BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10-Q
May 15, 2017
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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 March 31, 2017

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
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 15, 2017, there were 55,341,463 shares of company Common Stock issued and 55,325,972 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)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash	$ 35,219	$ 32,019
Accounts receivable, net	7,102	3,569
Inventory	8,145	3,368
Prepaid expenses and other current assets	3,942	4,136
Total current assets	54,408	43,092
Property and equipment, net	4,549	4,230
Goodwill	2,715	2,715
BELBUCA® license and distribution rights intangible	45,000	
Other intangible assets, net	918	2,285
Total assets	$ 107,590	$ 52,322
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 30,521	$ 18,174
Deferred revenue, current		1,716
Total current liabilities	30,521	19,890
Notes payable, less current maturities, net	34,800	29,272
Deferred revenue, long-term		20,000
Other long-term liabilities	4,050	825
Total liabilities	69,371	69,987
Commitments and contingencies (Notes 11 and 14)		
Stockholders 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 both March 31, 2017 and December 31, 2016, respectively.	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 55,341,463 and 54,133,511 shares issued; 55,325,972 and 54,118,020 shares outstanding at	55	54

March 31, 2017 and December 31, 2016, respectively.		
Additional paid-in capital	300,225	292,667
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(262,016)	(310,341)
Total stockholders equity (deficit)	38,219	(17,665)
Total liabilities and stockholders equity (deficit)	$ 107,590	$ 52,322

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 March 31,	
	2017	**2016**
Revenues:		
Product sales	$ 7,795	$ 2,102
Product royalty revenues	1,661	934
Research and development reimbursements	22	4
Contract revenues	20,000	
Total Revenues:	29,478	3,040
Cost of sales	5,645	2,550
Expenses:		
Research and development	2,671	5,377
Selling, general and administrative	13,259	13,055
Total Expenses:	15,930	18,432
Income (loss) from operations	7,903	(17,942)
Interest expense, net	(2,886)	(778)
Other expense, net		(13)
Bargain purchase gain	27,336	
Income (loss)	$ 32,353	$ (18,733)
Income tax benefit	15,972	
Net income (loss) attributable to common stockholders	$ 48,325	$ (18,733)
Basic		
Basic income (loss) per share:	$ 0.89	$ (0.36)
Weighted average common stock shares outstanding:	54,519,574	52,230,648
Diluted		
Diluted income (loss) per share:	$ 0.87	$ (0.36)

Diluted weighted average common stock shares outstanding:	55,431,628	52,230,648

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)

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

(Unaudited)

	Preferred Stock Series A		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balances, January 1, 2017	2,093,155	$ 2	54,133,511	$ 54	$ 292,667	$ (47)	$ (310,341)	$ (17,665)
Stock-based compensation					3,070			3,070
Restricted stock awards			1,207,952	1	(1)			
Issuance of warrants					4,489			4,489
Net income							48,325	48,325
Balances, March 31, 2017	2,093,155	$ 2	55,341,463	$ 55	$ 300,225	$ (47)	$ (262,016)	$ 38,219

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)

	Three months ended March 31,	
	2017	**2016**
Operating activities:		
Net income (loss)	$ 48,325	$ (18,733)
Depreciation	111	86
Accretion of debt discount and loan costs	1,040	99
Amortization of intangible assets	1,369	243
Stock-based compensation expense	3,070	4,111
Deferred income taxes	(15,972)	
Bargain purchase gain	(27,336)	
Changes in assets and liabilities:		
Accounts receivable	(3,531)	356
Inventories, net of effect of acquisition	633	(2,263)
Prepaid expenses and other assets	194	118
Accounts payable and accrued expenses, net of effect of acquisition	4,811	(438)
Deferred revenue	(21,716)	(235)
Net cash flows from operating activities	(9,002)	(16,656)
Investing activities:		
Purchase of equipment		(236)
Net cash flows from investing activities		(236)
Financing activities:		
Proceeds from notes payable	45,000	
Payment of notes payable	(30,000)	
Payment of deferred financing fees	(2,798)	
Equity financing costs		40
Proceeds from exercise of stock options		225
Proceeds from issuance of common stock		2,460
Net cash flows from financing activities	12,202	2,725
Net change in cash and cash equivalents	3,200	(14,167)
Cash and cash equivalents at beginning of year	32,019	83,560

Cash and cash equivalents at end of period	**$ 35,219**	**$ 69,393**
Cash paid for interest	$ 946	$ 679

See notes to condensed consolidated financial statements

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

SUPPLEMENTAL CASH FLOW INFORMATION

(U.S. DOLLARS IN THOUSANDS EXCEPT SHARE DATA)

Non-cash Financing and Investing Activities:

The Company recorded the fair value of the bargain purchase price of the BELBUCA® acquisition totaling $27.3 million to income during the three months ended March 31, 2017 in accordance with US GAAP (note 7).

The Company recorded the fair value of warrants totaling $4.5 million to equity with an offsetting amount to Notes payable in connection with the CRG term loan during the three months ended March 31, 2017 in accordance with US GAAP (note 12).

See notes to 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, 2016 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, 2016. 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, 2016.

Operating results for the three month periods ended March 31, 2017 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 in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates. The Company reviews all significant estimates affecting the consolidated financial statements on a recurring basis and records the effect of any necessary adjustments prior to their issuance. Significant estimates of the Company include: revenue

recognition, sales allowances such as returns of product sold, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales commissions, amortization, stock-based compensation, determination of fair values of assets and liabilities in connection with business combinations, and deferred income taxes.

Reacquisition of BELBUCA®

On December 7, 2016, the Company entered into an agreement (the Termination Agreement) with Endo Pharmaceuticals, Inc. (Endo) terminating Endo s licensing of rights to the Company s BELBUCA® (buprenorphine) buccal film product (BELBUCA®). The closing of the Termination Agreement, and the formal termination of the BELBUCA® license to Endo and closing of the transactions further described below occurred on January 6, 2017 (see note 7, Business Combinations and Asset Acquisitions).

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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):

Inventory

Other than the inventory purchased from Endo which is stated at fair value, inventories are stated at the lower of cost or net realized value with costs determined for each batch under the first-in, first-out method and specifically allocated to remaining inventory. Inventory consists of raw materials, work in process and finished goods. Raw materials include amounts of active pharmaceutical ingredient for a product to be manufactured, work in process includes the bulk inventory of laminate (the Company s drug delivery film) 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. The Company recorded $0.2 million in inventory allowances as of March 31, 2017. There were no allowances recorded as of December 31, 2016.

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 and related supply agreements. 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.

The Company, until January 1, 2017, deferred sales of its BUNAVAIL® (buprenorphine and naloxone) buccal film, Schedule 3 (CIII) product (BUNAVAIL®) and recognized such revenue when the product was sold through to the end user. There were no product sales of BELBUCA® before January 2017.

Revenue recognition

Net product sales

Beginning in the first quarter of 2017, the Company has determined that it has sufficient experience with BELBUCA® and BUNAVAIL® to estimate its returns at time of ex-factory sales. The Company recognizes revenue when it is realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (a) persuasive evidence of an arrangement exists; (b) delivery has occurred or services have been rendered; (c) the Company s price to the buyer is fixed or determinable; and (d) collectability is reasonably assured. The

Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company recognizes revenue from sales transactions where the buyer has the right to return the product at the time of sale only if (1) the Company s price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the Company, or the buyer is obligated to pay the Company and the obligation is not contingent on resale of the product, (3) the buyer s obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from any provided by the Company, (5) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. The Company recognizes product sales net of estimated allowances for rebates, price adjustments, returns, chargebacks and prompt payment discounts. Given the sufficient experience with BELBUCA® and BUNAVAIL®, the Company can reasonably estimate the amount of future product returns, and therefore, the risk of estimating product return has been substantially eliminated. The effect in income from operations and on net income is that the Company is able to recognize revenue earlier on the sell-in method, net of a provision for estimated returns, since the Company can record revenue once sold to the wholesaler rather than waiting until the product is sold to the end user on a sell-through basis.

The Company establishes allowances for estimated rebates, chargebacks and product returns based on numerous qualitative and quantitative factors, including:

the number of and specific contractual terms of agreements with customers;

estimated levels of inventory in the distribution channel;

historical rebates, chargebacks and returns of products;

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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):

direct communication with customers;

anticipated introduction of competitive products or generics;

anticipated pricing strategy changes by the Company and/or its competitors;

analysis of prescription data gathered by a third-party prescription data provider;

the impact of changes in state and federal regulations; and

the estimated remaining shelf life of products.

In its analyses, the Company uses prescription data purchased from a third-party data provider to develop estimates of historical inventory channel sell-through. The Company utilizes an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, management develops an estimate of the quantity of product in the channel which may be subject to various rebate, chargeback and product return exposures. To estimate months of ending inventory in the Company s distribution channel, the Company divides estimated ending inventory in the distribution channel by the Company s recent prescription data, not taking into account any future anticipated demand growth beyond the succeeding quarter. Monthly for each product line, the Company prepares an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel.

Product Returns- Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products.

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 BELBUCA® and 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 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 the wholesalers regarding their sales of the Company s products and actual on hand inventory levels of its products. During the three months ended March 31, 2017, the three large wholesalers account for approximately 92% of the Company voucher and Medicaid accruals. This enables the Company to execute accurate provisioning procedures. Consistent with the pharmaceutical industry, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products.

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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):

Cost of sales

Cost of sales includes the direct costs attributable to the production of BREAKYL (the Company s out-licensed breakthrough cancer pain therapies). It includes all costs related to creating the product at the Company s contract manufacturing location in Germany. The Company s contract manufacturer bills 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.

For BELBUCA® and BUNAVAIL®, cost of sales includes raw materials, production costs at the Company s three contract manufacturing sites, quality testing directly related to the products, and depreciation on equipment that the Company has purchased to produce BELBUCA® and BUNAVAIL®. It also includes any batches not meeting specifications and raw material yield losses. Yield losses and batches not meeting specifications are expensed as incurred. Prior to January 1, 2017, cost of sales was recognized as actual product was sold through to the end user. Beginning January 1, 2017, cost of sales is recognized when sold to the wholesaler.

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 in the process of evaluating the impact that this new ASU will have on its condensed consolidated financial statements.

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

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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 accounting policies (continued):

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 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 has adopted this ASU in the first quarter of 2017; however, the adoption of the ASU had no significant impact on its condensed consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. The amendments in this update provide a screen to determine when an integrated set of assets and activities (a set) is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. The new guidance will be effective for the Company beginning on January 1, 2018 and early adoption is permitted. The Company is evaluating the impact of the adoption of the new guidance on its condensed consolidated financial statements.

In January 2017, the FASB issued ASU Update No. 2017-04, Intangibles Goodwill and Other (Topic 350): Simplifying the Test of Goodwill Impairment. This ASU simplifies the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step of the goodwill impairment test under ASC 350. Under previous guidance, if the fair value of a reporting unit is lower than its carrying amount (Step 1), an entity calculates any impairment charge by comparing the implied fair value of goodwill with its carrying amount (Step 2). The implied fair value of goodwill is calculated by deducting the fair value of all assets and liabilities of the reporting unit from the reporting unit s fair value as determined in Step 1. To determine the implied fair value of goodwill, entities estimate the fair value of any unrecognized intangible assets (including in-process research and development) and any corporate-level assets or liabilities that were included in the determination of the carrying amount and fair value of the reporting unit in Step 1. Under this new guidance if a reporting unit s carrying value exceeds its fair value,

an entity will record an impairment charge based on that difference with such impairment charge limited to the amount of goodwill in the reporting unit. This ASU does not change the guidance on completing Step 1 of the goodwill impairment test. An entity will still be able to perform today s optional qualitative goodwill impairment assessment before determining whether to proceed to Step 1. This ASU will be applied prospectively and is effective for annual and interim impairment test performed in periods beginning after December 15, 2019 for public business enterprises. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. 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 March 31, 2017, the Company had cash of approximately $35.2 million. The Company generated $3.2 million of cash during the three months ended March 31, 2017 and had stockholders equity of $38.2 million, versus stockholders deficit of $17.7 million at December 31, 2016. The Company expects that it has sufficient cash to manage the business as currently planned into the second half of 2018. This estimation assumes that the Company does not accelerate the development of existing, or acquire other drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect the Company s cash requirements.

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. DOLLARS, IN THOUSANDS)

(Unaudited)

2. Liquidity and management s plans (continued):

Additional capital will be required to support the commercialization of the Company s reacquired BELBUCA® product, ongoing commercialization activities for BUNAVAIL®, the reformulation project for and the anticipated commercial relaunch of ONSOLIS® (which is out-licensed to Collegium Pharmaceutical, Inc. (Collegium) in the US), the continued development of 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 life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all.

3. Inventory:

The following table represents the components of inventory as of:

	March 31, 2017	December 31, 2016
Raw materials & supplies	$ 1,854	$ 978
Work-in-process	2,526	1,660
Finished goods	3,765	730
Total inventories	$ 8,145	$ 3,368

4. Accounts payable and accrued liabilities:

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

	March 31, 2017	December 31, 2016

Accounts payable	$ 12,381	$ 9,397
Accrued price adjustments	1,420	592
Accrued returns	760	
Accrued acquisition consideration	7,536	
Accrued rebates	4,228	3,842
Accrued chargebacks	52	10
Accrued compensation and benefits	1,574	2,052
Accrued royalties	586	518
Accrued clinical trial costs	397	615
Accrued legal costs	1,109	490
Accrued manufacturing costs	200	200
Accrued sales and marketing costs		193
Accrued other	278	265
Total accounts payable and accrued expenses	$ 30,521	$ 18,174

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5. Property and equipment:

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

	March 31, 2017	December 31, 2016
Machinery & equipment	$ 4,907	$ 4,476
Computer equipment & software	464	464
Office furniture & equipment	202	202
Leasehold improvements	53	53
Idle equipment	1,486	1,486
Total	7,112	6,681
Less accumulated depreciation	(2,563)	(2,451)
Total property, plant & equipment, net	$ 4,549	$ 4,230

Depreciation expense was approximately $0.1 million and $0.09 million for the three month periods ended March 31, 2017 and 2016, respectively.

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. The Company s most significant license and development agreements are as follows:

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 year ended December 31, 2015. There was no remaining U.S.-related contract revenue

to record during the year ended December 31, 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, which terminated on May 11, 2016 upon the signing of the Termination and Revenue Sharing Agreement (the Agreement).

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 the second half of 2017.

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

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6. License and development agreements (continued):

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;

$3 million payable to the Company related to ONSOLIS® patent milestone (earned March 2017 but payable by Collegium to the Company first half of 2018);

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 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 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 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.

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6. License and development agreements (continued):

Endo license and development agreement (continued)

Pursuant to the Endo Agreement, the Company has received the following payments:

$30 million non-refundable upfront license fee (earned in January 2012);

$15 million for enhancement of intellectual property rights (earned in May 2012);

$20 million for full enrollment in two clinical trials ($10 million earned in January 2014 and $10 million earned in June 2014);

$10 million upon FDA acceptance of filing NDA (earned in February 2015);

$50 million upon regulatory approval, earned in October 2015 and received in November 2015. Of the $50 million received in November 2015, $20 million related to a patent extension and was recorded as deferred revenue because all or a portion of such $20 million was contingently refundable to Endo if a third party generic product was introduced in the U.S. during the patent extension period from 2020 to 2027. However, due to the Company and Endo entering into a Termination Agreement on December 7, 2016 which terminated the BELBUCA® license to Endo effective January 6, 2017, the deferred $20 million was recognized as revenue during the three months ended March 31, 2017 in the accompanying condensed consolidated statement of operations (see note 7).

7. Business combination and asset acquisitions:

On December 7, 2016, the Company entered into an agreement (the Termination Agreement) with Endo terminating Endo s licensing of rights for BELBUCA®. The closing of the Termination Agreement, and the formal termination of the BELBUCA® license to Endo and closing of the transactions further described below to be undertaken in connection therewith (the Endo Closing), occurred on January 6, 2017.

At the Endo Closing, the Company purchased from Endo the following assets (the Assets): (i) current BELBUCA® product inventory, raw material and work-in-progress, (ii) material manufacturing contracts related to BELBUCA®, (iii) BELBUCA®-related domain names and trademarks (including the BELBUCA® trademark), (iv) BELBUCA®-related manufacturing equipment, and (v) all pre-approval regulatory submissions, including any Investigational New Drug Applications and New Drug Applications, regulatory approvals and post-approval regulatory submissions concerning BELBUCA®. The purchase price for the Assets (the Asset Purchase Price) is equal to the sum of (i) the aggregate book value of the portion of the transferred product inventory forecasted to be used or sold by the Company, (ii) the aggregate book value of the raw material and work-in-progress inventory, and (iii) the assumption of any assumed liabilities. Upon the Endo Closing, the Company accepted transfer of the Assets and assumed and agreed to discharge when due all applicable liabilities assumed by the Company, which consisted of post-closing obligations for liabilities and payments associated with the Assets, the assumed contracts related to the Assets and applicable taxes (with the obligation for pre-closing and other certain liabilities resulting from the acts or omissions of Endo being retained by Endo).

The Asset Purchase Price, together with all other payments (including a non-compete covenant payment) due to Endo under the Termination Agreement, will be paid to Endo in cash in four quarterly installments on the last calendar day of each quarter in 2017. Furthermore, the Company is not responsible for future royalties or milestone payments to Endo and Endo is not obligated to any future milestone payments to the Company. The Termination Agreement contains customary representations and warranties and mutual releases and indemnification.

At the Endo Closing, the Company and Endo entered into a Transition Services Agreement which governed the post-closing rights and responsibilities of the Company and Endo in connection with the license termination and the transfer of the Assets to the Company. Under this agreement, the Company and Endo agreed to the handling of transition matters such as managing customer contracts, BELBUCA® price reporting, payments, returns and rebates, and customer and managed care relations. In connection therewith, Endo has agreed to provide to the Company an agreed upon number of work hours to be provided by Endo personnel during the transition for certain of these transition services and other assistance with respect to the transition of BELBUCA® to the Company.

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7. Business combination and asset acquisitions (continued):

The BELBUCA® acquisition was accounted for as a business combination in accordance with ASC No. 805, *Business Combinations* which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values. The purchase price allocation is preliminary with respect to taxes and certain accruals and includes the use of estimates based on information that was available to management at the time these unaudited condensed consolidated financial statements were prepared. The Company believes the estimates used are reasonable and the significant effects of the BELBUCA® acquisition are properly reflected. However, the estimates are subject to change as additional information becomes available and is assessed by the Company.

Asset acquisition BELBUCA®

The following table summarizes the consideration paid to acquire BELBUCA® and the estimated values of assets acquired and liabilities assumed in the accompanying condensed consolidated balance sheet based on their fair values on January 6, 2017 (the date of the Endo Closing):

Asset purchase price:	
Deferred cash consideration to Endo	$ 7,536
Total asset purchase price	$ 7,536
Estimated fair value of assets acquired:	
Current BELBUCA® product inventory and work-in process	$ 5,412
BELBUCA®-related manufacturing equipment	432
License and distribution rights intangible assets	45,000
Deferred tax liability	(15,972)
Amount attributable to assets acquired	$ 34,872
Bargain purchase gain	$ (27,336)

Inventories acquired included raw materials, work-in-progress and finished goods. The fair value of the acquired finished goods inventory was estimated by adjusting the anticipated selling price costs to sell and an appropriate profit on selling activities. For work-in-process, in addition to those inputs used to estimate the fair value of finished goods,

the cost and estimated profit on completing the manufacturing are also included. The fair value of the raw materials represent cost to acquire the materials from suppliers.

The fair value of the equipment was determined by consultations with a third-party equipment vendor, which considered replacement cost and equipment condition. The equipment will be depreciated over seven years based on its estimated remaining useful life.

The fair value of the license and distribution intangible assets were estimated primarily using the income method, which starts with a forecast of all expected future cash flows. Some of the more significant assumptions inherent in the development of intangible asset values, from the perspective of a market participant, include: the amount and timing of projected future cash flows (including net revenue, cost of sales, commercial expenses, research and development costs and working capital requirements) as well as estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset s life cycle and the competitive trends impacting the asset, among other factors. The license and distribution rights intangible assets will be amortized over ten years, which approximates the current, remaining patent life of the BELBUCA® intellectual property.

As a result of the business combination, the Company recognized a deferred tax liability of $16.0 million. This deferred tax liability was netted against its deferred tax assets as of March 31, 2017. Because a full valuation allowance has been provided against the Company s deferred tax assets as it is considered more likely than not that they will not be utilized, the Company released a corresponding amount of its valuation allowance during the three months ended March 31, 2017 and recognized a $16.0 million tax benefit in the accompanying condensed consolidated statement of operations.

The Company recorded the asset acquisition as a bargain purchase gain of $27.3 million in the accompanying condensed consolidated statement of operations.

Pro forma impact of acquisition

The following pro forma combined results of operations are provided for the year ended December 31, 2016, as though the BELBUCA® acquisition had been completed as of January 1, 2016. These supplemental pro forma results of operations are provided for illustrative purposes only and do not purport to be indicative of the actual results that would have been achieved by the combined

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7. Business combination and asset acquisitions (continued):

company for the periods presented or that may be achieved by the combined company in the future. The pro forma results of operations do not include any cost savings or other synergies that resulted, or may result, from the BELBUCA® acquisition or any estimated costs that will be incurred to integrate the BELBUCA® product line, nor do they reflect the bargain purchase gain recognized. Future results may vary significantly from the results in this pro forma information because of future events and transactions, as well as other factors.

(in thousands, except per share data)

	2016* (unaudited)
Revenue	$ 25,010
Net loss	$ (201,769)
Pro forma net loss per common share	
Basic	$ (3.76)
Diluted	$ (3.76)

The Company s historical financial information was adjusted to give effect to the pro forma events that were directly attributable to the BELBUCA® acquisition and factually supportable. The unaudited pro forma consolidated results include historical revenues and expenses of assets acquired in the acquisition with the following adjustments:

Adjustment to recognize incremental amortization expense based on the fair value of intangibles acquired;

Adjustment to recognize incremental depreciation expense for equipment acquired in the acquisition.

*BELBUCA® was launched February 22, 2016, and therefore, results as of March 31, 2016 were not readily available.

The Company has recognized net product sales for BELBUCA® subsequent to the Endo Closing on January 7, 2017 in the amount of $4.6 million. Non-recurring transaction costs related to the acquisition for the year ended December 31, 2016 were minimal. These non-recurring transaction costs have been excluded from the pro forma results in the above table.

8. License obligations:

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.

This product candidate is currently in the pre-clinical stage of development. An Investigational New Drug Application (IND) for the treatment of opioid dependence was filed in the fourth quarter 2016 and plans are underway to file a pain IND in 2017.

9. 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 upfront 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 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 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, the Company received a payment of $0.2 million from TTY, which related to royalties based on product purchased in Taiwan by TTY of PAINKYL which is recorded in the accompanying condensed consolidated statement of operations for the three months ended March 31, 2016. There were no payments received during the three months ended March 31, 2017.

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10. 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 that certain Amended and Restated Credit and Security Agreement, dated as of May 29, 2015 (the Credit Agreement), between the Company and MidCap.

On February 21, 2017, the Company entered into a term loan agreement (the Term Loan Agreement) with CRG Servicing LLC (CRG), as administrative agent and collateral agent, and the lenders named in the Term Loan Agreement (the Lenders). The Company utilized approximately $29.4 million of the initial loan proceeds to repay all of the amounts owed by the Company under its existing Amended and Restated Loan and Security Agreement, dated May 29, 2015, with MidCap (the Prior Agreement). Upon the repayment of all amounts owed by the Company under the Prior Agreement, all commitments under the Prior Agreement have been terminated and all security interests granted by the Company and its subsidiary guarantors (the Subsidiary Guarantors) under the Prior Agreement have been released (see note 11). The warrants issued to MidCap in May 2016 related to the extension of the interest only period were not terminated and are outstanding as of March 31, 2017. During the three months ended March 31, 2017, $0.7 million of deferred loan costs were expensed and recorded as interest expense in the accompanying condensed consolidated statement of operations.

11. Term loan agreement (CRG):

Pursuant to the Term Loan Agreement, the Company borrowed $45.0 million from the Lenders as of the Closing Date, and may be eligible to borrow up to an additional $30.0 million in two tranches of $15.0 million each contingent upon achievement of certain conditions, including: (i) in the case of the first tranche, representing the second potential draw under the Loan Agreement (the Second Draw), satisfying both (a) certain minimum net revenue thresholds on or before September 30, 2017 or December 31, 2017 and (b) a certain minimum market capitalization threshold for a period of time prior to the funding of the Second Draw (provided, that if the Company does not achieve the minimum net revenue thresholds necessary for the Second Draw but does achieve a certain minimum market capitalization threshold for a period of time prior to December 31, 2017, the Company would be eligible for a Second Draw funding in the amount of $5.0 million); and (ii) in the case of the second tranche, representing the third potential draw under the Loan Agreement (the Third Draw), satisfying both (a) certain minimum net revenue thresholds on or before June 30, 2018 or September 30, 2018 and (b) a certain minimum market capitalization threshold for a period of time prior to the funding of the Third Draw.

The Company intends to use the remainder of the initial proceeds under the Term Loan Agreement (after deducting loan origination costs and broker and other fees) of approximately $13.7 million, plus any additional amounts that may be borrowed in the future, for general corporate purposes and working capital.

The Term Loan Agreement has a six-year term with three years of interest-only payments (which can be extended to four years if the Company achieves certain net revenue and market capitalization thresholds prior to December 31, 2019), after which quarterly principal and interest payments will be due through the December 31, 2022 maturity date. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 12.50%, 3.5% of which (i.e., a resultant 9.0% rate) may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. On each borrowing date (including the Closing Date), the Company is required to pay CRG a financing fee based on the loan drawn on that date. The Company is also required to pay the Lenders a final payment fee equivalent to 9% of the original loan amount upon repayment of the Loans in full, in addition to prepayment amounts described below.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice to the Lenders subject to a certain prepayment fees during the first five years of the term (which fees are

lowered over time) and no prepayment fee thereafter. In certain circumstances, including a change of control and certain asset sales or licensing transactions, the Company is required to prepay all or a portion of the loan, including the applicable prepayment premium of on the amount of the outstanding principal to be prepaid.

As security for its obligations under the Term Loan Agreement, on the funding date of the initial borrowing, the Company and the Subsidiary Guarantors entered into a security agreement with CRG whereby the Company and the Subsidiary Guarantors granted to CRG, as collateral agent for the Lenders, a lien on substantially all of its assets including intellectual property (subject to certain

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11. Term loan agreement (CRG) (continued):

exceptions). The Term Loan Agreement requires the Company to maintain minimum cash and cash equivalents balance and, each year through the end of 2022, to meet a minimum net annual revenue threshold. In the event that the Company does not meet the minimum net annual revenue threshold, then the Company can satisfy the requirement for that year by raising two (2) times the shortfall by way of raising equity or subordinated debt.

The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including covenants that limit or restrict the Company s ability to, among other things (but subject in each case to negotiated exceptions), incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into transactions with affiliates, pay dividends or make distributions, license intellectual property rights on an exclusive basis or repurchase stock.

The Term Loan Agreement includes customary events of default that include, among other things, non-payment, inaccuracy of representations and warranties, covenant breaches, a material adverse change (as defined in the Term Loan Agreement), cross default to material indebtedness or material agreements, bankruptcy and insolvency, material judgments and a change of control. The occurrence and continuance of an event of default could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply on all outstanding obligations during the existence of an event of default under the Term Loan Agreement.

The amount disclosed in Notes payable, less current maturities, in the accompanying condensed consolidated balance sheets for year ended December 31, 2016 reflects the February 21, 2017 repayment of loan obligations to MidCap Financial Trust and the simultaneous entry into a term loan agreement with CRG Servicing LLC.

The following table represents future maturities of the CRG obligation as of March 31, 2017:

2017	$
2018	
2019	
2020	15,000
2021	15,000
2022	15,162
Total maturities	$ 45,162

Unamortized discount and loan costs	(10,362)
Total CRG obligation	$ 34,800

12. Stockholders equity:
Stock-based compensation

During the three months ended March 31, 2017, a total of 615,155 options to purchase Common Stock, with an aggregate fair market value of approximately $1.2 million, were granted to Company employees. The options granted have a term of 10 years from the grant date and vest ratably over a three year period. 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,	
Stock-based compensation expense	**March 31, 2017**	**March 31, 2016**
Research and Development	$ 401	$ 1,128
Selling, General and Administrative	$ 2,669	$ 2,983

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.