BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
August 15, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2011

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

For the transition period from to

Commission file number 001-31361

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

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

801 Corporate Center Drive, Suite #210

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of August 10, 2011, there were 29,577,146 shares of company common stock issued and 29,561,655 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF JUNE 30, 2011 AND DECEMBER 31, 2010

	June 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,188,100	$ 18,208,659
Accounts receivable, other	222,628	633,216
Prepaid expenses and other current assets	842,738	236,112
Total current assets	22,253,466	19,077,987
Equipment, net	3,344,353	3,424,869
Goodwill	2,715,000	2,715,000
Other intangible assets:		
Licenses	1,900,000	1,900,000
Acquired product rights	8,000,000	8,000,000
Accumulated amortization	(3,304,147)	(2,858,657)
Total other intangible assets	6,595,853	7,041,343
Derivative asset, warrant (note 6)	590,540	1,299,031
Other assets	21,976	21,976
Total assets	$ 35,521,188	$ 33,580,206
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 5,402,673	$ 4,656,295
Deferred revenue, current	12,523,099	12,491,907
Derivative liabilities (note 6)	3,385,199	4,989,993
Total current liabilities	21,310,971	22,138,195
Deferred revenue, long-term	1,660,401	1,655,681
Total liabilities	22,971,372	23,793,876
Commitments and contingencies		
Stockholders equity:		
Common Stock, $.001 par value; 45,000,000 shares authorized, 29,577,146 and 24,038,445 shares issued; 29,561,655 and 24,022,954 shares outstanding in 2011 and 2010, respectively	29,578	24,039
Additional paid-in capital	98,931,543	82,055,934
Treasury stock, at cost, 15,491 shares, 2011 and 2010	(47,183)	(47,183)
Accumulated deficit	(86,364,122)	(72,246,460)
Total stockholders equity	12,549,816	9,786,330
Total liabilities and stockholders equity	$ 35,521,188	$ 33,580,206

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues:				
Product royalties	$	$ 1,745,896	$ 34,225	$ 1,796,135
Research revenues	33,606	220,194	226,843	397,337
Contract revenues	4,800	250,476	6,800	250,476
Total Revenues:	38,406	2,216,566	267,868	2,443,948
Cost of product royalties	(425,930)	796,525	(128,510)	808,954
Expenses:				
Research and development	4,720,208	1,521,531	11,410,882	2,970,996
General and administrative	1,930,875	2,196,886	3,695,364	4,401,647
Related party general and administrative, net:	18,750	21,500	37,500	(339,000)
Impairment of intangible license		243,648		243,648
Total Expenses:	6,669,833	3,983,565	15,143,746	7,277,291
Loss from operations	(6,205,497)	(2,563,524)	(14,747,368)	(5,642,297)
Interest income	48,411	4,280	86,194	7,571
Derivative gain	1,046,869	3,306,470	559,556	6,176,442
Other income (expense), net	11,866	28,635	(16,044)	42,923
Net (loss) income	(5,098,351)	775,861	(14,117,662)	584,639
Net (loss) income attributable to common stockholders	$ (5,098,351)	$ 775,861	$ (14,117,662)	$ 584,639
Basic earnings per share:	$ (0.18)	$ 0.03	$ (0.52)	$ 0.03
Diluted earnings per share:	$ (0.18)	$ 0.01	$ (0.52)	$ 0.00

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE SIX MONTHS ENDED JUNE 30, 2011

(Unaudited)

	Common Stock					Total
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Stockholders Equity
Balances, January 1, 2011	24,038,445	$ 24,039	$ 82,055,934	$ (47,183)	$ (72,246,460)	$ 9,786,330
Stock-based compensation			448,693			448,693
Stock option exercises	129,888	130	349,546			349,676
Reclassification of derivative liability to equity			336,747			336,747
Exercise of warrants	601,120	601	1,748,658			1,749,259
Private placement offering, net	4,807,693	4,808	13,991,965			13,996,773
Net loss					(14,117,662)	(14,117,662)
Balances, June 30, 2011	29,577,146	$ 29,578	$ 98,931,543	$ (47,183)	$ (86,364,122)	$ 12,549,816

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

	Six Months Ended June 30,	
	2011	**2010**
Operating activities:		
Net (loss) income	$ (14,117,662)	$ 584,639
Adjustments to reconcile net (loss) income to net cash flows from operating activities:		
Depreciation and amortization	653,764	610,171
Derivative gain	(559,556)	(6,176,442)
Stock-based compensation expense	448,693	660,594
Intangible license impairment		243,648
Gain on settlement		(382,800)
Changes in assets and liabilities:		
Accounts receivable	410,589	249,362
Prepaid expenses and other assets	(606,626)	(14,848)
Accounts payable and accrued expenses	791,001	(872,424)
Deferred revenue	35,913	512,603
Income tax payable		(350,000)
Net cash flows used in operating activities	(12,943,884)	(4,935,497)
Investing activities:		
Purchase of equipment	(127,760)	(96,831)
Purchase of intangible assets		(1,000,000)
Net cash flows from investing activities	(127,760)	(1,096,831)
Financing activities:		
Proceeds from issuance of common stock	13,996,773	9,747,500
Proceeds from exercise of stock options	349,676	97,882
Proceeds from exercise of warrants	1,749,259	
Change in amounts due to related parties	(44,623)	(2,566,519)
Net cash flows from financing activities	16,051,085	7,278,863
Net change in cash and cash equivalents	2,979,441	1,246,535
Cash and cash equivalents at beginning of period	18,208,659	23,873,403
Cash and cash equivalents at end of period	$ 21,188,100	$ 25,119,938

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

1. Basis of presentation:

Overview:

The accompanying unaudited condensed consolidated financial statements of BioDelivery Sciences International, Inc., together with its wholly-owned subsidiaries, Arius Pharmaceuticals, Inc. (Arius One) and Arius Two, Inc. (Arius Two) and its majority-owned, inactive subsidiary, Bioral Nutrient Delivery, LLC (BND) (collectively, the Company or we , us or similar terminology) have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at June 30, 2011 and for all periods presented, have been made. All intercompany accounts and transactions have been eliminated.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2010, included in the Company s 2010 Annual Report on Form 10-K, filed with the SEC on March 11, 2011 (the 2010 Annual Report) The accompanying condensed consolidated balance sheet at December 31, 2010 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements.

As used herein, the term Common Stock means the Company s common stock, par value $.001 per share.

The results of operations for the three and six month periods ended June 30, 2011 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2010 Annual Report.

BDSI ®, BEMA® and Bioral® are registered trademarks of BioDelivery Sciences International, Inc. ONSOLIS® is a registered trademark of Meda Pharmaceuticals, Inc.

Fair value of financial assets and liabilities:

The Company measures the fair value of financial assets and liabilities in accordance with GAAP which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. GAAP also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. GAAP describes three levels of inputs that may be used to measure fair value:

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

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

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

1. Basis of presentation (continued):

The following table summarizes assets and liabilities measured at fair value on a recurring basis at June 30, 2011 and December 31, 2010, respectively:

	June 30, 2011				December 31, 2010			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Fair Value Measurements Using:								
Assets								
Derivative asset (warrant)	$	$ 590,540	$	$ 590,540	$	$ 1,299,031	$	$ 1,299,031
Liabilities								
Derivative liabilities	$	$ 3,385,199	$	$ 3,385,199	$	$ 4,989,993	$	$ 4,989,993

The table below provides a reconciliation of the beginning and ending balances for the assets and liabilities measured at fair value using significant observable inputs (Level 2). The table reflects net gains and losses for all financial assets and liabilities categorized as Level 2 as of June 30, 2011 and December 31, 2010.

	$	Number of Warrants
Assets:		
Warrant asset as of January 1, 2011	$ 1,299,031	2,000,000
Decrease in fair value of warrants	(708,491)	
Warrant asset as of June 30, 2011	$ 590,540	2,000,000
Liabilities:		
Warrant liability as of January 1, 2011	$ 4,989,993	4,322,421
Increase in fair value of warrants issued in April 2010 financing due to anti-dilution adjustment of exercise price to $3.12 from $4.67 as a result of March 2011 private placement offering	460,452	
Decrease due to exercise of warrants by CDC	(336,747)	(601,120)
Decrease in fair value of warrants	(1,728,499)	
Warrant liability as of June 30, 2011	$ 3,385,199	3,721,301

New accounting pronouncements:

In April 2010, the FASB issued Accounting Standards Update 2010-12 (ASU 2010-12), Income Taxes (Topic 740): Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts. On March 30, 2010, the President of the United States signed the Health Care and Education Reconciliation Act of 2010, which is a reconciliation bill that amends the Patient Protection and Affordable Care Act that was signed on March 23, 2010 (collectively, the Acts). ASU No. 2010-12 allows entities to consider the two Acts together for accounting purposes. Upon adoption, the elimination of the future tax deduction for prescription drug costs associated with the Company s post-retirement medical and dental plans was not material to the Company s financial position, results of operations or cash flows. The Company does not believe this amendment will have a material impact on the Company s financial statements.

In December 2010, the FASB released Accounting Standards Update 2010-28 (ASU 2010-28), Intangibles-Goodwill and Other (Topic 350): When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts. The update requires a company to perform Step 2 of the goodwill impairment test if the carrying value of the reporting unit is zero or negative and adverse qualitative factors indicate that it is more likely than not that a goodwill impairment exists. The qualitative factors to consider are consistent with the existing guidance and examples in Topic 350, which requires that goodwill of a reporting unit be tested for impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying amount. The requirements in ASU 2010-28 are effective for public companies in the first annual period beginning after December 15, 2010. ASU 2010-28 has not had a material impact on the Company s consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

1. Basis of presentation (continued):

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs (ASU 2011-04). ASU 2011-04 is intended to result in convergence between U.S. GAAP and International Financial Reporting Standards (IFRS) requirements for measurement of and disclosures about fair value. The amendments are not expected to have a significant impact on companies applying U.S. GAAP. Key provisions of the amendment include: a prohibition on grouping financial instruments for purposes of determining fair value, except when an entity manages market and credit risks on the basis of the entity s net exposure to the group; an extension of the prohibition against the use of a blockage factor to all fair value measurements (that prohibition currently applies only to financial instruments with quoted prices in active markets); and a requirement that for recurring Level 3 fair value measurements, entities disclose quantitative information about unobservable inputs, a description of the valuation process used and qualitative details about the sensitivity of the measurements. In addition, for items not carried at fair value but for which fair value is disclosed, entities will be required to disclose the level within the fair value hierarchy that applies to the fair value measurement disclosed. ASU 2011-04 is effective for interim and annual periods beginning after December 15, 2011. The Company will adopt these standards on January 1, 2012 and does not expect the adoption to have a material impact on its condensed consolidated financial statements.

2. Liquidity and management s plans:

Since inception, the Company has financed its operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, funded research arrangements and revenue generated as a result of its agreements with Meda AB (Meda) regarding the Company s one approved product, ONSOLIS® (see Note 3). The Company intends to finance its research and development and commercialization efforts and its working capital needs from existing cash, royalty revenue, debt and/or equity financings, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

Significant financing and revenue for the six months ended June 30, 2011 consisted of:

- $14 million in net proceeds from a private placement offering of Common Stock in March 2011;
- Approximately $1.7 million from the exercise of Common Stock warrants;
- Approximately $0.2 million in research revenues from various contractor agreements; and
- Approximately $0.3 million from the exercise of Common Stock options.

Significant financing and revenue for the fiscal year ended December 31, 2010 consisted of:

$9.7 million in net proceeds from registered direct offering of Common Stock and warrants in April 2010;

Approximately $1 million in net royalties;

Approximately $0.7 million in research revenues from various contractor agreements;

Approximately $0.5 million in contract revenue from licensing and supply agreements;

Approximately $0.2 million in sponsored research revenue from the U.S. Government s Qualifying Therapeutic Discovery Project; and

Approximately $0.1 million from the exercise of Common Stock options.

Company management believes that the Company s existing cash and cash equivalents are sufficient to finance planned operations into the second quarter of 2012.

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FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

2. Liquidity and management s plans (continued):

The Company believes that it will be able to secure outside funding or loans at levels sufficient to support planned operations. However, there can be no assurance that additional capital or loans will be available on favorable terms, if at all. If adequate outside funds are not available, the Company would likely be required to significantly reduce or refocus its planned operations or to obtain funds through arrangements that may require it to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on the Company s financial condition and viability.

In addition, if the Company is faced with disruptions or crises in the worldwide financial markets as occurred in 2008 and 2009 and very recently in 2011, the Company s future ability to raise funds (and the cost of raising such funds) through the debt or equity markets could be materially more expensive or could make such markets unavailable at a time when the Company requires additional financial investment. If the Company is unable to attract additional funds it may adversely affect the Company s ability to achieve its development and commercialization goals, which could have a material and adverse effect on the Company s business, results of operations, financial condition and stock price.

3. Meda License, Development and Supply Agreements:

In September 2007 and August 2006, the Company entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda to develop and commercialize ONSOLIS®, respectively, the United States, Mexico and Canada (the Meda U.S. Licensing Agreements) and in certain countries in Europe (the Meda EU Licensing Agreements). These agreements were subsequently amended to cover all territories worldwide other than South Korea and Taiwan. These arrangements have license terms which commence on the date of first commercial sale in each respective territory and end on the earlier of the entrance of a generic product to the market or upon expiration of the patents, which begin to expire in January 2017. Meda may terminate the Meda U.S. Licensing Agreements at any time after a specified notice to the Company and may terminate the Meda EU Licensing Agreements only upon breach of a material provision of the contract. The Company s rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

Contractual Rights and Obligations	Cash flows received and revenue deferred June 30, 2011	December 31, 2010
North America		
License rights to ONSOLIS® (BEMA® Fentanyl) and milestone payments	$ 59,800,000	$ 59,800,000
Research and Development Services for:		
Non-Cancer subsequent indication of product and further development of initial product	$ 1,536,770	$ 1,541,570
Total North America Agreement Milestones	$ 61,336,770	$ 61,341,570

Europe and Rest of World		
License rights to BREAKYL (BEMA® Fentanyl) and milestone payments	$ 8,000,000	$ 8,000,000
Research and Development Services for:		
BREAKYL product through governmental approval in a EU country	$ 4,565,500	$ 4,522,788
Total Europe and Rest of World Milestones	$ 12,565,500	$ 12,522,788
Total All Milestones	**$ 73,902,270**	**$ 73,864,358**
Release of Milestones upon and subsequent to first sale	$ (59,718,860)	$ (59,716,770)
Remaining Deferred Revenue	$ 14,183,410	$ 14,147,588

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

3. Meda License, Development and Supply Agreements (continued):

The Company has, in accordance with GAAP, assessed these arrangements and their deliverables to determine if such deliverables are considered separate units of accounting at the inception or upon delivery of the items required in the arrangements. The assessment requires subjective analysis and requires management to make estimates and assumptions about whether deliverables within multiple-element arrangements are separable and, if so, to determine the fair value to be allocated to each unit of accounting.

The Company determined that, upon inception of both the Meda Agreements, all deliverables are to be considered one combined unit of accounting since the fair value of the undelivered license was not determinable and the research and development efforts provided do not have standalone value apart from the license. As such, all cash payments from Meda that were related to these deliverables were recorded as deferred revenue. All cash payments from Meda for upfront and milestone payments and research and development services provided are nonrefundable. Upon commencement of the license term (date of first commercial sale in each territory), the license and certain deliverables associated with research and development services were deliverable to Meda. The first commercial sale in the U.S. occurred in October 2009. As a result, $59.7 million of the aggregate milestones and services revenue were recognized. Upon first commercial sale in a European country, an estimated $18.0 million will be recognized, which includes an additional $5.0 million in milestones and approximately $0.5 million in research and development services. At June 30, 2011, there was remaining deferred revenue of $14.2 million, of which $12.6 million is related to the EU Meda arrangement milestones and EU Meda research and development services. The Company has estimated the amount of time and associated dollars (based on comparable services provided by outside third parties), as further noted below. As time progresses, the Company will continue to estimate the time required for ongoing obligations, and adjust the remaining deferral accordingly on a quarterly basis.

In connection with delivery of the license to Meda, the Company has determined that each of the undelivered obligations have stand-alone value to Meda as these post-commercialization services encompass additional clinical trials on different patient groups but do not require further product development and these services and product supply obligations can be provided by third-party providers available to Meda. Further, the Company obtained third-party evidence of fair value for the non-cancer and other research and development services and other service obligations, based on hourly rates billed by unrelated third-party providers for similar services contracted by the Company. The Company also obtained third-party evidence of fair value of the product supply deliverable based on the outsourced contract manufacturing cost charged the Company from the third-party supplier of the product. The arrangements do not contain any general rights of return. Therefore, the remaining deliverables to the arrangements will be accounted for as three separate units of accounting to include (1) product supply, (2) research and development services for the non-cancer indication and further research and development of the first indication of the ONSOLIS® product and (3) the combined requirements related to the remaining other service-related obligations due Meda to include participation in committees and certain other specified services. A portion of the upfront payments attributed to other service-related obligations will be recognized as revenue as services are provided through expiration of the license. This represents approximately $1.6 million (under the Meda U.S. Agreements) and $0.1 million (under the Meda EU Agreements).

In accordance with GAAP, the Company has determined that it is acting as a principal under the Meda Agreements and, as such, will record product supply revenue, research and development services revenue and other services revenue amounts on a gross basis in the Company s consolidated financial statements. The Company earns royalties based on a percentage of net sales revenue of the ONSOLIS® product. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured and all other revenue recognition criteria are met.

ONSOLIS® was approved by the Canadian regulatory authorities in May 2010, and is the first product approved in Canada for the management of breakthrough cancer pain. ONSOLIS® will be marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between Meda and Valeant Canada Limited. It is expected that the commercial launch of ONSOLIS® in Canada will take place in the third quarter of 2011.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

3. Meda License, Development and Supply Agreements (continued):

On October 20, 2010, the Company and Meda announced approval of BEMA® Fentanyl in Europe via the Decentralized Procedure, with Germany acting as Reference Member State. BEMA® Fentanyl is indicated for the management of breakthrough pain in opioid tolerant, adult patients with cancer. National marketing authorization approvals, enabling commercial sales in each of the 25 individual EU countries, are now expected over the next several months. BEMA® Fentanyl will be marketed as BREAKYL (fentanyl buccal film) in Europe. Under the terms of its licensing agreement with Meda, the Company will receive a milestone payment of $2.5 million triggered by the first national marketing authorization of BREAKYL and another $2.5 million at the time of the first commercial sale that is anticipated sometime prior to the end of 2011. Additionally, the Company will receive a double-digit royalty on net sales.

4. Other License Agreements and Acquired Product Rights:

Kunwha License Agreement

In May 2010, the Company entered into a License and Supply Agreement (the Kunwha License Agreement) with Kunwha Pharmaceutical Co., Ltd., (Kunwha) a corporation organized under the laws of the Republic of Korea, to develop, manufacture, sell and distribute the Company s BEMA® Fentanyl product in the Republic of Korea. The Kunwha License Agreement is for a term beginning on May 26, 2010 until the date of expiration of PCT/US07/16634 (WO 2008/011194) filed in South Korea as 10-2009-7003532, or July 23, 2027, whichever is later. Either the Company or Kunwha may terminate the Kunwha License Agreement prior to the expiration of the term: (i) upon or after the cessation of operations of the other party or the bankruptcy, insolvency, dissolution or winding up of the other party (other than dissolution or winding up for the purposes or reconstruction or amalgamation); or (ii) upon or after the breach of any material provision of Kunwha License Agreement by the other party if the breaching party has not cured such breach within a period of time after written notice thereof by the non-breaching party. In addition, both the Company and Kunwha have the right to terminate the Kunwha License Agreement on advanced written notice upon the occurrence of certain specified events such as failure to pay required royalties or the loss, revocation, suspension, termination or expiration of approvals to engage in the activities covered by the Kunwha License Agreement.

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for BEMA® Fentanyl in the Republic of Korea, while the Company will retain all other licensing rights to BEMA® Fentanyl not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million in May 2010 (net of taxes the company received approximately $0.25 million) and will be responsible to make certain milestone payments which could aggregate up to $1.3 million (net of taxes the company receives approximately $1.1 million). In addition, Kunwha will pay royalties to the Company based on Net Sales (as defined in the Kunwha License Agreement) and will purchase all supplies of BEMA® Fentanyl from the Company.

Kunwha will be responsible for payment of all costs associated with BEMA® Fentanyl in the Republic of Korea. Kunwha and the Company will own any Improvements (as defined in the Kunwha License Agreement) made exclusively by such party with respect to the Licensed Product and will jointly own any Improvements that are the product of collaboration.

The upfront payment from Kunwha $0.3 million (net of taxes, approximately $0.25 million) received in June 2010 was recorded as contract revenue upon receipt. The Company early adopted the provisions of ASU 2010-17 in analyzing the up-front milestone in the license agreement.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

4. Other License Agreements and Acquired Product Rights:

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement (the TTY Agreement) with TTY Biopharm Ltd. (TTY) for the exclusive rights to develop and commercialize BEMA® Fentanyl (marketed as ONSOLIS® in the U.S.) in the Republic of China, Taiwan. The TTY Agreement results in potential milestone payments to the Company of up to $1.3 million, which includes an already received upfront payment of $0.3 million that was recorded as contract revenue upon receipt. In addition, the Company will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filing of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The term of the TTY Agreement is for the period from October 4, 2010 until the date fifteen (15) years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement. Either the Company or TTY may terminate the TTY Agreement prior to the expiration of the term: (i) upon or after the cessation of operations of the other party or the bankruptcy, insolvency, dissolution or winding up of the other party (other than dissolution or winding up for the purposes or reconstruction or amalgamation); or (ii) upon or after the breach of any material provision of TTY Agreement by the other party if the breaching party has not cured such breach within a period of time after written notice thereof by the non-breaching party. In addition, TTY may terminate the TTY Agreement on advanced written notice to the Company, and both the Company and TTY have the right to terminate the TTY Agreement on advanced written notice upon the occurrence of certain specified events such as failure to pay required royalties or the loss, revocation, suspension, termination or expiration of approvals to engage in the activities covered by the TTY Agreement.

Agreement with QLT to Purchase Non-US BEMA® Rights

The Company s August 2006 agreement with QLT USA, Inc. (QLT) to purchase the non-US rights to the BEMA® delivery technology required a payment by the Company of $1.0 million to QLT upon the approval in the first BEMA-related product in a non-US country. This payment, included in acquired product rights in the accompanying condensed consolidated balance sheet, was triggered by the Company s announcement on May 10, 2010 of the approval of a New Drug Submission by Health Canada, the regulatory authority in Canada, for ONSOLIS®. The Company made a payment to QLT of $0.75 million in June 2010 with the remaining $0.25 million expected to be paid in 2011 upon the complete transfer of all required patent documentation.

License Amendment with CDC

On May 12, 2011, the Company entered into an Amendment to Clinical Development and License Agreement (the CDLA Amendment) by and among CDC V, LLC (CDC), NB Athyrium LLC (Athyrium). The Company is a party to a Clinical Development and License Agreement, dated as of July 14, 2005 (as amended, the CDLA), with a predecessor to CDC pursuant to which CDC provided funding for the development of the Company s ONSOLIS® product. Athyrium holds certain rights, acquired from CDC, to receive royalties on sales of ONSOLIS®.

Under the terms of the CDLA Amendment, among other matters, the parties agreed to increase the royalty rate to be received by CDC/Athyrium retroactively to the initial launch date of ONSOLIS® and, accordingly, the Company has recorded $0.3 million as additional cost of product royalties for the six months ended June 30, 2011. In addition, certain terms of the CLDA were amended and restated to clarify that royalty payments by the Company under the CDLA will be calculated based on Meda s sales of ONSOLIS®, whereas previous Company royalty payments to CDC were calculated based on Company sales of ONSOLIS® to Meda. The difference between these two calculations resulted in a $1.1 million overpayment by the Company. This will be rectified by adjusting future royalty payments.

As a result, the Company did not pay the March 31, 2011 quarterly royalty payment due to CDC/Athyrium and will not be required to pay another royalty payment until December 31, 2011. Accordingly, for the six months ended June 30, 2011, there is a $0.4 million prepaid royalty recorded in the accompanying condensed consolidated balance sheet and a corresponding credit in cost of product royalties which was recorded for the three months ending June 30, 2011.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE SIX MONTHS ENDED JUNE 30, 2011 AND 2010

(Unaudited)

5. Related Party Transactions:

On December 30, 2009, the Company entered into an Emezine Settlement Agreement (the Settlement Agreement) with Accentia Biopharmaceuticals, Inc., a related party (Accentia), Arius One and Accentia Pharmaceuticals, Inc. f/k/a TEAMM Pharmaceuticals Inc., a subsidiary of Accentia (TEAMM). Pursuant to the Settlement Agreement, the Company has received a warrant to purchase 2 million shares of common stock of Accentia s majority-owned subsidiary, Biovest International, Inc. (Biovest), from Accentia. Such warrant has an exercise price equal to 120% of the closing bid price of Biovest s common stock as of the date the bankruptcy court overseeing Accentia s Chapter 11 reorganization entered a final order authorizing Accentia to carry out the Settlement Agreement, which was $0.89 per share. The warrant was recorded at December 31, 2009 with a Black-Scholes value of $0.6 million. However, the warrant was not received by the Company until February 17, 2010 (the Settlement Date), the date which the bankruptcy court issued the final order authorizing the Settlement Agreement. At the settlement date, the warrant was valued using the Black-Scholes model, which resulted in a gain on settlement of $0.4 million for the six months ended June 30, 2010, and is included in related party general and administrative in the accompanying condensed consolidated statement of operations. Subsequent to the Settlement Date and prior to the end of the six months ended June 30, 2010, the stock price of Biovest s common stock increased, resulting in a derivative gain of $2.1 million and is included in derivative (loss) gain in the accompanying condensed consolidated statement of operations. During the six months ended June 30, 2011, the stock price of Biovest s common stock declined, resulting in a derivative loss of $0.7 million and is included in derivative gain in the accompanying condensed consolidated statement of operations.

6. Derivative Financial Instruments:

The Company generally does not use derivative instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. However, certain other financial instruments, such as warrants and embedded conversion features that are indexed to the Company s Common Stock, are classified as liabilities when either: (a) the holder possesses rights to net-cash settlement or (b) physical or net-share settlement is not within the control of the Company. In such instances, net-cash settlement is assumed for financial accounting and reporting, even when the terms of the underlying contracts do not provide for net-cash settlement. Such financial instruments are initially recorded at fair value estimated on the settlement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate, and then adjusted to fair value at the close of each reporting period.

The following tabular presentation reflects the components of derivative assets and liabilities as of June 30, 2011 and December 31, 2010:

	June 30, 2011	December 31, 2010
Derivative assets at fair value:		
Free standing warrants related party	$ 590,540	$ 1,299,031

	June 30, 2011	December 31, 2010
Shares into which derivative asset can be settled:		
Free standing warrants related party	2,000,000	2,000,000

	June 30, 2011	December 31, 2010
Derivative liability at fair value:		
Free standing warrants*	$ 3,385,199	$ 4,989,993

*