IGI LABORATORIES, INC
Form 10-Q
May 15, 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 March 31, 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	**01-0355758**
(State or other Jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
105 Lincoln Avenue **Buena, New Jersey**	**08310**
(Address of Principal Executive Offices)	*(Zip Code)*

(856) 697-1441

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes 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 47,122,121 shares, net of treasury stock, as of May 10, 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 March 31,	
	2014	**2013**
Revenues:		
Product sales, net	$ 6,383	$ 3,467
Research and development income	313	159
Licensing, royalty and other revenue	157	57
Total revenues	6,853	3,683
Costs and Expenses:		
Cost of sales	3,987	2,575
Selling, general and administrative expenses	1,282	679
Product development and research expenses	1,365	658
Total costs and expenses	6,634	3,912
Operating income (loss)	219	(229)
Interest expense and other, net	(52)	(28)
Net Income (Loss)	$ 167	$ (257)
Basic income (loss) per share	$0.00	$(0.01)
Diluted income (loss) per share	$0.00	$(0.01)
Weighted average shares of common stock outstanding:		
Basic	46,826,733	42,933,146

Diluted	48,529,603	42,933,146

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) March 31, 2014	December 31, 2013*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,414	$ 2,101
Accounts receivable, net	4,120	4,947
Inventories	2,661	2,869
Prepaid expenses and other receivables	691	641
Total current assets	9,886	10,558
Property, plant and equipment, net	2,598	2,623
Product acquisition costs	1,736	1,766
Restricted cash, long term	54	54
License fee, net	175	200
Debt issuance costs, net	61	69
Other	157	157
Total assets	$ 14,667	$ 15,427
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,339	$ 1,523
Accrued expenses	2,004	2,915
Deferred income, current	360	768
Capital lease obligation, current	11	15
Total current liabilities	3,714	5,221
Note payable, bank	3,000	3,000
Other long term liabilities	12	15
Total liabilities	6,726	8,236
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.01 par value, 60,000,000 shares authorized; 47,019,121 and 46,748,575 shares issued and outstanding as of March 31, 2014 and		

December 31, 2013, respectively		490		487
Additional paid-in capital		52,121		51,541
Accumulated deficit		(44,670)		(44,837)
Total stockholders equity		7,941		7,191
Total liabilities and stockholders equity	$	14,667	$	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

(in thousands)

(Unaudited)

	Three Months Ended March 31,	
	2014	**2013**
Cash flows from operating activities:		
Net income (loss)	$ 167	$ (257)
Reconciliation of net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	93	94
Amortization of license fee	25	25
Stock-based compensation expense	259	57
Provision for write down of inventory	14	12
Amortization of debt issuance costs	8	8
Amortization of product acquisition costs	30	-
Changes in operating assets and liabilities:		
Accounts receivable	827	(1,546)
Inventories	194	(279)
Prepaid expenses and other current assets	(50)	(211)
Accounts payable and accrued expenses	(1,095)	426
Deferred income	(409)	77
Net cash provided by (used in) operating activities	63	(1,594)
Cash flows from investing activities:		
Capital expenditures	(68)	(60)
Product acquisition costs	-	(1,426)
Net cash used in investing activities	(68)	(1,486)
Cash flows from financing activities:		
Proceeds from note payable, bank	-	1,000
Principal payments on capital lease obligation	(6)	(4)
Costs related to stock issuance	(3)	(42)
Proceeds from exercise of common stock warrants	327	236
Net cash provided by financing activities	318	1,190
Net increase (decrease) in cash and cash equivalents	313	(1,890)

Cash and cash equivalents at beginning of period	2,101	2,536
Cash and cash equivalents at end of period	$ 2,414	$ 646
Supplemental cash flow information:		
Cash payments for interest	54	9
Cash payment for taxes	7	8

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 three months ended March 31, 2014

(in thousands, except share information)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2013	46,748,575	$ 487	$ 51,541	$ (44,837)	$ 7,191
Stock based compensation expense stock options			75		75
Stock based compensation expense restricted stock			184		184
Stock warrants exercised	270,546	3	324		327
Costs related to stock issuance			(3)		(3)
Net income	-	-	-	167	167
Balance, March 31, 2014	47,019,121	$ 490	$ 52,121	$ (44,670)	$ 7,941

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

1. Organization

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 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.

Currently, we have two platforms for growth:

Manufacturing, developing, and marketing a portfolio of generic pharmaceutical products in our own label in topical dosage forms; and,
Increasing our current contract manufacturing and formulation services business.

In addition, we will 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 fourteen 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. 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.

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.

2. Liquidity

The Company s principal sources of liquidity are cash and cash equivalents of approximately $2,414,000 at March 31, 2014, the $2,000,000 available under the $5,000,000 credit facility detailed below and cash from operations. The Company had net income of $167,000 for the three months ended March 31, 2014 and a net loss of $257,000 for the three months ended March 31, 2013, and had working capital of $6,172,000 at March 31, 2014.

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 use of proceeds was intended for general working capital needs 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 also entered into a $3,000,000 line of credit. On July 26, 2013, the Company entered into an amendment to the loan and security agreement. The amendment increased the line of credit to $5,000,000 on December 31, 2013 upon the Company s compliance with certain covenants (See Note 8). As of March 31, 2014 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 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 May 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, 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.

Income (Loss) Per Share

Basic net income (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 income (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

March 31, 2013, the effect of the Company s potential dilutive common stock equivalents was anti-dilutive for that 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 calculation for the three months ended March 31, 2013 due to their anti-dilutive effect, and amounted to 6,160,610.

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.

Gross-To-Net Sales Deductions

Three months ended March 31,

	2014	2013
Gross IGI product sales	$ 5,025	$ 2,266
Reduction to gross product sales:		
Chargebacks and billbacks	1,584	660
Sales discounts and other allowances	498	190
Total reduction to gross product sales	$ 2,082	$ 850
Net IGI product sales	$ 2,943	$ 1,416

Accounts receivable are presented net of SRA balances of $1.5 million and $0.8 million at March 31, 2014 and 2013, respectively. Accounts payable and accrued expenses include $0.2 million and $0.3 million at March 31, 2014 and 2013, respectively, for certain fees related to services provided by the wholesalers. Wholesale fees of $0.2 million and $0.3 for the three month periods ended March 31, 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. The royalty is calculated based on contracted terms of 40% of net sales for the three 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 $0.9 million and $0.5 at March 31, 2014 and 2013, respectively, related to these royalties. Royalty expense of $1.3 million and $0.5 was included in cost of goods sold for the three months ended March 31, 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 March 31, 2014, three of our customers accounted for 50% of our revenue. For the three months ended March 31, 2013, four of our customers accounted for 70% of our revenue. One of these customers is the same for both periods. Accounts receivable related to the Company s major customers comprised 55% of all accounts receivable as of March 31, 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

There were no new accounting pronouncements for the three months ended March 31, 2014 that have a material impact on the Company s consolidated financial statements.

4. Inventories

Inventories are valued at the lower of cost, using the first-in, first-out (FIFO) method, or market. Inventories at March 31, 2014 and December 31, 2013 consist of:

	March 31, 2014 (Unaudited)	**December 31, 2013** (Audited)