

IGI LABORATORIES, INC  
Form 10-Q  
August 13, 2012

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended June 30, 2012**

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

**08310**  
*(Zip Code)*

**(856) 697-1441**

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  
 No

The number of shares outstanding of the issuer's common stock is 39,538,096 shares, net of treasury stock, as of August 3, 2012.

**PART I**  
**FINANCIAL INFORMATION**

**ITEM 1. Financial Statements.****IGI LABORATORIES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except share and per share information)

(Unaudited)

	<b>Three months ended June 30,</b>		<b>Six months ended June 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Revenues:				
Product sales	\$ 1,861	\$ 1,724	\$ 3,371	\$ 3,085
Research and development income	564	268	872	420
Licensing, royalty and other income	12	32	26	93
Total revenues	2,437	2,024	4,269	3,598
Cost and expenses:				
Cost of sales	1,683	1,393	3,049	2,634
Selling, general and administrative expenses	615	758	1,273	1,691
Product development and research expenses	644	752	1,116	1,131
Total costs and expenses	2,942	2,903	5,438	5,456
Operating loss	(505)	(879)	(1,169)	(1,858)
Interest expense and other, net	(83)	(68)	(154)	(122)
<b>Net loss</b>	<b>\$ (588)</b>	<b>\$ (947)</b>	<b>\$(1,323)</b>	<b>\$(1,980)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.01)</b>	<b>\$ (0.02)</b>	<b>\$ (0.03)</b>	<b>\$ (0.05)</b>
<b>Weighted Average of Common Stock and Common Stock Equivalents Outstanding</b>				
Basic and diluted	39,522,868	39,482,968	39,511,745	39,398,497

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)

	<b>June 30, 2012</b>	<b>December 31, 2011*</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,651	\$ 2,914
Accounts receivable, less allowance for doubtful accounts of \$16 as of June 30, 2012 and December 31, 2011	1,579	1,208
Inventories	1,246	1,195
Other receivables	9	239
Prepaid expenses	181	130
Total current assets	4,666	5,686
Property, plant and equipment, net	2,863	2,800
Restricted cash, long term	54	54
License fee, net	350	400
Debt issuance costs, net	558	639
Other	180	57
Total assets	\$ 8,671	\$ 9,636
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 740	\$ 629
Accrued expenses	658	611
Deferred income, current	39	38
Capital lease obligation, current	37	38
Total current liabilities	1,474	1,316
Note payable, related party	500	500
Deferred income, long term	22	25
Capital lease obligation, long term	43	30
Total liabilities	2,039	1,871

## Commitments and contingencies

## Stockholders' equity:

Series A Convertible Preferred stock, liquidation preference - \$500,000 at June 30, 2012 and December 31, 2011	500	500
Series C Convertible Preferred stock, liquidation preference - \$1,725,171 at June 30, 2012 and \$1,686,527 at December 31, 2011	1,517	1,517
Common stock	415	415
Additional paid-in capital	46,436	46,246
Accumulated deficit	(40,841)	(39,518)
Less treasury stock, 1,965,740 common shares at cost	(1,395)	(1,395)
Total stockholders' equity	6,632	7,765
Total liabilities and stockholders' equity	\$ 8,671	\$ 9,636

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

\* Derived from the audited December 31, 2011 financial statements.

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

(Unaudited)

	<b>Six months ended June 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(1,323)	\$(1,980)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation	172	156
Amortization of license fee	50	50
Stock-based compensation expense	164	185
Provision for write down of inventory	61	90
Amortization of debt issuance costs	81	81
Loss on abandonment of property	11	-
Changes in operating assets and liabilities:		
Accounts receivable	(371)	(549)
Inventories	(112)	(216)
Prepaid expenses and other assets	179	26
Accounts payable and accrued expenses	159	(43)
Deferred income	(2)	(9)
Net cash used in operating activities	(931)	(2,209)
<b>Cash flows from investing activities:</b>		
Capital expenditures	(336)	(78)
Net cash used in investing activities	(336)	(78)
<b>Cash flows from financing activities:</b>		
Proceeds from note payable, related party	-	500
Principal payments on capital lease obligation	(22)	(15)
Proceeds from exercise of common stock options	26	73
Net cash provided by financing activities	4	558
Net decrease in cash and cash equivalents	(1,263)	(1,729)
Cash and cash equivalents at beginning of period	2,914	5,116
Cash and cash equivalents at end of period	\$ 1,651	\$ 3,387



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Supplemental cash flow information:

Cash payments for interest	\$ 64	\$ 55
Cash payment for taxes	\$ 9	\$ 5

Non cash investing and financing transactions:

Equipment purchases financed through capital leases	\$ 30	\$ -
Cashless exercise of warrants	\$ -	\$ 2
Restricted stock forfeited	\$ -	\$ 1

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY**

**For the six months ended June 30, 2012**

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

	<b>Series A</b>		<b>Series C</b>		<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Treasury</b>	<b>Total</b>
	<b>Preferred</b>	<b>Stock</b>	<b>Preferred</b>	<b>Stock</b>	<b>Shares</b>	<b>Amount</b>	<b>Paid-In</b>	<b>Deficit</b>	<b>Stock</b>	<b>Stockholders</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Capital</b>			<b>Equity</b>
Balance, December 31, 2011 (Audited)	50	\$ 500	1,550	\$1,517	41,463,836	\$ 415	\$ 46,246	\$ (39,518)	\$(1,395)	\$ 7,765
Stock based compensation expense - stock options							51			51
Stock based compensation expense - restricted stock							113			113
Stock options exercised					40,000		26			26
Net loss	-	-	-	-	-	-	-	(1,323)	-	(1,323)
Balance, June 30, 2012 (Unaudited)	50	\$ 500	1,550	\$1,517	41,503,836	\$ 415	\$ 46,436	\$ (40,841)	\$(1,395)	\$ 6,632

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, 2011. The condensed consolidated balance sheet as of December 31, 2011 has been derived from those audited consolidated financial statements. Operating results for the six month period ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012.*

**1.**

**Organization**

IGI Laboratories, Inc. is a Delaware corporation formed in 1977. As used in this report, the terms the Registrant, the Company, IGI and IGI Laboratories refer to IGI Laboratories, Inc., unless the context requires otherwise. The Company's office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. IGI develops, manufactures, fills and packages topical semi-solid and liquid products for cosmetic, cosmeceutical and pharmaceutical customers. The Company's products are used for cosmetic, cosmeceutical and prescription applications for the treatment of symptoms of dermatitis, acne, psoriasis and eczema. The Company is building upon this foundation by filing its own Abbreviated New Drug Applications (ANDAs) and continuing to expand into the prescription pharmaceutical arena. The Company's strategy is based upon three initiatives: increasing the current contract services business, developing a portfolio of generic formulations in topical dosage forms and creating unique opportunities around its licensed Novasome® technology. All of its product development and manufacturing is performed at its 25,000 sq. ft. facility in Buena, NJ.

**2.**

**Liquidity**

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$1,651,000 at June 30, 2012, the \$2,500,000 available on the \$3,000,000 credit facility detailed below and cash from operations. The Company sustained a net loss of \$1,323,000 for the six months ended June 30, 2012, and had working capital of \$3,192,000 at June 30, 2012.

The Company's business operations have been primarily funded over the past three years through private placements of our capital stock. In 2010, we also entered into a \$3,000,000 line of credit. As of June 30, 2012, the outstanding balance on the line of credit was \$500,000. 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. It may be accomplished via 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 also have the ability to defer certain product development and other programs, if necessary. We believe that our existing capital resources will be sufficient to support our current business plan beyond August 2013.

### 3.

#### **Summary of Significant Accounting Policies**

##### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowance, stock based compensation, 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 June 30, 2012 and 2011 and the six months ended June 30, 2012 and 2011, the effect of the Company's potential dilutive common stock equivalents was anti-dilutive for each period; as a result, the basic and diluted weighted average number of common shares outstanding and net loss per common share are the same. Potentially dilutive common stock equivalents include options and warrants to purchase the Company's common stock and the conversion of preferred stock, which were excluded from the net loss per share calculations due to their anti-dilutive effect amounted to 6,058,641 for 2012 and 5,357,015 for 2011.

**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 manufactured product, licensing of technology, 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:** The Company recognizes revenue when title transfers to its customers, which is generally upon shipment of products. The revenues associated with these transactions, net of appropriate cash discounts, product returns and sales reserves, are recorded upon shipment of the products.

**Licensing and Royalty Income:** Revenues earned under licensing or sublicensing contracts are recognized as earned in accordance with the terms of the agreements. The Company recognizes royalty revenue based on royalty reports received from the licensee.

**Research and Development Income:** The Company enters into 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 each phase of development and when we have no future performance obligations relating to such phase of development. Revenue recognition requires the Company to assess progress against contracted obligations to assure completion of each stage. Payments under these arrangements are generally non-refundable and are reported as deferred until they are recognized as revenue. If no such arrangement exists, product development fees are recognized ratably over the entire period during which the services are performed.

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

### **Major Customers**

Major customers of the Company are defined as having revenue greater than 10% of total gross revenue. For the three months ended June 30, 2012, five of our customers accounted for 74% of our revenue. For the three months ended June 30, 2011, two of our customers accounted for 56% of our revenue. For the six months ended June 30, 2012 and 2011, three of our customers accounted for 64% and one of our customers accounted for 43% of our revenue, respectively. One of these customers is the same for all periods. Accounts receivable related to the Company's major customers comprised 90% of all accounts receivable as of June 30, 2012. 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 six months ended June 30, 2012 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 June 30, 2012 and December 31, 2011 consist of:

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
	(Unaudited)	(Audited)
	(amounts in thousands)	
Raw materials	\$ 1,184	\$ 1,070
Work in progress	49	16
Finished goods	13	109
Total	\$ 1,246	\$ 1,195

**5.****Stock-Based Compensation**

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

The 1999 Director Stock Option Plan, as amended (the Director Plan ), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. An aggregate of 1,975,000 shares have been approved and authorized for issuance pursuant to this plan. A total



of 2,049,798 options have been granted to non-employee directors through June 30, 2012 and 410,766 of those have been forfeited through June 30, 2012 and returned to the option pool. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years.

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

On June 26, 2009, the Board of Directors adopted, and the Company's stockholders subsequently approved by partial written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the 2009 Plan ). The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company's current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. On April 12, 2010, the Board of Directors adopted, and the Company's stockholders subsequently approved, an amendment and restatement of the 2009 Equity Incentive Plan to increase the number of shares of common stock available for grant under such plan by adding 2,000,000 shares of common stock. The 2009 Plan, as amended on May 19, 2010, authorizes up to 4,000,000 shares of the Company's common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of June 30, 2012, options to purchase 839,500 shares of common stock were outstanding under the 2009 Plan and 1,039,000 shares of restricted stock had been granted under the 2009 Plan.

On April 2, 2012, the Company granted a total of 283,500 options to purchase common stock to the current employees. These options were issued from the 2009 Equity Incentive Plan and had an exercise price of \$1.10, the closing price of the Company's stock on the date of the grant.

## Stock Options

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

	<b>For the six months ended June 30, 2012</b>	
Expected volatility	43.5%	54.5%
Expected term (in years)	3.2	3.3 years
Risk-free rate	0.53%	
Expected dividends	0%	

A summary of option activity under the 1999 Plan, the Director Plan and the 2009 Plan as of June 30, 2012 and changes during the period are presented below:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding as of January 1, 2012	1,448,016	\$1.16
Issued	459,500	\$1.10
Exercised	(40,000)	\$0.65
Forfeited	(30,000)	\$1.18
Expired	(15,000)	\$0.65
Outstanding as of June 30, 2012	1,822,516	\$1.16
Exercisable as of June 30, 2012	1,138,016	\$1.21

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options granted during the six months ended June 30, 2012 was \$0.38.

The following table summarizes information regarding options outstanding and exercisable at June 30, 2012:

**Outstanding:**

<b>Range of Exercise Prices</b>		<b>Stock Options Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life</b>
\$0.55	\$1.00	252,000	\$0.72	6.27
\$1.01	\$1.50	1,338,500	\$1.17	7.30
\$1.51	\$1.74	232,016	\$1.64	6.79
Total		1,822,516	\$1.16	7.09

**Exercisable:**

<b>Range of Exercise Prices</b>		<b>Stock Options Exercisable</b>	<b>Weighted Average Exercise Price</b>
\$0.55	\$1.00	252,000	\$0.71
\$1.01	\$1.50	654,000	\$1.26
\$1.51	\$1.74	232,016	\$1.64
Total		1,138,016	\$1.21

As of June 30, 2012, the intrinsic value of the options outstanding is \$78,900 and the intrinsic value of the options exercisable is \$78,840. The total intrinsic value of the options exercised during the six months ended June 30, 2012 was \$15,200. As of June 30, 2012, there was approximately \$214,000 of total unrecognized compensation cost that will be recognized through June 2015 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 approximately \$56,500 of compensation expense during each of the three months ended June 30, 2012 and 2011, and approximately \$113,000 of compensation expense during the six months ended June 30, 2012 and 2011 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At June 30, 2012, the Company had approximately \$145,000 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized from July 2012 through April 2013.

	<b>Number of Restricted Stock</b>	<b>Weighted Average Exercise Price</b>
Non-vested balance at January 1, 2012	626,000	\$ 0.71
Changes during the period:		
Shares granted	-	-
Shares vested	(313,000)	0.71
Shares forfeited	-	-
Non-vested balance at June 30, 2012	313,000	\$ 0.71

## 6.

### Income Taxes

As a result of the Company's history of continuing tax losses, the Company does not have a current tax provision and has recorded a full valuation allowance against its net deferred tax asset. The Company has not recorded a liability for unrecognized tax benefits at June 30, 2012 and no significant changes are expected in the next twelve months. The tax

years 2008-2011 remain open to examination by the major taxing jurisdictions to which the Company is subject.

There was no accrued interest related to unrecognized tax benefits at June 30, 2012.

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 is currently examining the application of Section 382 with respect to an ownership change that took place during 2009 and 2010, as well as the possibility of such limitation having any material effect on the application of net operating loss carry forwards in the immediate future. The Company believes that it is likely that a change in ownership took place and that the net operating loss carryforwards 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 exclusive use of the Novasome® lipid vesicle encapsulation and certain other technologies (each a Microencapsulation Technology, and collectively, the Technologies) in the fields of (i) animal pharmaceuticals, biologicals and other animal health products; (ii) foods, food applications, nutrients and flavorings; (iii) cosmetics, consumer products and dermatological over-the-counter and prescription products (excluding certain topically delivered hormones); (iv) fragrances; and (v) chemicals, including herbicides, insecticides, pesticides, paints and coatings, photographic chemicals and other specialty chemicals, and the processes for making the same (collectively, the IGI Field) through 2015. This payment is being amortized ratably over the ten-year period. The Company recorded amortization expense of \$25,000 related to this agreement for each of the three month periods ended June 30, 2012 and 2011 and amortization expense of \$50,000 related to this agreement for each of the six months ended June 30, 2012 and 2011.

8.

**Note Payable Related Party**

On December 21, 2010, the Company entered into a Credit Agreement with Amzak Capital Management, LLC (the *Lender*) pursuant to which the Lender has agreed to extend a \$3,000,000 credit facility to the Company (the *Credit Agreement*). The Company drew down \$500,000 in principal amount in March 2011.

To secure payment of the amounts financed under the Credit Agreement, the Company has granted to the Lender a security interest in and against, generally, all of its tangible and intangible assets, except intellectual property, pursuant to that certain Pledge and Security Agreement with the Lender dated December 21, 2010. In addition, the Company has pledged to the Lender its equity interests in IGEN, Inc., one of the Company's wholly-owned subsidiaries.

Under the Credit Agreement the Company has agreed to certain covenants customarily found in such agreements including, but not limited to, a covenant prohibiting the Company from entering into a merger or acquisition of the Company without the prior consent of the Lender if any advances remain outstanding and a covenant requiring the Company to maintain a certain loan to collateral ratio. Upon the breach of a covenant, without cure, the Lender will have certain remedies customarily found in such agreements including, but not limited to, the ability to cause all of the loans outstanding to be immediately due and payable and to terminate the Credit Agreement.

Upon funding of each Advance (as defined therein), the Company shall make payments of accrued interest on the unpaid Accreted Principal Amount (as defined therein) of each promissory note. The interest rate applicable to each promissory note shall be 14% per annum and interest payments are due on each March 31, June 30, September 30 and December 31 during the term of the Credit Agreement. The Company may prepay any Advance in connection with the consummation of a Liquidity Event (as defined therein) or at any time subsequent to December 21, 2012. On June 29, 2012, the Credit Agreement was amended to extend the termination of the right to receive advances from June 30, 2012 to August 31, 2012.

In addition, as consideration for entering into the Credit Agreement, on December 21, 2010, the Company issued to the Lender a ten-year warrant to purchase certain shares of the Company's common stock, at an exercise price of \$0.01 per share (the *Warrant*). The Warrant is immediately exercisable for 881,331 shares of Common Stock (the *Initial Warrant Shares*) with the remaining shares of Common Stock representing 1% of the Fully Diluted Shares (as defined therein) as of the Conditional Warrant Exercise Date (as defined therein) (the *Conditional Warrant Shares*) becoming exercisable July 1, 2012 if the Company has achieved certain milestones related to the Company's product

development or financial growth. The Warrant is accounted for as an equity instrument. The fair value of the Initial Warrant of \$723,541 will be recorded as debt issuance costs and amortized on a straight-line basis over the stated term of the Credit Agreement which is five years. Amortization expense of \$40,000 was recognized for each of the three months ended June 30, 2012 and 2011 and \$81,000 for each of the six months ended June 30, 2012 and 2011. The Company anticipates amortization expense to be approximately \$160,000 for the years 2012 to 2016. On December 21, 2010, the fair value of the Conditional Warrant was not considered to be material. The Company completed its obligations under certain milestones related to the Company's product development, and as such the Conditional Warrant will not be exercisable, and no additional expense was recognized.

The complete statement of the parties' rights and obligations under the Credit Agreement, the Pledge and Security Agreement, the Warrant and the Registration Rights Agreements is qualified in its entirety by reference to the terms and conditions of such documents which are filed as exhibits to the Company's Current Report on Form 8-K filed on December 22, 2010.

The Lender is a shareholder of the Company and participated in the private placement previously disclosed in a Current Report on Form 8-K filed with the Securities and Exchange Commission on December 8, 2010.

## 9.

**Stock Warrants**

Stock Warrants activity for the quarters ended June 30, 2012 and 2011 consisted of:

	<u>2012</u>	<u>Weighted</u>	<u>2011</u>	<u>Weighted</u>
	<u>Warrants</u>	<u>Average</u>	<u>Warrants</u>	<u>Average</u>
		<u>Exercise Price</u>		<u>Exercise Price</u>
Beginning balance	1,235,877	\$0.35	1,498,377	\$0.36
Stock warrants granted	-	-	-	-
Stock warrants expired	-	-	-	-
Stock warrants exercised	-	-	(262,500)	0.41
Ending balance	1,235,877	\$0.35	1,235,877	\$0.35

In connection with the private placement of the Company's Common Stock on December 8, 2010, the Company granted Common Stock Warrants to purchase 338,182 and 16,364, respectively, to each of its two placement agents for \$1.21 per share which expire on December 8, 2015.

In connection with the Credit Agreement with the Lender as more fully described in Note 8, the Company issued a ten-year warrant to purchase 881,331 shares of the Company's Common Stock for \$.01 per share.

In connection with the private placement offering to certain investment funds affiliated with Signet Healthcare Partners, G.P. (the Offering) on March 13, 2009, the Company granted its placement agent for the Offering a Common Stock Warrant to purchase 350,000 shares of common stock for \$0.41 per share, which expires on March 13, 2012. On December 2, 2009, the Common Stock Warrant was amended to include a partial transfer for 87,500 shares of common stock. On December 2, 2009, the warrant to purchase 87,500 was exercised using the Cashless Exercise provision and 51,681 shares of common stock were issued. On February 25, 2011, the warrant to purchase the remaining 262,500 shares of common stock was exercised using the Cashless Exercise provision and 200,646 shares of common stock were issued.



**10.**

**Changes in the Board of Directors**

On April 25, 2012, Jane E. Hager notified the Company and its Board of Directors of her decision to retire from the Board of Directors and not to stand for re-election at the Company's 2012 annual meeting of stockholders (the Annual Meeting). Ms. Hager continued to serve as a director until the Annual Meeting that was held on May 22, 2012.

**11.**

**Subsequent Events**

On July 30, 2012, the Company announced that Jason Grenfell-Gardner has been appointed the Company's new President and Chief Executive Officer, effective July 30, 2012. Charles E. Moore left his employment with the Company and resigned as a member of the Company's board of directors (the Board), effective July 30, 2012. The Board appointed Mr. Grenfell-Gardner to fill the vacant Board seat created by Mr. Moore's resignation, effective July 30, 2012.

The Company entered into an employment agreement with Mr. Grenfell-Gardner, effective as of July 30, 2012. Under the terms of such employment agreement, Mr. Grenfell-Gardner will receive an annual salary of \$315,000. As soon as practicable following the effective date of his employment agreement and subject to the approval of the Board, Mr. Grenfell-Gardner will also receive an award of 325,000 shares of restricted stock, an option to purchase 975,000 shares of the Company's common stock (the Primary Option ) and a supplemental option to purchase 50,000 shares of the Company's common stock (the Supplemental Option ), the vesting terms of which are explained below. In addition, Mr. Grenfell-Gardner will be entitled to participate in certain of the Company's benefit programs on the same terms and conditions generally provided by the Company to its executive employees. Mr. Grenfell-Gardner will also be eligible to receive an annual performance bonus for each calendar year during the term of his employment, which may be payable in either, cash, stock options and/or restricted stock. Mr. Grenfell-Gardner's target bonus will be equal to 70% of his base salary for the applicable fiscal year. All performance targets pursuant to such plan shall be determined by the Board's Compensation Committee. Mr. Grenfell-Gardner is also subject to certain restrictive covenants as set forth in his employment agreement, including confidentiality, non-solicitation and non-competition covenants. Mr. Grenfell-Gardner's employment agreement further provides for payments upon certain types of employment termination events as further set forth in his employment agreement.

The above referenced stock option grants will have an exercise price equal to the closing price of the Company's common stock on the date of grant, and the Primary Option and the restricted stock will become fully vested over a period of three years as follows: (i) one-third shall vest on the first anniversary of the date of the grant; (ii) one-third shall vest on the second anniversary of the date of the grant and (iii) one-third shall vest on the third anniversary of the date of the grant. One-half of the shares subject to the Supplemental Option shall become fully vested immediately upon their grant and the remaining one-half of the shares subject to such award shall vest on the first anniversary of the effective date of Mr. Grenfell-Gardner's employment. In addition, any options or restricted stock that remain unvested immediately prior to a change in control will become vested, provided that the executive remains in continuous service with the Company through the consummation of the change in control.

## **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 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 Company undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

### **Company Overview**

#### *Strategic Overview*

IGI is engaged in the formulation, development, manufacture and packaging of topical semi-solid and liquid products for pharmaceutical, cosmeceutical and cosmetic customers. The Company's strategic plan is to build upon this foundation by expanding into the prescription pharmaceutical arena. This strategy is based upon three initiatives: increasing the current contract manufacturing and contract formulation services business, developing a generic portfolio of formulations in topical dosage forms, and creating unique opportunities around the Company's licensed Novasome® technology and novel dosage forms.

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

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

IGI plans to build a prescription pharmaceutical portfolio in the specialty areas of topical dosage forms. This will be accomplished through in-house formulation and development, and submission of ANDAs to the FDA. The entire approval process can take 3-5 years before a product is approved, of which the FDA approval portion is approximately 18 - 36 months, with an average review time currently of 32 months. The Company's target is to submit 4-6 ANDAs each year. To date, IGI has submitted eight ANDAs. We filed one application in September 2010, January 2011 and December 2011, two applications in November 2011, one application in May 2012 and two applications in June of 2012. All of the submissions are for generic topical prescription drugs.

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

*Recent Events*

During the first six months of 2012, the Company entered into supply agreements with two new customers. Both agreements call for the Company to manufacture and package topical pharmaceutical products.

The first agreement was with a brand pharmaceutical company and provides for the site transfer of a well-recognized branded topical drug product to the Company's facility in Buena, NJ. The Company will be the sole manufacturing and packaging site for the product.

Under the second agreement, the Company will develop generic versions of two topical drug products on behalf of the customer. Upon FDA approval, the Company will manufacture and package the products in the customer's label.

In February 2012, the Company successfully completed our first pre-approval inspection with the FDA.

During the second quarter of 2012, the Company submitted three additional ANDAs with the US FDA, bringing the total number of the Company's submissions to date to eight.

*Results of Operations*

**Three months ended June 30, 2012 compared to June 30, 2011**

The Company had a net loss of \$588,000, or \$0.01 per share, for the three months ended June 30, 2012, compared to \$947,000, or \$0.02 per share, in the comparable period for 2011, which resulted from the following:

**Revenues (in thousands):**

<b>Components of Revenue:</b>	<b>Three Months Ended June 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2012</b>	<b>2011</b>	<b>\$</b>	<b>%</b>
<b>Product sales</b>	\$1,861	\$1,724	\$ 137	8 %
<b>Research and development income</b>	564	268	296	110 %
<b>Licensing, royalty, and other income</b>	12	32	(20)	(63)%
<b>Total Revenues</b>	\$2,437	\$2,024	\$ 413	20 %

The increase in product sales for the three months ended June 30, 2012 as compared to the same period in 2011 was primarily due to increased product sales to the one of the Company's major customer. The increase in research and development income during the three months ended June 30, 2012 as compared to the same period in 2011 is attributable to new customer relationships established in the first quarter of 2012 and their desire to have the Company develop, manufacture and package their new products or line extensions and the continued strong relationships with our current customer base. Licensing, royalty and other income decreased due to the decrease in sales of Novasome based products marketed by our licensees. The Company believes the loss of certain royalties is related to the normal life cycle of the products and that certain royalties of the Company may continue to decline.

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

	<b>Three Months Ended June 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2012</b>	<b>2011</b>	<b>\$</b>	<b>%</b>
<b>Cost of sales</b>	\$1,683	\$1,393	\$ 290	21 %
<b>Selling, general and administrative</b>	615	758	(143)	(19)%
<b>Product development and research</b>	644	752	(108)	(14)%
<b>Totals costs and expenditures</b>	\$2,942	\$2,903	\$ 39	1 %

Cost of sales increased for the three months ended June 30, 2012 as a result of increased product sales as compared to the same period in 2011. Cost of sales as a percentage of revenue was 69% for the three month period ended June 30, 2012 as compared to 69% for the comparable period in 2011. Cost of sales as a percentage of product sales can vary depending on product mix. Cost of sales percentage remained unchanged due to the product mix in both periods, an increase in the reserves for obsolete and expired inventory and partially offset by the increased manufacturing of product for the contract manufacturing and contract formulation business for the three months ended June 30, 2012, which allowed the Company to absorb more of its overhead costs.

Selling, general and administrative expenses for the three month period ended June 30, 2012 decreased by \$143,000 as compared to the same period in 2011 as a result of a decrease of \$85,000 in professional fees, a decrease of \$43,000 in recruiting fees, a decrease of \$25,000 in the allocation of overhead costs due to the changes in headcount in the departments as compared to the prior year, a decrease of \$19,000 in listing fees, a decrease of \$12,000 in expenses related to stockholder meetings and reports and a decrease of \$5,000 in compensation payable in stock, offset by an increase of \$49,000 in salaries and related expenses.

Product development and research expenses for the three months ended June 30, 2012 decreased by \$108,000 as compared to the same period for 2011 as follows. Clinical studies, pilot batch expense and outside testing decreased by \$185,000. These decreases were partially offset by an increase of \$38,000 in salaries and related costs, an increase of \$25,000 in overhead costs related to repairs and maintenance and a change in the allocation of overhead costs due to the changes in headcount in the departments as compared to the prior year.

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

	Three Months Ended June 30,		Increase/(Decrease)	
	2012	2011	\$	%
Interest Income	\$ -	\$(4)	\$(4)	(100)%
Interest Expense	\$72	\$72	\$ -	0 %
Other Expense	\$11	\$ -	\$11	100 %

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

	Three Months Ended June 30,		Increase/(Decrease)	
	2012	2011	\$	%
Net loss	\$(588)	\$(947)	\$(359)	(38)%
Net loss per share	\$ (.01)	\$ (.02)	\$ (.01)	(50)%

The decrease in net loss for the three months ended June 30, 2012 as compared to the same period in 2011 is due to the increase in revenues notes above and the decrease in costs and expenses also noted above.

#### Six months ended June 30, 2012 compared to June 30, 2011

The Company had a net loss of \$1,323,000, or \$0.03 per share, for the six months ended June 30, 2012, compared to \$1,980,000, or \$0.05 per share, in the comparable period for 2011, which resulted from the following:

#### Revenues (in thousands):

Components of Revenue:	Six Months Ended June 30,		Increase/(Decrease)	
	2012	2011	\$	%
Product sales	\$3,371	\$3,085	\$286	9 %
Research and development income	872	420	452	108 %
Licensing, royalty and other income	26	93	(67)	(72)%
Total Revenues	\$4,269	\$3,598	\$671	19 %



The increase in product sales for the six months ended June 30, 2012 as compared to the same period in 2011 was primarily due to increased product sales to the one of the Company's major customer. The increase in research and development income during the three months ended June 30, 2012 as compared to the same period in 2011 is attributable to new customer relationships established in the first quarter of 2012 and their desire to have the Company develop, manufacture and package their new products or line extensions and the continued strong relationships with our current customer base. Licensing, royalty and other income decreased due to the decrease in sales of Novasome based products marketed by our licensees. The Company believes the loss of certain royalties is related to the normal life cycle of the products and that certain royalties of the Company may continue to decline.

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

	<b>Six Months Ended June 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2012</b>	<b>2011</b>	<b>\$</b>	<b>%</b>
<b>Cost of sales</b>	\$3,049	\$2,634	\$ 415	16 %
<b>Selling, general and administrative</b>	1,273	1,691	(418)	(25)%
<b>Product development and research</b>	1,116	1,131	(15)	(1)%
<b>Totals costs and expenditures</b>	\$5,438	\$5,456	\$ (18)	(0)%

Cost of sales increased for the six months ended June 30, 2012 as a result of increased product sales as compared to the same period in 2011. Cost of sales as a percentage of revenue was 71% for the six month period ended June 30, 2012 as compared to 73% for the comparable period in 2011. Cost of sales as a percentage of product sales can vary depending on product mix. Cost of sales percentage improved due to the product mix in both periods and increased product sales and research and development income for the three months ended June 30, 2012, which allowed the Company to absorb more of its overhead costs.

Selling, general and administrative expenses for the six month period ended June 30, 2012 decreased as compared to the same period in 2011 due to a decrease of \$170,000 in professional fees, a net decrease in salaries and related expenses of \$80,000 due to severance agreements of \$164,000 in 2011, a decrease of \$57,000 in the allocation of overhead costs due to the changes in headcount in the departments as compared to prior year, a decrease of \$56,000 in consulting fees, a decrease of \$31,000 in compensation payable in stock and a decrease of \$19,000 in listing fees, partially offset by an increase in recruiting fees of \$18,000.

Product development and research expenses for the six months ended June 30, 2012 decreased as compared to the same period for 2011 as follows. Clinical Studies and outside testing decreased by \$287,000, partially offset by an increase of \$142,000 in pilot batch expense, an increase of \$54,000 in salaries and related expenses, an increase of \$30,000 in consulting fees, an increase of \$38,000 in overhead due to repairs and maintenance and an increase in the

allocation of overhead costs due to the changes in headcount in the departments from prior year.

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

	Six Months Ended June 30,		Increase/(Decrease)	
	2012	2011	\$	%
<b>Interest Income</b>	\$ -	\$ (11)	\$(11)	(100)%
<b>Interest Expense</b>	\$144	\$135	\$ 9	7 %
<b>Other (Income) Expense</b>	\$ 10	\$ (2)	\$ 12	600 %

Interest income decreased for the six months ended June 30, 2012 as compared to the same period in 2011 due to lower cash balances in 2012. Interest expense increased for the six months ended June 30, 2012 as compared to the same period in 2011 due the fact that \$500,000 of the Notes Payable Related Party (See Note 8) was drawn down in March 2011, and the debt was outstanding during the full six months ended June 30, 2012.

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

	<b>Six Months Ended June 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2012</b>	<b>2011</b>	<b>\$</b>	<b>%</b>
<b>Net loss</b>	\$ (1,323)	\$ (1,980)	\$ (657)	(33)%
<b>Net loss per share</b>	(.03)	(.05)	(.02)	(40)%

The decrease in net loss for the six months ended June 30, 2012 as compared to the same period in 2011 is due to the increase in revenues notes above and the decrease in costs and expenses also noted above.

**Liquidity and Capital Resources**

The Company's operating activities used \$0.9 million of cash during the six months ended June 30, 2012 compared to \$2.2 million used in the comparable period of 2011. The use of cash for both the six months ended June 30, 2012 and 2011 was substantially a result of the net loss for each period, which included costs related to product development and research of \$1.1 million and \$1.1 million for the six months ended June 30, 2012 and 2011, respectively.

The Company's investing activities used \$0.3 million of cash in the six months ended June 30, 2012 compared to \$0.1 million of cash used in investing activities in the first six months of 2011. The funds used for the periods ended June 30, 2012 and 2011 were for additional equipment and improvements for the compounding area, packaging and filing lines and additional equipment and related services for the analytical area.

The Company's financing activities provided \$4,000 of cash in the six months ended June 30, 2012 compared to \$0.6 million provided in the six months ended June 30, 2011. The cash provided for the six month period ended June 30, 2012 was the proceeds from the exercise of stock options less payments on capital lease obligations. The cash provided for the six month period ended June 30, 2011 was mainly the proceeds from the draw down of the Note Payable Related Party as more fully described in Note 8 to the Company's Consolidated Financial Statements.

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$1.6 million at June 30, 2012 and future cash from operations. The Company had working capital of \$3.2 million at June 30, 2012.

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 including the remaining \$2.5 million availability under the line of credit detailed in Note 8 will be sufficient to support our current business plan beyond August 2013.

### **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, 2011 for a complete list of all Critical Accounting Policies and Estimates. See also Note 3 to the Company's Consolidated Financial Statements.

**ITEM 4. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2012. Based on that evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that, as of June 30, 2012, the Company's disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including our Chief Executive Officer and Acting Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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

## **PART II**

### **OTHER INFORMATION**

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

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

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

Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2011 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, 2011 have not materially changed.

#### **Risks Related to Our Business**

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

We depend on a limited number of customers for a large portion of our revenue. For the three months ended June 30, 2012 and 2011, five of our customers accounted for 74% and two of our customers accounted for 56% of our revenue,

respectively. For the six months ended June 30, 2012 and 2011, three of our customers accounted for 64% and one of our customers accounted for 43% of our revenue, respectively. The loss of one or more of these customers could have a significant impact on our revenues and harm our business and results of operations.

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

Our expenses have exceeded our revenue in each of the last eight years, and no net income has been available to common stockholders during each of these years. As of June 30, 2012, our stockholders' equity was \$6.7 million and we had an accumulated deficit of \$41 million. Our future profitability depends on revenue exceeding expenses, but we cannot assure you that this will occur. If we do not become profitable or continue to raise external financing, we could be forced to curtail operations and sell or liquidate our business, and you could lose some or all of your investment.

### **Risks Related to Our Securities**

**Shares of our Common Stock are relatively illiquid which may affect the trading price of our Common Stock.**

For the six months ended June 30, 2012, the average daily trading volume of our Common Stock on the NYSE Amex was approximately 6,600 shares. As a result of our relatively small public float, our Common Stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our Common Stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

**If we fail to meet the continued listing standards of the NYSE Amex our Common Stock could be delisted and our stock price could suffer.**

On May 6, 2008, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. Specifically, we are required to reflect income from continuing operations and/or net income in one of our five most recent fiscal years and a minimum of \$6 million in stockholders' equity to remain listed on the exchange. We had net income from continuing operations in our 2002 fiscal year, but had net losses and losses from continuing operations in each of our 2003 through 2011 fiscal years. Our stockholders' equity at June 30, 2012 was \$6.7 million.





On June 8, 2008, we submitted a plan to NYSE Amex for compliance with the continued listing standards. On July 15, 2008, NYSE Amex notified us of its acceptance and granted us an extension until May 6, 2009 to regain compliance subject to periodic review by NYSE Amex during the extension period.

On March 13, 2009, we completed a \$6,000,000 private placement offering with certain investment funds affiliated with Signet Healthcare Partners, G.P. In recognition of our efforts in connection with the offering, NYSE Amex granted us an extension from May 6, 2009 until May 31, 2009 to regain compliance with these continued listing standards.

On June 19, 2009, we were notified by NYSE Amex that we had resolved its continued listing deficiencies and would retain our status as a listed issuer on NYSE Amex. However, as of March 31, 2010 and December 31, 2009, our stockholders equity had again fallen below the \$6 million threshold.

On May 25, 2010, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. Specifically, we are required to reflect a minimum of \$6 million in stockholders equity to remain listed on the exchange. On June 24, 2010, we submitted a plan to NYSE Amex for compliance with the continued listing standards, which included our plan to increase our stockholders equity through additional offerings.

On August 6, 2010, NYSE Amex notified us that it accepted our plan of compliance and granted us an extension until February 25, 2011 to regain compliance with the continued listing standards. We were subject to periodic review by NYSE Amex Staff during the extension period. On December 10, 2010, NYSE Amex notified us that we had resolved our continued listing deficiencies referenced in its May 2010 letter, and that we were in compliance with the NYSE Amex alternative listing standards, which require at least a \$50 million market capitalization.

If we fail to meet the continued listing standards, our Common Stock could be delisted and our stock price could suffer. A delisting of our Common Stock could negatively impact us by further reducing the liquidity and market price of our Common Stock and the number of investors willing to hold or acquire our Common Stock, which could negatively impact our ability to raise equity financing.

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

None.

**ITEM 3. Defaults Upon Senior Securities.**

None.

**ITEM 4. (Removed and Reserved).**

**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.