IGI LABORATORIES, INC
Form 10-Q
November 13, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

¨ **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** *(Zip Code)*

(Address of Principal Executive Offices)

(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 þ 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 þ 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	þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No þ

The number of shares outstanding of the issuer's common stock is 52,787,787 shares, net of treasury stock, as of November 6, 2014.

PART I

FINANCIAL INFORMATION

ITEM 1. Financial Statements

IGI LABORATORIES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except shares and per share information)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Revenues:				
Product sales, net	$ 6,005	$ 3,950	$ 18,525	$ 11,124
Research and development income	635	10	1,385	278
Licensing, royalty and other revenue	28	35	95	97
Total revenues	6,668	3,995	20,005	11,499
Costs and Expenses:				
Cost of sales	4,036	2,684	11,603	7,932
Selling, general and administrative expenses	1,124	692	3,563	2,078
Product development and research expenses	1,652	661	5,045	2,123
Total costs and expenses	6,812	4,037	20,211	12,133
Operating loss	(144)	(42)	(206)	(634)
Interest expense and other, net	(58)	(53)	(174)	(121)
Net loss	$ (202)	$ (95)	$ (380)	$ (755)
Basic and diluted loss per share	$ 0.00	$ 0.00	($ 0.01)	($ 0.02)
Weighted average shares of common stock outstanding:				
Basic and diluted	52,457,938	43,395,980	48,811,328	43,179,898

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)

	(Unaudited) September 30, 2014	December 31, 2013*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,248	$ 2,101
Accounts receivable, net	6,369	4,947
Inventories	3,218	2,869
Prepaid expenses and other receivables	1,011	641
Total current assets	33,846	10,558
Property, plant and equipment, net	3,169	2,623
Product acquisition costs, net	10,135	1,766
Restricted cash, long term	54	54
License fee, net	125	200
Debt issuance costs, net	45	69
Other	143	157
Total assets	$ 47,517	$ 15,427
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,143	$ 1,523
Accrued expenses	3,359	2,915
Payable for product acquisition costs	6,000	-
Deferred income, current	34	768
Capital lease obligation, current	131	15
Total current liabilities	11,667	5,221
Note payable, bank	2,854	3,000
Other long term liabilities	105	15
Total liabilities	14,626	8,236
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 60,000,000 shares authorized; 52,577,787 and 46,748,575 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	545	487
Additional paid-in capital	77,563	51,541
Accumulated deficit	(45,217)	(44,837)

Total stockholders’ equity	32,891	7,191
Total liabilities and stockholders' equity	$ 47,517	$ 15,427

*Derived from the audited December 31, 2013 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 nine months ended September 30, 2014 and 2013

(in thousands)

(Unaudited)

	2014	2013
Cash flows from operating activities:		
Net loss	$(380)	$(755)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation	292	280
Amortization of license fee	75	75
Stock-based compensation expense	649	169
Provision for write down of inventory	114	94
Amortization of debt issuance costs	24	23
Amortization of product acquisition costs	90	30
Changes in operating assets and liabilities:		
Accounts receivable	(1,422)	(1,318)
Inventories	(463)	(844)
Prepaid expenses and other receivables	(547)	21
Other assets	211	(12)
Accounts payable and accrued expenses	1,064	729
Deferred income	(737)	117
Net cash used in operating activities	(1,030)	(1,391)
Cash flows from investing activities:		
Capital expenditures	(618)	(223)
Product acquisition costs	(2,459)	(1,826)
Net cash used in investing activities	(3,077)	(2,049)
Cash flows from financing activities:		
Proceeds from issuance of stock, net	24,866	(53)
Proceeds from exercise of common stock warrants and options	565	372
Principal payments on capital lease obligation	(31)	(13)
Payments on note payable, bank	(146)	-
Proceeds from note payable, bank	-	2,000
Net cash provided by financing activities	25,254	2,306
Net increase (decrease) in cash and cash equivalents	21,147	(1,134)
Cash and cash equivalents at beginning of period	2,101	2,536
Cash and cash equivalents at end of period	$23,248	$1,402

Supplemental Cash flow information:		
Cash payments for interest	$139	$102
Cash payments for taxes	$23	$10
Non cash investing and financing transactions:		
Payable related to product acquisition costs	$6,000	$-
Common stock issued for Series A Convertible Preferred stock	$-	$500

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, 2014 (unaudited)

(in thousands, except share information)

	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2013	46,748,575	$ 487	$ 51,541	$ (44,837)	$ 7,191
Issuance of stock pursuant to a public offering, net of associated fees of $1,868	5,347,500	53	24,813		24,866
Stock based compensation expense – stock options			191		191
Stock based compensation expense - restricted stock			458		458
Stock warrants exercised	270,546	3	325		328
Stock options exercised	211,166	2	235		237
Net loss	-	-	-	(380)	(380)
Balance, September 30, 2014 (unaudited)	52,577,787	$ 545	$ 77,563	$ (45,217)	$ 32,891

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, or 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 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, 2013. The condensed consolidated balance sheet as of December 31, 2013 has been derived from those audited consolidated financial statements. Operating results for the nine month period ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014.

1. Organization and Business

IGI Laboratories, Inc. is a Delaware corporation incorporated in 1977. On May 7, 2008, the stockholders of IGI, Inc. approved the name change of the Company from IGI, Inc. to IGI Laboratories, Inc. 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. In its own label, the Company currently sells generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. The Company also provides contract manufacturing and formulation services to the pharmaceutical, over-the-counter, or (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.

In addition, we may continue to explore ways to accelerate our growth through the creation of unique opportunities from the acquisition of additional intellectual property, and the expansion of the use of our existing intellectual property, including our licensed Novasome ® technology.

To date, we have filed nineteen Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA, for additional pharmaceutical products. 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 at least ten ANDAs in 2014 through our internal research and development program. On March 12, 2014, the Company received our first approval from the FDA for an ANDA. The FDA has approved IGI's application for lidocaine hydrochloride USP 4% topical solution. On May 7, 2014, the Company received tentative approval from the FDA for its ANDA for diclofenac sodium 1.5% topical solution. On June 26, 2014, the Company executed an agreement to enable it to launch the product in March 2015 after final FDA approval. 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%, which we launched in September 2013.

On September 24, 2014, we acquired from AstraZeneca ANDAs and NDAs associated with eighteen products, seventeen of which were injectable products. On September 30, 2014, we acquired ANDAs and NDAs associated with two ophthalmic products from Valeant, in addition to the exclusive right to acquire three additional injectable products from Valeant.

We also develop, manufacture, fill, and package 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. We are currently exploring various options to enable us to expand our development and manufacturing capabilities to include sterile injectable and ophthalmic products.

2. Liquidity

The Company's principal sources of liquidity are cash and cash equivalents of approximately $23,248,000 at September 30, 2014, the $2,000,000 available under the $5,000,000 credit facility detailed below and cash from operations. The Company had a net loss of $380,000 for the nine months ended September 30, 2014 and a net loss of $755,000 for the nine months ended September 30, 2013, and had working capital of $22,179,000 at September 30, 2014. The Company will be required to pay up to an additional aggregate of $6,000,000 related to the assets purchased from AstraZeneca (see Note 10).

On June 27, 2014, the Company announced the pricing of its underwritten public offering of 4,650,000 shares of its common stock at a price to the public of $5.00 per share (See Note 12). The offer closed on July 2, 2014, and, after giving effect to the underwriters' exercise of the over-allotment option in full, 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 was approximately $24.9 million.

Prior to the most recent public offering, the Company's business operations have been primarily funded over the past five years through 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 proceeds from these private placements were used for general working capital as well as the acquisition of econazole nitrate cream 1%, which was purchased on February 1, 2013 and launched in September 2013.

In August 2012, the Company entered into a $3,000,000 line of credit, which was amended on July 26, 2013. The amendment increased the line of credit to $5,000,000 effective as of December 31, 2013 upon the Company's compliance with certain covenants (See Note 8). As of September 30, 2014 the outstanding principal balance on the line of credit was $2,854,000. 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 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 November 2015.

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 sales returns, chargebacks, rebates, cash discounts, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowance, stock based compensation, 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, 2014 and 2013 and the nine months ended September 30, 2014 and 2013, the effect of the Company’s potential dilutive common stock equivalents was anti-dilutive for those periods; as a result, the basic and diluted weighted average number of shares of common stock 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 calculation for those periods due to their anti-dilutive effect. Potentially dilutive common stock equivalents amounted to 2,588,334 and 5,602,089 at September 30, 2014 and 2013, respectively.

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 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 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 are adjusted as estimates are 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.

Gross-To-Net Sales Deductions

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Gross IGI product sales	$ 14,823	$ 3,038	$ 25,618	$ 7,417
Reduction to gross product sales:				
Chargebacks and billbacks	10,365	1,395	13,832	2,618
Sales discounts and other allowances	1,445	254	2,446	619
Total reduction to gross product sales	$ 11,810	$ 1,649	$ 16,278	$ 3,237
Net IGI product sales	$ 3,013	$ 1,389	$ 9,340	$ 4,180

Accounts receivable are presented net of SRA balances of $4.2 million and $0.5 million at September 30, 2014 and 2013, respectively. Accounts payable and accrued expenses include $0.8 million and $0.3 million at September 30, 2014 and 2013, respectively, for certain fees related to services provided by the wholesalers. Wholesale fees of $0.8 million and $0.1 million for the three month periods ended September 30, 2014 and 2013, respectively, were included in cost of goods sold. Wholesale fees of $1.5 million and $0.4 million for the nine month periods ended September 30, 2014 and 2013, respectively, were included in cost of goods sold. In addition, in connection with four of the six 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. 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 $0.7 million and $0.5 million at September 30, 2014 and 2013, respectively, related to these royalties. Royalty expense of $0.7 million and $0.5 million was included in cost of goods sold for the three months ended September 30, 2014 and 2013, respectively. Royalty expense of $2.9 million and $1.5 million was included in cost of goods sold for the nine months ended September 30, 2014 and 2013, 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, 2014, four of the Company's customers accounted for 59% of the Company's revenue. For the three months ended September 30, 2013, three of the Company's customers accounted for 49% of the Company's revenue. Two of these customers are the same for both periods. For the nine months ended September 30, 2014 and 2013, four of the Company's customers accounted for 53% and four of the Company's customers accounted for 55% 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 65% of all accounts receivable as of September 30, 2014. 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 May 2014, 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, 2016 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, FASB issued Accounting Standards Update ("ASU") 2014-15, "Presentation of Financial Statements — Gong 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.

4. Inventories

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

Inventories at September 30, 2014 and December 31, 2013 consist of:

	September 30, 2014	December 31, 2013
	(Unaudited)	(Audited)
	(amounts in thousands)	
Raw materials	$ 2,647	$ 2,172
Work in progress	50	271
Finished goods	521	426
Total	$ 3,218	$ 2,869

5.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 2,339,798 options have been granted to non-employee directors through September 30, 2014 and 807,782 of those have been forfeited through September 30, 2014 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 partial 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 and May 19, 2010, 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 September 30, 2014, options to purchase 1,872,334 shares of common stock were outstanding under the 2009 Plan. As of September 30, 2014, 1,473,748 shares of restricted stock had been granted under the 2009 Plan and 230,420 of those have been forfeited through September 30, 2014 and returned to the pool.

In summary, there are 2,504,334 options outstanding under the 1999 Plan, the Director Plan and the 2009 Plan, collectively as of September 30, 2014.

There are 2,250,820 options available for issuance under the Director Plan and the 2009 Plan collectively as of September 30, 2014.

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 September 30, 2014
Expected volatility	44.0% - 51.0%
Expected term (in years)	3.2 -3.3 years
Risk-free rate	0.74% - 1.11%
Expected dividends	0%

A summary of option activity under the 1999 Plan, the Director Plan and the 2009 Plan as of September 30, 2014 and changes during the period are presented below:

	Number of Options	Weighted Average Exercise Price
Outstanding as of January 1, 2014	2,643,500	$ 1.13
Issued	228,000	$ 3.74
Exercised	(211,166)	$ 1.13
Forfeited	(156,000)	$ 2.71
Expired	-	-
Outstanding as of September 30, 2014	2,504,334	$ 1.27
Exercisable as of September 30, 2014	1,790,997	$ 1.11

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, 2014 was $1.24.

The following table summarizes information regarding options outstanding and exercisable at September 30, 2014:

Outstanding:

Range of Exercise Prices	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.55 - $1.00	167,000	$ 0.74	3.70
$1.01 - $1.50	2,023,500	$ 1.09	7.14
$1.51 - $7.47	313,834	$ 2.68	8.12
Total	2,504,334	$ 1.27	7.04

Exercisable:

Range of Exercise Prices	Stock Options Exercisable	Weighted Average Exercise Price
$0.55 - $1.00	167,000	$ 0.74
$1.01 - $1.50	1,499,997	$ 1.10
$1.51 - $7.47	124,000	$ 1.67
Total	1,790,997	$ 1.11

As of September 30, 2014, the intrinsic value of the options outstanding is $20,170,218 and the intrinsic value of the options exercisable is $14,709,580. The intrinsic value of options exercised during the nine months ended September 30, 2014 was $1,730,487. As of September 30, 2014, there was approximately $242,000 of total unrecognized compensation cost that will be recognized through September 2017 related to non-vested share-based compensation arrangements granted under the 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 $458,000 and $14,700 of compensation expense during the nine months ended September 30, 2014 and 2013, respectively, related to restricted stock awards. Stock

compensation expense is recognized over the vesting period of the restricted stock. At September 30, 2014, the Company had approximately $163,000 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized from October 2014 through July 2015.

	Number of Restricted Stock	Weighted Average Exercise Price
Non-vested balance at January 1, 2014	246,001	$ 2.64
Changes during the period:		
Shares granted	-	-
Shares vested	(137,667)	2.46
Shares forfeited	-	-
Non-vested balance at September 30, 2014	108,334	$ 2.86

6. Income Taxes

The Company has a history of tax losses and has recorded a full valuation allowance against its net deferred tax assets. The Company has not recorded a significant tax provision at September 30, 2014, as it has estimated its effective tax rate for 2014 (after considering utilization of existing net operating losses) to be insignificant. The tax years 2010-2013 remain open to examination by the major taxing jurisdictions to which the Company is subject.

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 in 2009 and that the net operating loss carry forwards generated prior to such date 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 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 $75,000 related to this agreement for each of the nine month periods ended September 30, 2014 and 2013.

8. Note Payable - Bank

On August 31, 2012, IGI Laboratories, Inc. and its subsidiaries 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. At September 30, 2014, $2,854,000 in principal was outstanding.

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 September 30, 2014, 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, and the Company is finalizing negotiations to extend the drawdown period.

In accordance with the Loan and Security Agreement, the Company had to maintain a liquidity ratio of at least 1.25 to 1.00 (the “LQR Threshold”), provided that the LQR Threshold was reduced to 1.00 so long as the Company had 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 would be increased to 1.25 to 1.00. “Liquidity” means the sum of: (i) unrestricted cash in bank plus (ii) the Borrowing Base (as defined under the Loan and Security Agreements, or the amount drawn to date). In accordance with the Loan and Security Agreement, liquidity ratio means the ratio of Liquidity to all Indebtedness (as defined under the Loan and Security Agreement) 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, 2014, the Company was in compliance with the LQR Threshold required under the Loan and Security Agreement.

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. On December 31, 2013, the aggregate borrowing amount was increased from $3,000,000 to $5,000,000.

9. Stock Warrants

Stock Warrant activity for the quarters ended September 30, 2014 and 2013 consisted of:

	2014		2013	
	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Beginning balance	354,546	$ 1.21	782,259	$ 0.85
Stock warrants granted	-	-	-	-
Stock warrants expired	-	-	-	-
Stock warrants exercised	(270,546)	1.21	(427,713)	0.55
Ending balance	84,000	$ 1.21	354,546	$ 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.

In addition, as of December 31, 2012 the Company executed a settlement agreement with Amzak Capital Management, LLC in connection with a common stock purchase warrant that we 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 Agreements

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 and has the FDA 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 $1,400,000 in cash and an additional aggregate of $400,000 upon the occurrence of certain 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, milestone payment and related costs to acquire the asset are included as part of product acquisition costs totaling $1,800,000. The Company capitalized 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. Beginning in the third quarter of 2013, the Company's product sales included sales of the product.

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

On October 23, 2013, the Company announced that it had received formal approval from the 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, New Jersey.

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 $500,000 in cash and will be required to pay up to an additional aggregate of $6,000,000 upon the occurrence of a certain milestone event. 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 $3,000,000. 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 $6,914,000. The Company capitalized and amortized the costs over fifteen years, the useful life of the acquired products and product rights.

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 one 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 relating 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 $1,500,000 in cash. In consideration for the purchase of the Additional Assets, the Company may exercise any Option, in its sole discretion, and pay $750,000 for each of two additional products and $500,000 for one additional product, for a total aggregate of $2,000,000 if all Options are exercised. 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 $1,545,000. The Company capitalized and amortized the costs over fifteen years, the useful life of the acquired product and product rights.

11. 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 December 19, 2013, the Company filed a complaint in the United States District Court for the District of Delaware against Mallinckrodt LLC, Mallinckrodt, Inc. and Nuvo Research Inc. (collectively, “Mallinckrodt”) seeking a declaration of non-infringement of United States Patent Nos. 8,217,078 and 8,546,450 so that the Company can bring its generic diclofenac sodium topical solution 1.5% to market at the earliest possible date under applicable statutory and FDA regulatory provisions.

On January 10, 2014, Mallinckrodt filed an answer and counterclaim alleging that IGI Laboratories, Inc. infringes the patents at issue. On January 28, 2014, the Company filed a motion to dismiss Mallinckrodt's counterclaim and, on March 5, 2014, Mallinckrodt filed an opposition to such motion. On April 22, 2014, the court issued a Memorandum Order, granting in part and denying in part IGI's motion to dismiss Mallinckrodt's counterclaims.

On June 26, 2014, the Company entered into an agreement with Mallinckrodt to settle a declaratory judgment action brought by IGI, concerning the Company's filing of an ANDA with the FDA seeking approval to market a generic version of Pennsaid® (diclofenac sodium topical solution) 1.5% w/w. Under the terms of this agreement, Mallinckrodt granted the Company a non-exclusive license to launch its diclofenac sodium topical solution 1.5% product on March 28, 2015. There was no material impact on the financial statements as a result of the settlement. The Company received tentative approval of its diclofenac sodium topical solution 1.5% from the FDA on May 7, 2014.

12. 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 (the "shares "), 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 Securities and Exchange Commission (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.

The Company intends to use the net proceeds of the offering for general corporate purposes, including, without limitation, research and development, general and administrative, manufacturing and marketing expenses, and potential not yet identified acquisitions of companies, products, ANDAs, technologies and assets that complement the Company's business.

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, 2013, 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 specialty generic pharmaceutical company. Our mission is to become a leader in the specialty generic pharmaceutical market. Under our IGI label, we currently 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.

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.

In addition, we may continue to explore ways to accelerate our growth through the creation of unique opportunities from the acquisition of additional intellectual property, and the expansion of the use of our existing intellectual property, including our licensed Novasome® technology.

To date, we have filed nineteen Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA for additional pharmaceutical products. 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 at least ten ANDAs in 2014 through our internal research and development program. On March 12, 2014, the Company received our first approval from the FDA for an ANDA. The FDA has approved IGI's application for lidocaine hydrochloride USP 4% topical solution. On May 7, 2014, the Company received tentative approval from the FDA for its ANDA for diclofenac sodium 1.5% topical solution. On June 26, 2014, the Company executed an agreement to enable it to launch the product in March 2015 after final FDA approval. 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%, which we launched in September 2013.

On September 24, 2014, we acquired from AstraZeneca ANDAs and NDAs associated with eighteen products, seventeen of which were injectable products. On September 30, 2014, we acquired ANDAs and NDAs associated with two ophthalmic products from Valeant, in addition to the exclusive right to acquire three additional injectable products from Valeant.

We also develop, manufacture, fill, and package 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. We are currently exploring various options to enable us to expand our development and manufacturing capabilities to include sterile injectable and ophthalmic products.

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.

Recent Events

On March 12, 2014, we received our first approval from the FDA for an ANDA. Lidocaine hydrochloride USP 4% topical solution is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract. Based on November 2013 IMS Health data, the total addressable market for the generic version of this product is approximately $1.8 million, in which IGI will currently compete with two other manufacturers. IGI originally submitted this ANDA to the FDA in May 2012.

On May 7, 2014, we received a tentative approval from the FDA for an ANDA. Diclofenac sodium topical solution, 1.5% is a nonsteroidal anti-inflammatory drug indicated for the treatment of the pain of osteoarthritis of the knee. Based on recent IMS Health data, the total addressable market for this product is approximately $29 million. IGI originally submitted this ANDA to the FDA in December 2010.

On June 26, 2014, we entered into an agreement with Mallinckrodt to settle a declaratory judgment action brought by the Company, concerning our filing of an ANDA with the FDA seeking approval to market a generic version of Pennsaid® (diclofenac sodium topical solution) 1.5% w/w. Under the terms of this agreement, Mallinckrodt granted us a non-exclusive license to launch our diclofenac sodium topical solution 1.5% product on March 28, 2015. We received tentative approval of our diclofenac sodium topical solution 1.5% from the FDA on May 7, 2014.

On July 2, 2014, after giving effect to the underwriters' exercise of the over-allotment option in full, we closed the sale of an aggregate of 5,347,500 shares of common stock in a public underwritten offering at a public offering price of $5.00 per share. The net proceeds of the offering was approximately $24.9 million.

On September 24, 2014, we acquired from AstraZeneca ANDAs and NDAs associated with eighteen AstraZeneca products, seventeen of which were injectable products.

On September 30, 2014, we acquired ANDAs and NDAs associated with two ophthalmic products from Valeant, in addition to the exclusive right to acquire three additional injectable products from Valeant.

Results of Operations

Three months ended September 30, 2014 compared to September 30, 2013

We had a net loss of $202,000, or $0.00 per share, for the three months ended September 30, 2014, compared to $95,000, or $0.01 per share, for the three months ended September 30, 2013, which resulted from the following:

Revenues (in thousands):

	Three Months Ended September 30,			
Components of Revenue:	2014	2013	$ Change	% Change
Product sales, net	$ 6,005	$ 3,950	$2,055	52 %
Research and development income	635	10	625	6250 %
Licensing, royalty and other revenue	28	35	(7)	(20)%
Total Revenues	$ 6,668	$ 3,995	$2,673	67 %

The increase in product sales for the three months ended September 30, 2014 as compared to the same period in 2013 was primarily due to increased revenue from our own generic pharmaceutical product line that was launched in the first quarter of 2013, the launch of econazole nitrate cream 1% in September 2013 and the launch of two additional IGI label products in June 2014. In addition we increased product sales in our contract manufacturing services to three of our major pharmaceutical customers, which was only partially offset by decreased sales to three of our cosmetic customers and 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. Licensing, royalty and other revenue decreased slightly due to a decrease in other revenue while licensing and royalty revenue remained the same.

Costs and expenses (in thousands):

	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
Cost of sales	$ 4,036	$ 2,684	$1,352	50 %
Selling, general and administrative	1,124	692	432	62 %
Product development and research	1,652	661	991	150 %
Totals costs and expenditures	$ 6,812	$ 4,037	$2,775	69 %

Cost of sales increased for the three months ended September 30, 2014 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 61% for the three months ended September 30, 2014 as compared to 67% for the three months ended September 30, 2013. The decrease in cost of sales as a percentage of product sales for 2014 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. 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, 2014 increased by $432,000 as compared to the same period in 2013. There were increases of $246,000 in salaries, bonuses and related costs, $74,000 in the expense from the issuance of stock based compensation related to options and restricted stock, $72,000 in professional fees, $21,000 in dues and subscriptions and $15,000 in travel related.

Product development and research expenses for the three months ended September 30, 2014 increased by $991,000 as compared to the same period in 2013. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased spending on clinical studies by $246,000, pilot batch expense by $224,000, outside testing and supplies by $267,000, consulting fees by $248,000 and salaries, bonuses and related costs by $27,000. These increases were partially offset by a decrease of $23,000 in fees related to the Generic Drug User Fee Act and the associated filing of our applications with the FDA.

Interest expense and other, net (in thousands):

	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
Interest expense	$ 58	$ 53	$ 5	9 %

Interest expense increased for the three months ended September 30, 2014 as compared to the same period in 2013 due to the increase in the amount of the Note Payable – Bank (see Note 8 to the Company's Consolidated Financial Statements) outstanding during the three months ended September 30, 2014 as compared to the same period in 2013.

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

	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
Net loss	$ (202)	$ (95)	$107	113 %
Net loss per share	$ 0.00	$ 0.00	$0.00	0 %

Net loss for the three months ended September 30, 2014 was $202,000 as compared to $95,000 in the same period last year. The increase is due to the increases in costs and expenses described above, partially offset by the increases in revenues.

Nine months ended September 30, 2014 compared to September 30, 2013

The Company had a net loss of $380,000, or $0.01 per share, for the nine months ended September 30, 2014, compared to $755,000, or $0.02 per share, in the comparable period in 2013, which resulted from the following:

Revenues (in thousands):

	Nine Months Ended September 30,			
Components of Revenue:	2014	2013	$ Change	% Change
Product sales	$ 18,525	$ 11,124	$7,401	67 %
Research and development income	1,385	278	1,107	398 %
Licensing, royalty and other income	95	97	(2)	(2)%
Total Revenues	$ 20,005	$ 11,499	$8,506	74 %

The increase in product sales for the nine months ended September 30, 2014 as compared to the same period in 2013 was primarily due to the increased revenue from our own generic pharmaceutical product line that was launched in the first quarter of 2013, the launch of econazole nitrate cream 1% in September 2013 and the launch of two additional

IGI label products in June 2014. In addition we increased product sales in our contract services business to two of our pharmaceutical customers, which was only partially offset by decreased sales to two of our cosmetic 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. Licensing, royalty and other revenue decreased slightly due to a decrease in other revenue while licensing and royalty revenue remained the same.

Costs and expenses (in thousands):

	Nine Months Ended September 30,				
	2014	2013	$ Change	% Change	
Cost of sales	$ 11,603	$ 7,932	$3,671	46	%
Selling, general and administrative	3,563	2,078	1,485	71	%
Product development and research	5,045	2,123	2,922	138	%
Totals costs and expenditures	$ 20,211	$ 12,133	$8,078	67	%

Cost of sales increased for the nine months ended September 30, 2014 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 58% for the nine months ended September 30, 2014 as compared to 69% for the nine months ended September 30, 2013. Cost of sales as a percentage of total revenue declined as a result of an increase in revenue from our own generic pharmaceutical product line and a shift in the mix of our contract manufacturing product sales to include greater higher margin pharmaceutical products. We expect cost of sales as a percentage of product sales to decline over time.

Selling, general and administrative expenses for the nine months ended September 30, 2014 increased by $1,485,000 as compared to the same period in 2013. There were increases in salaries and related costs of $550,000 due to an increase in headcount, professional fees of $277,000, $478,000 in the expense from the issuance of stock based compensation related to options and restricted stock, travel related costs of $47,000, $60,000 in amortization of product acquisition costs and dues, subscriptions and corporate fees of $98,000 during the nine months ended September 30, 2014 as compared to the same period in 2013. These increases were partially offset by a decrease of $31,000 in trade show expenses.

Product development and research expenses for the nine months ended September 30, 2014 increased by $2,922,000 as compared to the same period in 2013. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased headcount, which resulted in an increase of $65,000 in salaries and related costs, we increased spending on clinical studies by $874,000, pilot batch expense by $677,000, outside testing and supplies by $529,000 and consulting fees by $248,000. In addition, fees related to the Generic Drug User Fee Act, and the associated filing of our applications with the FDA increased by $531,000.

Interest expense and other, net (in thousands):

	Nine Months Ended September 30,			
	2014	2013	$ Change	% Change
Interest expense	$ 163	$ 126	$37	29 %
Other (income) expense	$ 11	$ (5)	$16	320 %

Interest expense increased for the nine months ended September 30, 2014 as compared to the same period in 2013 due to the increase in the amount of the Note Payable – Bank (see Note 8 to the Company's Consolidated Financial Statements) outstanding during the nine months ended September 30, 2014 as compared to the same period in 2013.

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

	Nine Months Ended September 30,			
	2014	2013	$ Change	% Change
Net loss	$ (380)	$ (755)	$(375)	(50)%
Net loss per share	$ (0.01)	$ (0.02)	$(0.01)	(50)%

The decrease in net loss for the nine months ended September 30, 2014 as compared to the same period in 2013 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 $1,030,000 of cash during the nine months ended September 30, 2014 compared to $1,391,000 of cash used in operating activities during the nine months ended September 30, 2013. The cash used by operating activities for the nine months ended September 30, 2014 was partially a result of the net loss, in addition to non-cash expenses for the period offset by a net increase in operating assets and liabilities. The use of cash for the nine months ended September 30, 2013 was a result of the net loss and the changes in operating assets and liabilities, particularly a significant increase in accounts receivable related to the launch of our IGI label products.

The Company’s investing activities used $3,077,000 during the nine months ended September 30, 2014 compared to $2,049,000 of cash used in investing activities during the nine months ended September 30, 2013. The funds used for the nine months ended September 30, 2014 were for the purchase of products (see Note 10 to the Company’s Condensed Consolidated Financial Statements) and capital expenditures related to additional computer equipment and scientific equipment and improvements incurred to expand our R & D area. 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 Condensed Consolidated Financial Statements) and additional equipment and improvements in the compounding area and packaging and filling lines.

The Company's financing activities provided $25,254,000 of cash during the nine months ended September 30, 2014 compared to $2,306,000 of cash provided during the nine months ended September 30, 2013. The cash provided for the nine months ended September 30, 2014 was mainly the $24,870,000 proceeds from the issuance of stock (see Note 12 to the Company’s Consolidated Financial Statements) and the $565,000 proceeds from the exercise of common stock warrants and options and the cash provided for the nine month period ended September 30, 2013 was mainly the proceeds of $2,000,000 from the drawdown of the Note Payable (see Note 8 to the Company’s Consolidated Financial Statements) and $372,000 of proceeds from the exercise of common stock warrants and options.

The Company’s principal sources of liquidity are cash and cash equivalents of approximately $23,248,000 at September 30, 2014, the $2,000,000 available on the $5,000,000 credit facility detailed in Note 8 and future cash from operations. The Company had working capital of $22,179,000 at September 30, 2014. The Company will be required to pay up to an additional aggregate of $6,000,000 related to the assets purchased from AstraZeneca Pharmaceuticals LP (see Note 10).

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 November 2015.

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, 2013 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

This item is not required as we are a smaller reporting company.

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 September 30, 2014. Based on that evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that, as of September 30, 2014, 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 third 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. 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 December 19, 2013, we filed a complaint in the United States District Court for the District of Delaware against Mallinckrodt LLC, Mallinckrodt, Inc. and Nuvo Research Inc. (collectively, "Mallinckrodt") seeking a declaration of non-infringement of United States Patent Nos. 8,217,078 and 8,546,450 so that we can bring our generic diclofenac sodium topical solution 1.5% to market at the earliest possible date under applicable statutory and FDA regulatory provisions.

On January 10, 2014, Mallinckrodt filed an answer and counterclaim alleging that IGI Laboratories, Inc. infringes the patents at issue. On January 28, 2014, we filed a motion to dismiss Mallinckrodt's counterclaim and, on March 5, 2014, Mallinckrodt filed an opposition to such motion. On April 22, 2014, the court issued a Memorandum Order, granting in part and denying in part IGI's motion to dismiss Mallinckrodt's counterclaims.

On June 26, 2014, we entered into an agreement with Mallinckrodt to settle a declaratory judgment action brought by IGI, concerning our filing of an ANDA with the FDA seeking approval to market a generic version of Pennsaid® (diclofenac sodium topical solution) 1.5% w/w. Under the terms of this agreement, Mallinckrodt granted us a non-exclusive license to launch our diclofenac sodium topical solution 1.5% product on March 28, 2015. We received tentative approval of our diclofenac sodium topical solution 1.5% from the FDA on May 7, 2014.

ITEM 1A. Risk Factors.

Part I, Item 1A, “Risk Factors,” of our Annual Report on Form 10-K for the year ended December 31, 2013 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, 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. Four of our customers accounted for 59% of our revenue for the three months ended September 30, 2014 and three of our customers accounted for 49% of our revenue for the three months ended September 30, 2013. Four of our customers accounted for 53% of our revenue for the nine months ended September 30, 2014 and four of our customers accounted for 55% of our revenue for the nine months ended 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.

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, 2014, our stockholders’ equity was $33 million and we had an accumulated deficit of $45 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.

We may not be able to fully realize the expected benefits from the acquisition of certain products.

Our recent acquisition of certain products subjects us to additional operational and financial risks, including the following:

- additional costs that we may need to incur in order to return the products to the market and to comply with regulatory requirements;
- difficulties in coordinating research and development activities;
- uncertainties in the business relationships with our customers and suppliers; and
- lack of previous experiences in manufacturing, commercializing, and distributing products in therapeutic areas outside of the topical generic pharmaceutical market.

Our approved products may not achieve commercialization at levels of market acceptance that allow us to achieve profitability, which could have a material adverse effect on its business, financial position and results of operations.

We seek to develop, license or acquire products that we can commercialize at levels of market acceptance that would allow us to recoup the costs of development and commercialization, grow market share, and achieve profitability. Even if we are able to obtain regulatory approvals for certain pharmaceutical products, if we fail to accurately predict demand for such products, our business, financial position, and results of operations could be adversely impacted. Levels of market acceptance for products could be impacted by several factors, including but not limited to:

- the availability of alternative products from our competitors;
- the price of our products relative to that of our competitors;
- the effectiveness of our marketing relative to that of our competitors;
- the timing of our market entry;
- the ability to market our products effectively to the retail level; and
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control and, if any arises, our profitability, business, financial position and results of operations could be materially adversely affected.

Future acquisitions and investments could disrupt our business and harm our financial condition and operating results.

Our growth will depend, in part, on its continued ability to develop, commercialize and expand its drug products, including in response to changing regulatory and competitive pressures. In some circumstances, we accelerate our growth through the acquisition of complementary products and technologies rather than through internal development. The identification of suitable products to be acquired can be difficult, time-consuming and costly, and we may not be able to successfully complete or successfully execute strategies for identified acquisitions. The risks faced in connection with acquisitions include:

- diversion of management time and focus from operating the Company's business to addressing acquisition and/or product integration challenges;
- coordination of research and development and sales and marketing functions;
- retention of key employees from the acquired company;
- integration of the acquired company’s accounting, management information, human resources and other administrative systems;
- the need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked effective controls, procedures and policies;
- liability for activities of the acquired company and/or products before the acquisition, including patent infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company or product, including claims from product users, former stockholders or other third parties.

In any acquisition that we may undertake, our failure to address these risks or other problems encountered in connection with any acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally.

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, 2014, the average daily trading volume of our Common Stock on the NYSE MKT was approximately 506,000 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, 2014, 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: November 13, 2014 By: /s/ Jason Grenfell-Gardner
Jason Grenfell-Gardner
President and Chief Executive Officer

Date: November 13, 2014 By: /s/ Jenniffer Collins
Jenniffer Collins
Chief Financial Officer

Exhibit Index

Exhibit Number	Description
10.1†	Asset Purchase Agreement dated as of September 24, 2014, by and between IGI Laboratories, Inc. and AstraZeneca Pharmaceuticals LP
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, 2014, 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.

† Confidential treatment has been requested with respect to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission as part of an application for confidential treatment pursuant to the Securities and Exchange Act of 1934, as amended.