BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 13, 2011
Table of Contents

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 March 31, 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 ¨ 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 May 12, 2011, there were 28,976,026 shares of company common stock issued and 28,960,535 shares of company common stock outstanding.

Table of Contents

BioDelivery Sciences International, Inc. and Subsidiaries

Quarterly Report on Form 10-Q

TABLE OF CONTENTS

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF MARCH 31, 2011 AND DECEMBER 31, 2010

	March 31, 2011 (Unaudited)	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,221,117	$ 18,208,659
Accounts receivable, other	741,343	633,216
Prepaid expenses and other current assets	380,833	236,112
Total current assets	27,343,293	19,077,987
Equipment, net	3,322,088	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	(3,081,402)	(2,858,657)
Total other intangible assets	6,818,598	7,041,343
Derivative asset, warrant (note 6)	704,140	1,299,031
Other assets	21,976	21,976
Total assets	$ 40,925,095	$ 33,580,206
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 6,569,754	$ 4,656,295
Deferred revenue, current	12,601,622	12,491,907
Derivative liabilities (note 6)	4,882,416	4,989,993
Total current liabilities	24,053,792	22,138,195
Deferred revenue, long-term	1,654,001	1,655,681
Total liabilities	25,707,793	23,793,876
Commitments and contingencies		
Stockholders equity:		
Common Stock, $.001 par value; 45,000,000 shares authorized, 28,921,936 and 24,038,445 shares issued; 28,906,445 and 24,022,954 shares outstanding in 2011 and 2010, respectively	28,923	24,039
Additional paid-in capital	96,501,333	82,055,934
Treasury stock, at cost, 15,491 shares, 2011 and 2010	(47,183)	(47,183)
Accumulated deficit	(81,265,771)	(72,246,460)
Total stockholders equity	15,217,302	9,786,330
Total liabilities and stockholders equity	$ 40,925,095	$ 33,580,206

See notes to condensed consolidated financial statements

1

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE MONTHS ENDED MARCH 31, 2011 AND 2010

(Unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Revenues:		
Product royalty revenues	$ 34,225	$ 12,532
Research fees	193,238	177,143
Contract revenue	2,000	37,707
Total Revenue:	229,463	227,382
Cost of product royalties	297,419	12,429
Expenses:		
Research and development	6,690,674	1,449,465
General and administrative	1,764,489	2,204,761
Related party general and administrative, net	18,750	(360,500)
Total Expenses:	8,473,913	3,293,726
Loss from operations	(8,541,869)	(3,078,773)
Interest income	37,784	3,291
Derivative (loss) gain	(487,313)	2,869,972
Other (expense) income, net	(27,913)	14,288
Net Loss	(9,019,311)	(191,222)
Net Loss attributable to common stockholders	$ (9,019,311)	$ (191,222)
Per share amounts, basic and diluted:	$ (0.36)	$ (0.01)
Weighted average common stock shares outstanding- basic and diluted:	25,105,563	21,177,116

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

FOR THE THREE MONTHS ENDED MARCH 31, 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			246,056			246,056
Stock option exercises	75,798	76	207,378			207,454
Private placement offering, net	4,807,693	4,808	13,991,965			13,996,773
Net loss					(9,019,311)	(9,019,311)
Balances, March 31, 2011	28,921,936	$ 28,923	$ 96,501,333	$ (47,183)	$ (81,265,771)	$ 15,217,302

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2011 AND 2010

(Unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Operating activities:		
Net loss	$ (9,019,311)	$ (191,222)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	326,923	303,949
Derivative loss (gain)	487,313	(2,869,972)
Stock-based compensation expense	246,056	433,524
Gain on settlement		(382,000)
Changes in assets and liabilities:		
Accounts receivable	(108,126)	802,312
Prepaid expenses and other assets	(144,721)	73,131
Accounts payable and accrued expenses	1,964,333	(2,305,765)
Deferred revenue	108,035	220,140
Income tax payable		(350,000)
Net cash flows used in operating activities	(6,139,498)	(4,265,903)
Investing activities:		
Purchase of equipment	(1,398)	(91,480)
Net cash flows from investing activities	(1,398)	(91,480)
Financing activities:		
Proceeds from issuance of common stock	13,996,773	
Proceeds from exercise of stock options	207,454	97,881
Change in amounts due to related parties	(50,873)	(2,503,063)
Net cash flows from financing activities	14,153,354	(2,405,182)
Net change in cash and cash equivalents	8,012,458	(6,762,565)
Cash and cash equivalents at beginning of period	18,208,659	23,873,403
Cash and cash equivalents at end of period	$ 26,221,117	$ 17,110,838

See notes to condensed consolidated financial statements

Table of Contents

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 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 March 31, 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 month period ended March 31, 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)

5

Table of Contents

1. Basis of presentation (continued):

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

	March 31, 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)	$	$ 704,140	$	$ 704,140	$	$ 1,299,031	$	$ 1,299,031
Liabilities								
Derivative liabilities	$	$ 4,882,415	$	$ 4,882,415	$	$ 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 March 31, 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	(594,891)	
Warrant asset as of March 31, 2011	$ 704,140	2,000,000
Liabilities:		
Warrant liability as of January 1, 2011	$ 4,989,994	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 in fair value of warrants	(568,030)	
Warrant liability as of March 31, 2011	$ 4,882,416	4,322,421

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 is not expected to materially impact the Company s consolidated financial statements.

Table of Contents

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, new sources of financing, 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 period ended March 31, 2011 consisted of:

- $14 million in net proceeds from a private placement offering of Common Stock in March 2011;
- Approximately $0.2 million in research revenues from various contractor agreements; and
- Approximately $0.2 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 agreement;
- Approximately $0.2 million in sponsored research revenue from the U.S. Government s Qualifying Therapeutic Discovery Project (see note 13); 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.

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, 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 our ability to achieve our 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.

7

Table of Contents

3. Meda License, Development and Supply Agreements:

In August 2006 and September 2007, the Company entered into license, development and supply agreements (collectively referred to as the Meda Agreements) with Meda to develop and commercialize ONSOLIS® in 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. The Company s rights and obligations under these arrangements and related contractual cash flows from Meda are as follows:

	Cash flows received and revenue deferred	
Contractual Rights and Obligations	**March 31, 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	$ 1,541,570	$ 1,541,570
Total North America Agreement Milestones	$ 61,341,570	$ 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	$ 4,632,823	$ 4,522,788
Total Europe and Rest of World Milestones	$ 12,632,823	$ 12,522,788
Total All Milestones	**$ 73,974,393**	**$ 73,864,358**
Release of Milestones upon and subsequent to first sale	$ (59,718,770)	$ (59,716,770)
Remaining Deferred Revenue	$ 14,255,623	$ 14,147,588

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 March 31, 2011, there was remaining deferred revenue of $14.3 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.

Table of Contents

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

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. The estimated portion of the upfront payments of approximately $1.6 million (under the Meda U.S. Agreements) and $0.1 million (under the Meda EU Agreements) attributed to these other service-related obligations will be recognized as revenue as services are provided through expiration of the license terms.

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. ONSOLIS® is expected to launch in Canada by the end of the second quarter of 2011.

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., a corporation organized under the laws of the Republic of Korea (Kunwha), to develop, manufacture, sell and distribute the Company s BEMA® Fentanyl product (the Licensed Product) in the Republic of Korea (the Territory). 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.

Table of Contents

4. Other License Agreements and Acquired Product Rights (continued):

Under the terms of the Kunwha License Agreement, Kunwha was granted exclusive licensing rights for the Licensed Product in the Territory, while the Company will retain all other licensing rights to the Licensed Product not previously granted to third parties. Kunwha paid to the Company an upfront payment of $0.3 million (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 approximating $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 the Licensed Product from the Company.

Kunwha will be responsible for payment of all costs associated with the Licensed Product in the Territory. 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, approximating $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.

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement with 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 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 agreement with TTY 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.

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.

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 quarter ended March 31, 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 three months ended March 31, 2010, the stock price of Biovest s common stock increased, which resulted 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 three months ended March 31, 2011, the stock price of Biovest s common stock declined, which resulted in a derivative loss of $0.6 million is included in derivative (loss) gain in the accompanying condensed consolidated statement of operations.

10

Table of Contents

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 March 31, 2011 and December 31, 2010:

	March 31, 2011	December 31, 2010
Derivative assets at fair value:		
Free standing warrants related party	$ 704,140	$ 1,299,031

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

	March 31, 2011	December 31, 2010
Derivative liability at fair value:		
Free standing warrants	$ 4,882,416	$ 4,989,993

The following tabular presentation reflects the components of derivative financial instruments for the three month periods ended March 31, 2011 and 2010:

	3 months ending Mar 31, 2011	3 months ending Mar 31, 2010
Shares into which derivative liability can be settled:		
Free standing warrants	4,322,421	4,211,284

	3 months ending Mar 31, 2011	3 months ending Mar 31, 2010
Derivative (expense) income in the accompanying statement of operations is related to the individual derivatives as follows:		
Free standing warrants assets, related party	$ (594,891)	$ 2,103,000
Free standing warrants liabilities	107,578	766,972
	$ (487,313)	$ 2,869,972

11

Table of Contents

7. Stockholders Equity:

Stock-based compensation:

During the three months ended March 31, 2011, 296,174 options with fair market value of approximately $1 million were granted to Company employees and directors. The employee options granted have a term of 10 years from the grant date and vest ratably over a three year period. Director options vest immediately. The fair value of each option is amortized as compensation expense evenly through the vesting period. The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from historical volatility of the Common Stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the three months ended March 31, 2011 follows:

Expected price volatility	72.29%-73.21%
Risk-free interest rate	1.93%-1.99%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the three months ended March 31, 2011 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2011	4,311,539	$ 3.65	
Granted			
Officers and Directors	57,256		
Others	238,918		
Exercised	(75,798)		
Forfeitures	(7,324)		
Outstanding at March 31, 2011	4,524,591	$ 3.66	$ 2,576,379

Options outstanding at March 31, 2011 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	3,583,346	6.91	$ 2.97	
$ 5.01 10.00	941,245	6.48	$ 6.27	
	4,524,591			$ 2,576,379

Table of Contents

7. Stockholders Equity (continued):

Options exercisable at March 31, 2011 are as follows:

Range of Exercise Prices	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 1.00 5.00	2,466,219	5.98	$ 2.84	
$ 5.01 10.00	921,245	6.44	$ 6.29	
	3,387,464			$ 2,011,598

The weighted average grant date fair value of options granted during the three months ended March 31, 2011 was $3.44. There were no options granted during the three months ended March 31, 2011 whose exercise price was lower than the estimated market price of the stock at the grant date.

A summary of the status of the Company s non-vested stock options as of January 1, 2011, and changes during the three months ended March 31, 2011 is summarized as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Nonvested at January 1, 2011	1,036,960		
Granted	296,174		
Vested	(208,683)		
Forfeited	(7,324)		
Nonvested at March 31, 2011	1,117,127	$ 3.21	$ 579,653

As of March 31, 2011, there was approximately $1.7 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next two years.

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements. Warrants outstanding at March 31, 2011, all of which are exercisable are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 5.00	4,798,921	2.06	$ 3.54	

$ 5.01	10.00	475,000	0.30	$ 5.55	
		5,273,921			$ 1,456,276

Table of Contents

8. Net Loss per Common Share

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

	Three Months Ended March 31,	
	2011	2010
Net loss	$ (9,019,311)	$ (191,222)
Basic and Diluted:		
Weighted average shares outstanding (denominator)	25,105,563	21,177,116
Net loss per common share basic and diluted	$ (0.36)	$ (0.01)

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

9. Impairment of License:

The Company holds patents and patent applications for the Bioral® (cochleate) drug delivery technology, and is the worldwide, exclusive licensee of the technology pursuant to licensing agreements with the University of Medicine and Dentistry of New Jersey and Albany Medical College (the Bioral® License Agreements). Since 2004, the Company s development and commercialization activities have focused increasingly (and from 2008 through 2010, almost exclusively) on its BEMA® delivery technology and related products and product candidates. The most advanced development of the Bioral® technology was a Phase 1 study performed with Bioral® Amphotericin B, on which preliminary results were reported in February 2009. Regarding the most recent developments with the Bioral® platform, on January 20, 2009, the Company entered into a Research Collaboration and License Agreement with the Drugs for Neglected Diseases initiative (DNDi), a not-for-profit foundation, for the development and distribution of Bioral® Amphotericin B for Visceral Leishmaniasis, and on October 6, 2009, the Company announced it was awarded a $1.3 million grant from the Walter Reed Army Institute of Research (WRAIR) to support the clinical study of Bioral® Amphotericin B in the treatment of Cutaneous Leishmaniasis. Both infections are typically found in third world countries. To date, $50,000 of WRAIR grant has been funded to the Company.

During the period ended June 30, 2010, an animal study undertaken by DNDi was found to be marginally positive, but treatment of the infection did not warrant further consideration with Bioral® Amphotericin B. Also during the period ended June 30, 2010, the Company elected not to pursue the application of Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis, and as such to not continue the WRAIR agreement, which was terminated. Accordingly, the aforementioned initial $50,000 funded by WRAIR was refunded in July 2010 and is included in General and Administrative expenses in the Condensed consolidated statements of income. In addition, as previously reported, in September 2009 the Company vacated its Newark, New Jersey research facility (where research on the Bioral® technology was being undertaken) and terminated its relationship with Dr. Raphael Mannino, the Company s then Chief Scientific Officer and the inventor of many of the patents directed to the cochleate technology. The Company dedicated very limited resources to the Bioral® platform during the first half of 2010. The Bioral® platform and its associated intellectual property are presently being reviewed for potential strategic, commercial, licensing and divestiture opportunities.

As a result of these developments, at June 30, 2010, the Company performed an impairment test on the carrying value of the Bioral® License Agreements and determined an impairment charge for the full unamortized carrying value of approximately $0.2 million was warranted. The amount is shown in the accompanying income statement as impairment of intangible license. There were no impairments as of the three months ending March 31, 2011.

Table of Contents

9. Subsequent Events:

On May 12, 2011, the Company and its wholly owned subsidiaries, Arius One and Arius Two, 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 CDLA Amendment amends certain terms of that certain Clinical Development and License Agreement, dated as of July 14, 2005 and as amended (the CDLA), under which CDC s predecessors provided funding for the clinical development of the Company s ONSOLIS® product. Athyrium is a party to the CDLA Amendment as CDC has previously, in addition to providing certain other rights to Athyrium, assigned certain of CDC s rights to receive royalties from the Company under the CDLA to Athyrium. Arius and Arius Two are parties to the CDLA as they legally hold certain intellectual property rights to 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 quarter ended March 31, 2011.

Table of Contents

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the Condensed Consolidated Financial Statements and Notes thereto included elsewhere in this Quarterly Report. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company s actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Quarterly Report and in the Company s other filings with the Securities and Exchange Commission (the SEC). See Cautionary Note Regarding Forward Looking Statements below.

For the three months ended March 31, 2011 compared to the three months ended March 31, 2010

Product Royalty Revenues. We recognized $0.03 million and $0.01 million in product royalty revenue during the three months ended March 31, 2011 and 2010, respectively, under our license agreement with Meda. For both periods, we did not ship product to Meda. Therefore, the revenue recognized was for minor pricing reconciliations.

Research Revenues. We recognized $0.2 million of revenue related to a research and development agreement with Meda during the three months ended March 31, 2011 and 2010, respectively.

Contract Revenues. We recognized $0.002 million and $0.04 million during the three months ended March 31, 2011 and 2010, respectively, in contract revenue related to previously deferred revenue under our license agreement with Meda.

Cost of Product Royalties. We recognized $0.3 million and $0.01 million during the three months ended March 31, 2011 and 2010, respectively, in cost of product royalties related to pricing adjustments owed to CDC IV, LLC (CDC), since no product was shipped during both periods. Beginning in 2005, we entered into agreements with CDC s predecessor under which CDC provided funds to us for the development of ONSOLIS®. As a result, we owe a royalty to CDC based on net sales of ONSOLIS®. An interpretation of a provision of our agreement calls for adjustments to the CDC royalty based on the pricing of competitive products to ONSOLIS®. After analysis of this provision, we have amended our agreement with CDC and as a result of that amendment, agreed to increase the royalty rate retroactively to the initial launch date of ONSOLIS® and accordingly have recorded $0.3 million as additional cost of product royalties in this quarter. This explains the relatively large expense for the three months ended March 31, 2011 in spite of having no corresponding revenue for the period.

Research and Development Expenses. During the three months ended March 31, 2011 and 2010, research and development expenses totaled $6.7 million and $1.5 million, respectively. The increase in research and development expenses can be attributed to the ramp-up of the Buprenorphine clinical trials. Our scientific staff continued to work toward development and application of our BEMA® delivery technology, but particularly with respect to ONSOLIS® and Buprenorphine. Funding of this research in 2011 and 2010 was obtained through deferred license revenue, a private placement stock offering, exercise of options by employees and directors and sales of securities. Research and development expenses generally include compensation for 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® drug delivery technologies.

General and Administrative Expenses, net. During the three months ended March 31, 2011 and 2010, general and administrative expenses totaled $1.8 million, respectively. General and administrative costs include legal, accounting, and management wages, legal and professional fees, office supplies, travel costs, compensation costs, consulting fees and business development costs. During the three months ended March 31, 2010, we recorded a gain on settlement for a warrant from a related party which totaled approximately $0.4 million (See Note 5 to the accompanying financial statements). This is included in related party general and administrative, net.

Interest Income. During the three months ended March 31, 2011 and 2010 we had interest income of $0.04 million and $0.004 million, respectively.

Table of Contents

Derivative (loss) gain. Derivative (loss) gain is related to the adjustment to fair value of derivative assets and liabilities. Our related party derivative asset consists of 2 million Biovest options. Biovest stock price dropped during the three months ended March 31, 2011. This was the primary cause of our derivative loss. For the three months ended March 31, 2010, the opposite occurred. The Biovest share price increased, causing a large derivative gain.

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from short-term borrowings or convertible notes, the sale of a royalty stream asset, sponsored research, funded research arrangements and from various strategic and licensing agreements, including a clinical development agreement with CDC IV, LLC and commercialization agreements with Meda relating to ONSOLIS®. We intend to finance our research and development programs, commercialization efforts and our working capital needs from existing cash, product royalty revenue, new sources of financing, licensing and commercial partnership agreements and, potentially, through the exercise of outstanding Common Stock options and warrants to purchase Common Stock.

On March 11, 2011, we consummated a private placement offering to institutional investors of an aggregate of 4,807,693 shares of our common stock at a price equal to $3.12 per share, representing a 10% discount to an agreed upon volume weighted average price of our stock. Gross proceeds we received from the offering were $15 million (net proceeds approximating $14 million). No warrants were issued to investors in the Offering. Proceeds from this offering are expected to be used principally for the clinical development of our pipeline of products, particularly BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone. The proceeds also strengthen the Company s balance sheet as the Company participates in commercial partnering discussions for BEMA® Buprenorphine.

Our cash used in operations will continue beyond our ONSOLIS® agreements with Meda as we research, develop, and potentially, manufacture and commercialize additional drug formulations with our BEMA® technology. We believe further application of our BEMA® delivery technology to other drugs will result in license agreements (and potential upfront, milestone and/or royalty payments to us) with other commercial partners such as Meda, and so our plan of operations for the foreseeable future will be to develop additional products with our BEMA® technology. Our near term focus will not be on the marketing, production or sale of FDA approved products, although we may seek to develop these capabilities in the future as part of our longer term plans.

At March 31, 2011, we had cash and cash equivalents of approximately $26.2 million. We used $6.1 million of cash from operations during the three months ended March 31, 2011. As of March 31, 2011, we had stockholders equity of $15.2 million, versus $9.8 million at December 31, 2010. Our existing cash and cash equivalents are believed by our management to be sufficient to finance planned operations into the second quarter of 2012.

However, additional capital may be required in order to proceed with our support of the manufacturing of ONSOLIS®, clinical development programs for other products in our pipeline such as BEMA® Buprenorphine (the scale of which is dependent in part on the success of ONSOLIS® and on the results from our clinical studies for each of these products), and for general working capital. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. Accordingly, we anticipate that we may be required to raise additional capital through a variety of sources, including:

public equity markets;

private equity financings;

collaborative arrangements;

Table of Contents

grants and new license revenues;

bank loans;

equipment financing;

public or private debt; and

exercise of existing warrants.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations in 2011 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

In addition, if we are faced with worldwide financial and credit crises as occurred in 2008 and 2009, it may make the future cost of raising funds through the debt or equity markets more expensive or make financial markets unavailable to us at times when we require additional financing.

If we are unable to attract additional funds it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

Update on Timing for Canadian Launch of Onsolis®

On November 9, 2010, we announced that due to a temporary stoppage of manufacturing at Aveva Drug Delivery Systems, Inc., our ONSOLIS® manufacturer (which stoppage ended shortly after such announcement), we estimated that launch stocks of ONSOLIS® for shipment in the Canadian market would be available in late March or April of 2011. By way of update, all product necessary to supply the Canadian launch of ONSOLIS® and to continue to supply the United States has now been manufactured at Aveva. However, due to an analytical method testing issue encountered recently at Aveva that must be resolved in order to release the product into the marketplace , the commercial launch in Canada has been further delayed. Our current expectation is that the issue will be resolved during the second quarter of 2011 allowing for shipment of product to Canada by the end of the second quarter. Commercial supply of ONSOLIS® in the United States could be impacted should this problem persist during this same time period. Our ONSOLIS® commercial partner, Meda Pharmaceuticals, has implemented a program in the United States to extend the shelf life of product currently in their inventory that could assist in minimizing disruption of product supply in the United States.

Contractual Obligations and Commercial Commitments

Our contractual obligations as of March 31, 2011 are as follows:

	Payments Due by Period				
		Less than			More than
	Total	1 year	1-3 years	3-5 years	5 years
Operating lease obligations	$ 226,213	$ 121,924	$ 104,289	$	$
Employment agreements	727,125	727,125			
Minimum royalty expenses*	12,000,000	375,000	3,000,000	3,000,000	5,625,000
Total contractual cash obligations	$ 12,953,338	$ 1,224,049	$ 3,104,289	$ 3,000,000	$ 5,625,000

* Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC regardless of actual sales. Minimum royalties began in the second quarter of 2011.

Table of Contents

Off - Balance Sheet Arrangements

As of March 31, 2011, we had no off-balance sheet arrangements.

Effects of Inflation

We do not believe that inflation has had a material effect on our financial position or results of operations. However, there can be no assurance that our business will not be affected by inflation in the future.

Critical Accounting Policies

Valuation of Goodwill and Intangible Assets

Our intangible assets include goodwill, product rights, and licenses, all of which are accounted for based on GAAP related to Goodwill and Other Intangible Assets. Accordingly, goodwill is not amortized but is tested annually in December 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 benefit, ranging from eleven to thirteen years. Our carrying value of goodwill at March 31, 2011 was $2.715 million.

We amortize intangibles with limited useful lives based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements or the underlying patents. Our carrying value of other amortizing intangible assets at March 31, 2011 was $6.8 million, net of accumulated amortization of $3.1 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, which is performed in December, 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.

In accordance with generally accepted accounting principles related to the 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.

There were no impairment charges during the three months ended March 31, 2011. We recorded a $0.2 million impairment charge in 2010. The impairment charge removed the remaining intangible asset related to Bioral®. We determined not to pursue Bioral® Amphotericin B for the treatment of Cutaneous Leishmaniasis (see Note 9 to the accompanying financial statements).

Table of Contents

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

We account for stock-based awards to employees and non-employees in accordance with generally accepted accounting principles related to share based payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our Common Stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide the service in exchange for the award. We use the Black-Scholes options-pricing model to determine the fair value of stock option and warrant grants. We also use the Black-Scholes option pricing model as the primary basis for valuing our derivative liabilities and assets at each reporting date (both embedded and free-standing derivatives). The underlying assumptions used in this determination are primarily the same as are used in the determination of stock-based compensation discussed in the previous paragraph except contractual lives of the derivative instruments are utilized rather than expected option terms as discussed in the previous paragraph.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents include Ultra Short Term Government Funds. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents with financial institutions in the United States. The Federal Deposit Insurance Corporation (FDIC) covers $0.25 million for substantially all depository accounts. We from time to time may have amounts on deposit in excess of the insured limits. As of March 31, 2011, we had approximately $26.2 million which exceed these insured limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Market indexed security risk

We have a warrant to purchase 2 million shares of common stock of Biovest International. This warrant investment is re-measured to its fair value at each reporting period with changes in its fair value recorded as derivative (loss) gain in the condensed consolidated statement of operations. We use the Black-Scholes model for valuation of the warrants.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

20

Table of Contents

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

Changes in Internal Control over Financial Reporting

Further, there were no changes in the Company s internal control over financial reporting during the Company s first fiscal quarter of 2011 that materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Limitations on the Effectiveness of Internal Controls

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

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form 10-Q, including in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations (and the Liquidity and Capital Resources section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes forward-looking statements within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as projects , may , could , would , should , believes , expects , anticipates , estimates , intends , plans or similar expressions. These statements are based upon the c and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the Securities and Exchange Commission. Actual results, including, without limitation: (i) actual sales results and royalty or milestone payments, if any, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for completion, and results of, scheduled or additional clinical trials and the FDA s review and/or approval and commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Such factors include, among others, those listed under Item 1A of the Company s 2010 Annual Report and other factors detailed from time to time in our other filings with the Securities and Exchange Commission. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Quarterly Report. We undertake no obligation to publically update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On November 5, 2010, we received notice of a possible legal action against us for alleged patent infringement involving a third-party patent. The aforementioned legal action was filed by MonoSol Rx, LLC (MonoSol) in the Federal District Court of New Jersey on November 2, 2010, and we were formally served on January 19, 2011. MonoSol claims that our manufacturing process for ONSOLIS®, which has never been disclosed publicly and which we and our partners maintain as a trade secret, infringes its patent (United States Patent No. 7,824,588). MonoSol also has made a claim of false marking as part of its complaint. Of note, the BEMA® technology itself is not at issue in the case, but rather only the manner in which ONSOLIS®, which incorporates the BEMA® technology, is manufactured.

We refute as without merit MonoSol s assertion of patent infringement, which relates to our confidential, proprietary manufacturing process for ONSOLIS®. We further refute MonoSol s claim of false marking. On February 23, 2011, we filed our initial answer in this case. In our answer, we stated our position that our products, methods and/or components do not infringe MonoSol s patent because they do not meet the limitations of any valid claim of MonoSol s patent. Moreover, in our answer, we stated our position that MonoSol s patent which is the subject of the case, is actually invalid and unenforceable for failure to comply with one or more of the requirements of applicable U.S. patent law.

For these and other reasons, we intend to defend this case vigorously, and we anticipate that MonoSol s claims will be rejected. However, in an effort to avoid such litigation, we are presently engaged in settlement discussions with MonoSol as it relates to the purported patent infringement litigation. These discussions are part of the normal course of such an action but does not alter our view of non infringement and invalidity of the subject patent. We will continue to defend our position vigorously should business discussions with MonoSol not result in a settlement agreement. A case management conference has been scheduled for May 26, 2011 to establish a calendar of dates for proceedings in the case.

Item 1A. Risk Factors.

There were no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On March 11, 2011, we consummated a private placement offering (the Offering) to institutional investors of an aggregate of 4,807,693 shares of the our Common Stock (the Shares) at a price equal to $3.12 per share as further disclosed in a Current Report on Form 8-K filed with the SEC on March 16, 2011. The Offering commenced and concluded on March 11, 2011. Gross proceeds from the Offering were approximately $15 million, which was also the amount sold and the aggregate offering price sold in the Offering. The net proceeds of the Offering to us after deducting expenses were approximately $14 million.

Proceeds from the Offering are expected to be used to progress the clinical development of our pipeline of products, particularly BEMA® Buprenorphine and BEMA® Buprenorphine/Naloxone. The proceeds also strengthen our balance sheet as we progress through commercial partnering negotiations for BEMA® Buprenorphine.

In order to fulfill certain contractual obligations to the investors in the Offering, on April 1, 2011, we filed Registration Statement of Form S-3 covering the public resale of the Shares. Which registration was declared effective by the SEC on April 13, 2011.

William Blair & Company, L.L.C. acted as the exclusive placement agent for the Offering and received placement agent fees in the amount of $825,000.

Table of Contents

Item 3. Defaults upon Senior Securities.
None.

Item 4. (Removed and Reserved).

Item 5. Other Information.
None.

Item 6. Exhibits.

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

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

Table of Contents

SIGNATURES

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: May 13, 2011

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

(Principal Executive Officer)

Date: May 13, 2011

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

(Principal Financial Officer)

S-1