

IGI LABORATORIES, INC  
Form 10-Q  
November 14, 2013

**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 September 30, 2013**

..

**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*

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

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

*incorporation or organization)*

**105 Lincoln Avenue**  
**Buena, New Jersey**  
*(Address of Principal Executive Offices)*

**08310**  
*(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

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 43,758,415 shares as of November 1, 2013.

**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)

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Revenues:				
Product sales, net	\$ 3,950	\$ 1,464	\$ 11,124	\$ 4,835
Research and development income	10	496	278	1,368
Licensing, royalty and other income	35	26	97	52
Total revenues	3,995	1,986	11,499	6,255
Cost and expenses:				
Cost of sales	2,684	1,222	7,932	4,271
Selling, general and administrative expenses	692	980	2,078	2,254
Product development and research expenses	661	620	2,123	1,735
Total costs and expenses	4,037	2,822	12,133	8,260
Operating loss	(42)	(836)	(634)	(2,005)
Interest expense and other, net	(53)	(586)	(121)	(740)
<b>Net loss</b>	<b>\$ (95)</b>	<b>\$ (1,422)</b>	<b>\$ (755)</b>	<b>\$ (2,745)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.00)</b>	<b>\$ (0.04)</b>	<b>\$ (0.02)</b>	<b>\$ (0.07)</b>

**Weighted Average of Common Stock and  
Common Stock Equivalents Outstanding**

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

Basic and diluted	43,395,980	39,508,217	43,179,898	39,510,540
-------------------	------------	------------	------------	------------

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)

	September 30, 2013	December 31, 2012*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,402	\$ 2,536
Accounts receivable, net	2,895	1,577
Inventories	2,523	1,773
Prepaid expenses and other receivables	232	253
Total current assets	7,052	6,139
Property, plant and equipment, net	2,634	2,691
Product acquisition costs, net	1,796	
Restricted cash, long term	54	54
License fee, net	225	300
Debt issuance costs, net	77	100
Other	155	143
Total assets	\$ 11,993	\$ 9,427
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,561	\$ 1,091
Accrued expenses	1,079	820
Deferred income, current	179	48
Capital lease obligation, current	8	17
Total current liabilities	2,827	1,976
Note payable, bank	3,000	1,000
Deferred income, long term	6	20
Capital lease obligation, long term		4
Total liabilities	5,833	3,000
Commitments and contingencies		
Stockholders equity:		
Series A Convertible Preferred stock, liquidation preference - \$0		
at September 30, 2013 and \$500,000 at December 31, 2012		500

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

Series C Convertible Preferred stock, liquidation preference -  
\$1,822,205 at

	1,517	1,517
September 30, 2013 and \$1,764,240 at December 31, 2012		
Common stock	457	446
Additional paid-in capital	48,386	47,409
Accumulated deficit	(44,200)	(43,445)
Total stockholders' equity	6,160	6,427
Total liabilities and stockholders' equity	\$ 11,993	\$ 9,427

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

\* Derived from the audited December 31, 2012 financial statements

**IGI LABORATORIES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

(Unaudited)

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (755)	\$ (2,745)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation	280	264
Amortization of license fee	75	75
Stock-based compensation expense	169	320
Provision for write down of inventory	94	74
Amortization of debt issuance costs	23	642
Amortization of product acquisition costs	30	
Loss on abandonment of property		13
Changes in operating assets and liabilities:		
Accounts receivable	(1,318)	22
Inventories	(844)	(162)
Prepaid expenses and other assets	9	210
Accounts payable and accrued expenses	729	96
Deferred income	117	(10)
Net cash used in operating activities	(1,391)	(1,201)
<b>Cash flows from investing activities:</b>		
Capital expenditures	(223)	(323)
Product acquisition costs	(1,826)	
Net cash used in investing activities	(2,049)	(323)
<b>Cash flows from financing activities:</b>		
Proceeds from note payable, bank	2,000	1,000
Payment of debt issuance costs		(114)
Payment on note payable, related party		(500)
Principal payments on capital lease obligation	(13)	(36)
Proceeds from exercise of common stock options and warrants	372	35
Costs related to stock issuance	(53)	
Net cash provided by financing activities	2,306	385



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

Net decrease in cash and cash equivalents	(1,134)	(1,139)
Cash and cash equivalents at beginning of period	2,536	2,914
Cash and cash equivalents at end of period	\$ 1,402	\$ 1,775
Supplemental cash flow information:		
Cash payments for interest	\$ 102	\$ 81
Cash payment for taxes	\$ 10	\$ 9
Non cash investing and financing transactions:		
Common stock issued for Series A Convertible Preferred stock	\$ 500	\$
Equipment purchases financed through capital leases	\$	\$ 30
Forfeiture of restricted stock	\$	\$ 1

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 nine months ended September 30, 2013**

**(in thousands, except share information)**

	<b>Series A</b>		<b>Series C Convertible</b>		<b>Common Stock</b>		<b>Additional Paid-In Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders Equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Capital</b>	<b>Deficit</b>	<b>Equity</b>
Balance, December 31, 2012 (Audited)	50	\$ 500	1,550	\$ 1,517	42,705,032	\$ 446	\$ 47,409	\$ (43,445)	\$ 6,427
Stock based compensation expense stock options							154		154
Stock based compensation expense restricted stock							15		15
Stock warrants exercised					427,713	5	231		236
Stock options exercised					125,670	1	135		136
Costs related to stock issuance							(53)		(53)
Common stock issued for Series A Convertible Preferred stock	(50)	(500)			500,000	5	495		
Net loss								(755)	(755)
			1,550						

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

Balance, September 30, 2013 (Unaudited)	\$	\$ 1,517,437,584,415	\$ 457	\$ 48,386	\$ (44,200)	\$ 6,160
--	----	----------------------	--------	-----------	-------------	----------

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles 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 U.S. generally accepted accounting principles for complete financial statements. 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, 2012. The condensed consolidated balance sheet as of December 31, 2012 has been derived from those audited consolidated financial statements. Operating results for the three and ninth month period ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013.*

**1.**

**Organization**

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 developer, manufacturer, and marketer of topical formulations. The Company's goal is to become a leader in the generic topical pharmaceutical market. In its own label, the Company 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. The Company's strategy is based on three initiatives:

- Manufacturing, developing, and marketing a portfolio of generic pharmaceutical products in its own label in topical dosage forms;
- Increasing the Company's current contract manufacturing and development business; and
- Creating unique opportunities through the acquisition of additional intellectual property, and the expansion of the use of the Company's existing intellectual property, including its licensed Novasome® technology.

In December, 2012, the Company completed implementation of its commercial infrastructure and launched its first generic topical pharmaceutical products under the IGI label. As of November 14, 2013, the Company has filed thirteen Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA to date. As discussed in Note 10, on February 1, 2013, the Company acquired product rights to econozale nitrate cream 1%. The Company is now actively marketing four IGI label products in eight presentations of those products. The remainder of product sales are under contract manufacturing agreements. The Company performs all of its product development and manufacturing at its 25,000 square foot facility in Buena, New Jersey.

2.

## **Liquidity**

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$1,402,000 at September 30, 2013 and cash from operations. The Company sustained net losses of \$755,000 and \$2,745,000 for the nine months ended September 30, 2013 and 2012, respectively, and had working capital of \$4,225,000 at September 30, 2013.

The Company's business operations have been primarily funded over the past four years through funds available on its credit facility and private placements of its capital stock. The Company raised an aggregate of \$2,000,000 through private placements of equity with accredited investors in 2012, \$7,213,000 in 2010 and \$5,304,000 in 2009 principally from private equity investors. The use of proceeds is intended for general working capital needs as well as the acquisition of econozale nitrate cream 1% which was purchased on February 1, 2013. The Company purchased a product and certain product rights which are expected to provide contribution to its gross profit in 2013 (See Note 10). In August 2012, the Company also entered into a \$3,000,000 line of credit (See Note 8) and simultaneously drew down \$1,000,000 under the credit facility. In February 2013, the Company drew down an additional \$1,000,000 from the available credit facility and on August 2, 2013, the Company drew down an additional \$1,000,000 from the available credit facility. As of September 30, 2013, the outstanding balance on the line of credit was \$3,000,000. 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. 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 its existing capital resources will be sufficient to support its current business plan and operations for at least the next twelve months.

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 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 allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowance, stock based compensation, provisions for sales returns, chargebacks and other allowances, and accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

#### **Loss Per Share**

Basic net loss per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted net 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. Due to the net loss for the three months ended September 30, 2013 and 2012 and the nine months ended September 30, 2013 and 2012, the effect of the Company's potential dilutive common stock equivalents was anti-dilutive for each period; as a result, the basic and diluted weighted average number of common shares outstanding and net loss per common share are the same. Potentially dilutive common stock equivalents include options and warrants to purchase the Company's common stock and the conversion of preferred stock, which were excluded from the net loss per share calculations due to their anti-dilutive effect amounted to 5,602,089 for 2013 and 5,913,604 for 2012.

#### **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, 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 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 sales returns and allowances ( 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. Currently these provisions are based on industry standards and current contract sales terms with direct and indirect customers. Over time, these provisions will be adjusted as estimates will be 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 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.

<b>Gross-To-Net Sales Deductions</b>	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Gross IGI product sales	\$ 3,038	\$ -	\$ 7,417	\$ -
Reduction to gross product sales:				
Chargebacks	(1,395)	-	(2,618)	-
Sales discounts and other allowances	(254)	-	(619)	-
Total reduction to gross product sales	\$ (1,649)	-	\$ (3,237)	-
Net IGI product sales	\$ 1,389	-	\$ 4,180	-

Accounts receivable are presented net of SRA balances of \$0.5 million and \$0 at September 30, 2013 and 2012, respectively. Accounts payable and accrued expenses include \$0.3 million and \$0 at September 30, 2013 and 2012, respectively, for certain fees related to services provided by the wholesalers. Wholesale fees of \$0.1 million and \$0 for the three month periods ended September 30, 2013 and 2012, respectively, were included in cost of goods sold. Wholesale fees of \$0.4 million and \$0 for the nine month periods ended September 30 for 2013 and 2012, respectively, were included in cost of goods sold. In addition, in connection with three of the four products the Company currently manufactures, markets and distributes in 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. In accordance with the agreement, net sales excludes fees related to services provided by the wholesalers. Accounts payable and accrued expenses include \$0.5 million and \$0 at September 30, 2013 and 2012, respectively, related to these royalties. Royalty expense of \$0.5 million and \$0 was included in cost of goods sold for the three months ended September 30, 2013 and 2012, respectively. Royalty expense of \$1.5 million and \$0 was included in cost of goods sold for the nine months ended September 30 for 2013, and 2012 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 September 30, 2013, three of the Company's customers accounted for 49% of the Company's revenue. For the three months ended September 30, 2012, four of the Company's customers accounted for 80% of the Company's revenue. One of these customers is the same for both periods. For the nine months ended September 30, 2013 and 2012, four of the Company's customers accounted for 55% and three of the Company's customers accounted for 65% of the Company's revenue, respectively. Two of these customers are the same for both periods. Accounts receivable related to the Company's major customers comprised 54% of all accounts receivable as of September 30, 2013. 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.

### **Recent Accounting Pronouncements**

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When A Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists ( ASU 2013-11 ), which provides guidance on the presentation of unrecognized tax benefits when net operating loss carryforwards, similar tax losses, or tax credit carryforwards exist. The amendments in this update are effective for fiscal years (and interim periods within those years) beginning after December 15, 2013. The amendments should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. The Company does not expect ASU 2013-11 to have a material effect on its financial condition, results of operation or cash flows. This update will be effective for the Company for the year beginning January 1, 2014.

4.

### **Inventories**

Inventories are valued at the lower of cost, using the first-in, first-out ( FIFO ) method, or market. Inventories at September 30, 2013 and December 31, 2012 consist of:

	<b>September 30, 2013</b> (Unaudited)	<b>December 31, 2012</b> (Audited)
	(amounts in thousands)	
Raw materials	\$ 2,081	\$ 1,673
Work in progress	162	26
Finished goods	280	74
Total	\$ 2,523	\$ 1,773

**5.**

**Stock-Based Compensation**

Under the 1998 Directors Stock Plan, as amended, 600,000 shares of the Company s common stock are authorized under the plan and reserved for issuance to non-employee directors, in lieu of payment of directors fees in cash. In November 2009, the Company s Board of Directors approved the elimination of payment of directors fees in stock under this plan beginning in the fourth quarter of 2009.

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 2,179,798 options have been granted to non-employee directors through September 30, 2013 and 727,782 of those have been forfeited through September 30, 2013 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 (the "1999 Plan"), replaced all previously authorized employee stock option plans, and no additional options may be granted under those 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, has been granted at 100% of the fair market value of the Company's common stock at the time of grant. Options outstanding under the 1999 Plan are generally exercisable in cumulative increments over four years commencing one year from the date of grant.

On June 26, 2009, the Board of Directors adopted, and the Company's stockholders subsequently approved by partial written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the "2009 Plan"). 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 and restatement 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. The 2009 Plan, as amended on May 19, 2010, authorizes up to 4,000,000 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 September 30, 2013, options to purchase 1,882,666 shares of common stock were outstanding under the 2009 Plan and 1,148,748 shares of restricted stock had been granted under the 2009 Plan, 230,420 of those have been forfeited through September 30, 2013 and returned to the pool.

In aggregate, there are 2,606,666 options outstanding under the 1999 Plan, the Director Plan and the 2009 Plan, collectively, as of September 30, 2013.

#### Stock Options

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 nine months ended**

	<b>September 30, 2013</b>	
Expected volatility	36.9%	40.4%
Expected term (in years)	3.2	3.3 years
Risk-free rate	0.49%	
Expected dividends	0%	

A summary of option activity under the 1999 Plan, the Director Plan and the 2009 Plan as of September 30, 2013 and changes during the period are presented below:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding as of January 1, 2013	2,606,500	\$1.10
Issued	205,500	\$1.20
Exercised	(125,670)	\$1.08
Forfeited	(79,664)	\$1.31
Expired		
Outstanding as of September 30, 2013	2,606,666	\$1.10
Exercisable as of September 30, 2013	1,356,831	\$1.14

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options granted during the nine months ended September 30, 2013 was \$0.33.

The following table summarizes information regarding options outstanding and exercisable at September 30, 2013:

**Outstanding:**

Range of Exercise Prices		Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
\$0.55	\$1.00	218,000	\$0.76	5.08
\$1.01	\$1.50	2,218,666	\$1.09	8.17
\$1.51	\$1.95	170,000	\$1.68	7.54
Total		2,606,666	\$1.10	7.87

**Exercisable:**

Range of Exercise Prices		Stock Options Exercisable	Weighted Average Exercise Price
\$0.55	\$1.00	214,000	\$0.75
\$1.01	\$1.50	992,831	\$1.14
\$1.51	\$1.95	150,000	\$1.67
Total		1,356,831	\$1.14

As of September 30, 2013, the intrinsic value of the options outstanding is \$1,873,180 and the intrinsic value of the options exercisable is \$929,055. The total intrinsic value of the options exercised during the nine months ended September 30, 2013 was \$92,976. As of September 30, 2013, there was approximately \$312,000 of total unrecognized compensation cost that will be recognized through September 2016 related to non-vested share-based compensation arrangements granted under the equity plans.

Restricted Stock

The Company periodically grants restricted stock awards to certain officers and other employees that typically vest one to three years from their grant date. The Company recognized \$4,900 and \$104,200 of compensation expense during the three months ended September 30, 2013 and 2012, respectively, related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At September 30, 2013, the Company had approximately \$6,500 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized from July 2013 through January 2014.

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

	<b>Number of Restricted Stock</b>	<b>Weighted Average Exercise Price</b>
Non-vested balance at January 1, 2013	29,334	\$ 1.00
Changes during the period:		
Shares granted		
Shares vested		
Shares forfeited		
Non-vested balance at September 30, 2013	29,334	\$ 1.00

6.

### **Income Taxes**

As a result of the Company's history of continuing tax losses, the Company does not have a current tax provision and has recorded a full valuation allowance against its net deferred tax asset. The Company has not recorded a liability for unrecognized tax benefits at September 30, 2013 and no significant changes are expected in the next twelve months. The tax years 2009-2012 remain open to examination by the major taxing jurisdictions to which the Company is subject.

There was no accrued interest related to unrecognized tax benefits at September 30, 2013.

The Company's ability to use net operating loss carry forwards may be subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code, 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 2009 and 2010, as well as the possibility of such limitation having any material effect on the application of net operating loss carry forwards in the immediate future. The Company believes that it is likely that a change in ownership took place and that the net operating loss carry forwards will be limited.

7.

### **License Fee**

On December 12, 2005, the Company extended its license agreement for an additional ten years with Novavax, Inc. for \$1,000,000. This extension entitles the Company to exclusively use of the Novasome® lipid vesicle encapsulation and certain other 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 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 September 30, 2013 and 2012 and amortization expense of \$75,000 related to this agreement for each of the nine months ended September 30, 2013 and 2012.



8.

**Note Payable - Bank**

On August 31, 2012, IGI Laboratories, Inc. and its subsidiaries, Igen, Inc. and IGI Labs, Inc., 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 (the *Financing* ). The Company drew down \$1,000,000 in principal amount on August 31, 2012, \$1,000,000 in principal amount on February 5, 2013 and \$1,000,000 in principal amount on August 2, 2013.

To secure payment of the amounts financed under the Loan and Security Agreement, the Company has granted to the Lender a continuing security interest in and against, generally, all of its tangible and intangible assets, except intellectual property.

Under the Loan and Security Agreement, the Company can request revolving loan advances under (a) the Formula Revolving Line and (b) the Non-Formula Revolving Line, and term loan advances under the term loans. The aggregate total borrowings under the facilities cannot exceed the total borrowing limit of \$3,000,000 at any one time outstanding. Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 1.9% above the prime rate then in effect, and (B) 5.65%. Non-Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 2.15% above the prime rate then in effect, and (B) 5.9%. Term loan advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 2.4% above the prime rate then in effect, and (B) the rate in effect at December 31, 2012, which was 6.15%.

The term of the Formula Revolving Line and the Non-Formula Revolving Line is one year from the date of the Loan and Security Agreement and can be extended by mutual agreement of the parties. The term of the term loans is 42 months from the date of the Loan and Security Agreement, but term loan advances are available to the Company only until February 28, 2014.

In accordance with the Loan and Security Agreement, the Company must maintain a liquidity ratio of at least 1.25 to 1.00 (the LQR Threshold ), provided that the LQR Threshold shall be reduced to 1.00 to 1.00 so long as the Company has achieved minimum Revenue, measured monthly on a trailing three month basis, of at least the amounts listed in the document for the corresponding reporting periods. To further clarify, if at any time the Company is not in compliance with the minimum revenue amounts set forth below, the LQR Threshold shall be increased to 1.25 to 1.00.

Liquidity means the sum of: (i) unrestricted cash in bank plus (ii) the Borrowing Base (the amount drawn to date). In accordance with the Loan and Security Agreement, liquidity ratio means the ratio of Liquidity to all Indebtedness to the Lender (but excluding any Indebtedness to the Lender which is secured by cash held in a segregated deposit account at the Lender). As of September 30, 2013, the Company was in compliance with the LQR Threshold required under the Loan and Security Agreement.

In connection with the Financing, the Company paid in full its existing credit facility with Amzak Capital Management, LLC (see Note 9 below) and executed a Release and Termination Note and Credit Agreement with Amzak Capital Management, LLC to release the Company from any future obligations under the Credit Agreement executed on December 21, 2010 (the *Amzak Credit Facility* ).

On July 26, 2013, the Company entered into an Amendment to the Loan and Security Agreement (the *Amendment* ). In accordance with the Amendment, notwithstanding the existing LQR Thresholds, for so long as the Company is in compliance with the minimum revenue requirements established in this Amendment, the Company shall be permitted to maintain a liquidity ratio of not less than .90 to 1.00 for a continuous 60 day period every 12 months. In connection with the lower liquidity ratio, in accordance with the Amendment, under the Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 4.9% above the prime rate then in effect, and (B) 8.65%. Non-Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 5.15% above the prime rate then in effect, and (B) 8.9%, until such time that the lower liquidity ratio is no longer in place. If the Company remains in compliance through the end of December of 2013, the aggregate borrowing amount will be increased from \$3,000,000 to \$5,000,000.

**9.**

**Stock Warrants**

Stock Warrants activity for the nine months ended September 30, 2013 and 2012 consisted of:

2013	2012
Weighted	Weighted

	<b>Warrants</b>	<b>Average Exercise Price</b>	<b>Warrants</b>	<b>Average Exercise Price</b>
Beginning balance	782,259	\$0.85	1,235,877	\$0.35
Stock warrants granted				
Stock warrants expired				
Stock warrants exercised	(427,713)	0.55		
Ending balance	354,546	\$1.21	1,235,877	\$0.35

In connection with the private placement of the Company's Common Stock on December 8, 2010, the Company granted common stock warrants to purchase 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. In connection with the private placement of the Company's common stock in 2012, the Company granted common stock warrants to purchase 387,201 shares for \$0.01 per share, which expire December 2022.

In addition, the Company executed as of December 31, 2012 a settlement agreement with Amzak Capital Management, LLC ( Amzak ) in connection with a common stock purchase warrant issued to Amzak on December 21, 2012 under which the Company issued a ten-year warrant to purchase up to 427,713 shares of the Company's common stock, with an exercise price of \$0.55 per share. The warrants were exercised in full on February 8, 2013. The amount of the fair value of the warrant issued was \$209,000, and included as interest expense in 2012, as it related to the credit agreement which was terminated in August of 2012.

**10.**

**Asset Purchase Agreement**

On February 1, 2013, the Company entered into an Asset Purchase Agreement (the *Purchase Agreement*) with Prasco, LLC, an Ohio limited liability company ( *Prasco* ), pursuant to which the Company purchased from Prasco assets associated with econazole nitrate cream 1% (the *Product* ), which is available in 15g, 30g, and 85g tubes has United States Food and Drug Administration approved indications for the treatment of tinea pedis, tinea cruris, and tinea corporis as well as the treatment of cutaneous candidiasis and tinea versicolor.

In consideration for the purchase of the assets pursuant to the Purchase Agreement, the Company paid Prasco \$1.4 million in cash and paid an additional aggregate of \$400,000 upon the occurrence of the milestone events (the *Milestone Payment* ). The Milestone Payment is secured by a first-priority security interest in the acquired assets under the Purchase Agreement. 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 asset are included as part of product acquisition costs totaling \$1.4 million. The Company capitalized the remaining milestone payment and related acquisition costs and amortized the costs over fifteen years, the useful life of the acquired product and product rights.

Under and subject to the terms and conditions of the Purchase Agreement, Prasco continued to distribute the Product during a six-month period following the closing of the Purchase Agreement, and the Company completed the technical transfer of the Product and begun manufacturing the Product under its own label during the third quarter of 2013. The Company's product sales in the third quarter included sales of the product.

In addition, the Purchase Agreement contains certain non-compete restrictions preventing Prasco from selling the Product in United States for a period of seven years.

On October 23, 2013, the Company announced that it had received formal approval from the U.S. Food and Drug Administration (FDA) for the CBE-30 supplemental filing to approve the site transfer of the econazole nitrate cream 1%, to the Company's manufacturing facility in Buena, NJ.



## **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. 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. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our Annual Report on Form 10-K filed on March 28, 2013, as amended, our Quarterly Report on Form 10-Q filed on May 15, 2013 and our Quarterly Report on Form 10-Q filed on August 14, 2013 and any future reports we file with the Securities and Exchange Commission. 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 required by law.

### **Company Overview**

#### *Strategic Overview*

IGI Laboratories is a developer, manufacturer, and marketer of topical formulations. Our goal is to become a leader in the generic topical pharmaceutical market. Under our IGI label, we sell generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. We also provide development, formulation, and manufacturing services to the pharmaceutical, over-the-counter (OTC), and cosmetic markets.

Our strategy is based on three initiatives:

Manufacturing, developing, and marketing a portfolio of generic pharmaceutical products in our own label in topical dosage forms;

Increasing our current contract manufacturing and development business; and

Creating unique opportunities through the acquisition of additional intellectual property, and the expansion of the use of our existing intellectual property, including our licensed Novasome ® technology.

In December, 2012, we completed the implementation of our commercial infrastructure and launched our first generic topical pharmaceutical products under the IGI label. We now market four products under our own label. As of November 14, 2013, we have filed thirteen Abbreviated New Drug Applications, or ANDAs, to date with the United States Food and Drug Administration, or FDA, for additional pharmaceutical products. We filed one application in each of September 2010, January 2011 and December 2011, we filed two applications in each of November 2011, and June 2012, and one application in each of November 2012, January 2013, April 2013, July 2013, September 2013 and October 2013. All of the submissions are for generic prescription drugs. Our plan is 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 six ANDAs per year through our internal research and development program. There is no assurance we will obtain FDA approvals. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio. On February 1, 2013, we acquired assets and intellectual property, including an ANDA, for econazole nitrate cream 1%.

IGI also develops, manufactures, fills, and packages topical semi-solid and liquid products for branded and generic pharmaceutical customers as well as the OTC and cosmetic markets. These products are used in a wide range of applications from cosmetics and cosmeceuticals to the prescription treatment of conditions like dermatitis, psoriasis, and eczema.

Over the past two years, IGI has structured a new management team to implement this plan. The team brings a wealth of experience in the generic pharmaceutical industry to IGI. IGI's facilities and manufacturing equipment have been designed to produce topical and liquid products and support the Company's target prescription dosage forms.

Contract manufacturing services will continue to be crucial to IGI's success. The customer base for these services is pharmaceutical companies as well as cosmetic, cosmeceutical, and OTC product marketers who require product development/manufacturing support. This is a highly-competitive market with a number of larger, greater-resourced companies offering similar services. IGI looks to create niche opportunities for itself by providing high quality, customer-oriented service.

IGI has exclusive rights for the use of Novasome® technology in topical formulations and intends to pursue collaboration opportunities with established pharmaceutical companies seeking to develop topical products with unique properties. In addition, the Company will explore line extension opportunities through innovative packaging or alternate dosage forms of existing pharmaceutical molecules.

#### *Recent Events*

The Company filed five Abbreviated Drug Application, or ANDA, with the U.S. Food and Drug Administration (FDA), one in January 2013, one in April 2013, one in July 2013, September 2013 and one in October 2013.

#### *Results of Operations*

##### **Three months ended September 30, 2013 compared to September 30, 2012**

The Company had a net loss of \$95,000, or \$0.002 per share, for the three months ended September 30, 2013, compared to \$1,422,000, or \$0.04 per share, in the comparable period for 2012, which resulted from the following:

##### **Revenues (in thousands):**



<b>Components of Revenue:</b>	<b>Three Months Ended September 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2013</b>	<b>2012</b>	<b>\$</b>	<b>%</b>
<b>Product sales</b>	\$ 3,950	\$ 1,464	\$ 2,486	170 %
<b>Research and development income</b>	10	496	(486)	(98)%
<b>Licensing, royalty, and other income</b>	35	26	9	35 %
<b>Total Revenues</b>	\$ 3,995	\$ 1,986	\$ 2,009	101 %

The increase in product sales for the three months ended September 30, 2013 as compared to the same period in 2012 was primarily due to the launch of our own generic pharmaceutical product line, in addition to increased product sales to four of our pharmaceutical customers and one of our cosmetic customers, which was only partially offset by decreased sales to one of our pharmaceutical customers. Research and development income will not be consistent and will vary, from period to period, depending on the required timeline of each development project. The decrease in research and development income during the three months ended September 30, 2013 as compared to the same period in 2012 is attributable primarily to three new customer relationships with pharmaceutical partners established at the end of 2011 and the beginning of 2012. We completed several site transfers, formulation services, 510 (k) submissions for medical devices and filing of two ANDAs for these customers in 2012. Licensing, royalty and other revenue decreased due to a decrease in other revenue while licensing and royalty revenue remained the same.

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

	<b>Three Months Ended September 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2013</b>	<b>2012</b>	<b>\$</b>	<b>%</b>
<b>Cost of sales</b>	\$ 2,684	\$ 1,222	\$ 1,462	120 %
<b>Selling, general and administrative</b>	692	980	(288)	(29)%
<b>Product development and research</b>	661	620	41	7 %
<b>Totals costs and expenditures</b>	\$ 4,037	\$ 2,822	\$ 1,215	43 %

Cost of sales increased for the three months ended September 30, 2013 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 67% for the three months ended September 30, 2013 as compared to 62% for the three months ended September 30, 2012. The increase in cost of sales as a percentage of product sales for the three months ended was attributable to the decline in revenue from research and development contracts, which was substantially offset by increased revenue from the launch of our first four IGI label products and a shift in the mix of our product sales to include greater higher margin pharmaceutical products. 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 three months ended September 30, 2013 decreased by \$288,000 as compared to the same period in 2012 as a result of the severance agreement with our former President and CEO of \$150,000 in 2012 and a decrease of \$118,000 in employees' compensation payable in stock, a decrease of \$84,000 in recruiting fees, a decrease of \$16,000 in shareholder meetings and reports and a decrease of \$8,000 in professional fees. These decreases were partially offset by increases in salaries and related costs of \$30,000, amortization of product acquisition costs of \$30,000 and an increase of \$6,000 in the allocation of overhead costs during the three months ended September 30, 2013 as compared to the same period in 2012.

Product development and research expenses for the three months ended September 30, 2013 increased by \$41,000 as compared to the same period in 2012. Consistent with our strategy to expand our portfolio of generic prescription topical pharmaceutical products, we increased headcount, which resulted in an increase of \$62,000 in salaries and related costs. During the three months ended September 30, 2013, the allocation of overhead costs increased by \$10,000 as compared to the same period in 2012. In addition, we incurred approximately \$125,000 in fees related to the Generic Drug User Fee Act, and the associated filing of our applications with the FDA in the three months ended September 30, 2013. These increases were partially offset by a decrease of \$147,000 in spending on clinical studies, outside testing, pilot batch expense and supplies and a decrease of \$14,000 in professional fees.

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

	Three Months Ended September 30,		Increase/(Decrease)	
	2013	2012	\$	%
Interest Expense	\$ 53	\$ 584	\$ (531)	(91)%
Other Expense	\$	\$ 2	\$ (2)	(100)%

Interest expense decreased for the three months ended September 30, 2013 as compared to the same period in 2012 due to the inclusion in 2012 of approximately \$545,000 of amortization of debt issuance costs related to the Note Payable Related Party that was paid in full and terminated on August 31, 2012.

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

	<b>Three Months Ended September 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2013</b>	<b>2012</b>	<b>\$</b>	<b>%</b>
<b>Net loss</b>	\$ (95)	\$ (1,422)	\$ (1,327)	(93)%
<b>Net loss per share</b>	\$ (0.002)	\$ (0.04)	\$ (0.038)	(95)%

The decrease in net loss for the three months ended September 30, 2013 as compared to the same period in 2012 is due to the increase in revenues partially offset by the increases in costs and expenses noted above.

**Nine months ended September 30, 2013 compared to September 30, 2012**

The Company had a net loss of \$755,000, or \$0.02 per share, for the nine months ended September 30, 2013, compared to \$2,745,000, or \$0.07 per share, in the comparable period in 2012, which resulted from the following:

**Revenues (in thousands):**

Components of Revenue:	Nine Months Ended September 30,		Increase/(Decrease)	
	2013	2012	\$	%
Product sales	\$ 11,124	\$ 4,835	\$ 6,289	130 %
Research and development income	278	1,368	(1,090)	(80)%
Licensing, royalty and other income	97	52	45	87 %
<b>Total Revenues</b>	<b>\$ 11,499</b>	<b>\$ 6,255</b>	<b>\$ 5,244</b>	<b>84 %</b>

The increase in product sales for the nine months ended September 30, 2013 as compared to the same period in 2012 was primarily due to the launch of our own generic pharmaceutical product line, which accounted for \$4.2 million of net product sales year to date in 2013 as compared to \$0 in 2012. In addition, we increased product sales to four of our contract manufacturing pharmaceutical customers and one of our cosmetic customers, which was only partially offset by decreased sales to one of our pharmaceutical customers. This resulted in a shift in the mix of our product sales to include greater higher margin pharmaceutical products. Research and development income will not be consistent and will vary, from period to period, depending on the required timeline of each development project. The decrease in research and development income during the nine months ended September 30, 2013 as compared to the same period in 2012 is attributable primarily to three new customer relationships with pharmaceutical partners established at the end of 2011 and the beginning of 2012. We completed several site transfers, formulation services, 510 (k) submissions for medical devices and filing of two ANDAs for these customers in 2012. Licensing, royalty and other revenue increased due to an increase in other revenue while licensing and royalty revenue remained the same.

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

	Nine Months Ended September 30,		Increase/(Decrease)	
	2013	2012	\$	%
Cost of sales	\$ 7,932	\$ 4,271	\$ 3,661	86 %
Selling, general and administrative	2,078	2,254	(176)	(8)%
Product development and research	2,123	1,735	388	22 %

<b>Totals costs and expenditures</b>	\$ 12,133	\$ 8,260	\$ 3,873	47 %
--------------------------------------	-----------	----------	----------	------

Cost of sales increased for the nine months ended September 30, 2013 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 69% for the nine months ended September 30, 2013 as compared to 68% for the nine months ended September 30, 2012. Cost of sales as a percentage of product sales was consistent with the prior period, as result of a shift in the mix of our product sales to include greater higher margin pharmaceutical products as well as revenue from our the launch of first three IGI label products, which was however offset by the decline in research and development income. 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 nine months ended September 30, 2013 decreased by \$176,000 as compared to the same period in 2012 as a result of the severance agreement with our former President and CEO of \$150,000 in 2012 and a decrease of \$204,000 in employees compensation payable in stock, a decrease of \$145,000 in recruiting fees and a decrease of \$16,000 in commissions. These decreases were partially offset by increases in salaries and related costs of \$155,000, an increase of \$41,000 in professional fees, an increase of \$41,000 in the expense from the issuance of stock options, amortization of product acquisition costs of \$30,000, an increase of \$20,000 in shows and exhibits, an increase of \$17,000 in the allocation of overhead costs and an increase of \$11,000 in travel related costs during the three months ended September 30, 2013 as compared to the same period in 2012.

Product development and research expenses for the nine months ended September 30, 2013 increased by \$388,000 as compared to the same period in 2012. Consistent with our strategy to expand our portfolio of generic prescription topical pharmaceutical products, we increased headcount, which resulted in an increase of \$190,000 in salaries and related costs, we increased spending on clinical studies, outside testing, pilot batch expense and supplies by \$16,000 and overhead costs by \$27,000. In addition, we incurred approximately \$269,000 in fees related to the Generic Drug User Fee Act, and the associated filing of our applications with the FDA. These increases were partially offset by a decrease of \$94,000 in consulting fees and a decrease of \$18,000 in professional fees.

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

	Nine Months Ended September 30,		Increase/(Decrease)	
	2013	2012	\$	%
Interest Expense	\$ 126	\$ 728	\$ (602)	(83)%
Other (Income) Expense	\$ (5)	\$ 12	\$ (17)	(142)%

Interest expense decreased for the nine months ended September 30, 2013 as compared to the same period in 2012 due to the lower interest rate on the Note Payable Bank (see Note 8 to the Company's Consolidated Financial Statements) that was outstanding for the nine months ended September 30, 2013 as compared to the interest rate on the Notes Payable that was outstanding in the comparable period in 2012, and the inclusion in 2012 of approximately \$545,000 of amortization of debt issuance costs related to the Note Payable Related Party that was paid in full and terminated on August 31, 2012.

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

	Nine Months Ended September 30,		Increase/(Decrease)	
	2013	2012	\$	%
Net loss	\$ (755)	\$ (2,745)	\$ (1,990)	(72)%
Net loss per share	\$(0.02)	\$ (0.07)	\$ (0.05)	(75)%

The decrease in net loss for the nine months ended September 30, 2013 as compared to the same period in 2012 is due to the increase in revenues partially offset by the increases in costs and expenses noted above.

**Liquidity and Capital Resources**

The Company's operating activities used \$1,391,000 of cash during the nine months ended September 30, 2013 compared to \$1,201,000 used in the comparable period of 2012. The use of cash for both the nine months ended September 30, 2013 and 2012 was substantially a result of the net loss for each period, which included costs related to product development and research of \$2,123,000 and \$1,735,000 for the nine months ended September 30, 2013 and 2012, respectively.

The Company's investing activities used \$2,049,000 of cash in the nine months ended September 30, 2013 compared to \$323,000 of cash used in investing activities in the first nine months of 2012. The funds used for the period ended September 30, 2013 were for the purchase of econazole nitrate cream (see Note 10 to the Company's Consolidated Financial Statements) and minor additional equipment and improvements in the compounding area and packaging and filling lines and the funds used for the period ended September 30, 2012 were for additional equipment and improvements for the packaging and filling lines and additional equipment and related services for the analytical area.

The Company's financing activities provided \$2,306,000 of cash in the nine months ended September 30, 2013 compared to \$385,000 provided in the nine months ended September 30, 2012. The cash provided for the nine month period ended September 30, 2013 was mainly the proceeds of \$2,000,000 from the drawdowns of the Note Payable (see Note 8 to the Company's Consolidated Financial Statements) and \$372,000 of proceeds from the exercise of options and warrants to purchase common stock. The cash provided for the nine month period ended September 30, 2012 was the net proceeds the new credit facility less repayment of the Note Payable Related Party as more fully described in Note 8 to the Company's Consolidated Financial Statements.

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$1,402,000 at September 30, 2013 and future cash from operations. The Company had working capital of \$4,225,000 at September 30, 2013.

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, future cash from our operations, and additional funds of \$2,000,000 which will become available to the Company at December 31, 2013, if the Company remains in compliance with its liquidity requirements under the line of credit detailed in Note 8, will be sufficient to support our current business plan for the next 12 months as indicated in the Financial Statements.

### **Off Balance Sheet Arrangements**

The Company does not have any off balance sheet arrangements as of September 30, 2013.

### **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, 2012 for a complete list of all Critical Accounting Policies and Estimates. See also Note 3 to the Company's Condensed Consolidated Financial Statements.



#### **ITEM 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our Principal 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 September 30, 2013. Based on that evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that, as of September 30, 2013, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including our Principal Executive Officer and Principal Financial and Accounting Officer, as appropriate to allow timely decisions regarding required disclosure.

#### *Changes in Internal Control over Financial Reporting*

There was no change in our internal control over financial reporting during our third quarter ended September 30, 2013 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. 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.

**ITEM 1A. Risk Factors.**

Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2012 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, 2012, as updated in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2013 and June 30, 2013, 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 September 30, 2013 and 2012, three of our customers accounted for 49% and four of our customers accounted for 80% of our revenue, respectively. For the nine months ended September 30, 2013 and 2012, four of our customers accounted for 55% and three of our customers accounted for 65% 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 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.**

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 September 30, 2013, our stockholders' equity was \$6.2 million and we had an accumulated deficit of \$44 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 Our Securities**

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

For the nine months ended September 30, 2013, the average daily trading volume of our common stock on the NYSE MKT was approximately 46,600 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**

N/A

**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 September 30, 2013, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (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.

\*\*

Furnished 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: November 14, 2013

By: /s/ Jason Grenfell-Gardner  
Jason Grenfell-Gardner  
President and Chief Executive Officer

Date: November 14, 2013

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 September 30, 2013, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (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.

\*\*

Furnished herewith.