

IGI LABORATORIES, INC  
Form 10-Q  
August 10, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 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 June 30, 2015**

**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 001-08568**

**IGI Laboratories, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other Jurisdiction of  
incorporation or organization)*

**01-0355758**  
*(I.R.S. Employer Identification No.)*

**105 Lincoln Avenue**  
**Buena, New Jersey**

**08310**

*(Address of Principal Executive Offices) (Zip Code)*

**(856) 697-1441**

*(Registrant's telephone number, including area code)*

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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  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

The number of shares outstanding of the issuer's common stock is 52,863,453 shares as of August 3, 2015.

**PART I****FINANCIAL INFORMATION****ITEM 1. Financial Statements****IGI LABORATORIES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except share and per share information)****(Unaudited)**

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
<b>Revenues:</b>				
Product sales, net	\$ 8,647	\$ 6,021	\$ 19,157	\$ 12,520
Research and development income	187	437	238	750
Licensing, royalty and other revenue	59	25	169	66
Total revenues	8,893	6,483	19,564	13,336
<b>Costs and Expenses:</b>				
Cost of revenues	5,227	3,580	10,270	7,567
Selling, general and administrative expenses	2,141	1,156	4,041	2,438
Product development and research expenses	3,436	2,028	6,066	3,393
Total costs and expenses	10,804	6,764	20,377	13,398
Operating loss	(1,911 )	(281 )	(813 )	(62 )
<b>Other Income (Expense):</b>				
Change in the fair value of derivative liability	14,519	-	23,144	-
Interest and other expense, net	(3,232 )	(52 )	(6,400 )	(104 )
Income (loss) before income tax expense	9,376	(333 )	15,931	(166 )
Income tax expense	-	12	-	12
Net income (loss)	\$ 9,376	\$ (345 )	\$ 15,931	\$ (178 )
Basic earnings (loss) per share	\$ 0.18	(\$0.01 )	\$ 0.30	\$0.00
Diluted loss per share	(\$0.03 )	(\$0.01 )	(\$0.02 )	\$0.00

Weighted average shares of common stock  
outstanding:

Edgar Filing: IGI LABORATORIES, INC - Form 10-Q

Basic	52,861,167	47,107,094	52,851,587	46,967,688
Diluted	67,125,905	47,107,094	67,174,546	46,967,688

The accompanying notes are an integral part of the condensed consolidated financial statements.

**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands, except share and per share information)**

	June 30, 2015 (Unaudited)	December 31, 2014*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 150,221	\$ 158,883
Accounts receivable, net	17,285	14,366
Inventories	4,096	2,784
Prepaid expenses and other receivables	1,530	1,185
Total current assets	173,132	177,218
Property, plant and equipment, net	4,300	3,262
Product acquisition costs, net	12,061	10,604
Debt issuance costs, net	4,762	5,132
Other	460	862
Total assets	\$ 194,715	\$ 197,078
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,589	\$ 1,643
Accrued expenses	4,440	5,141
Payable for product acquisition costs	6,000	6,000
Other current liabilities	180	218
Total current liabilities	13,209	13,002
Convertible 3.75% senior notes, net of debt discount (face of \$143,750)	103,544	100,311
Fair value of derivative liability - convertible 3.75% senior notes	-	41,400
Note payable, bank	3,160	3,160
Other long term liabilities	210	71
Total liabilities	120,123	157,944
Stockholders' equity:		
Series A Convertible Preferred stock, \$0.01 par value, 100 shares authorized; 0 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	-	-
Series C Convertible Preferred stock, \$0.01 par value, 1,550 shares authorized; 0 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	-	-
Common stock, \$0.01 par value, 100,000,000 and 60,000,000 shares authorized; 52,862,453 and 52,819,787 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	548	548
Additional paid-in capital	97,699	78,172

Edgar Filing: IGI LABORATORIES, INC - Form 10-Q

Accumulated deficit	(23,655	)	(39,586	)
Total stockholders' equity	74,592		39,134	
Total liabilities and stockholders' equity	\$ 194,715		\$ 197,078	

\*Derived from the audited December 31, 2014 financial statements

The accompanying notes are an integral part of the condensed consolidated financial statements.

**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****For the six months ended June 30, 2015 and 2014****(in thousands)****(Unaudited)**

	June 30, 2015	June 30, 2014
Cash flows from operating activities:		
Net income (loss)	\$ 15,931	\$ (178 )
Reconciliation of net income (loss) to net cash used in operating activities		
Depreciation and amortization of fixed assets	240	185
Amortization of license fee	50	50
Stock based compensation	906	519
Amortization of debt issuance costs	397	16
Amortization of product acquisition costs	60	60
Provision for write down of inventory	50	114
Amortization of debt discount on convertible 3.75% senior notes	3,233	-
Change in the fair value of derivative liability	(23,144 )	-
Changes in operating assets and liabilities		
Accounts receivable	(2,919 )	(304 )
Inventories	(1,362 )	32
Prepaid expenses and other assets	7	(371 )
Accounts payable and accrued expenses	842	42
Deferred income	(84 )	(635 )
Net cash used in operating activities	(5,793 )	(470 )
Cash flows from investing activities:		
Product acquisition costs	(1,517 )	-
Capital expenditures	(1,278 )	(312 )
Net cash used in investing activities	(2,795 )	(312 )
Cash flows from financing activities:		
Proceeds from exercise of common stock options and warrants	18	456
Principal payments on capital lease obligations	(65 )	(9 )
Debt issuance costs	(27 )	-
Costs related to stock issuance	-	(4 )
Net cash (used in) provided by financing activities	(74 )	443

Edgar Filing: IGI LABORATORIES, INC - Form 10-Q

Net decrease in cash and cash equivalents	(8,662 )	(339 )
Cash and cash equivalents at beginning of period	158,883	2,101
Cash and cash equivalents at end of period	\$ 150,221	\$ 1,762
Supplemental Cash flow information:		
Cash payments for interest	\$2,777	\$ 123
Cash payments for income taxes	106	16
Non cash investing and financing transactions:		
Issuance of restricted stock	\$347	\$ -

The accompanying notes are an integral part of the condensed consolidated financial statements.



**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY****For the six months ended June 30, 2015****(in thousands, except share information)****(Unaudited)**

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2014	52,819,787	\$ 548	\$ 78,172	\$ (39,586)	) \$ 39,134
Stock based compensation expense			906		906
Stock options exercised	10,166		18		18
Issuance of restricted stock	32,500		347		347
Reclassification of derivative liability to equity			18,256		18,256
Net income	-	-	-	15,931	15,931
Balance, June 30, 2015	52,862,453	\$ 548	\$ 97,699	\$ (23,655)	) \$ 74,592

The accompanying notes are an integral part of the condensed consolidated financial statements.

## **IGI LABORATORIES, INC. AND SUBSIDIARIES**

### **NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014, as updated by other reports we may file from time to time with the Securities and Exchange Commission (“SEC”). The condensed consolidated balance sheet as of December 31, 2014 has been derived from those audited consolidated financial statements. Operating results for the six month period ended June 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.*

#### **1. Organization and Business**

IGI Laboratories, Inc. is a Delaware corporation incorporated in 1977. The Company’s office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. The Company is a specialty generic pharmaceutical company. The Company’s mission is to become a leader in the specialty generic pharmaceutical market. Under its own label, the Company currently sells generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. The Company also provides development, formulation and manufacturing services to the pharmaceutical, over-the-counter (“OTC”) and cosmetic markets.

#### **2. Liquidity**

The Company’s principal sources of liquidity are cash and cash equivalents of approximately \$150.2 million at June 30, 2015, the \$6.8 million available under the \$10 million credit facility detailed below and cash from operations. The Company will be required to pay up to an additional aggregate of \$6 million, payable at the time of the Company’s first filling with the United States Food and Drug Administration (the “FDA”) related to any asset purchased from AstraZeneca Pharmaceuticals LP (see Note 14).

The Company may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, the Company may continue to seek to raise additional capital through the sale of its equity or through a strategic alliance with a third party. There may also be additional acquisition and

growth opportunities that may require external financing. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. The Company also has the ability to defer certain product development and other programs, if necessary. The Company believes that our existing capital resources will be sufficient to support its current business plan and operations beyond August 2016.

### **3. Summary of Significant Accounting Policies**

#### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“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 financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include valuation of the derivative liability, sales returns and allowances (“SRA”), allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowances, stock based compensation and accruals for environmental cleanup and remediation costs.

**Fair Value of Financial Instruments**

The carrying amounts of cash and cash equivalents, trade receivables, restricted cash, notes payable, accounts payable, capital leases and other accrued liabilities at June 30, 2015 approximate their fair value for all periods presented. The Company measures fair value in accordance with ASC 820-10 "Fair Value Measurements and Disclosures". ASC 820-10 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820-10 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The Company measured its derivative liability at fair value. The derivative convertible option related to Notes (as defined in Note 6) issued December 16, 2014 was valued using the "with" and "without" analysis. A "with" and "without" analysis is a standard valuation technique for valuing embedded derivatives by first considering the value of the Notes with the option and then considering the value of the Notes without the option. The difference is the fair value of the embedded derivatives. The embedded derivative was classified within Level 3 because it was valued using the "with" and "without" method, which does utilize inputs that are unobservable in the market.

On May 20, 2015, the Company received approval to increase its authorized shares sufficient to allow for the conversion of the embedded option into equity at the annual shareholders meeting. Therefore, the derivative liability of \$183 million was reclassified into stockholders equity. Based on the closing price of the Company's common stock as of June 30, 2015, the fair value of the Notes was approximately \$103.5 million compared to their face value of \$143.75 million as of June 30, 2015. However, this variance is due to the conversion feature in the Notes rather than to changes in market interest rates. The Notes carry a fixed interest rate and therefore do not subject the Company to interest rate risk. The Company recorded a change in the fair value of the derivative liability through May 20, 2015 of

\$14.5 million for the three months ended June 30, 2015 and \$23.1 million for the six months ended June 30, 2015 on the condensed consolidated statements of operations. On May 20, 2015, the Company recorded the final change in fair value and subsequently reclassified the value of the derivative liability into stockholders equity due to the approval of sufficient shares.

**Net Earnings Per Share**

Basic earnings (loss) per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share of common stock is computed using the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period. Potential dilutive common stock equivalents include shares issuable upon the conversion of the Notes and the exercise of options and warrants.

(in thousands except shares and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Basic earnings per share computation:				
Net income (loss) - basic	\$ 9,376	\$ (345 )	\$ 15,931	\$ (178 )
Weighted average common shares - basic	52,861,167	47,107,094	52,851,587	46,967,688
Basic earnings (loss) per share	\$ 0.18	\$ (0.01 )	\$ 0.30	\$ (0.00 )
Dilutive earnings per share computation:				
Net income (loss) - basic	\$ 9,376	\$ (345 )	\$ 15,931	\$ (178 )
Interest expense related to convertible 3.75% senior notes	1,348	-	2,695	-
Amortization of discount related to convertible 3.75% senior notes	1,643	-	3,233	-
Change in the fair value of derivative	(14,519 )	-	(23,144 )	-
Net loss - diluted	\$ (2,152 )	\$ (345 )	\$ (1,285 )	\$ (178 )
Share Computation:				
Weighted average common shares - basic	52,861,167	47,107,094	52,851,587	46,967,688
Effect of convertible 3.75% senior notes	12,732,168	-	12,732,168	-
Effect of dilutive stock options and warrants	1,532,570	-	1,590,791	-
Weighted average common shares outstanding - diluted	67,125,905	47,107,094	67,174,546	46,967,688
Diluted loss per share	(\$0.03 )	(\$0.01 )	(\$0.02 )	(\$0.00 )

**Revenue Recognition**

The Company considers revenue realized or realizable and earned when it has persuasive evidence of an arrangement, delivery has occurred or contractual services rendered, the sales price is fixed or determinable, and collection is reasonably assured in conformity with ASC 605, "Revenue Recognition".

The Company derives its revenues from three basic types of transactions: sales of its own generic pharmaceutical topical products, sales of manufactured product for its customers included in product sales, and research and product development services performed for third parties. Due to differences in the substance of these transaction types, the transactions require, and the Company utilizes, different revenue recognition policies for each.

**Product Sales: Product Sales includes IGI Product Sales and Contract Manufacturing Sales.**

IGI Product Sales: The Company records revenue from IGI product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery of products to the customer.

*Revenue and Provision for Sales Returns and Allowances*

As is customary in the pharmaceutical industry, the Company's gross product sales from IGI label products are subject to a variety of deductions in arriving at reported net product sales. When the Company recognizes revenue from the sale of products, an estimate of SRA is recorded, which reduces product sales. Accounts receivable and/or accrued expenses are also reduced and/or increased by the SRA amount. These adjustments include estimates for chargebacks, rebates, cash discounts and returns and other allowances. These provisions are estimates based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and current contract sales terms with direct and indirect customers. The estimation process used to determine our SRA provision has been applied on a consistent basis and no material adjustments have been necessary to increase or decrease our reserves for SRA as a result of a significant change in underlying estimates. The Company will use a variety of methods to assess the adequacy of our SRA reserves to ensure that our financial statements are fairly stated. These will include periodic reviews of customer inventory data, customer contract programs, subsequent actual payment experience, and product pricing trends to analyze and validate the SRA reserves.

The provision for chargebacks is our most significant sales allowance. A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to the Company by our wholesale customer for a particular product and the negotiated contract price that the wholesaler's customer pays for that product. The Company's chargeback provision and related reserve varies with changes in product mix, changes in customer pricing and changes to estimated wholesaler inventories. The provision for chargebacks also takes into account an estimate of the expected wholesaler sell-through levels to indirect customers at contract prices. The Company will validate the chargeback accrual quarterly through a review of the inventory reports obtained from our largest wholesale customers. This customer inventory information is used to verify the estimated liability for future chargeback claims based on historical chargeback and contract rates. These large wholesalers represent 90% - 95% of the Company's chargeback payments. The Company continually monitors current pricing trends and wholesaler inventory levels to ensure the liability for future chargebacks is fairly stated.

Net revenues and accounts receivable balances in the Company's consolidated financial statements are presented net of SRA estimates. Certain SRA balances are included in accounts payable and accrued expenses.

### Gross-To-Net Sales Deductions

(in thousands)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Gross IGI product sales	\$ 27,861	\$ 5,770	\$ 50,180	\$ 10,795
Reduction to gross product sales:				
Chargebacks and billbacks	15,576	1,884	28,088	3,468
Sales discounts and other allowances	5,612	504	7,322	1,001
Total reduction to gross product sales	21,188	2,388	35,410	4,469
IGI product sales, net	\$ 6,673	\$ 3,382	\$ 14,770	\$ 6,326

Net IGI product sales of \$6.7 million and \$3.4 million for the three months ended June 30, 2015 and 2014, respectively are included in Product sales, net in the Condensed Consolidated Statements of Operations. Net IGI product sales of \$14.8 million and \$6.3 million for the six months ended June 30, 2015 and 2014, respectively are included in Product sales, net in the Condensed Consolidated Statements of Operations. Accounts receivable are presented net of SRA balances of \$9.3 million and \$1.4 million at June 30, 2015 and 2014, respectively. Accounts payable and accrued expenses include \$1.5 million and \$0.4 million at June 30, 2015 and 2014, respectively, for certain fees related to services provided by the wholesalers. Wholesale fees of \$1.7 million and \$0.5 million for the three month periods ended June 30, 2015 and 2014, respectively, were included in cost of goods sold. Wholesale fees of \$3.4 million and \$0.7 million for the six month periods ended June 30, 2015 and 2014, respectively, were included in cost of goods sold. In addition, in connection with four of the seven products the Company currently manufactures,



markets and distributes under its own label, in accordance with an agreement entered into in December of 2011, the Company is required to pay a royalty calculated based on net sales to one of its pharmaceutical partners. The royalty is calculated based on contracted terms of 40% of net sales for the four products which is to be paid quarterly to the pharmaceutical partner. In accordance with the agreement, net sales excludes fees related to services provided by the wholesalers. Accounts payable and accrued expenses include \$0.8 million and \$0.6 million at June 30, 2015 and 2014, respectively, related to these royalties. Royalty expense of \$0.7 million and \$0.8 million was included in cost of goods sold for the three months ended June 30, 2015 and 2014, respectively. Royalty expense of \$1.6 million and \$2.1 million was included in cost of goods sold for the six months ended June 30, 2015 and 2014, respectively. The Company includes significant estimates to arrive at net product sales arising from wholesaler chargebacks, Medicaid and Medicare rebates, allowances and other pricing and promotional programs.

Contract Manufacturing Sales: The Company recognizes revenue when title transfers to its customers, which is generally upon shipment of products. These shipments are made in accordance with sales commitments and related sales orders entered into with customers either verbally or in written form. The revenues associated with these transactions, net of appropriate cash discounts, product returns and sales reserves, are recorded upon shipment of the products.

**Research and Development Income:** The Company establishes agreed upon product development agreements with its customers to perform product development services. Product development revenues are recognized in accordance with the product development agreement upon the completion of the phases of development and when the Company has no future performance obligations relating to that phase of development. Revenue recognition requires the Company to assess progress against contracted obligations to assure completion of each stage. These payments are generally non-refundable and are reported as deferred until they are recognizable as revenue. If no such arrangement exists, product development fees are recognized ratably over the entire period during which the services are performed.

In making such assessments, judgments are required to evaluate contingencies such as potential variances in schedule and the costs, the impact of change orders, liability claims, contract disputes and achievement of contractual performance standards. Changes in total estimated contract cost and losses, if any, are recognized in the period they are determined. Billings on research and development contracts are typically based upon terms agreed upon by the Company and customer and are stated in the contracts themselves and do not always align with the revenues recognized by the Company.

### **Major Customers**

Major customers of the Company are defined as having revenue greater than 10% of total gross revenue. For the three months ended June 30, 2015, one of the Company's customers accounted for 44% of our revenue. For the three months ended June 30, 2014, three of the Company's customers accounted for 46% of our revenue. One of these customers is the same for both periods. For the six months ended June 30, 2015 and 2014, two of the Company's customers accounted for 56% and two of the Company's customers accounted for 31% of the Company's revenue, respectively. One of these customers is the same for both periods. Accounts receivable related to the Company's major customers comprised 44% of all accounts receivable as of June 30, 2015. The loss of one or more of these customers could have a significant impact on our revenues and harm our business and results of operations.

The Company had net revenue from one product, econazole nitrate cream, which accounted for 51% and 26% of total revenues for the three months ended June 30, 2015 and 2014, respectively, and 52% and 20% of total revenues for the six months ended June 30, 2015 and 2014, respectively.

### **Derivatives**

The Company accounts for its derivative instruments in accordance with ASC 815-10, "Derivatives and Hedging". ASC 815-10 establishes accounting and reporting standards requiring that derivative instruments, including derivative instruments embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value. ASC 815-10 also requires that changes in the fair value of derivative instruments be recognized currently in

results of operations unless specific hedge accounting criteria are met. The Company has not entered into hedging activities to date. The Company's derivative liability was the embedded convertible option of its Notes issued December 16, 2014 (see Note 6), which has been recorded as a liability at fair value and was revalued at each reporting date, with changes in the fair value of the instruments included in the consolidated statements of operations as non-operating income (expense). Due to the approval of the sufficient shares at the Company's annual shareholder meeting, the liability for the embedded derivative was reclassified to equity on May 20, 2015.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers". This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This ASU is effective for annual reporting periods beginning after December 15, 2017 and early adoption is not permitted. Accordingly, the Company will adopt this ASU on January 1, 2017. Companies may use either a full retrospective or modified retrospective approach to adopt this ASU and management is currently evaluating which transition approach to use. The Company is currently evaluating the impact of ASU 2014-09.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements — Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". This ASU requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable) and provide related disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2014-15.

In April 2015, the FASB issued ASU 2015-03, “Simplifying the Presentation of Debt Issuance Costs,” which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of debt discounts or premiums. The ASU is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The Company is currently evaluating the impact of ASU 2015-03.

In July 2015, the FASB issued ASU 2015-11, “Inventory (Topic 330): Simplifying the Measurement of Inventory”. ASU 2015-11 requires inventory measured using any method other than last-in, first out (“LIFO”) or the retail inventory method to be subsequently measured at the lower of cost or net realizable value, rather than at the lower of cost or market. Under this ASU, subsequent measurement of inventory using the LIFO and retail inventory method is unchanged. ASU 2015-11 is effective prospectively for fiscal years, and for interim periods within those years, beginning after December 15, 2016. Early application is permitted. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

#### **4. License Fee**

On December 12, 2005, the Company extended its license agreement with Novavax, Inc. for an additional ten years for \$1 million. This extension entitles the Company to the exclusive use of the Novasome® lipid vesicle encapsulation and certain other technologies (each a “Microencapsulation Technology”, and collectively, the “Technologies”) in the fields of (i) animal pharmaceuticals, biologicals and other animal health products; (ii) foods, food applications, nutrients and flavorings; (iii) cosmetics, consumer products and dermatological over-the-counter and prescription products (excluding certain topically delivered hormones); (iv) fragrances; and (v) chemicals, including herbicides, insecticides, pesticides, paints and coatings, photographic chemicals and other specialty chemicals, and the processes for making the same (collectively, the “IGI Field”) through 2015. This payment is being amortized ratably over the ten-year period. The Company recorded amortization expense of \$25,000 related to this agreement for each of the three month periods ended June 30, 2015 and 2014 and \$50,000 for each of the six month periods ended June 30, 2015 and 2014. Remaining amortization of this license fee will amount to \$50,000 in 2015.

#### **5. Inventories**

Inventories are valued at the lower of cost or market, using the first-in-first-out method.

Inventories at June 30, 2015 and December 31, 2014 consist of:

	June 30, 2015	December 31, 2014
	(Unaudited)	(Audited)
	(amounts in thousands)	
Raw materials	\$ 3,385	\$ 2,299
Work in progress	29	140
Finished goods	682	345
Total	\$ 4,096	\$ 2,784

## 6. Convertible 3.75% Senior Notes

On December 16, 2014, the Company issued \$125 million aggregate principal amount of 3.75% Convertible Senior Notes due 2019 (the "Notes"). On December 22, 2014, the Company announced the closing of the initial purchasers' exercise in full of their option to purchase an additional \$18.75 million aggregate principal amount. The Notes were offered and sold only to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The net proceeds from the sale of the Notes were approximately \$139 million, after deducting underwriting fees and other related expenses of approximately \$4.8 million. Accrued interest in the amount of \$0.2 million related to the Notes was included in accrued expenses as of June 30, 2015.

The Notes bear interest at a fixed rate of 3.75% per year, payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2015 and mature on December 15, 2019, unless earlier repurchased, redeemed or converted. The Notes are convertible into shares of the Company's common stock, cash or a combination thereof.

On May 20, 2015, the Company received shareholder approval for the increase in the number of shares of common stock authorized and available for issuance upon conversion of the Notes. As a result, the conversion option can now be share-settled in full, and now qualifies for equity classification, and the bifurcated derivative liability no longer needs to be accounted for as a separate derivative on a prospective basis as of May 20, 2015. The remaining unamortized debt discount that arose at the date of debt issuance from the original bifurcation will continue to be amortized using the effective interest method through interest expense. After adjusting the derivative liability to market value on May 20, 2015, the Company reclassified the remaining \$18.3 million value of the derivative liability to stockholders equity due to the approval of sufficient shares.

The Notes are convertible at an initial conversion price of approximately \$11.29 per share, which is equivalent to an initial conversion rate of 88.5716 shares per \$1,000 principal amount of Notes, subject to adjustment in certain events, such as distributions of dividends or stock splits. Holders may convert their Notes at their option prior to September 15, 2019, when or if certain conditions have been met or circumstances have occurred, such as if the Company's stock price exceeds 130% of the conversion price under the Notes for a designated period of time, or the trading price of the Notes is, for a designated period of time, less than 98% of the closing sale price of the Company's common stock multiplied by the then-current conversion rate of the Notes, or the Company calls Notes for redemption, or certain specified corporate events occur. Holders may also convert their Notes at their option at any time on or after September 15, 2019 and prior to the close of business on the business day immediately preceding the stated maturity date. In addition, following the occurrence of certain changes of control of the Company described in the Indenture governing the Notes or termination of trading of the Company's common stock or other securities into which the Notes are convertible (a "make-whole fundamental change") or the delivery by the Company of a notice of redemption, the conversion rate for a holder who elects to convert its Notes in connection with such make-whole fundamental change or such notice of redemption will increase. Additionally, if certain conditions have been met or circumstances have occurred, such as if the Company's stock price exceeds 150% of the conversion price under the Notes for a designated period of time, or the trading of the Notes is, for a designated period of time, less than 98% of the closing sale price of the Company's stock multiplied by the then-current conversion rate of the Notes, or the Company calls Notes for redemption, the Company may redeem for cash any or all outstanding Notes on or after December 19, 2017 in an amount equal to the outstanding principal amount of such Notes, plus accrued and unpaid interest.

The Notes and any common stock issuable upon conversion of the Notes have not been registered under the Securities Act, applicable state securities laws or the securities laws of any other jurisdiction, and may not be offered or sold in the United States without registration or an applicable exemption from registration requirements. The Company does not intend to file a registration statement for the resale of the Notes or any common stock issuable upon conversion of the Notes, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation, or sale would be unlawful.

Since the Company did not have sufficient authorized shares available to share-settle the conversion option in full prior to May 20, 2015, the embedded conversion option did not qualify for equity classification and instead was separately valued and accounted for as a derivative liability. On December 16, 2014, the initial value allocated to the derivative liability was \$43.7 million of the \$143.75 million principal amount of the Notes, which represents a discount to the debt to be amortized through interest expense using the effective interest method through the maturity of the Notes. Accordingly, the effective interest rate used to amortize the debt discount on the Notes is 12.94%. During each reporting period, the derivative liability was marked to fair value through May 20, 2015 with the change in fair value recorded in the consolidated statement of operations. This resulted in a change in the fair value of the derivative liability of \$14.5 million for the three months ended June 30, 2015, and a change in the fair value of the derivative liability of \$23.1 million for the six months ended June 30, 2015.

The Notes are being accounted for in accordance with ASC 470-20. Under ASC 470-20, issuers of convertible debt instruments that may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components.

The application of ASC 470-20 resulted in the recognition of \$0.0 million as the value for the liability at June 30, 2015. The remaining unamortized discount and unamortized debt financing costs will be amortized over the remaining term of 4.47 years. At June 30, 2015 the net carrying amount of the liability component and the remaining unamortized debt discount were as follows:

	June 30, 2015
Face amount of the Notes	\$ 143,750
Unamortized discount of the liability component	40,206
Carrying amount of the Notes	\$ 103,544

Deferred financing costs associated with the Notes include fees of \$4.4 million at June 30, 2015. The assumptions used in connection with the valuation of the convertible option of the Notes issued December 16, 2014 utilizing the "with" and "without" method, discussed in Note 3 was as follows:

	Initial Measurement December 16, 2014		Measurement December 31, 2014		Measurement May 20, 2015	
Issue date	12/17/2014		12/17/2014		12/17/2014	
Maturity date	12/15/2019		12/15/2019		12/15/2019	
Term	4.99		4.92		4.57	
Principal (millions)	143.75		143.75		143.75	
Coupon	3.75	%	3.75	%	3.75	%
Seniority	Senior unsecured		Senior unsecured		Senior unsecured	
Conversion shares	88.572		88.572		88.572	
Conversion price	\$11.29		\$11.29		\$11.29	
Stock price	\$9.45		\$8.80		\$5.73	
Risk free rate	1.61	%	1.64	%	1.44	%
Volatility (rounded)	40.00	%	40.00	%	46.00	%



Edgar Filing: IGI LABORATORIES, INC - Form 10-Q

The table below provides a reconciliation of beginning and ending balances for the liability measured at fair value using significant observable and unobservable inputs (Level 3). The table reflects the gains associated with the decrease in fair value and the reclassification of the balance of the derivative liability.

	Initial Measurement			Decrease in Fair Value	Reclassification	
	December 16, 2014	Decrease in Fair Value	December 31, 2014	January 1, 2015 to May 20, 2015	of derivative liability to equity on May 20, 2015	June 30, 2015
Fair value of convertible feature of 3.75% senior notes	\$ 43,700	\$ 2,300	\$ 41,400	\$ 23,144	\$ 18,256	\$ -

For the three months and the six months ended June 30, 2015, the Company recorded the following expenses in relation to the Notes:

	Three months ended June 30, 2015 (in thousands)	Six months ended June 30, 2015 (in thousands)
Interest Expense at 3.75% coupon rate (1)	\$ 1,347	\$ 2,695
Debt discount amortization (1)	1,643	3,233
Amortization of deferred financing costs (1)	180	353
	\$ 3,170	\$ 6,281

(1) Included within "Interest and other expense, net" on the Condensed Consolidated Statements of Operations

#### 7. Note Payable - General Electric Capital Corporation

On November 18, 2014, the Company entered into an asset-based revolving senior secured credit facility (the "Credit Agreement") with General Electric Capital Corporation, as agent (the "Agent"), and GE Capital Bank and the other financial institutions party thereto, as lenders (the "Lenders"), pursuant to which the Lenders agreed to extend credit facilities to the Company (the "Financing").

To secure payment of the amounts financed under the Credit Agreement, the Company and the Agent entered into a Guaranty and Security Agreement (the "Guaranty and Security Agreement"). Under the terms of the Guaranty and Security Agreement, the Company granted to the Agent, for the benefit of the Lenders and other secured parties, a continuing security interest in and against substantially all of its tangible and intangible assets, except intellectual property, and each of the Company's direct and indirect future subsidiaries shall guarantee the Company's obligations under the Credit Agreement.

Under the Credit Agreement, the Company can request revolving loan advances up to an aggregate total amount of \$10 million, which may be increased to \$15 million at the request of the Company if certain conditions are met. The Company may also request an incremental facility for revolving loan commitments of up to \$10 million. Borrowings under the Credit Agreement may be made as prime rate loans with an applicable margin of 3.0% per annum or 1, 2, 3 or 6 month LIBOR loans with an applicable margin of 4.0% per annum. At June 30, 2015, the interest rate in effect was 4.2%. Availability under the Credit Agreement is calculated as 85% of the book value of eligible accounts at such time multiplied by a liquidity factor, less any reserves established by the Agent. As of June 30, 2015, the outstanding balance of the credit facility was \$3.2 million. In accordance with the Credit Agreement, the Company is required to provide the Lenders information related to working capital by which the Lenders will calculate the available line of credit, defined in the agreement as the Borrowing Base Certificate. As of June 30, 2015, the Company had a

remaining availability of \$6.8 million.

The term of the Credit Agreement is up to five years from November 18, 2014. The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock, in each case, subject to customary exceptions for a loan facility of this size and type. In addition, the Credit Agreement contains customary events of default (subject to customary cure periods for certain events of default), including, among others, non-payment, inaccuracy of representations and warranties, covenant defaults, cross-default to material agreements, cross-default to material indebtedness, bankruptcy and insolvency and material judgment defaults. The Company must meet certain financial reporting and audit requirements, as defined by the Credit Agreement. The Company was in compliance with all covenants of the Credit Agreement as of June 30, 2015.

In connection with this Financing, the Company paid in full its existing credit facility with Square 1 Bank (see Note 8) and executed a Release and Termination Note and Credit Agreement with Square 1 Bank to release the Company from any future obligations under the Credit Agreement executed on August 31, 2012, as amended July 26, 2013.

### **8. Note Payable - Square 1 Bank**

On August 31, 2012, as amended on July 26, 2013, the Company entered into a Loan and Security Agreement (the “*Loan and Security Agreement*”) with Square 1 Bank (the “*Lender*”) pursuant to which the Lender agreed to extend credit facilities to the Company.

On November 18, 2014, the Company paid in full its existing credit facility with the Lender under the Loan and Security Agreement. The Company recorded amortization expense in the amount of \$42,000 to write-off the remaining unamortized debt issuance costs during the year ended December 31, 2014.

### **9. Stock-Based Compensation**

#### **Stock Options**

The 1999 Director Stock Option Plan, as amended (the “*Director Plan*”), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. An aggregate of 1,975,000 shares have been approved and authorized for issuance pursuant to this plan. A total of 2,514,798 options have been granted to non-employee directors through June 30, 2015 and 807,782 of those have been forfeited through June 30, 2015 and returned to the option pool. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years.

The 1999 Stock Incentive Plan, as amended (“*1999 Plan*”), replaced all previously authorized employee stock option plans, and no additional options may be granted under those previous plans. Under the 1999 Plan, options or stock awards may be granted to all of the Company's employees, officers, directors, consultants and advisors to purchase a maximum of 3,200,000 shares of common stock. However, pursuant to the terms of the 1999 Plan, no awards may be granted after March 16, 2009. A total of 2,892,500 options, having a maximum term of ten years, have been granted at 100% of the fair market value of the Company's common stock at the date of grant. Options outstanding under the 1999 Plan are generally exercisable in cumulative increments over four years commencing one year from date of grant.

On June 26, 2009, the Board of Directors adopted, and the Company's stockholders subsequently approved by written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan became effective on July 29, 2009. The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company's current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. On April 12, 2010, the Board of Directors adopted, and the Company's stockholders subsequently approved, an amendment of the 2009 Plan to increase the number of shares of Common Stock available for grant under such plan by adding 2,000,000 shares of common stock. On May 29, 2014, the Board of Directors adopted and the Company's stockholders approved a further amendment of the 2009 Plan to increase the number of shares of common stock available for grant under such plan by adding 1,000,000 shares of common stock. The 2009 Plan, as amended on May 29, 2014, authorizes up to 5,000,000 shares of the Company's common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of June 30, 2015, options to purchase 2,473,168 shares of common stock were outstanding under the 2009 Plan. As of June 30, 2015, 112,750 restricted stock units ("RSUs") were outstanding under the 2009 Plan. As of June 30, 2015, 1,618,998 shares of restricted stock had been granted under the 2009 Plan and 230,420 of those have been forfeited through June 30, 2015 and returned to the pool.

In summary, there are 3,048,168 options outstanding under the 1999 Plan, the Director Plan and the 2009 Plan, collectively as of June 30, 2015.

There are 1,319,570 options available for issuance under the Director Plan and the 2009 Plan collectively as of June 30, 2015.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities and risk-free interest rates are based upon the expected life of the grant. The interest rates used are the U.S. Treasury yield curve in effect at the time of the grant.

For the six months ended  
June 30, 2015

Expected volatility	52.7% - 63.8%
Expected term (in years)	3.2 -3.3 years
Risk-free rate	0.89%-1.20%
Expected dividends	0%

A summary of option activity under the 1999 Plan, the Director Plan and the 2009 Plan as of June 30, 2015 and changes during the period are presented below:

	Number of Options	Weighted Average Exercise Price
Outstanding as of January 1, 2015	2,436,834	\$ 1.79
Issued	640,000	\$ 9.89
Exercised	(10,166 )	\$ 1.83
Forfeited	(18,500 )	\$ 5.10
Expired	-	-
Outstanding as of June 30, 2015	3,048,168	\$ 3.47
Exercisable as of June 30, 2015	1,820,666	\$ 1.21

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options granted during the six months ended June 30, 2015 was \$3.78.

The following table summarizes information regarding options outstanding and exercisable at June 30, 2015:

**Outstanding:**

Range of Exercise Prices	Stock Options Outstanding	Weighted	
		Weighted Average Exercise Price	Average Remaining Contractual Life
\$0.76 - \$1.00	95,000	\$ 0.78	2.59
\$1.01 - \$1.50	1,881,000	\$ 1.07	6.65
\$1.51 - \$10.67	1,072,168	\$ 7.92	9.04
Total	3,048,168	\$ 3.47	7.36

**Exercisable:**

	Stock Options	Weighted Average Exercise Price
Range of Exercise Prices	Exercisable	
\$0.76 - \$1.00	95,000	\$ 0.78
\$1.01 - \$1.50	1,523,166	\$ 1.08
\$1.51 - \$10.67	202,500	\$ 2.37
Total	1,820,666	\$ 1.21

As of June 30, 2015, the intrinsic value of the options outstanding was \$11.3 million and the intrinsic value of the options exercisable was \$9.3 million. The intrinsic value of options exercised during the six months ended June 30, 2015 was \$45,405. As of June 30, 2015, there was approximately \$2.4 million of total unrecognized compensation cost that will be recognized through July 2018 related to non-vested share-based compensation arrangements granted under the Director Plan and the 2009 Plan.

**Restricted Stock and RSUs**

The Company periodically grants restricted stock and RSU awards to certain officers and other employees that typically vest one to three years from their grant date. The Company recognized \$149,000 and \$183,000 of compensation expense during the three months ended June 30, 2015 and 2014, respectively, and \$248,000 and \$365,000 during the six months ended June 30, 2015 and 2014, respectively related to restricted stock and RSU awards. Stock compensation expense is recognized over the vesting period of the restricted stock and RSUs. At June 30, 2015, the Company had approximately \$1.1 million of total unrecognized compensation cost related to non-vested restricted stock and RSUs, all of which will be recognized through February 2018.

	Number of Restricted Stock	Weighted Average Exercise Price
Non-vested balance at January 1, 2015	108,334	\$ 2.86
Changes during the period:		
Shares granted	32,500	10.67
Shares vested	(32,500)	10.67
Shares forfeited	-	-
Non-vested balance at June 30, 2015	108,334	\$ 2.86

	Number of RSUs	Weighted Average Exercise Price
Non-vested balance at January 1, 2015	-	\$ -



Edgar Filing: IGI LABORATORIES, INC - Form 10-Q

Changes during the period:

Shares granted	145,250	10.67
Shares vested	(32,500 )	10.67
Shares forfeited	-	-

Non-vested balance at June 30, 2015      112,750      \$ 10.67

**10. Stock Warrants**

Stock Warrant activity for the quarters ended June 30, 2015 and 2014 consisted of:

	2015		2014	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at January 1,	84,000	\$ 1.21	354,546	\$ 1.21
Changes during the period:				
Stock warrants granted	-	-	-	-
Stock warrants expired	-	-	-	-
Stock warrants exercised	-	-	(270,546)	1.21
Balance at June 30,	84,000	\$ 1.21	84,000	\$ 1.21

In connection with the private placement of the Company's common stock on December 8, 2010, the Company granted common stock warrants to purchase up to 338,182 and 16,364 shares, respectively, to each of its two placement agents for \$1.21 per share which expire on December 8, 2015. On March 7, 2014, 270,546 of the 338,182 warrants were exercised.

**11. Income Taxes**

The Company's ability to use net operating loss carry forwards is subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which limit the utilization of net operating losses upon a more than 50% change in ownership of the Company's stock that is held by 5% or greater stockholders. The Company examined the application of Section 382 with respect to an ownership change that took place during 2010, as well as the limitation on the application of net operating loss carry forwards. The Company believes that operating losses subsequent to the change date in 2010 (aggregating \$7.8 million) are not subject to Section 382 limitations. The Company has estimated that the annual limitation starting in 2010 aggregates from \$1.0 million to \$2.3 million per year including the effect of amortization of built in gains.

The Company is subject to the provisions of ASC 740-10-25, "Income Taxes" ("ASC 740"). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. On a quarterly basis, the Company undergoes a process to evaluate whether income tax accruals are in accordance with

ASC 740 guidance on uncertain tax positions. The Company has not recorded a significant tax provision at June 30, 2015, as it has estimated its effective tax rate for 2015 (after considering utilization of existing net operating losses) to be insignificant. For federal purposes, post 1998 tax years remain open to examination as a result of net operating loss carryforwards. The Company is currently open to audit by the appropriate state income taxing authorities for tax years 2011 to 2014.

## 12. Legal

The Company is involved from time to time in claims which arise in the ordinary course of business. In the opinion of management, the Company has made adequate provision for potential liabilities, if any, arising from any such matters. However, litigation is inherently unpredictable, and the costs and other effects of pending or future litigation, governmental investigations, legal and administrative cases and proceedings (whether civil or criminal), settlements, judgments and investigations, claims and changes in any such matters, and developments or assertions by or against the Company relating to intellectual property rights and intellectual property licenses, could have a material adverse effect on its business, financial condition and operating results.

On May 21, 2015, Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, "Horizon") filed a complaint in the United States District Court for the District of New Jersey against the Company alleging infringement of certain United States patents in relation to the Company's submission to the FDA of an ANDA seeking FDA approval to market diclofenac topical solution 2% w/w before the expiration of the patents asserted in the complaint. On June 30, 2015, Horizon filed another complaint in the United States District Court for the District of New Jersey against the Company alleging infringement of another United States Patent in relation to the Company's submission of the same ANDA.

On July 21, 2015, the Company filed an answer, affirmative defenses and counterclaims in to the first complaint filed by Horizon alleging that the patents asserted in that complaint, as well as the patent asserted in the second complaint filed by Horizon, are invalid and not infringed by the Company.

Given that the Company is a specialty generic pharmaceutical company, the Company believes that the claims made by Horizon are ordinary course. Moreover, the Company believes that its counterclaims and defenses have merit, but based on the early stage of these cases, the Company is unable to predict the outcome at this time.

### 13.2014 Public Offering

On June 27, 2014, the Company entered into an underwriting agreement with Roth Capital Partners, LLC and Oppenheimer & Co., as representatives of the several underwriters named therein (the “Underwriters”), relating to the underwritten public offering and sale of up to an aggregate of 4,650,000 shares of the Company’s common stock, par value \$0.01, at a price to the public of \$5.00 per share (the “Offering”). The Company also granted the underwriters a 30-day option to purchase up to an aggregate of 697,500 shares to cover over-allotments, if any.

The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (Registration No. 333-196543), filed on June 5, 2014 with the SEC and declared effective by the SEC on June 16, 2014, as well as the prospectus supplement describing the terms of the Offering, dated June 27, 2014.

On July 2, 2014, the Company closed the Offering, and after giving effect to the underwriters’ exercise of the over-allotment option, the Company sold an aggregate of 5,347,500 shares of common stock in the Offering at a public offering price of \$5.00 per share. The net proceeds of the Offering were approximately \$24.9 million, after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

### 14. Asset Purchase Agreements

#### Astra Zeneca

On September 24, 2014, the Company entered into an Asset Purchase Agreement (the “AZ Purchase Agreement”) with AstraZeneca Pharmaceuticals LP, a Delaware corporation (“AstraZeneca”), pursuant to which the Company acquired all rights, titles and interests of AstraZeneca and its affiliates in Abbreviated New Drug Applications and New Drug Applications associated with eighteen products (collectively the “Purchased Regulatory Approvals”) and certain documents relating thereto (together with the Purchased Regulatory Approvals, the “Purchased Assets”).

In consideration for the purchase of the Purchased Assets, the Company paid AstraZeneca \$0.5 million in cash and will pay up to an additional aggregate of \$6 million upon the compliance of a certain milestone event. The \$6 million is accrued at June 30, 2015 and December 31, 2014 in the payable for product acquisition costs. In addition, the Company has agreed to pay, for each product manufactured by the Company pursuant to a Purchased Regulatory Approval, a royalty on future gross profits from product sales. Notwithstanding the foregoing, at any time prior to December 1, 2015, the Company may satisfy in full its royalty obligations with a single payment of \$3 million. The transaction is accounted for as a purchase of the product and product rights, and as such the initial payment, milestone payment and related costs to acquire the asset are included as part of product acquisition costs totaling \$6.9 million. The Company and will amortize the costs over fifteen years, the useful life of the acquired products and product

rights, commencing when the product can be sold.

Valeant

On September 30, 2014, the Company entered into two Asset Purchase Agreements (each, a “Valeant Purchase Agreement” and together, the “Valeant Asset Purchase Agreements”), one with Valeant Pharmaceuticals North America LLC and the other with Valeant Pharmaceuticals Luxembourg SARL (together, “Valeant”), pursuant to which the Company acquired all rights, titles and interests of Valeant and their respective affiliates in Abbreviated New Drug Applications and New Drug Applications associated with two products (collectively, the “Valeant Purchased Regulatory Approvals”) and certain documents related thereto (together with the Valeant Purchased Regulatory Approvals, the “Valeant Purchased Assets”). Pursuant to the terms of the Valeant Asset Purchase Agreements, the Company also acquired the option (each, an “Option” and, collectively, the “Options”) to purchase Abbreviated New Drug Applications and New Drug Applications associated with three additional products (the “Additional Assets”).

In consideration for the purchase of the Valeant Purchased Assets, the Company paid Valeant an aggregate of \$1.5 million in cash. In consideration for the purchase of the Additional Assets, the Company may exercise any Option, in its sole discretion, and pay \$0.8 million for each of two additional products and \$0.5 million for one additional product, for a total aggregate of \$2 million if all Options are exercised. The Company exercised its Option and purchased the one additional product for \$0.5 million on November 18, 2014. On March 27, 2015, the Company exercised its Option and purchased the two additional products for a total of \$1.5 million in cash. The transaction is accounted for as a purchase of the product and product rights, and as such the initial payment and related costs to acquire the Valeant Purchased Assets are included as part of product acquisition costs totaling \$3.5 million. The Company will amortize the costs over fifteen years, the useful life of the acquired product and product rights, commencing when the product can be sold.

## **ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

This "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other sections of this Quarterly Report on Form 10-Q contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, that are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and on management's beliefs and assumptions. In addition, other written or oral statements, which constitute forward-looking statements, may be made by or on behalf of the Company. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are based on current expectations of management and are not guarantees of future performance, and involve certain risks, uncertainties and assumptions, which are difficult to predict. These risks and uncertainties include, without limitation, competitive factors, outsourcing trends in the pharmaceutical industry, the general economic conditions in the markets in which the Company operates, levels of industry research and development spending, the Company's ability to continue to attract and retain qualified personnel, the fixed price nature of product development agreements or the loss of customers and other factors described in the Company's filings with the Securities and Exchange Commission, including the "Risk Factors" section as set forth in our Annual Report on Form 10-K for the year ended December 31, 2014, as updated below in this Quarterly Report on Form 10-Q. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements. The forward-looking statements set forth herein speak only as of the date of this report. The Company undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable law.

### **Company Overview**

#### *Strategic Overview*

IGI Laboratories, Inc. is a Delaware corporation incorporated in 1977. The Company's office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena New Jersey. The Company is a specialty generic pharmaceutical company. The Company's mission is to become a leader in the specialty generic pharmaceutical market. Under its own label, the Company currently sells generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. The Company also provides development, formulation, and manufacturing services to the pharmaceutical, OTC and cosmetic markets.

Currently, we have two platforms for growth:

Developing, manufacturing and marketing a portfolio of generic pharmaceutical products in our own label in topical, injectable, complex and ophthalmic dosage forms; and

§ Managing our current contract manufacturing and formulation services business.

We currently operate and generate revenue in one segment, which includes the manufacture and development of topical pharmaceutical, OTC and cosmetic products. We have been in the contract manufacturing and development of topical products business since the early 1990s, but our strategy since 2010 has been focused on the growth of our own generic pharmaceutical business. Since 2010, we have focused on transitioning our business to include more customers in the topical pharmaceutical industry. In 2014, we focused on the transformation of a business that was working toward being a leader in the topical generic pharmaceutical industry into becoming a leader in the broader specialty generic pharmaceutical markets. We believe that expanding our development and commercial base beyond topical generics, historically the cornerstone of our expertise, to include injectable generics, complex generics and ophthalmic generics (what we call our “TICO strategy”), will leverage existing expertise and capabilities, and broaden our platform for strategic growth.

To date, we have filed 30 Abbreviated New Drug Applications, (“ANDAs”), with the FDA for additional pharmaceutical products of which two have received final approval from the FDA. We expect to continue to expand our presence in the generic topical pharmaceutical market through the filing of additional ANDAs with the FDA and the subsequent launch of products as these applications are approved. Our target is to file up to 20 ANDAs in 2015 through our internal research and development program. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio.

The manufacturing and commercialization of generic specialty pharmaceutical markets is competitive, and there are established manufacturers, suppliers and distributors actively engaged in all phases of our business. We currently only manufacture and sell topical generic pharmaceutical products under our own label. As we continue to execute our TICO strategy, we will compete in other markets, including the injectable and ophthalmic generic pharmaceutical markets, and expect to face other competitors.

For the three months ended June 30, 2015, 54% of our total product sales, net were to one of the three large wholesale drug distributors noted below. For the three months ended June 30, 2014, 33% of our total product sales, net were to one of the three large wholesale drug distributors noted below. For the six months ended June 30, 2015, 59% of our total product sales, net were to one of the three large wholesale drug distributors noted below. For the six months ended June 30, 2014, 29% of our total product sales, net were to one of the three large wholesale drug distributors noted below. The three large wholesale drug distributors are: AmerisourceBergen Corporation, (“ABC”), Cardinal Health, Inc., (“Cardinal”), and McKesson Drug Company, (“McKesson”).

ABC accounted for approximately 42% and 24% of our accounts receivable as of June 30, 2015 and 2014, respectively.

ABC, Cardinal and McKesson are key distributors of our products, as well as a broad range of health care products for many other companies. None of these distributors is an end user of our products. Generally speaking, if sales to any one of these distributors were to diminish or cease, we believe that the end users of our products would likely find little difficulty obtaining our products either directly from us or from another distributor. However, the loss of one or more of these distributors, together with a delay or inability to secure an alternative distribution source for end users, could have a material negative impact on our revenue, business, financial condition and results of operations. Furthermore, ABC, Cardinal and McKesson have recently entered into strategic alliances with Walgreens, CVS Caremark and Rite-Aid, respectively. Since Walgreens, CVS Caremark and Rite-Aid are customers for several of our products, the loss of our distributor relationship with any of the three large wholesalers could result in a reduction to our revenues.

We consider our business relationships with ABC, Cardinal and McKesson to be in good standing and have fee for services contracts with each of them. However, a change in purchasing patterns, a decrease in inventory levels, an increase in returns of our products, delays in purchasing products and delays in payment for products by one or more of these distributors could have a material negative impact on our revenue, business, financial condition and results of operations. We experienced a change in purchasing patterns at ABC in April 2015. We are currently evaluating the financial impact of this change on our business, and are analyzing the market for other opportunities to expand our current relationships with other customers. While we continue to seek to diversify our existing portfolio of specialty generic drug products through internal research and development, we expect to file up to 14 more ANDAs in 2015 in addition to the 30 ANDAs we have filed with the FDA. In addition, we continue to explore business development opportunities to add additional products and /or capabilities to our existing portfolio.



Our customers in the contract manufacturing business generally consist of pharmaceutical companies, as well as cosmetic and OTC product marketers, who require product development/manufacturing support. For the three months ended June 30, 2015, approximately 75% of our revenue was derived from pharmaceutical customers, as compared to 81% of total contract manufacturing revenue for the three months ended June 30, 2014. For the six months ended June 30, 2015, approximately 77% of our revenue was derived from pharmaceutical customers, as compared to 75% of total contract manufacturing revenue for the six months ended June 30, 2014. No contract manufacturing customers represented greater than 10% of revenue for the three months ended June 30, 2015, and one of our contract manufacturing services customers represented 18% of total revenue for the three months ended June 30, 2014. One of our contract manufacturing services customers represented 11% of total revenue for the six months ended June 30, 2015 and two of our contract manufacturing services customers represented 24% of total revenue for the six months ended June 30, 2014. We do not expect any contract manufacturing or formulation services customers to exceed 10% of revenue for 2015 and beyond.

***Recent Events***

On July 9, 2015, we announced that we had launched our seventh product, diclofenac sodium 1.5% topical solution after receipt of the final approval from the FDA for an ANDA. We now market seven products in twelve presentations under our own label.

As of June 30, 2015, we filed five ANDAs in 2015. On June 30, 2015, we announced that we believe that our then current pipeline of twenty-seven submissions, exclusive of partnered submissions, pending approval by the FDA had a combined addressable market of over \$939 million based on May 2015 data from IMS Health.

On March 27, 2015, we acquired ANDAs and New Drug Applications associated with two injectable products from Valeant, as part of Valeant Asset Purchase Agreements, which we executed on September 30, 2014.

On March 23, 2015, we appointed John Celentano to our Board of Directors. Mr. Celentano also serves on the Company's Audit Committee.

***Results of Operations*****Three months ended June 30, 2015 compared to June 30, 2014**

We had net income of \$9,376,000, or \$0.18 per share, for the three months ended June 30, 2015, compared to a net loss of \$345,000, or \$0.01 per share, for the three months ended June 30, 2014, which resulted from the following:

**Revenues (in thousands):**

Components of Revenue:	Three Months Ended June 30,		\$ Change	% Change	
	2015	2014			
Product sales, net	\$ 8,647	\$ 6,021	\$2,626	44	%
Research and development income	187	437	(250 )	(57	%)

Edgar Filing: IGI LABORATORIES, INC - Form 10-Q

Licensing, royalty and other revenue	59	25	34	136	%
Total Revenues	\$ 8,893	\$ 6,483	\$2,410	37	%

The increase in product sales for the three months ended June 30, 2015 as compared to the same period in 2014 was primarily due to increased revenue from our own generic pharmaceutical product line that was launched in the first quarter of 2013, including the launch of two additional IGI label products in June 2014. This increase was partially offset by a decrease in product sales in our contract manufacturing services. Research and development income will not be consistent and will vary, from period to period, depending on the required timeline of each development project. Licensing, royalty and other revenue increased slightly due to an increase in other revenue while licensing and royalty revenue remained the same.

**Costs and Expenses (in thousands):**

	Three Months Ended June 30,		\$ Change	% Change	
	2015	2014			
Cost of sales	\$ 5,227	\$ 3,580	\$1,647	46	%
Selling, general and administrative	2,141	1,156	985	85	%
Product development and research	3,436	2,028	1,408	69	%
Totals costs and expenditures	\$ 10,804	\$ 6,764	\$4,040	60	%

Cost of sales increased for the three months ended June 30, 2015 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 59% for the three months ended June 30, 2015 as compared to 55% for the three months ended June 30, 2014. The increase in cost of sales as a percentage of product sales for 2015 was attributable to the difference in product mix for the three months ended June 30, 2015 as compared to the same period in 2014. Our research and development income results primarily from services rendered under contractual agreements, and therefore cost of sales as a percentage of our research and development income is relatively low. We expect the product mix to continue to shift in the second half of 2015 and the cost of sales as a percentage of total revenue to decline over time.

Selling, general and administrative expenses for the three months ended June 30, 2015 increased by \$985,000 as compared to the same period in 2014. There were increases of \$269,000 in salaries, bonuses and related costs, \$224,000 in the expense from the issuance of stock based compensation related to options and restricted stock, \$210,000 in professional fees, \$77,000 in commissions, \$34,000 in stockholder relations expenses, \$29,000 in travel related expenses, \$29,000 in recruiting expenses and \$100,000 in overhead costs.

Product development and research expenses for the three months ended June 30, 2015 increased by \$1,408,000 as compared to the same period in 2014. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased spending on clinical studies by \$637,000, consulting fees by \$598,000, salaries, bonuses and related costs by \$184,000, outside testing, pilot batch expense and supplies by \$177,000, overhead costs by \$36,000, \$23,000 in the expense from the issuance of stock based compensation and professional fees by \$15,000. These increases were partially offset by a decrease of \$273,000 in fees related to the Generic Drug User Fee Act and the associated filing of our applications with the FDA.

**Other Income (Expense) (in thousands):**

	Three Months Ended June 30,				
	2015	2014	\$ Change	% Change	
Interest and other expense	\$ (3,232 )	\$ (52 )	\$ (3,180 )	6,115	%
Change in the fair value of derivative liability	14,519	-	14,519	-	

Interest expense increased for the three months ended June 30, 2015 as compared to the same period in 2014 due to the inclusion of approximately \$3,170,000 of interest expense, amortization of debt discount and amortization of debt issuance costs related to the Notes (see Note 6 to the Company's Consolidated Financial Statements) in the three months ended June 30, 2015. We also recorded a \$14,519,000 change in the fair value of the derivative liability as a result of the decrease in the price of our common stock in the three months ended June 30, 2015.

**Net Income (in thousands, except per share numbers):**

	Three Months Ended June 30,				
	2015	2014	\$ Change	% Change	
Net income (loss)	\$ 9,376	\$ (345 )	\$ 9,721	2818	%
Basic earnings (loss) per share	0.18	(0.01)	0.19	1900	%

Net income for the three months ended June 30, 2015 was \$9,376,000 as compared to a net loss of \$345,000 in the same period last year. The increase is due to the change in the fair value of derivative liability, partially offset by the increases in revenues and the increases in costs and expenses noted above.

**Six months ended June 30, 2015 compared to June 30, 2014**

We had net income of \$15,931,000, or \$0.30 per share, for the six months ended June 30, 2015, compared to a net loss of \$178,000, or \$0.00 per share, for the six months ended June 30, 2014, which resulted from the following:

**Revenues (in thousands):**

Components of Revenue:	Six Months Ended June 30,		\$ Change	% Change	
	2015	2014			
Product sales, net	\$ 19,157	\$ 12,520	\$6,637	53	%
Research and development income	238	750	(512 )	(68	%)
Licensing, royalty and other revenue	169	66	103	156	%
Total Revenues	\$ 19,564	\$ 13,336	\$6,228	47	%

The increase in product sales for the six months ended June 30, 2015 as compared to the same period in 2014 was primarily due to increased revenue from our own generic pharmaceutical product line that was launched in the first quarter of 2013, including the launch of two additional IGI label products in June 2014. This increase was partially offset by a decrease in product sales in our contract manufacturing services. Research and development income will not be consistent and will vary, from period to period, depending on the required timeline of each development project. Licensing, royalty and other revenue increased slightly due to an increase in other revenue while licensing and royalty revenue remained the same.

**Costs and Expenses (in thousands):**

	Six Months Ended June 30,		\$ Change	% Change	
	2015	2014			
Cost of sales	\$ 10,270	\$ 7,567	\$2,703	36	%
Selling, general and administrative	4,041	2,438	1,603	66	%
Product development and research	6,066	3,393	2,673	79	%
Totals costs and expenditures	\$ 20,377	\$ 13,398	\$6,979	52	%

Cost of sales increased for the six months ended June 30, 2015 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 52% for the six months ended June 30, 2015 as compared to 57% for the six months ended June 30, 2014. The decrease in cost of sales as a percentage of product sales for 2015 was attributable

to increased revenue from our own generic pharmaceutical product line, which has higher margins, and a shift in the mix of our contract manufacturing product sales to include greater higher margin pharmaceutical products, which was partially offset by the effect of a price decline in one product during 2015. During the six months ended June 30, 2015, 77% of our revenue in contract manufacturing was from pharmaceutical customers as compared to 75% for the same period in 2014. Our research and development income results primarily from services rendered under contractual agreements, and therefore cost of sales as a percentage of our research and development income is relatively low. Consistent with our strategy, we expect cost of sales as a percentage of total revenue to decline over time.

Selling, general and administrative expenses for the six months ended June 30, 2015 increased by \$1,603,000 as compared to the same period in 2014. There were increases of \$438,000 in salaries, bonuses and related costs, \$369,000 in professional fees, \$315,000 in the expense from the issuance of stock based compensation related to options and restricted stock, \$86,000 in travel related expenses, \$77,000 in commissions, \$51,000 in contributions, \$46,000 in overhead costs, \$40,000 in stockholder relations expenses, \$38,000 in recruiting expenses and \$136,000 in other corporate expenses.

Product development and research expenses for the six months ended June 30, 2015 increased by \$2,673,000 as compared to the same period in 2014. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased spending on clinical studies by \$1,289,000, consulting fees by \$721,000, outside testing, supplies and maintenance contracts by \$400,000, salaries, bonuses and related costs by \$271,000, pilot batch expense by \$164,000, overhead costs by \$62,000, professional fees by \$47,000 and \$35,000 in the expense from the issuance of stock based compensation related to stock options. These increases were partially offset by a decrease of \$319,000 in fees related to the Generic Drug User Fee Act and the associated filing of our applications with the FDA.

**Other Income (Expense) (in thousands):**

	Six Months Ended June 30,			
	2015	2014	\$ Change	% Change
Interest and other expense	\$ (6,400 )	\$ (104 )	\$ (6,296 )	6054 %
Change in the fair value of derivative liability	23,144	-	23,144	-

Interest expense increased for the six months ended June 30, 2015 as compared to the same period in 2014 due to the inclusion of approximately \$6,281,000 of interest expense, amortization of debt discount and amortization of debt issuance costs related to the Notes (see Note 6 to the Company's Consolidated Financial Statements) in the six months ended June 30, 2015. We also recorded a \$23,144,000 change in the fair value of the derivative liability as a result of the change in the fair value of our derivative liability, caused primarily by the decrease in the price of our common stock in the six months ended June 30, 2015.

**Net Income (in thousands, except per share numbers):**

	Six Months Ended June 30,			
	2015	2014	\$ Change	% Change
Net income (loss)	\$ 15,931	\$ (178 )	\$ 16,109	9050 %
Basic earnings (loss) per share	\$ 0.30	\$ 0.00	\$ 0.30	-

Net income for the six months ended June 30, 2015 was \$15,931,000 as compared to a net loss of \$178,000 in the same period last year. The increase is due to the change in the fair value of derivative liability, partially offset by the increases in revenues and the increases in costs and expenses noted above.

**Liquidity and Capital Resources**

The Company's operating activities used \$5,722,000 of cash during the six months ended June 30, 2015, compared to \$470,000 during the six months ended June 30, 2014. The cash used in operating activities for the six months ended June 30, 2015 was a result of the net income, offset by the change in the fair value of derivative liability and the non-cash expenses for the period. The cash used in operating activities for the six months ended June 30, 2014 was a result of the net loss, adjusted for non-cash activity and a net decrease in operating assets and liabilities for the period.



The Company's investing activities used \$2,795,000 during the six months ended June 30, 2015, compared to \$312,000 of cash used in investing activities during the six months ended June 30, 2014. The funds used for the six months ended June 30, 2015 were for the purchase of two additional products (see Note 14 to the Company's Condensed Consolidated Financial Statements) and capital expenditures related to additional equipment for the compounding and packaging areas and additional IT equipment. The funds used for the six months ended June 30, 2014 were for capital expenditures related to additional computer equipment and scientific equipment and improvements incurred to expand our R & D area.

The Company's financing activities used \$145,000 of cash during the six months ended June 30, 2015, compared to \$443,000 of cash provided during the six months ended June 30, 2014. The cash used in the six months ended June 30, 2015 was mainly the \$71,000 added to restricted cash, the \$65,000 principal payments on capital lease obligations and the \$27,000 of debt issuance costs offset by the \$18,000 proceeds from the exercise of common stock options and the cash provided for the six months ended June 30, 2014 was mainly the \$456,000 proceeds from the exercise of common stock warrants.

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$150,221,000 at June 30, 2015, the \$6,840,000 available on the \$10,000,000 credit facility detailed in Note 7 and future cash from operations. The Company had working capital of \$159,923,000 at June 30, 2015.

The Company may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, the Company may continue to seek to raise additional capital through the sale of its equity or through a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. We believe that our existing capital resources will be sufficient to support our current business plan beyond August 2016.

### **Off Balance Sheet Arrangements**

The Company does not have any off balance sheet arrangements as of the date of this report.

### **Critical Accounting Policies and Estimates**

IGI's condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, which require management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from these estimates.

Please refer to the Company's Form 10-K for the year ended December 31, 2014 for a complete list of all Critical Accounting Policies and Estimates. See also Note 3 to the Company's Consolidated Financial Statements.

### **ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

As of June 30, 2015, our principal debt obligation was related to our Notes. Interest accrues at a fixed rate of 3.75% on the outstanding principal amount of the Notes and is paid semi-annually every June 15 and December 15 until the Notes mature on December 15, 2019. Since the interest rate is fixed, we have no market risk related to the Notes.

Our revolving Credit and Security Agreement with GECC calls for interest to accrue based on a premium above either the current prime rate or current LIBOR rates. Therefore, borrowings pursuant to this revolving credit facility would be subject to market risk. As of June 30, 2015, we had \$3.2 million in outstanding loans with GECC.

Our financial instruments include cash and cash equivalents, accounts receivable, accounts payable and the Notes. The fair values of cash and cash equivalents, accounts receivable and accounts payable approximate book value because of the short maturity of these instruments. Based on the closing price of our common stock as of June 30, 2015, the fair value of our Notes was approximately \$103.5 million compared to their face value of \$143.75 million as of June 30, 2015. However, this variance is due to the conversion feature in the Notes rather than to changes in market interest rates. As noted above, the Notes carry a fixed interest rate and therefore do not subject us to interest rate risk. As a result in the change in fair value, we recorded a \$23.1 million change in the fair value of the derivative liability on our consolidated statements of operations.

**ITEM 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2015. Based on that evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that, as of June 30, 2015, the Company's disclosure controls and procedures were effective.

*Changes in Internal Control over Financial Reporting*

There was no change in our internal control over financial reporting during our second quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II**

### **OTHER INFORMATION**

#### **ITEM 1. Legal Proceedings**

We are involved from time to time in claims which arise in the ordinary course of business, including the claims described below. In the opinion of management, we have made adequate provision for potential liabilities, if any, arising from any such matters. However, litigation is inherently unpredictable, and the costs and other effects of pending or future litigation, governmental investigations, legal and administrative cases and proceedings (whether civil or criminal), settlements, judgments and investigations, claims and changes in any such matters, and developments or assertions by or against us relating to intellectual property rights and intellectual property licenses, could have a material adverse effect on our business, financial condition and operating results.

On May 21, 2015, Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, "Horizon") filed a complaint in the United States District Court for the District of New Jersey against us alleging infringement of certain United States patents in relation to our submission to the FDA of an ANDA seeking FDA approval to market diclofenac topical solution 2% w/w before the expiration of the patents asserted in the complaint. On June 30, 2015, Horizon filed another complaint in the United States District Court for the District of New Jersey against us alleging infringement of another United States Patent in relation to our submission of the same ANDA.

On July 21, 2015, we filed an answer, affirmative defenses and counterclaims in to the first complaint filed by Horizon alleging that the patents asserted in that complaint, as well as the patent asserted in the second complaint filed by Horizon, are invalid and not infringed by us.

Again, given that we are a specialty generic pharmaceutical company, we believe that the claims made by Horizon are ordinary course. Moreover, we believe that our counterclaims and defenses have merit, but based on the early stage of these cases, we are unable to predict the outcome at this time.

#### **ITEM 1A. Risk Factors.**

Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2014 includes a detailed discussion of risks and uncertainties which could adversely affect our future results. Except as set forth below, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2014 have not materially changed.

## **Risks Related to Our Business**

### **We rely on a limited number of customers for a large portion of our revenues.**

We depend on a limited number of customers for a large portion of our revenue. For the three months ended June 30, 2015, one of our customers accounted for 44% of our revenue. For the three months ended June 30, 2014, three of our customers accounted for 46% of our revenue. For the six months ended June 30, 2015 and 2014, two of our customers accounted for 56% and two of our customers accounted for 31% of our revenue, respectively. The loss of one or more of these customers could have a significant impact on our revenues and harm our business and results of operations.

We had net revenue from one product, econazole nitrate cream, which accounted for 51% and 26% of total revenues for the three months ended June 30, 2015 and 2014, respectively, and 52% and 20% of total revenues for the six months ended June 30, 2015 and 2014, respectively.

### **We have a history of losses and cannot assure you that we will become profitable, and as a result, we may have to cease operations and liquidate our business.**

Prior to 2014, our expenses have exceeded our revenue in each of the last nine years, and no net income has been available to common stockholders during each of these years. As of June 30, 2015, our stockholders' equity was \$74.6 million and we had an accumulated deficit of \$23.7 million. Our future profitability depends on revenue exceeding expenses, but we cannot assure you that this will occur. If we do not become profitable or continue to raise external financing, we could be forced to curtail operations and sell or liquidate our business, and you could lose some or all of your investment.

## **Risks Related to the Notes**

**We may not have the ability to raise the funds necessary to settle conversions of the Notes, purchase the Notes as required pursuant to the terms of the indenture governing the Notes or pay the redemption price for any Notes we redeem, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the notes.**

On December 16, 2014, we completed the sale of \$125 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2019 (the “Notes”) to Deutsche Bank Securities Inc. and J.P. Morgan Securities LLC as the initial purchasers and on December 22, 2014, we issued to the initial purchasers an additional \$18.75 million aggregate principal amount of the Notes. Pursuant to the terms of the indenture governing the Notes, following a certain events, holders of notes will have the right to require us to purchase their notes for cash. Such event may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the purchase price in cash with respect to any notes surrendered by holders for purchase at that time, make cash payments upon conversions or pay the redemption price for any notes we redeem. In addition, restrictions in our then existing credit facilities or other indebtedness, if any, may not allow us to purchase the notes (even if required pursuant to the terms of the indenture), make cash payments upon conversions of the notes or pay the redemption price for any notes we redeem would result in an event of default with respect to the notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and purchase the notes, make cash payments upon conversions thereof or pay the redemption price for any notes we redeem.

**Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.**

Our ability to make scheduled payments of the principal of, to pay interest on, to pay any cash due upon conversion of or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

## **Risks Related to Our Securities**

**Shares of our common stock are relatively illiquid which may affect the trading price of our common stock.**

For the six months ended June 30, 2015, the average daily trading volume of our common stock on the NYSE MKT was approximately 950,000 shares. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

**ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**ITEM 3. Defaults Upon Senior Securities**

None.

**ITEM 4. Mine Safety Disclosures**

Not applicable.

**ITEM 5. Other Information**

None.

**ITEM 6. Exhibits**

Exhibit

Number Description

- 31.1\* Certification of the President and Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\* Certification of the President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\* Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101\* The following financial information from this Quarterly Report on Form 10-Q for the period ended June 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Operations; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) the Notes to Consolidated Financial Statements, tagged as blocks of text.

\* Filed herewith.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IGI Laboratories, Inc.

Date: August 10, 2015 By: /s/ Jason Grenfell-Gardner  
Jason Grenfell-Gardner  
President and Chief Executive Officer

Date: August 10, 2015 By: /s/ Jenniffer Collins  
Jenniffer Collins  
Chief Financial Officer

Exhibit Index

Exhibit

Number Description

- 31.1\* Certification of the President and Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\* Certification of the President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\* Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101\* The following financial information from this Quarterly Report on Form 10-Q for the period ended June 30, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Operations; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) the Notes to Consolidated Financial Statements, tagged as blocks of text.

\* Filed herewith.