BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
November 09, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

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.)**
4131 ParkLake Ave., Suite 225	
Raleigh, NC	**27612**
(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 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

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

As of November 8, 2016, there were 54,133,511 shares of company Common Stock issued and 54,118,020 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

(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,682	$ 83,560
Accounts receivable, net	3,089	2,488
Inventory	4,018	2,558
Prepaid expenses and other current assets	4,470	3,933
Total current assets	56,259	92,539
Property and equipment, net	4,253	4,262
Goodwill	2,715	2,715
Other intangible assets, net	2,528	3,256
Total assets	$ 65,755	$ 102,772
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 18,839	$ 19,501
Notes payable, current maturities, net	11,446	6,707
Deferred revenue, current	1,922	1,875
Derivative liability	100	
Total current liabilities	32,307	28,083
Notes payable, less current maturities, net	17,726	22,168
Deferred revenue, long-term	20,000	20,000
Other long-term liabilities	825	825
Total liabilities	70,858	71,076
Commitments and contingencies (Notes 7 and 12)		
Stockholders (deficit) equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,093,155 shares of Series A Non-Voting Convertible Preferred Stock outstanding at September 30, 2016 and December 31, 2015	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 54,133,511 and 52,730,799 shares issued; 54,118,020 and 52,715,308 shares outstanding at September 30, 2016 and December 31, 2015, respectively	54	53
Additional paid-in capital	289,287	274,891

Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(294,399)	(243,203)
Total stockholders (deficit) equity	(5,103)	31,696
Total liabilities and stockholders (deficit) equity	$ 65,755	$ 102,772

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product sales	$ 2,009	$ 1,155	$ 6,221	$ 2,665
Product royalty revenues	1,065	25	2,393	689
Research and development reimbursements	497	55	501	909
Contract revenues			2,500	11,759
Total Revenues:	3,571	1,235	11,615	16,022
Cost of sales	2,314	1,699	8,958	5,443
Expenses:				
Research and development	4,402	4,473	13,786	15,527
General and administrative	12,054	14,715	37,606	41,185
Total Expenses:	16,456	19,188	51,392	56,712
Loss from operations	(15,199)	(19,652)	(48,735)	(46,133)
Interest expense, net	(786)	(785)	(2,477)	(1,732)
Derivative gain	14		36	
Other (expense) income, net	(6)	(2)	(20)	21
Net loss	$ (15,977)	$ (20,439)	$ (51,196)	$ (47,844)
Basic and diluted loss per share:	$ (0.30)	$ (0.39)	$ (0.96)	$ (0.92)
Weighted average common stock shares outstanding, basic and diluted:	53,767,099	52,542,715	53,531,770	52,286,757

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS (DEFICIT) EQUITY

(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(Unaudited)

	Preferred Stock Series A		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders (Deficit)
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Equity
Balances, January 1, 2016	2,093,155	$ 2	52,730,799	$ 53	$ 274,891	$ (47)	$ (243,203)	$ 31,696
Stock-based compensation					11,600			11,600
Exercise of stock options			147,425		297			297
Vesting of restricted stock awards			592,066					
Common stock issuance upon retirement			663,221	1	2,459			2,460
Equity financing costs					40			40
Net loss							(51,196)	(51,196)
Balances, September 30, 2016	2,093,155	$ 2	54,133,511	$ 54	$ 289,287	$ (47)	$ (294,399)	$ (5,103)

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

	Nine months ended September 30,	
	2016	**2015**
Operating activities:		
Net loss	$ (51,196)	$ (47,844)
Depreciation	325	248
Accretion of debt discount	297	400
Amortization of intangible assets	728	728
Derivative liability	100	
Stock-based compensation expense	11,600	12,703
Changes in assets and liabilities:		
Accounts receivable	(601)	1,734
Inventories	(1,460)	(59)
Prepaid expenses and other assets	(537)	(727)
Accounts payable and accrued expenses	(662)	477
Deferred revenue	47	(377)
Net cash flows from operating activities	(41,359)	(32,717)
Investing activities:		
Purchase of equipment	(316)	(619)
Net cash flows from investing activities	(316)	(619)
Financing activities:		
Equity financing costs	40	(40)
Proceeds from exercise of stock options	297	480
Proceeds from issuance of common stock	2,460	
Proceeds from exercise of common stock warrants		1
Payment on note payable		(3,335)
Proceeds from notes payable		20,667
Payment of deferred financing fees		(486)
Return of short swing profits		6
Net cash flows from financing activities	2,797	17,293
Net change in cash and cash equivalents	(38,878)	(16,043)

Cash and cash equivalents at beginning of year	83,560	70,472
Cash and cash equivalents at end of period	**$ 44,682**	**$ 54,429**
Cash paid for interest	$ 2,045	$ 1,201

See notes to condensed consolidated financial statements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

1. Organization, basis of presentation and summary of significant policies:

Overview

BioDelivery Sciences International, Inc., together with its subsidiaries (collectively, the Company or BDSI) is a specialty pharmaceutical company that is developing and commercializing, either on its own or in partnerships with third parties, new applications of approved therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. The Company is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

The accompanying unaudited condensed consolidated financial statements include all adjustments (consisting of normal and recurring adjustments) necessary for a fair presentation of these financial statements. The condensed consolidated balance sheet at December 31, 2015 has been derived from the Company s audited consolidated financial statements included in its annual report on Form 10-K for the year ended December 31, 2015. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP) have been condensed or omitted pursuant to the Securities and Exchange Commission (SEC) rules and regulations. It is suggested that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2015. The Company has made certain reclassifications in this report s footnote tables for the year ending December 31, 2015 to conform to the current period presentation. This reclassification had no effect on the measurement of total expenses, loss from operations, or net loss.

Operating results for the three and nine month periods ended September 30, 2016 are not necessarily indicative of results for the full year or any other future periods.

As used herein, the Company s common stock, par value $.001 per share, is referred to as the Common Stock.

Principles of consolidation

The condensed consolidated financial statements include the accounts of the Company, Arius Pharmaceuticals, Inc. (Arius), Arius Two, Inc. (Arius Two) and Bioral Nutrient Delivery, LLC (BND). For each period presented, BND has been an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Use of estimates in financial statements

The preparation of the accompanying condensed consolidated financial statements requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and

assumptions.

Inventory

Inventories are stated at the lower of cost or market value with costs determined on the first-in, first-out method. Inventory consists of raw materials, work in process and finished goods. Raw materials include the active pharmaceutical ingredients required for a product to be manufactured, work in process includes the bulk inventory of laminate prior to being packaged for sale, and finished goods include pharmaceutical products ready for commercial sale.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. There were no allowances recorded as of September 30, 2016 or December 31, 2015.

Deferred revenue

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

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

1. Organization, basis of presentation and summary of significant policies (continued):

Revenue recognition

Net Product Sales

Product Sales- The Company generally recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. For products that it commercializes on its own (currently only the Company s BUNAVAIL® product), the Company sells such products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for rebates, price adjustments chargebacks and prompt payment discounts. When the Company cannot reasonably estimate the amount of future product returns, it defers revenues until the risk of product return has been substantially eliminated.

As of September 30, 2016 and December 31, 2015, the Company had $1.9 million in each period, respectively, of deferred revenue related to sales to wholesalers for which future returns could not be reasonably estimated at the time of sale. Deferred revenue is recognized as revenue when the product is sold to the end user, based upon prescriptions filled. To estimate product sold to end users, the Company relies on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sales to customers. Deferred revenue is recorded net of estimated allowances for rebates, price adjustments, chargebacks, prompt payment and other discounts. Estimated allowances are recorded and classified as accrued expenses in the accompanying balance sheets as of September 30, 2016 and December 31, 2015 (see Note 4).

Product Returns- Consistent with industry practice, the Company offers contractual return rights that allow its customers to return product within an 18-month period that begins six months prior to and ends twelve months after the expiration of the products. The Company does not believe it has sufficient experience with BUNAVAIL® to estimate its returns at time of ex-factory sales. When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated, which is at the time the product is sold through to the end user.

Rebates- The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program s administrator.

Price Adjustments and Chargebacks- The Company s estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company s listed prices of its products. In the event that the sales mix to third-party payers is different from

the Company s estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated and such differences may be significant.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for BUNAVAIL® whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the actual redemption rates as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company s completed programs. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt Payment Discounts- The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 37 days after the invoice date depending on the customer and the products purchased.

Gross to Net Accruals- A significant majority of the Company s gross to net accruals are the result of its voucher program, commercial contracts and Medicaid rebates, with the majority of those programs having an accrual to payment cycle of anywhere from one to three months. In addition to this relatively short accrual to payment cycle, the Company receives daily information from its wholesalers regarding their sales of BUNAVAIL® and actual on hand inventory levels. During the quarter ended September 30, 2016, the Company s three largest wholesalers accounted for approximately 91% of the Company s voucher and Medicaid accruals. The Company believes that consistently working with these three large wholesalers enables the Company to execute more accurate provisioning procedures. Consistent with pharmaceutical industry practice, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products. However, since the Company does not have sufficient experience with measuring returns, at the time of ex-factory sales, the Company records revenue when the risk of product return has been substantially eliminated.

Once the Company has adequate experience with measuring returns, it will then be able to record sales ex-factory.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

1. Organization, basis of presentation and summary of significant policies (continued):

Deferred Cost of Sales

The Company defers its cost of sales in connection with BUNAVAIL® sales at time of ex-factory sales. These costs are recognized when the product is sold through to the end user. The Company had $1.9 million and $1.7 million of deferred costs of sales as of September 30, 2016 and December 31, 2015, respectively. These costs are included in other current assets in the accompanying condensed consolidated balance sheets.

Cost of Sales

For BUNAVAIL®, cost of sales includes raw materials, production costs at the Company s two contract manufacturing sites, quality testing directly related to the product, and depreciation on equipment purchased to produce BUNAVAIL®. It also includes any batches not meeting specifications and raw material yield loss. Yield losses and batches not meeting specifications are expensed as incurred. Cost of sales is recognized as actual product is sold through to the end user.

Cost of sales also includes the direct costs attributable to the production of the Company s BREAKYLand PAINKYL products, which are not self-commercialized by the Company, including all costs related to creating the product at the Company s contract manufacturing locations in the U.S. and Germany. The Company s contract manufacturers bill the Company for the final product, which includes materials, direct labor costs, and certain overhead costs as outlined in applicable supply agreements. Cost of sales also includes royalty expenses that the Company owes to third parties.

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)

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers,* which supersedes the revenue recognition requirements of Accounting Standards Codification (ASC) Topic 605, Revenue Recognition and most industry-specific guidance on revenue recognition throughout the ASC. The new standard is principles-based and provides a five step model to determine when and how revenue is recognized. The core principle of the new standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The new standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. In July 2015, the FASB agreed to defer the effective date of the standard from January 1, 2017 to January 1, 2018, with an option that permits companies to adopt the standard as early as the original effective date. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers* (Topic 606): Identifying Performance Obligations and Licensing. ASU 2016-10 clarifies the implementation guidance on identifying performance obligations. These ASUs apply to all companies that enter into contracts with customers to transfer goods or services. These two ASUs are effective for public entities for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, but not before interim and annual reporting periods beginning after December 15, 2016. Entities have the choice to apply these ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. The Company is currently evaluating the requirements of these standards and has not yet determined the impact on its condensed consolidated financial statements.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

1. Organization, basis of presentation and summary of significant policies (continued):

The FASB s new leases standard, ASU 2016-02 *Leases* (Topic 842), was issued on February 25, 2016. ASU 2016-02 is intended to improve financial reporting about leasing transactions. The ASU affects all companies and other organizations that lease assets such as real estate, airplanes, and manufacturing equipment. The ASU will require organizations that lease assets referred to as Lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. An organization is to provide disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements concerning additional information about the amounts recorded in the financial statements. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new ASU will require

both types of leases (i.e. operating and capital leases) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases. The leasing standard will be effective for calendar year-end public companies beginning after December 15, 2018. Public companies will be required to adopt the new leasing standard for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption will be permitted for all companies and organizations upon issuance of the standard. For calendar year-end public companies, this means an adoption date of January 1, 2019 and retrospective application to previously issued annual and interim financial statements for 2018 and 2017. Lessees with a large portfolio of leases are likely to see a significant increase in balance sheet assets and liabilities. The Company is currently in the process of evaluating the impact that this new leasing ASU will have on its condensed consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification (ASC) Topic 718, Compensation Stock Compensation. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company is currently in the process of evaluating the impact of adoption of the ASU on its condensed consolidated financial statements.

2. Liquidity and management s plans:

At September 30, 2016, the Company had cash and cash equivalents of approximately $44.7 million. The Company used $38.9 million of cash during the nine months ended, September 30, 2016 and had stockholders deficit of $5.1 million, versus stockholders equity of $31.7 million at December 31, 2015. Based on the Company s current operational plan and budget, the Company expects that it has sufficient cash to manage its business into the third quarter of 2017, although this estimation assumes that the Company does not accelerate the development of existing product candidates, or acquire other drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect the Company s cash requirements.

Additional capital will likely be required to support the Company s ongoing commercialization activities for BUNAVAIL®, the anticipated commercial relaunch of ONSOLIS®, the continued development of Clonidine Topical Gel and Buprenorphine Depot Injection, or other products which may be acquired or licensed by the Company, and for general working capital requirements. Based on product development timelines and agreements with the Company s development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development lifecycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding from any source (including, without limitation, milestone, royalty or other payments from commercialization agreements as well as equity or debt financings) may be unavailable on favorable terms, if at all.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

3. Inventory:

The following table represents the components of inventory as of:

	September 30, 2016	December 31, 2015
Raw materials & supplies	$ 995	$ 443
Work-in-process	1,979	1,216
Finished goods	1,044	899
Total inventories	$ 4,018	$ 2,558

4. Accounts payable and accrued liabilities:

The following table represents the components of accounts payable and accrued liabilities as of:

	September 30, 2016	December 31, 2015
Accounts payable	$ 10,533	$ 10,177
Accrued price adjustments	442	317
Accrued rebates	4,120	4,471
Accrued chargebacks	15	65
Accrued compensation and benefits	2,314	1,917
Accrued royalties	410	431
Accrued clinical trial costs	128	584
Accrued manufacturing costs	200	183
Accrued sales and marketing costs	8	880
Accrued other	669	476
Total accounts payable and accrued expenses	$ 18,839	$ 19,501

5. Property and Equipment:

Property and equipment, summarized by major category, consist of the following as of:

	September 30, 2016	December 31, 2015
Machinery & equipment	$ 4,434	$ 580
Computer equipment & software	463	460
Office furniture & equipment	202	200
Leasehold improvements	53	53
Idle equipment	1,440	4,983
Total	6,592	6,276
Less accumulated depreciation	(2,339)	(2,014)
Total property, plant & equipment, net	$ 4,253	$ 4,262

Depreciation expense for the nine month periods ended September 30, 2016 and September 30, 2015, was approximately $0.3 million and $0.2 million, respectively. Depreciation expense for the three month periods ended September 30, 2016 and September 30, 2015, was approximately $0.1 million and $0.08 million, respectively.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

6. License and Development Agreements:

The Company has periodically entered into license and development agreements to develop and commercialize certain of its products. The arrangements typically are multi-deliverable arrangements that are funded through upfront payments, milestone payments, royalties and other forms of payment to the Company.

Meda License, Development and Supply Agreements

On January 27, 2015, the Company announced that it had entered into an assignment and revenue sharing agreement with Meda to return to the Company the marketing authorization for ONSOLIS® in the U.S. and the right to seek marketing authorizations for ONSOLIS® in Canada and Mexico. Following the return of the U.S. marketing authorization from Meda, the Company submitted a prior approval supplement for the new formulation to the FDA in March 2015, which was approved in August 2016. In connection with the return of the U.S. marketing authorization by Meda to the Company in January 2015, the remaining U.S.-related deferred revenue of $1.0 million was recorded as contract revenue during the nine months ended September 30, 2015. There was no remaining U.S.-related contract revenue to record during the nine months ended September 30, 2016. On February 27, 2016, the Company entered into an extension of the assignment and revenue sharing agreement to extend the period until December 31, 2016.

Efforts to extend the Company s supply agreement with its ONSOLIS® manufacturer, Aveva, which is now a subsidiary of Apotex, Inc., were unsuccessful and the agreement expired. However, the Company identified an alternate supplier and requested guidance from the FDA on the specific requirements for obtaining approval to supply product from this new vendor. Based on the Company s current estimates, the Company will submit the necessary documentation to the FDA for qualification of the new manufacturer in early 2017, thus allowing for the reintroduction of ONSOLIS® by mid-2017.

On May 11, 2016, the Company and Collegium Pharmaceutical, Inc. (Collegium) executed a definitive License and Development Agreement (the License Agreement) under which the Company has granted the exclusive rights to develop and commercialize ONSOLIS® in the U.S. to Collegium. See Collegium License and Development Agreement below.

Collegium License and Development Agreement

On May 11, 2016, the Company and Collegium executed a License Agreement under which the Company granted Collegium the exclusive rights to develop and commercialize ONSOLIS® in the U.S.

Under the terms of the License Agreement, Collegium will be responsible for the manufacturing, distribution, marketing and sales of ONSOLIS® in the U.S. The Company is obligated to use commercially reasonable efforts to continue the transfer of manufacturing to the anticipated manufacturer for ONSOLIS® and to submit a corresponding Prior Approval Supplement (the Supplement) to the FDA with respect to the current NDA for ONSOLIS®. Following

approval of the Supplement, the NDA and manufacturing responsibility for ONSOLIS® (including the manufacturing relationship with the Company s manufacturer, subject to the Company entering into an appropriate agreement with such manufacturer that is acceptable and assignable to Collegium) will be transferred to Collegium.

Financial terms of the License Agreement include:

- a $2.5 million upfront non-refundable payment, payable to the Company within 30 days of execution of the License Agreement (received June 2016);
- reimbursement to the Company for a pre-determined amount of the remaining expenses associated with the ongoing transfer of the manufacturing of ONSOLIS®;
- $4 million payable to the Company upon first commercial sale of ONSOLIS® in the U.S;
- up to $17 million in potential payments to the Company based on achievement of certain performance and sales milestones; and
- upper-teen percent royalties payable by Collegium to the Company based on various annual U.S. net sales thresholds, subject to customary adjustments and the royalty sharing arrangements described below.

The License Agreement also contains customary termination provisions that include a right by either party to terminate upon the other party s uncured material breach, insolvency or bankruptcy, as well as in the event a certain commercial milestone is not met.

ONSOLIS® was originally licensed to, and launched in the U.S. by, Meda. In January 2015, the Company entered into an assignment and revenue sharing agreement (the ARS Agreement) with Meda pursuant to which Meda transferred the marketing authorizations for ONSOLIS® in the United States back to the Company. Under the ARS Agreement, financial terms were established that enable

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6. License and Development Agreements (continued):
Collegium License and Development Agreement (continued)

Meda to share a significant portion of the proceeds of milestone and royalty payments received by the Company from any new North American partnership for ONSOLIS® that may be executed by the Company. The execution of the License Agreement between the Company and Collegium also required the execution of a definitive termination agreement between the Company and Meda embodying those royalty-sharing terms, returning ONSOLIS®-related assets and rights in the U.S., Canada, and Mexico to the Company, and including certain other provisions. In addition, the Company s royalty obligations to CDC IV, LLC (CDC) and its assignees will remain in effect. CDC provided funding for the development of ONSOLIS® in the past.

Endo License and Development Agreement

In January 2012, the Company entered into a License and Development Agreement with Endo Pharmaceuticals, Inc. (Endo) pursuant to which the Company granted Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company s BELBUCA product and to complete U.S. development of such product candidate for purposes of seeking FDA approval (the Endo Agreement). BELBUCA is used for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

The remaining milestone payments owed pursuant to the Endo Agreement are expected to be recognized as revenue as they are achieved, except that $20 of the $50 million regulatory approval milestone received in November 2015. Such amount is associated with the Patent Life Extension and is contingently refundable from 2020 to 2027. The $20 million will be earned over the extended 84 month patent period as it is contingently refundable pending a generic product commercially launched in the U.S. during the patent extension period. Sales threshold payments and sales-based royalties will be recognized as they accrue under the terms of the Endo Agreement.

The Company is reimbursed by Endo for certain contractor costs when these costs go beyond set thresholds as outlined in the Endo Agreement. Endo reimburses the Company for this spending at cost and the Company receives no mark-up or profit. The gross amount of these reimbursed research and development costs are reported as research and development reimbursement revenue in the accompanying condensed consolidated statements of operations. The Company acts as a principal, has discretion to choose suppliers, bears credit risk and may perform part of the services required in the transactions. Therefore, these reimbursements are treated as revenue to the Company. The actual expenses creating the reimbursements are reflected as research and development expense.

Beginning in March 2014, total reimbursable contractor costs exceeded a set threshold, at which point all such expenses have been borne at a rate of 50% by Endo and 50% by the Company. Endo has continued to reimburse the Company for 100% of such costs, with 50% thereof to be taken by Endo as a credit against potential future milestones associated with achievement of certain regulatory events. During the nine months ended September 30, 2016 and 2015, the Company recognized $0.01 and $0.09 million, respectively, of reimbursable expenses related to the Endo Agreement, which is recorded as research and development reimbursement revenue on the accompanying condensed consolidated statement of operations. During the three months ended September 30, 2016 and 2015, the Company recognized $0.01 and $0.06 million, respectively, of reimbursable expenses related to the Endo Agreement, which is recorded as research and development reimbursement revenue on the accompanying condensed consolidated statement of operations.

On December 23, 2014, the Company and Endo announced the submission of an NDA for BELBUCA to the FDA, which was accepted February 23, 2015. On October 26, 2015, the Company and Endo announced that on October 23, 2015, the FDA approved BELBUCA. The FDA approval of BELBUCA triggered a milestone payment to the Company from Endo of $50 million pursuant to the Endo Agreement, less approximately $6 million of cumulative pre-payments. The Company received payment of such milestone in November 2015. The Company has deferred the aforementioned $20 million of the $50 million milestone payment.

On February 22, 2016, the Company and Endo announced the commercial availability of BELBUCA buccal film. BELBUCA, distributed and promoted by Endo, is now available nationwide.

7. License Obligations:

Arcion License Agreement

On March 26, 2013, the Company entered into a license agreement with Arcion Therapeutics, Inc. (the Arcion Agreement) pursuant to which Arcion granted to the Company an exclusive commercial world-wide license to develop, manufacture, market, and sell gel

products containing clonidine (or a derivative thereof) for the treatment of painful diabetic neuropathy (PDN) and other indications (the Arcion Products).

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7. License Obligations (continued):
Arcion License Agreement (continued)

On March 30, 2015, the Company announced that the primary efficacy endpoint in its initial Phase 3 clinical study of Clonidine Topical Gel compared to placebo for the treatment of PDN did not meet statistical significance, although certain secondary endpoints showed statistically significant improvement over placebo. Final analysis of the study identified a sizeable patient population with a statistically significant improvement in pain score vs placebo. Following thorough analysis of the data and identification of the reasons behind the study results, the Company initiated a second study. The study incorporated significant learnings from previously conducted studies and involved tightened and additional inclusion criteria to improve assay sensitivity, reduce bias and ensure compliance with enrollment criteria. On August 4, 2016, the Company announced that it had reached its target number of subjects to be randomized in its multi-center, double-blind, placebo-controlled Phase 2b study assessing the efficacy and safety of Clonidine Topical Gel in the treatment of PDN. Based on the timing of randomization of the last patient, the Company now expects topline results of the study will be available by the end of 2016, which puts it six to eight weeks ahead of schedule.

Evonik Development and Exclusive License Option Agreement

On October 27, 2014, the Company entered into a definitive Development and Exclusive License Option Agreement (the Development Agreement) with Evonik Corporation (Evonik) to develop and commercialize an injectable, extended release, microparticle formulation of buprenorphine for the treatment of opioid dependence (the Evonik Product). Under the Development Agreement, the Company also has the right to pursue development of the Evonik Product for pain management and Evonik has also granted to the Company two exclusive options to acquire exclusive worldwide licenses, with rights of sublicense, to certain patents and other intellectual property rights of Evonik to develop and commercialize certain products containing buprenorphine. If such options are exercised, such licenses would be memorialized in the Evonik License Agreement (as defined below).

Upon execution of the Development Agreement and the delivery by Evonik to the Company of certain data and results achieved by Evonik from prior work performed by Evonik relating to the Product, the Company is obligated to pay to Evonik an initial, non-refundable, non-creditable, one-time payment as well as development service fees for work to be completed, which together totals up to $2.16 million in accordance with an estimated budget set out in the Development Agreement (the Estimated Budget) for the mutually agreed Project. Evonik shall not bill the Company for amounts greater than the Estimated Budget unless change orders are executed by both parties. As of September 30, 2016, the Company has paid $2.85 million toward the Estimated Budget in addition to executed change orders.

Should Evonik and the Company enter into the Evonik License Agreement following the attainment of a Phase 1 ready formulation of the Evonik Product for one or both of the opioid dependence or pain management indications, the Company would pay Evonik a non-refundable, non-creditable one-time payment in conjunction with certain future regulatory filings and approvals and royalties on net sales of the Evonik Product.

The Development Agreement contains customary termination provisions, and the Company may additionally terminate the Development Agreement at any time after the completion of certain enumerated tasks as provided in the Development Agreement, for any reason or no reason, by providing written notice of termination to Evonik. Upon termination of the Development Agreement, Evonik will be paid any amounts owed to Evonik in accordance with the estimated budget for work performed under the Development Agreement through the effective date of termination, including any reasonable, documented, non-cancelable third party costs and any reasonable, documented wind-down costs reasonably incurred by Evonik in connection with the Evonik Project. Should the Company terminate for reasons other than for a material, uncured breach by Evonik or Evonik s bankruptcy, Evonik shall have the right to use any and all data and intellectual property generated under the Evonik Project for any purpose.

This product candidate is currently in the pre-clinical stage of development with plans underway for an Investigational New Drug Application submission in early 2017.

8. Other license agreements and acquired product rights:

TTY License and Supply Agreement

On October 7, 2010, the Company announced a license and supply agreement with TTY Biopharm Co., Ltd. (TTY) for the exclusive rights to develop and commercialize BEMA® Fentanyl in the Republic of China, Taiwan. The agreement results in potential milestone payments to the Company of up to $1.3 million, which include an initial upfront one-time non-refundable payment of $0.3 million that was received in 2010. In addition, the Company will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filings of BEMA® Fentanyl in Taiwan as well as future commercialization in that territory. The term of the agreement with TTY is for the

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8. Other license agreements and acquired product rights (continued):
TTY License and Supply Agreement

period from October 4, 2010 until the date fifteen years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

On February 4, 2016 and June 30, 2016, the Company received separate payments of $0.24 million each from TTY and on October 4, 2016 a payment of $0.4 million, all which related to royalties based on PAINKYL product purchased in Taiwan by TTY of PAINKYL.

9. Note Payable (MidCap Loan):
On May 29, 2015, the Company entered into a $30 million secured loan facility (the Loan) with MidCap Financial Trust, as agent and lender (MidCap), pursuant to the terms and conditions of the Amended and Restated Credit and Security Agreement, dated as of May 29, 2015 (the Credit Agreement), between the Company and MidCap. The Credit Agreement is a restatement, amendment and modification of a prior Credit and Security Agreement, dated as of July 5, 2013 (the Prior Agreement), between the Company, MidCap Financial SBIC, LLP, a predecessor to MidCap, and certain lenders thereto. The Credit Agreement restructures, renews, extends and modifies the obligations under the Prior Agreement and the other financing documents executed in connection with the Prior Agreement (the Prior Loan). The Company received net Loan proceeds in the aggregate amount of approximately $20.1 million and will use the Loan proceeds for general corporate purposes or other activities of the Company permitted under the Credit Agreement.

The Loan (as amended in May 2016 and as described below) has a term of 42 months, with interest only payments for the first 19 months. The interest rate is 8.45% plus a LIBOR floor of 0.5% (total of 8.95% at September 30, 2016), with straight line amortization of principal payments commencing on June 1, 2016, in an amount equal to $1.3 million per month. Upon execution of the Credit Agreement, the Company paid to MidCap a closing fee from the prior loan of approximately $0.4 million. Upon repayment in full of the Loan, the Company is obligated to make a final payment fee equal to 2.75% of the aggregate Loan amount. The 2.75% exit fee has been recorded as deferred loan costs, the current portion of which is included in notes payable, current maturities, net and the long-term portion is in note payable, less current maturities, net, being amortized over the life of the loan. The amounts payable are recorded as other long-term liabilities.

In addition, the Company may prepay all or any portion of the Loan at any time subject to a prepayment premium of: (i) 5% of the Loan amount prepaid in the first year following the execution of the Credit Agreement and (ii) 3% of the

Loan amount prepaid in each year thereafter.

The obligations of the Company under the Credit Agreement are secured by a first priority lien in favor of MidCap on substantially all of the Company s existing and after-acquired assets, but excluding certain intellectual property and general intangible assets of the Company (but not any proceeds thereof). The obligations of the Company under the Credit Agreement are also secured by a first priority lien on the equity interests held by the Company. The Company entered into and reaffirmed, as applicable, customary pledge and intellectual property security agreements to evidence the security interest in favor of MidCap.

Under the Credit Agreement, the Company is subject to affirmative covenants which are customary for financings of this type, including, but not limited to, the obligations of the Company to: (i) maintain good standing and governmental authorizations, (ii) provide certain information and notices to MidCap, (iii) deliver quarterly and annual financial statements to MidCap, (iv) maintain insurance, property and books and records, (v) discharge all taxes, (vi) protect its intellectual property and (vii) generally protect the collateral granted to MidCap.

The Company is also subject to negative covenants customary for financings of this type, including, but not limited to, that it may not: (i) enter into a merger or consolidation or certain change of control events without complying with the terms of the Credit Agreement, (ii) incur liens on the collateral, (iii) incur additional indebtedness, (iv) dispose of any property, (v) amend material agreements or organizational documents, (vi) change its business, jurisdictions of organization or its organizational structures or types, (vii) declare or pay dividends (other than dividends payable solely in Common Stock), (viii) make certain investments or acquisitions except under certain circumstances as set forth in the Credit Agreement, or (ix) enter into certain transactions with affiliates, in each case subject to certain exceptions provided for in the Credit Agreement. Notwithstanding the foregoing, the Credit Agreement amends certain negative covenants contained in the Prior Agreement such that (i) licensing and acquisitions are added as permitted business activities of the Company and (ii) the Company is no longer required to obtain the prior written consent of MidCap for any in-licensing, product

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9. Note Payable (MidCap Loan) continued:

or entity acquisitions by the Company by way of merger or consolidation, so long as no event of default has occurred and certain financial metrics are adhered to.

The Credit Agreement provides for several events of default under the Loan. Upon the occurrence of any event of default, the Company s obligations under the Credit Agreement will bear interest at a rate equal to the lesser of: (i) 4% above the rate of interest applicable to such obligations immediately prior to the occurrence of the event of default and (ii) the maximum rate allowable under law.

The debt discount is related to warrants on the Prior Loan, which was amended in 2015. The discount is being amortized to interest expense over the life of the amended loan. On May 5, 2016, the Company entered into an amendment to the Credit Agreement between the Company, MidCap and the lenders thereto (the Lenders) extending the interest only period of the Loan through the end of 2016. Beginning on January 1, 2017, the principal amount owed under the Loan will then be amortized over the remaining 23 months of the Loan. In association with the extension of the interest only period, the Lenders were issued warrants to purchase a total of 84,986 shares of Common Stock at an exercise price of $3.53 per share.

The balance of the Loan as of September 30, 2016 is $29.2 million, and is recorded in the accompanying condensed consolidated balance sheet, net of unamortized discount of $0.8 million.

10. 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 value 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 a 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 table summarizes assets and liabilities measured at fair value on a recurring basis at September 30, 2016 and December 31, 2015, respectively:

	September 30, 2016				December 31, 2015			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Fair Value Measurements Using:								
Liabilities								
Derivative liabilities- free standing warrants	$	$ 100	$	$ 100	$	$	$	$

The table below provides a reconciliation of the beginning and ending balances for the liabilities measured at fair value using observable inputs (Level 2). The table reflects net gains and losses for all financial liabilities categorized as Level 2 as of September 30, 2016 and December 31, 2015.

	$	Number of Warrants
Liabilities:		
Warrant liability as of December 31, 2015	$	
Increase due to issuance of warrants	136	84,986
Decrease due to fair value of warrants	(36)	
Warrant liability as of September 30, 2016	$ 100	84,986

The derivative gain recognized in the condensed consolidated statements of operations reflects the change in fair value of these warrant liabilities.

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11. Stockholders Equity:

Stock-based compensation

During the nine months ended September 30, 2016, a total of 481,303 options to purchase Common Stock, with an aggregate fair market value of approximately $1.6 million, were granted to Company employees, directors and contractors. The options granted have a term of 10 years from the grant date and vest ratably over a three year period for employees and contractors and options for directors vest half upon issuance and the remaining half the following year. The fair value of each option is amortized as compensation expense evenly through the vesting period.

The Company s stock-based compensation expense is allocated between research and development and selling, general and administrative as follows:

	Three months ended,		Nine months ended,	
Stock-based compensation expense	**September 30, 2016**	**September 30, 2015**	**September 30, 2016**	**September 30, 2015**
Research and Development	$ 0.5	$ 1.1	$ 2.1	$ 3.1
Selling, General and Administrative	$ 3.6	$ 3.9	$ 9.5	$ 9.6

The fair value of each option award is estimated on the grant date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on implied volatilities from historical volatility of the Common Stock, and other factors estimated over the expected term of the options. The expected term of options granted is derived using the simplified method which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. The weighted average for key assumptions used in determining the fair value of options granted during the nine months ended September 30, 2016 follows:

Expected price volatility	62.36% - 82.38%
Risk-free interest rate	0.56% - 1.70%
Weighted average expected life in years	6 years
Dividend yield	

Option activity during the nine months ended September 30, 2016 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2016	3,397,529	$ 5.42	
Granted in 2016			
Officers and Directors	95,000	2.34	
Others	386,303	3.49	
Exercised	(147,425)	2.01	
Forfeitures	(394,898)	9.06	
Outstanding at September 30, 2016	3,336,509	$ 4.83	$ 459

As of September 30, 2016, options exercisable totaled 2,559,949. There was approximately $17.2 million of unrecognized compensation cost related to non-vested share-based compensation awards, including options and restricted stock units (RSUs) granted. These costs will be expensed through 2019.

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11. Stockholders Equity (continued):

Earnings Per Share

During the nine months ended September 30, 2016 and 2015, outstanding stock options, RSUs, warrants and convertible preferred stock of 10,196,872 and 9,582,513, respectively, were not included in the computation of diluted earnings per share, because to do so would have had an antidilutive effect. During the three months ended September 30, 2016 and 2015, outstanding stock options, RSUs, warrants and convertible preferred stock of 9,986,447 and 9,743,687, respectively, were not included in the computation of diluted earnings per share, because to do so would have had an antidilutive effect.

Restricted Stock Units

During the nine months ended September 30, 2016, 1,406,000 restricted stock units (RSUs) were granted to the Company s executive officers, directors and employees, with a fair market value of approximately $4.6 million. The fair value of restricted units is determined using quoted market prices of the Common Stock and the number of shares expected to vest. These RSUs were issued under the Company s 2011 Equity Incentive Plan, as amended, and vest in equal installments over three years for the executive officers, vest in equal installments over two years for directors and vest in the following year for employees. Of the aforementioned RSUs granted during the nine months ended September 30, 2016, 40,000 were granted to certain Company employees as performance-based RSUs, which vest when certain profitability thresholds are achieved, as defined by the Compensation Committee of the Company s Board of Directors (the Compensation Committee).

Restricted stock activity during the nine months ended September 30, 2016 was as follows:

	Number of Restricted Shares	Weighted Average Fair Market Value Per RSU
Outstanding at January 1, 2016	4,298,154	$ 10.23
Granted:		
Executive officers	913,000	3.80
Directors	185,000	2.43
Employees		