted options for employees vest ratably over a three year period. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the option and each vesting date. The Company has estimated the fair value of all stock option awards as of the date of the grant by applying the Black-Scholes pricing valuation model. The application of this valuation model involves assumptions that are judgmental and sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted during the periods ended December 31, 2006 and 2005 are as follows:

	Year ended December 31, 2006	Year ended December 31, 2005
Expected price volatility	62.78%	75.00%
Risk-free interest rate	5.00%	5.00%
Weighted average expected life in years	6 years	5 years
Dividend yield	0	0

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

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

Fair value of financial instruments:

Fair value of cash and cash equivalents, accounts receivable, due from related party and accounts payable approximate their carrying amount due to their short maturity. The fair value of the convertible notes payable approximates the carrying value due to the adjustment of the carrying value to fair value in December 2006 as the result of the debt extinguishment discussed in Note 7. Notes payable and due to related party carrying value approximate fair value due to the short term nature of these liabilities.

The Company evaluates each of its financial instruments to determine if such instruments qualify as derivative instruments in accordance with FASB Statement No. 133 Accounting for derivative instruments and hedging activities and EITF 00-19, Accounting for derivative financial instruments indexed to, and potentially settled in, a Company s own stock .

The Company estimates fair values of derivative financial instruments using various techniques (and combinations thereof) that are considered to be consistent with the objective of measuring fair values. In selecting the appropriate techniques(s), management considers, among other factors, the nature of the instrument, the market risks that it embodies and the expected means of settlement. The Company generally uses the Black-Scholes option valuation technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary to fair value instruments. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the Company s trading market price which has high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company s income will reflect the volatility in these estimate and assumption changes.

The following tabular presentation reflects the components of derivative financial instruments on the Company s balance sheet at:

	Number of shares into which derivative liability can be settled	
Embedded derivative instruments that have been bifurcated	1,757,453	$ 1,993,655
Freestanding derivatives (principally warrants)	2,313,394	5,802,276
	4,070,847	$ 7,795,931

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

	Year Ending December 31,	
	2006	2005
Embedded derivative instruments	$ (702,201)	$ (294,344)
Freestanding derivatives (principally warrants)	(310,941)	323,274
	$ (1,013,142)	$ 28,930

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

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

Recent accounting pronouncements

The Financial Accounting Standards Board (FASB) has recently announced a new interpretation, FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which will be effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes . FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 is not expected to result in any changes to the beginning stockholders deficit and the Company s financial position.

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157). SFAS 157 clarifies the definition of fair value, describes methods used to appropriately measure fair value, and expands fair value disclosure requirements. This statement is effective for fiscal year beginning after November 15, 2007. The Company is currently in the process of assessing the impact that SFAS 157 will have on the consolidated financial statement.

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.

2. Bioral Nutrient Delivery, LLC corporate structure:

On January 8, 2003, the Company formed BND as a majority-owned subsidiary. BND presently has two classes of equity interests: Class A Shares and Class B Shares. As of the date of this report, BDSI owns approximately 94.5% of BND s Class B Shares and all 708,587 of BND s Class A Shares.

During 2003, BND filed a registration statement on Form SB-1 on behalf of BDSI. In connection therewith, the Company made plans to distribute to BDSI stockholders 3,545,431 of BND s Class B Shares, or approximately 43% of BND s outstanding equity interests, including the Class A Shares. After having reevaluated this strategic opportunity, the Company decided in early 2005 to forego the planned distribution of Class B Shares and presently have no intention of effecting any such distribution. BND is substantially inactive at December 31, 2006.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

3. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from convertible notes, through short-term borrowings, which were subsequently repaid, and from funded research arrangements. The Company has not generated revenue from the sale of any product but has generated deferred revenues from licensing arrangements and sponsored research in 2006 and 2005. The Company intends to finance its research and development efforts and its working capital needs from existing cash, new sources of financing and licensing agreements.

On September 3, 2004, the Company entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC (HCG), a principal stockholder of the Company which is controlled and partially-owned by the Company s Chairman. Pursuant to the Equity Line Agreement as amended, HCG will, at the Company s 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, $1.45 million had been drawn under the Equity Line Agreement. The equity line and all accrued interest was converted to 400,402 shares of common stock at $4.25 per share on January 12, 2007.

In February and May 2005, the Company consummated two separate $2.5 million secured convertible debt financings from Laurus Master Fund, Ltd., a Cayman Islands corporation (Laurus). Net proceeds from the financing were used primarily to retire the secured equipment loan with Gold Bank (on which approximately $300,000 was owed and was paid at the closing of the Laurus transaction) and were used to support research and development opportunities and for general working capital purposes. See Note 7 below for further information on the Laurus financings.

On May 16, 2006, the Company consummated a transaction with CDC pursuant to which $7 million in funds previously committed by CDC under the CDLA to fund the Company s clinical development of BEMA Fentanyl was converted into shares of the Company s common stock at a value of $3.50 per share. As a result of this transaction, CDC was issued 2 million shares of the Company s common stock and 904,000 common stock warrants at $3.00 each in return for accelerating the funding of the $4.2 million balance of $7 million of 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.

During March and April 2007 (see Note 13), the Company secured additional financings as follows:

HCG:

$1,000,000 non-interest bearing note payable which matures in June 2007.

$5,000,000 right and commitment by HCG to purchase a royalty from the Company related to BEMA Fentanyl. The Company s option to require the purchase and HCG s right to purchase expires in September 2007.

CDC:

$1,900,000 note payable bearing interest at 10.25%, due March 2008.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

3. Liquidity and management s plans (continued):

Additionally, the Company generated approximately $3,485,000 from the sale of Common Stock as the result of:

$3,235,000 from the exercise of warrants by Laurus Master Fund, Ltd. in April 2007

$250,000 from the sale of common stock to Sigma-Tau Pharma in January 2007

Finally, Laurus Master Fund, Ltd. converted approximately $3.04 million of principal of its convertible notes and $0.119 million of interest into common stock from January through April 2007 and also, on April 10, 2007, extended the maturity date of the $1.262 million balance of convertible notes until July, 2008.

The Company s existing cash and cash equivalent together with available financing and common stock sale proceeds discussed in the preceding paragraph is considered by management to be sufficient to finance the Company s basic operations (minimal research and development activities), capital expenditures and debt obligations into approximately the first quarter of 2008.

Additional capital will be required in order to proceed with the Company s planned expanded BEMA Fentanyl development activities, the scale of which is dependent upon the results of the BEMA Fentanyl Phase III efficacy study, which are expected in late April 2007. Management is currently negotiating with a number of funding sources and believes they will be successful in securing such funding at levels sufficient to support planned expanded operations. However, there can be no assurance that additional capital will be available at favorable terms, if at all. In addition, the Company is talking to a number of potential commercial partners in regards to the distribution rights for BEMA Fentanyl. It is believed that should a distribution partnership be consummated it is anticipated that the costs for the expanded program would be paid in full or in part by the distribution partner. If adequate funds either through a financial or distribution partner are not available, the Company would be required to significantly reduce or refocus its planned expanded operations (conduct only the basic operations as discussed in the preceding paragraph) or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company s financial condition in 2008 and beyond.

4. Research and development arrangements and related party transactions:

Upon its formation, BDSI originally secured license rights from two universities that have exclusive rights to certain technology. In exchange for these rights, BDSI issued shares of Common Stock and agreed to make future royalty payments to the universities upon (a) the licensing of rights to sub-licensees (up to 5% of fees as amended on December 16, 2002); (b) sales by sub-licensees (25% of BDSI proceeds); or (c) BDSI sales (3% of revenue). The amendment to the agreement on December 16, 2002 also provided for the granting of options to purchase 75,000 shares of the Common Stock to each of the two universities.

During 2004, the Company entered into a license agreement with TEAMM Pharmaceuticals, Inc., a subsidiary of Accentia Biopharmaceuticals, Inc. (Accentia), in which BDSI s Chairman is a significant stockholder. The license agreement granted exclusive rights to Emezine® to the Company recognized revenues which aggregated $1.0 million in 2004, which was earned upon satisfaction of milestones specified in the agreement. During the year ended December 31, 2005, BDSI recognized revenue of approximately $0.35 million in milestone payments. There were no revenues recognized in 2006 related to this product. BDSI will earn future royalties when and if the FDA approves the product. On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. We subsequently have had interaction with the FDA regarding Emezine®, and at the present time, given our level of resources and our focus on other initiatives, it is not likely that we will proceed with Emezine® in the foreseeable future.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

4. Research and development arrangements and related party transactions (continued):

In addition, the Company earned $0.07 million and $0.07 million from Accentia under the Accentia License Agreement in 2006 and 2005, respectively.

The Company had a collaborative research agreement with the University of Medicine and Dentistry of New Jersey (UMDNJ), an entity that is also a Company stockholder, under which BDSI pays salary for a UMDNJ employee, laboratory supplies and employee parking costs. The agreement expired at the end of 2005. As further discussed in Note 12, the Company also leases its Newark, New Jersey facility from UMDNJ under a non-cancelable operating lease agreement which expired on December 31, 2005. The Company is currently in negotiations to renew the lease. The Company incurred approximately $.2 million and $.5 million of research expense in the years ended December 31, 2006 and 2005 respectively. Amounts due to UMDNJ at December 31, 2006 are approximately $.2 million.

The Company has a license agreement with Albany Medical College (AMC), an entity that is also a Company stockholder, under which BDSI pays AMC royalty payments for licensed patents or technology. Amounts due to AMC at December 31, 2006 are approximately $.06 million.

The Company has an agreement with Pharmaceutical Product Development, Inc., a Company stockholder, for research work in connection with a product under development. The Company incurred research expense of $2.3 million and $0.4 million under this agreement in 2006 and 2005 respectively. Amounts due to PPD at December 31, 2006 are approximately $.7 million.

The Company rents office space for accounting and administrative staff in Tampa, Florida from Accentia, and shares three employees, with costs paid based on the approximate time spent on Company activities. Rent payments to Accentia were $0.02 million and $0.02 million in 2006 and 2005 respectively, and are included in general and administrative costs, related party. Amounts due to Accentia at December 31, 2006 are approximately $.01 million.

The Company pays costs for business-related aircraft travel to a company that is partially-owned by the Company s Chairman. Payments of $0.1 million and $0.05 million were made in 2006 and 2005 respectively and are included in general and administrative costs, related party.

See Note 9 regarding related party equity line of credit agreement.

5. Equipment:

Equipment consists of the following at December 31, 2006:

Office and laboratory equipment	1,906,300
Less accumulated depreciation and amortization	(1,526,646)
	$ 379,654

Depreciation expense related to equipment for the years ended December 31, 2006 and 2005 was approximately $0.3 million and $0.3 million, respectively.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

6. Note payable:

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

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

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

7. Convertible notes payable:

On February 22, 2005, the Company consummated a $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., which we refer to herein as Laurus. The February Laurus investment takes the form of a convertible note secured by certain of the Company s assets. The note has a 3-year term and is payable in monthly installments of $75,758 plus interest at prime plus 2%, with a floor of 7.5%. The note is convertible, under certain conditions, into shares of common stock at a price equal to $3.10 per share. As a result of the anti-dilution provisions of the February Laurus note and the pricing of an October 2005 public offering, the conversion price of the February Laurus note is now $2.45.

In connection with this financing, the Company also issued Laurus a common stock purchase warrant to purchase up to 350,000 shares of common stock at a price equal to $3.88 per share. A registration statement filed with the SEC to register the shares of common stock underlying the February Laurus note and the warrant was declared effective on June 20, 2005.

On May 31, 2005, the Company closed an additional $2.5 million secured convertible debt financing from Laurus. As with the February 2005 Laurus financing, this financing takes the form of a secured convertible note and a warrant to purchase 483,871 shares of common stock. The note has a 3-year term and is payable in monthly installments of $75,758 plus interest at prime plus 2%, with a floor of 8%. As a result of the anti-dilution provisions of the May Laurus note and the pricing of the October 2005 public offering, the conversion price of the May Laurus note is now $2.45.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

7. Convertible notes payable (continued):

From June 2005 through July 2006, the Company entered into amendments to the February and May 2005 financing agreements with Laurus under which Laurus agreed to defer certain principal payments otherwise required under the agreements. In consideration for these amendments, the Company issued Laurus warrants to purchase shares of the Company s common stock as follows:

Warrant Amendment Date	Number of Warrants	Exercise Price	Expiration Date
June 29, 2005	30,000	$ .001	June 29, 2012
December 29, 2005	69,274	$ .001	December 29, 2012
July 25, 2006	110,000	$ 3.00	July 25, 2013

Except for the exercise price of these warrants, these warrants issued to Laurus were substantially similar to the warrants issued on February 22 and May 31, 2005, and none of the loan modifications associated with the issuance of these warrants resulted in a debt extinguishment for financial reporting purposes.

On September 20, 2006, the Company issued Laurus a common stock purchase warrant to purchase up to 33,000 shares of common stock at an exercise price of $3.00 per share that expire September 20, 2011. This warrant was issued in satisfaction of penalties arising under registration rights agreements. Except for the exercise price of the warrants, the warrants issued to Laurus in September 2006 are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005.

On December 28, 2006, the Company entered into two separate fourth amendments to the February and May 2005 financing agreements with Laurus. Under the fourth amendments, Laurus has agreed to defer payments by the Company of certain monthly principal amounts under the Company s February and May 2005 Convertible Notes with Laurus ($1,818,192 in the aggregate), as well as certain other previously postponed principal amounts due under such notes ($2,018,541 in the aggregate), until the first business day of January 2008. During the first quarter of 2007, Laurus exercised its right to convert $2.4 million of principal and $0.1 million of interest, and as such the amount due at January 1, 2008 is $1.5 million.

In consideration of Laurus agreement to enter into the fourth amendments, the Company issued to Laurus two warrants, one to purchase 943,305 shares of Company common stock (in connection with the February amendment) and a second to purchase 556,695 shares of Company common stock (in connection with the May amendment) (such warrants collectively, the December 2006 Warrants). In each case, the December 2006 warrants are exercisable into shares of Company common stock at an exercise price of $3.05 per share and expire on December 28, 2013. The December 2006 warrants are substantially similar to the warrants issued to Laurus on February 22, 2005, May 31, 2005, June 29, 2005, December 28, 2005 and July 31, 2006. The Company has agreed to register the shares of common stock underlying the December 2006 Warrants with the Securities and Exchange Commission pursuant to a registration statement required to be filed by no later than July 31, 2007.

The Company applied the provisions of EITF 06-06, Debtor s Accounting for Modification (or exchange) of Convertible Debt Instruments to the amendments dated December 28, 2006. Since the post-modification present value of the cash flows to the lender, including the approximately $4,380,000 fair value of the December 2006 warrants, changed such cash flows before the modification by more than 10%, the debt modification was accounted for as a debt extinguishment, and as such, the debt was adjusted to its fair value; the $249,496 excess of that fair value over the then carrying value of the debt and the $4,380,000 fair value of the December 2006 was recorded as a loss on extinguishment of debt.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

7. Convertible notes payable (continued):

The Laurus financings included registration rights related to share settlement of the embedded conversion features and the warrants which the company has determined not to be within its control.

In addition, certain features associated with the financings, such as anti-dilution protection afforded to Laurus, render the number of shares issuable under the financings to be variable, (only when and if the Company sells stock for an amount less than the otherwise fixed conversion price). In these instances, EITF 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock , requires allocation of the proceeds between the various instruments and the derivative elements carried at fair value. The following tabular presentation reflects the allocation of the proceeds of the financing:

Principal balance of note	$ 5,000,000
Less reduction for:	
Fair value of beneficial conversion option	(1,450,404)
Fair value of warrants	(993,501)
Recorded at closing	2,556,095
Accretion of discount (interest expense) through December 31, 2005 using effective interest method	847,693
Conversion of debt to equity through December 31, 2005	(171,500)
Carrying value at December 31, 2005	3,232,288
Accretion of discount (interest expense) through December 31, 2006	1,044,203
Conversion of debt to equity through December 31, 2006	(522,737)
Adjustment of carrying value to fair value resulting from debt extinguishment	249,496
Carrying value at December 31, 2006	$ 4,003,250

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

Future maturities of convertible note payable are as follows:

Year Ended December 31,	
2008	4,305,761
Less unamortized discount	(302,511)
	$ 4,003,250

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

8. Income taxes:

The Company has no income tax expense or benefit for 2006 or 2005 as the Company has incurred net operating losses and has recognized valuation allowances for all deferred tax assets.

The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	Year Ended December 31,	
	2006 (restated)	2005
Federal statutory income tax rate	34.00 %	34.00 %
State taxes, net of federal benefit	3.45	3.45
Permanent difference - compensation expense	(2.83)	(2.90)
Research and development (R&D) credit	4.74	
Other	(0.05)	
Valuation allowance	(39.32)	(34.55)
	%	%

The tax effects of temporary differences and net operating losses that give rise to significant portions of deferred tax assets and liabilities consisted of the following:

	December 31,	
	2006 (restated)	2005
Deferred tax assets (liabilities)		
Deferred revenue	$ 962,646	$
Basis difference in equipment	(89,678)	(152,184)
Basis difference in intangibles	(1,950,382)	(1,490,743)
Accrued liabilities and other	115,168	34,590
R&D Credit	1,249,148	186,631
Derivative	1,733,998	
Net operating loss carry-forward	12,111,365	6,749,171
Less: valuation allowance	(14,132,265)	(5,327,465)
Net deferred tax	$	$

In 2005, the Company sold New Jersey net operating loss carryforwards and R&D credits for aggregate proceeds of $0.5 million. No R&D credits were sold in 2006. As a result of this sale in 2005, $7.5 million in New Jersey state tax operating loss carryforwards are no longer available. The Company has a federal net operating loss of approximately $33.0 million and a State net operating loss of $25.5 million as of December 31, 2006. These loss carryforwards expire principally beginning in 2021 and 2028 for federal and state purposes, respectively.

9. Stockholders equity:

Preferred stock:

The Company has authorized five million shares of $.001 par value preferred stock. At December 31, 2006, 2,588,236 shares were designated as follows:

Convertible Preferred Shares:	
Series A	1,647,059
Series B	941,177
	2,588,236

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

9. Stockholders equity (continued):

As part of the acquisition of Arius in August 2004, the Company issued to the former stockholders of Arius consideration comprised of an aggregate of 1,647,059 shares of a newly designated, non-voting and non-interest bearing, series of convertible preferred stock. The newly-created Series A Preferred is convertible (upon the satisfaction of certain conditions) into shares of common stock on a one for one basis. Shares of Series A Preferred are eligible for conversion upon the earlier to occur of: (i) FDA approval of Arius first proposed product (ii) 30 days notice to the Company of a Conversion Event (hereinafter defined) or (iii) five (5) years from the closing date of the acquisition. The term Conversion Event is defined in the Certificate of Designation of the Series A Preferred to mean our failure to provide at least $3.0 million to Arius as required to: (i) pay Atrix $1.0 million by August 24, 2004 pursuant to the terms of a license agreement between Arius and Atrix and (ii) fund, in a total amount of no less than $2.0 million, the operations of Arius. The Company believes they have satisfied both of these conditions. The holders of the Series A Preferred enjoy certain other rights and privileges.

On August 23, 2004, the Company entered into a private, unregistered Equity Line Agreement with HCG, a principal stockholder of the Company, whereby HCG will, as requested by the Company, 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 of BDSI (the Series B Preferred). As of December 31, 2006 and 2005, $1.45 million had been drawn under the Equity Line Agreement. The holders of the Series B Preferred are entitled to receive a 4.5% annual cumulative dividend. In addition, the Series B Preferred is convertible into shares of Common Stock at any time as of or after April 1, 2006, or earlier upon a change of control of the Company, in each case at a price equal to $4.25 per share. The Series B Preferred ranks senior to shares of the Company s Common Stock and the Series A Preferred and has certain piggyback registration rights, dividend and liquidation preferences and certain other privileges. HCG is an affiliated entity of the Company which is controlled and partially-owned by the Company s Chairman.

Additionally, the Company has the right, in its discretion at any time, to redeem the shares of Series B Preferred stock for cash equal to the amount invested under the Equity Line Agreement plus accrued and unpaid dividends thereon. Furthermore, the Certificate of Designations for the Series B Preferred provides for certain limitations on the conversion of the Series B Preferred into shares of Common Stock without the prior approval of the Company s stockholders. Finally, HCG has no rights to cause the redemption or buy-back by the Company of the Series B Preferred.

In early October 2005, the Company announced the consummation of a follow on public offering of 4,400,000 shares of Common Stock, resulting in gross proceeds of $8.8 million to the Company. The public price per share for the offering was $2.00. The offering was underwritten by Ferris, Baker Watts Incorporated, Maxim Group LLC and Gunn Allen Financial, Inc. The underwriters were granted an option to purchase up to an additional 660,000 shares of Common Stock to cover over-allotments, which option was partially exercised in late October 2005, generating additional gross proceeds of $107,900.

Stock options:

The Company has a stock option plan, which covers a total of 3,500,000 shares of Common Stock (as amended). Options may be awarded during the ten-year term of the 2001 stock option plan to Company employees, directors, consultants and other affiliates.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

9. Stockholders equity (continued):

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2005	1,861,480	$ 5.03	
Granted in 2005:			
Officers and Directors	417,761	2.96	
Others	142,703	4.60	
Exercised			
Forfeitures	(236,349)	5.44	
Outstanding at December 31, 2005	2,185,595	$ 4.43	$ 165,608
Granted in 2006:			
Officers and Directors	235,000	2.08	
Others	241,255	2.32	
Exercised			
Forfeitures	(638,146)	6.39	
Outstanding at December 31, 2006	2,023,704	$ 3.04	$ 1,099,052

Options outstanding at December 31, 2006 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	1,858,653	7.03	$ 2.72	
$ 5.01 10.00	147,889	0.75	$ 5.75	
$10.01 15.00	8,581	0.87	$ 11.80	
$15.01 20.00	8,581	0.87	$ 17.48	
	2,023,704			$ 1,099,052

Options exercisable at December 31, 2006 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	1,461,532	7.03	$ 2.75	
$ 5.01 10.00	141,889	0.75	$ 5.76	
$10.01 15.00	8,581	0.87	$ 11.80	

$15.01	20.00	8,581	0.87	$	17.48
		1,620,583			$ 863,245

The weighted average grant date fair value of options granted during 2006 and 2005 whose exercise price is equal to the market price of the stock at the grant date was $2.08 and $2.97, respectively. The weighted average grant date fair value of options granted during 2005 whose exercise price is greater than the estimated market price of the stock at the grant date is $3.10. There were no options granted during 2006 whose exercise price is grater than the estimated market price of the stock at the grant date.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

9. Stockholders equity (continued):

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements.

Activity is as follows and includes 2,085,000 warrants issued in connection with the 2002 public offering of securities. Warrants outstanding at December 31, 2006 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 5.00	4,270,765	6.43	$ 3.11	
$ 5.01 10.00	2,310,000	0.67	$ 6.20	
	6,580,765			$ 999,683

Warrants exercisable at December 31, 2006 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 5.00	4,245,765	6.19	$ 3.11	
$ 5.01 10.00	2,310,000	0.67	$ 6.20	
	6,555,765			$ 965,433

10. Retirement Plan:

The Company sponsors a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation requirements. Participants may contribute up to 90% of their eligible earnings, as limited by law. The Company makes a matching contribution equal to 100% on the first 5% that a participant contributes to the plan. The Company made contributions of approximately $0.8 million and $0.8 million in 2006 and 2005, respectively.

11. National Institutes of Health Grant:

In 2002, the National Institutes of Health (NIH) awarded the Company a Small Business Innovation Research Grant (the SBIR), for $0.6 million, which has been utilized in research and development efforts.

During the years ended December 31, 2006 and 2005, the Company incurred approximately $0.07 million and $0.3 million of costs related to this agreement and received and recognized revenue of $0.07 million and $0.4 million, from this grant for the year ended December 31, 2006 and 2005, respectively. All available funds have been drawn from this grant at December 31, 2006.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

12. Commitments and contingencies:

Employment agreements:

The Company has employment agreements with certain employees, which extend for 36 months. These agreements provide for base levels of compensation and separation benefits. Future minimum payments under these employment agreements as of December 31, 2006 are $0.8 million, $0.8 million and $0.8 million for the years ended December 31, 2007, 2008 and 2009, respectively.

Operating leases:

Since April 2001, the Company leased a facility from UMDNJ (a stockholder), under an operating lease which expired on December 31, 2006. The Company is currently in negotiations to renew the lease. Lease expense for the years ended December 31, 2006 and 2005 was approximately $0.1 million and $0.06 million, respectively. Related party rent expense was $0.01 million for each year presented.

The future minimum commitments on all operating leases at December 31, 2006 are as follows:

Years ending December 31,	
2007	33,799
2008	7,691
2009	5,768
	$ 47,258

Indemnifications:

The Company indemnified its officers and directors against costs and expenses related to stockholder and other claims (i.e., only actions taken in their capacity as officers and directors) that are not covered by the Company s directors and officers insurance policy. This indemnification is ongoing and does not include a limit on the maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost. As of December 31, 2006, the Company has not recorded a liability for any obligations arising as a result of these indemnifications as the cause thereof is deemed nominal.

Litigation:

On or about April 19, 2004, the Company was named as the defendant in an action commenced by MAS Capital Inc. in the Vanderburgh Circuit Court in the State of Indiana (Cause No. 82C01-0404 PL 280). In the lawsuit, the plaintiff seeks monetary damages from the Company in the amount of $1.575 million based upon the allegation that MAS Capital procured an underwriter to raise capital for the Company through an initial public offering. The Company has provided MAS Capital s counsel with copies of documents executed by MAS Capital and its affiliates that the Company allege fully release them. Upon MAS Capital s refusal to dismiss the action notwithstanding the documents that fully release the Company; they 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 their 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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

12. Commitments and contingencies (continued):

Motion. Accordingly, the parties are to proceed until resolution of the Company s counterclaim for attorneys fees and costs and either party could appeal at that point in time. The parties are in the discovery phase with regard to the counterclaim for attorneys fees and costs and no hearing date has yet to be scheduled on said counterclaim. The Company believes that the plaintiff s claims are without merit and intend to continue to vigorously defend the lawsuit. No liability, if any, that may result from this matter has been recorded in the financial statements.

On August 21, 2006, The Company filed an action in New York State Supreme Court against Clinical Development Capital, LLC (CDC) seeking: (i) to enjoin CDC from filing a Schedule 13D filing with the Securities and Exchange Commission without first giving the Company an opportunity to review the proposed Schedule 13D filing for potential disclosures of their confidential information in violation of the Clinical development and licensing agreement (CDLA) and (ii) to compel CDC to adhere to the dispute resolution mechanisms set forth in the CDLA. The Company s motion for a preliminary junction enjoining the filing of CDC of the Schedule 13D was denied on August 22, 2006.

On August 30, 2006, The Company delivered to CDC the BDSI Notice pursuant to the CDLA. In the BDSI Notice, the Company claimed that CDC breached the CDLA and damaged them when it acted or failed to act in accordance with or in contravention of the terms of the CDLA. In the BDSI Notice, the Company reserved the right to make additional claims against CDC. Also on August 30, 2006, the Company received written notice from CDC of CDC s claim of termination of the CDLA. In its notice, CDC alleged that the Company undertook certain actions which materially breached the CDLA, which breaches, CDC alleged, require the Company to transfer certain specified rights and assets relating to BEMA TM Fentanyl to CDC. Pursuant to the CDLA, any claim of breach of material terms is subject to the dispute resolutions procedures, including arbitration, contained within the CDLA.

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

See Note 14 for resolutions of the CDC litigation.

13. Restatement of previously issued financial statements:

During the year ended December 31, 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 year ended December 31, 2006 since the company 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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

13. Restatement of previously issued financial statements (continued):

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 audited annual financial information as previously reported as of and for the period ended December 31, 2006 has been restated as follows:

	Balance Sheet December 31, 2006		
	As previously reported (1)	Restatement adjustment (2)	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	2,442,171		2,442,171
Acquired product rights	2,000,000		2,000,000
Accumulated amortization	(561,767)		(561,767)
Total other intangible assets	3,880,404		3,880,404
other assets	463,268		463,268
Total assets	$ 9,841,934	$	$ 9,841,934

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

	Balance Sheet December 31, 2006		
	As previously reported (1)	Restatement adjustment (2)	Restated
LIABILITIES AND STOCKHOLDER S DEFICIT			
Current Liabilities:			
Notes payable	$ 1,000,000	$	$ 1,000,000
Accounts payable and accrued expenses	2,032,765		2,032,765
Due to related party	1,001,177		1,001,177
Deferred revenue	70,360	2,500,000	2,570,360
Dividends payable	152,803		152,803
Derivative liability	7,795,931		7,795,931
Total current liabilities	12,053,036	2,500,000	14,553,036
Convertible notes payable	4,003,250		4,003,250
Total liabilities	16,056,286	2,500,000	18,556,286
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
Common stock, $.001 par value; 45,000,000 shares authorized, 14,048,637 shares issued; 14,033,146 shares outstanding	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)	(45,969,710)
Total stockholders deficit	(6,214,352)	(2,500,000)	(8,714,352)
Total liabilities and stockholders deficit	$ 9,841,934		$ 9,841,934

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

13. Restatement of previously issued financial statements (continued):

	As previously reported (1)	Statement of Operations Year Ended December 31,2006 Restatement adjustment(2)	Restated
Sponsored research revenues	$ 75,717	$	$ 75,717
Milestone and royalty revenues, related parties	65,061		65,061
License fees, European	2,500,000	(2,500,000)	
Research fees	135,000		135,000
	2,775,778	(2,500,000)	275,778
Expenses:			
Research and development	6,718,638		6,718,638
Related party research and development	2,550,058		2,550,058
Product development	746,591		746,591
General and administrative	4,947,506		4,947,506
Related party general and administrative	124,505		124,505
	15,087,298		15,087,298
Loss from operations	(12,311,520)	(2,500,000)	(14,811,520)
Other income, net	7,663		7,663
Other expense:			
Sale of tax loss carryforwards			
Interest expense, net	(1,948,264)		(1,948,264)
Derivative gain (loss)	(1,013,142)		(1,013,142)
Loss on extinguishment of debt	(4,629,946)		(4,629,946)
	(7,591,352)		(7,591,352)
Net loss	(19,895,209)	(2,500,000)	(22,395,209)
Preferred stock dividends	(65,250)		(65,250)
Loss attributable to common stockholders	$ (19,960,459)	$ (2,500,000)	$ (22,460,459)
Per share amounts, basic and diluted:			
Loss attributable to common stockholders	$ (1.49)		$ (1.67)
Weighted average common stock shares outstanding:			
Basic and diluted	13,435,091		13,435,091

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

13. Restatement of previously issued financial statements (continued):

	as previously reported (1)	Consolidated Statement of Cash Flows Year Ended December 31, 2006 restatement adjustment (2)	restated
Operating activities:			
Net loss	$ (19,895,209)	(2,500,000)	$ (22,395,209)
Adjustments to reconcile net loss to net cash flows from operating activities			
Expenses paid through the issuance of common stock	20,775		20,775
Expenses paid through the issuance of warrants	988,185		988,185
Depreciation	277,569		277,569
Amortization of deferred finance costs and intangible assets	795,321		795,321
Accretion of interest on convertible debentures	1,044,203		1,044,203
Derivative loss (gain)	1,013,142		1,013,142
Loss on extinguishment of debt	4,629,946		4,629,946
Stock-based compensation expense	576,627		576,627
Changes in assets and liabilities:			
Prepaid expenses and other assets	30,580		30,580
Accounts payable and accrued expenses	837,970		837,970
Deferred revenue		2,500,000	2,500,000
Net cash flows from operating activities	(9,680,891)		(9,680,891)
Investing activities:			
Purchase of equipment	(9,546)		(9,546)
Purchase of intangible assets	(1,000,000)		(1,000,000)
Net cash flows from investing activities	(1,009,546)		(1,009,546)
Financing activities:			
Proceeds from issuance of common stock and sale of warrants	7,000,900		7,000,900
Offering cost paid from issuance of Common Stock and Sale of Warrants	(25,000)		(25,000)
Proceeds from (repayment of) related party borrowings	971,906		971,906
Net cash flows from financing activities	7,947,806		7,947,806
Net change in cash and cash equivalents	(2,742,631)		(2,742,631)
Cash and cash equivalents at beginning of year	4,914,735		4,914,735
Cash and cash equivalents at end of year	$ 2,172,104	$	$ 2,172,104

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

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

4. Subsequent Events:

On January 10, 2007, Hopkins Capital Group II, LLC converted 341,176 shares of Series B Convertible Preferred Stock of The Company (the 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.

On January 24, 2007, Sigma Tau acquired 73,964 shares of the Company s Common Stock at a price of $3.38 per share in accordance with their Stock Purchase Agreement. The Stock Purchase 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 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.

On March 12, 2007, the Company entered into a Dispute Resolution Agreement (the DRA) with CDC IV, LLC. 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 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 has previously rejected CDC s August 2006 allegations and demands. The resolution of the disputes under the DRA is without prejudice to the Disputed Matters of both the Company and CDC. As such, no assurance can be given that CDC will not make similar additional claims against the Company. Simultaneously with the Company and CDC s entry into the DRA, the Company and CDC entered into an amendment to their Clinical Development and License Agreement, dated July 14, 2005 (as amended, 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. Under the CDLA, the Company must meet certain conditions or CDC can assume control of the BEMA Fentanyl project and related intellectual property assets. Concurrently with the parties negotiation of the DRA, CDC alleged that the Company had violated CDC s financing right of first refusal (as amended, the ROFN) provided for in the May 2006 Securities Purchase Agreement between the parties. 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.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

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YEARS ENDED DECEMBER 31, 2006 (RESTATED) AND 2005

14. Subsequent Events (continued):

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 (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.

The New CDC Financing involves a one-year, 10.25% loan from CDC and a warrant (the New CDC Warrant) to purchase 1 million shares of Company common stock with an exercise price of $3.80. The Company is not required to file a registration statement with the Securities and Exchange Commission to register the shares of Company common stock underlying the New CDC 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 New CDC Warrant contains weighted average anti-dilution protection. The proceeds from the New CDC Financing will be used for general corporate purposes and for the continued development of BEMA Fentanyl.

The holder of convertible notes payable, Laurus, has converted $3.044 million of principal and $0.119 million of interest into 1,290,861 shares of common stock from January 1, 2007 through April 10, 2007.

On March 30, 2007, HCG funded a $1.0 million unsecured, non-interest bearing note, due June 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 can be demanded by either the Company or HCG at any time before September 30, 2007, is $5.0 million. The royalty is 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. In addition, if the royalty purchase agreement is entered into, the Company 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). No assurances can be given that either the Company or HCG will elect to enter into the royalty purchase agreement.

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 and aggregate of 833,871 warrants previously issued to Laurus to purchase a like number of shares of Common Stock, resulting in cash proceeds of $3,183,567 to the Company and (ii) to defer all principal payments under the Company s May 2005 note with Laurus (which currently stands at $1.262 million) 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 a registration statement registering the shares underlying such warrant by July 31, 2007.

On April 13, 2007, the Compensation Committee of the Company s board of directors awarded the following options to the following senior executives of the Company: Mark Sirgo: 434,000 options; James McNulty: 100,000 options; and Andrew Finn 100,000 options. All of the foregoing options vest in three equal installments beginning on the first anniversary of the grant date (April 13, 2008) and have an exercise price of $6.63 per option share.

As a result of certain previous issuances by the Company of its securities at prices below the then current market price of the Common Stock (including a warrant issued to Laurus in April 2007 as described above), the exercise price of the Company s publicly-traded warrants was, effective April 10, 2007, adjusted downward from $6.30 to $6.11 pursuant to the terms of the warrant agreement entered into in connection with the Company s June 2002 initial public offering. The Company s publicly-traded warrants expire on June 24, 2007.

SIGNATURES

In accordance with Section 13 or 15(d) 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 21, 2007

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and Chief Executive Officer

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/s/ Francis E. O Donnell, Jr.	Chairman of the Board and Director	November 21, 2007
Francis E. O Donnell, Jr.		
/s/ Mark A. Sirgo	President and Chief Executive Officer	November 21, 2007
Mark A. Sirgo	(Principal Executive Officer)	
/s/ James A. McNulty	Chief Financial Officer, Secretary and Treasurer	November 21, 2007
James A. McNulty	(Principal Accounting Officer)	
/s/ Raphael J. Mannino	Executive Vice President, Chief Scientific	November 21, 2007
Raphael J. Mannino	Officer and Director	
/s/ William B. Stone	Director	November 21, 2007
William B. Stone		
/s/ John J. Shea	Director	November 21, 2007
John J. Shea		
/s/ Thomas D Alonzo	Director	November 21, 2007
Thomas D Alonzo		
/s/ William S. Poole	Director	November 21, 2007
William S. Poole		