

IGI LABORATORIES, INC  
Form 10-Q  
November 15, 2010

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE**

**ACT OF 1934**

**For the quarterly period ended September 30, 2010**

..

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

**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 35,373,112 shares, net of treasury stock, as of November 10, 2010.

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

(in thousands, except share and per share information)

(Unaudited)

|  | Three months ended September 30, |                 | Nine months ended September 30, |                  |
|--|----------------------------------|-----------------|---------------------------------|------------------|
|  | <u>2010</u>                      | <u>2009</u>     | <u>2010</u>                     | <u>2009</u>      |
| Revenues:  |                                  |                 |                                 |                  |
| Product sales  | \$ 1,531                         | \$ 668          | \$ 3,814                        | \$ 2,172         |
| Research and development income                      | 165                              | 83              | 348                             | 149              |
| Licensing and royalty income                         | 48                               | 47              | 206                             | 213              |
| Total revenues                                       | 1,744                            | 798             | 4,368                           | 2,534            |
| Cost and expenses:                                   |                                  |                 |                                 |                  |
| Cost of sales  | 1,286                            | 691             | 3,760                           | 2,220            |
| Selling, general and administrative expenses         | 760                              | 758             | 2,482                           | 2,717            |
| Product development and research expenses            | 373                              | 273             | 1,027                           | 542              |
| Operating loss                                       | (675)                            | (924)           | (2,901)                         | (2,945)          |
| Interest income (expense) and other income, net      | (4)                              | 6               | (1)                             | (945)            |
| <b>Net loss</b>                                      | <b>(679)</b>                     | <b>(918)</b>    | <b>(2,902)</b>                  | <b>(3,890)</b>   |
| Preferred stock dividends                            | (1,284)                          | -               | (1,284)                         | -                |
| Dividend accreted for beneficial conversion features | -                                | -               | -                               | (2,488)          |
| <b>Net Loss Attributable to Common Stockholders</b>  | <b>\$(1,963)</b>                 | <b>\$(918)</b>  | <b>\$(4,186)</b>                | <b>\$(6,378)</b> |
| <b>Basic and diluted loss per share</b>              | <b>\$ (.08)</b>                  | <b>\$ (.05)</b> | <b>\$ (.21)</b>                 | <b>\$ (.40)</b>  |

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

|                   |            |            |            |            |
|-------------------|------------|------------|------------|------------|
| Basic and diluted | 24,876,399 | 17,243,830 | 20,071,518 | 15,916,673 |
|-------------------|------------|------------|------------|------------|

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>September 30,<br/>2010<br/>(unaudited)</b> | <b>December 31,<br/>2009*</b> |
|---|---|-------------------------------|
| <b>ASSETS</b>   |   |                               |
| Current assets:   |   |                               |
| Cash and cash equivalents   | \$ 192  | \$ 1,124                      |
| Accounts receivable, less allowance for doubtful accounts<br>of \$90 in 2010 and 2009 | 654   | 741                           |
| Licensing and royalty income receivable   | 29  | 67                            |
| Inventories   | 886   | 874                           |
| Prepaid expenses and other current assets   | 326   | 212                           |
| Total current assets  | 2,087   | 3,018                         |
| Property, plant and equipment, net  | 2,826   | 2,764                         |
| Restricted cash, long term  | 54  | 54                            |
| License fee, net  | 525   | 600                           |
| Other   | 68  | 20                            |
| Total assets  | \$ 5,560                                      | \$ 6,456                      |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>  |   |                               |
| Current liabilities:  |   |                               |
| Accounts payable  | \$ 700  | \$ 542                        |
| Accrued expenses  | 242   | 422                           |
| Deferred income, current  | 86  | 137                           |
| Capital lease obligation, current   | 30  | -                             |
| Total current liabilities   | 1,058   | 1,101                         |
| Long term liabilities:  |   |                               |
| Deferred income, long term  | 31  | 34                            |
| Capital lease obligation, long term   | 77  | -                             |
| Total long term liabilities   | 108   | 34                            |
| Total liabilities   | 1,166   | 1,135                         |
| Commitments and contingencies   |   |                               |
| Stockholders equity:  | 500   | 500                           |

Series A Convertible Preferred stock, \$.01 par value, 100 shares authorized;  
50 shares

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|  |          |          |
|--|----------|----------|
| issued and outstanding as of September 30, 2010 and December 31, 2009;   |          |          |
| liquidation preference - \$500,000   |          |          |
| Series B-1 Convertible Preferred stock, \$.01 par value, 1,030 shares authorized; 0 and 1,006.879 shares issued and outstanding as of September 30, 2010 and December 31, 2009; liquidation preference - \$6,351,466         | -        | 5,852    |
| Series C Convertible Preferred stock, \$.01 par value, 1,550 shares authorized; 1,550 and 0 shares issued and outstanding as of September 30, 2010 and December 31, 2009, respectively; liquidation preference - \$1,589,493 | 1,517    | -        |
| Common stock, \$.01 par value, 50,000,000 shares authorized; 35,373,112 and 19,302,987 shares issued 33,407,372 and 17,337,247 shares outstanding as of September 30, 2010 and December 31, 2009, respectively               | 353      | 193      |
| Additional paid-in capital   | 39,409   | 31,975   |
| Accumulated deficit  | (35,990) | (31,804) |
| Less treasury stock, 1,965,740 common shares at cost   | (1,395)  | (1,395)  |
| Total stockholders' equity   | 4,394    | 5,321    |
| Total liabilities and stockholders' equity   | \$ 5,560 | \$ 6,456 |

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

\* Derived from the audited December 31, 2009 financial statements

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

(in thousands)

(Unaudited)

|  | <b>Nine months ended September 30,</b> |             |
|--|--|-------------|
|  | <b>2010</b>                            | <b>2009</b> |
| <b>Cash flows from operating activities:</b>                         |  |             |
| Net loss   | \$(2,902)                              | \$(3,890)   |
| Reconciliation of net loss to net cash used in operating activities: |  |             |
| Depreciation   | 198                                    | 183         |
| Amortization of license fee  | 75                                     | 75          |
| Bad debt expense   | -                                      | 11          |
| Stock-based compensation expense                                     | 450                                    | 327         |
| Directors' compensation payable in stock                             | -                                      | 48          |
| Interest expense on convertible note payable                         | -                                      | 41          |
| Amortization of discount on convertible note payable                 | -                                      | 33          |
| Amortization of discount on convertible note payable - related party | -                                      | 211         |
| Amortization of debt issuance costs                                  | -                                      | 659         |
| Changes in operating assets and liabilities:                         |  |             |
| Accounts receivable  | 87                                     | 82          |
| Licensing and royalty income receivable                              | 38                                     | 53          |
| Inventories  | (12)                                   | (370)       |
| Prepaid expenses and other assets                                    | (125)                                  | (78)        |
| Accounts payable and accrued expenses                                | (22)                                   | 74          |
| Deferred income  | (54)                                   | 172         |
| Net cash used in operating activities                                | (2,267)                                | (2,369)     |
| <b>Cash flows from investing activities:</b>                         |  |             |
| Capital expenditures   | (138)                                  | (624)       |
| Deposit for capital lease  | (37)                                   | -           |
| Net cash used in investing activities                                | (175)                                  | (624)       |
| <b>Cash flows from financing activities:</b>                         |  |             |
| Sale of Series C Convertible Preferred Stock, net of expenses        | 1,517                                  | -           |
| Principal payments on capital lease obligation                       | (15)                                   | -           |
| Sale of Series B-1 Convertible Preferred Stock, net of expenses      | -                                      | 1,073       |
| Proceeds from issuance of convertible note payable, net of expenses  | -                                      | 4,206       |
| Proceeds from exercise of common stock options                       | 8                                      | 24          |
| Recovery from stockholder, net                                       | -                                      | 4           |
| Net cash provided by financing activities                            | 1,510                                  | 5,307       |

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|   |        |          |
|---|--------|----------|
| Net increase (decrease) in cash and cash equivalents                                      | (932)  | 2,314    |
| Cash and cash equivalents at beginning of period  | 1,124  | 171      |
| Cash and cash equivalents at end of period  | \$ 192 | \$ 2,485 |
| Supplemental cash flow information:   |        |          |
| Cash payments for interest  | \$ 5   | \$ 14    |
| Cash payment for taxes  | -      | 11       |
| Non cash transactions:  |        |          |
| Equipment financed  | \$ 122 | \$ -     |
| Issuance of restricted stock  | 10     | 11       |
| Forfeiture of restricted stock  | (7)    | -        |
| Dividend accreted for beneficial conversion features                                      | -      | 2,488    |
| Issuance of stock to directors for compensation that was previously accrued               | -      | 20       |
| Conversion of note payable and accrued interest to Series B-1 Convertible Preferred Stock | -      | 4,779    |
| Conversion of note payable related party to common stock                                  | -      | 464      |
| Conversion of Series B-1 Convertible Preferred Stock into Common Stock                    | 7,136  | -        |

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, 2010

(in thousands, except share information)

|  | Series A<br>Preferred Stock |        | Series B-1<br>Convertible Preferred Stock |         | Series C<br>Convertible Preferred Stock |        | Common Stock |        | Additional         | Accumulated | Treasu  |
|--|-----------------------------|--------|---|---------|---|--------|--------------|--------|--------------------|-------------|---------|
|  | Shares                      | Amount | Shares                                    | Amount  | Shares                                  | Amount | Shares       | Amount | Paid-In<br>Capital | Deficit     | Stock   |
| Balance,<br>December 31,<br>2009<br>(Audited)  | 50                          | \$ 500 | 1,007                                     | \$5,852 | -                                       | \$ -   | 19,302,987   | \$ 193 | \$ 31,975          | \$ (31,804) | \$(1,39 |
| Issuance of<br>preferred<br>stock pursuant<br>to<br>a private<br>placement, net<br>of associated<br>fees of \$33                   |                             |        |   |         | 1,550                                   | 1,517  |              |        |                    |             |         |
| Conversion of<br>Series B-1<br>Convertible<br>Preferred<br>Stock and<br>accrued<br>dividends<br>of \$1,284 into<br>Common<br>Stock |                             |        | (1,007)                                   | (5,852) |   |        | 15,692,824   | 157    | 6,979              | (1,284)     |         |
| Stock-based<br>compensation<br>expense -<br>stock options  |                             |        |   |         |   |        |              |        | 189                |             |         |
| Stock-based<br>compensation<br>expense -<br>restricted<br>stock  |                             |        |   |         |   |        |              |        | 261                |             |         |
| Restricted<br>stock issuance   |                             |        |   |         |   |        | 1,019,00     | 10     | (10)               |             |         |

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|   |    |        |   |      |       |         |            |           |           |             |           |
|---|----|--------|---|------|-------|---------|------------|-----------|-----------|-------------|-----------|
| Restricted stock forfeiture             |    |        |   |      |       |         |            | (650,032) | (7)       | 7           |           |
| Stock options exercised                 |    |        |   |      |       |         |            | 8,333     | 8         |             |           |
| Net loss                                | -  | -      | - | -    | -     | -       | -          | -         | -         | -           | (2,902)   |
| Balance, September 30, 2010 (Unaudited) | 50 | \$ 500 | - | \$ - | 1,550 | \$1,517 | 35,373,112 | \$ 353    | \$ 39,409 | \$ (35,990) | \$(1,390) |

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, 2009. The condensed consolidated balance sheet as of December 31, 2009 has been derived from those audited consolidated financial statements. Operating results for the nine month period ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010.*

**1. Organization**

IGI Laboratories, Inc. is a Delaware corporation formed 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. As used in this report, the terms the Registrant, the Company, IGI, Inc., 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 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 principal sources of liquidity for IGI Laboratories, Inc. are cash and cash equivalents of approximately \$192,000 at September 30, 2010 and cash from operations. The Company sustained a net loss attributable to common stockholders of approximately \$4,186,000 for the nine months ended September 30, 2010 and had working capital of approximately \$1,029,000 at September 30, 2010.

On March 29, 2010, the Company completed a \$1,550,000 private placement with certain investors, including investment funds affiliated with Signet Healthcare Partners, G.P. and Jane E. Hager (the Series C Offering). As part of the Series C Offering, the Company issued 1,550 shares of Series C Convertible Preferred Stock. The Series C Convertible Preferred Stock has a par value of \$0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore, each share of Series C Preferred Stock is convertible into shares of common stock equal to (i) 1,000 plus any accrued and unpaid dividends, divided by (ii) \$0.69 (the closing price of the Company's common stock on the date of issuance of the Series C Convertible Preferred Stock).

The Company's business operations have been partially funded over the past three years through the exercise of stock options by our directors and officers, through private placements of our capital stock, the line of credit and issuance of debt. As described more fully in Footnotes 8, 10, 11 and 12, we raised an aggregate of \$5,304,000 in 2009 and \$1,517,000 for the nine months ended September 30, 2010 principally from private equity investors. We may continue to seek to raise additional capital through the sale of our equity. We may accomplish this via a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing.

We believe that we need an additional capital infusion in the fourth quarter of 2010 to support our business plan. However, the trading price of our common stock, our pending application to continue listing our common stock on NYSE Amex, a downturn in the U.S. equity and debt markets or the negative economic trends in general could make it more difficult to obtain financing through the issuance of equity securities or otherwise. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. In the event we do not obtain such financing, we will be required to delay or abandon certain development projects to avoid the associated costs.

### 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 nine months ended September 30, 2010 and 2009 and the three months ended September 30, 2010 and 2009, 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 convertible preferred stock and options and warrants to purchase the Company's common stock, which were excluded from the net loss per share calculations due to their anti-dilutive effect, and amounted to 4,340,629 for 2010 and 18,073,786 for 2009.

#### 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. 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.

Licensing and Royalty Income: Revenues earned under licensing or sublicensing contracts are recognized ratably over the life of the agreements. Advance payments by customers are initially recorded as deferred income on the Consolidated Balance Sheet and then recognized ratably over the life of the agreement or as

contract obligations are completed. Licensing and royalty income is not a material part of the Company's overall revenue.

**Research and Development Income:** The Company enters into 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.

**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, 2010 and 2009, two of our customers accounted for 51% and three of our customers accounted for 53% of our revenue, respectively. For the nine months ended September 30, 2010 and 2009, two of our customers accounted for 50% and three of our customers accounted for 35% of our revenue, respectively. Two of these customers are the same for the nine months ended September 30, 2010 and 2009. Accounts receivable related to the Company's major customers comprised 49% of all account receivables as of September 30, 2010. 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 April 2010, the Financial Accounting Standards Board, or FASB, provided guidance under ASC 605 on defining a milestone and determining when it is appropriate to apply the milestone method of revenue recognition for research and development transactions. Vendors can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period the milestone is achieved if the milestone meets all the criteria stated in the guidance to be considered substantive and must be considered substantive in its entirety. The Company adopted this standard for the three month period ended June 30, 2010 and the adoption is not expected to have a material impact on the Company's consolidated financial statements.

**Reclassification of Prior Period Balances**

Certain 2010 prior quarter balances have been reclassified to conform to the current quarter financial statement presentation. This reclassification of Quality Analytical expenses from January to September of 2010 which related to the Company's work performed for ANDA filing for FDA submission has no impact on net loss or cash flows for the prior periods.

**4. Inventories**

Inventories are valued at the lower of cost, using the first-in, first-out ( FIFO ) method, or market. Inventories at September 30, 2010 and December 31, 2009 consist of:

|                  | <b>September 30, 2010</b><br>(Unaudited) | <b>December 31, 2009</b><br>(Audited) |
|------------------|--|---------------------------------------|
|                  | (amounts in thousands)                   |                                       |
| Raw materials    | \$ 765                                   | \$ 751                                |
| Work in progress | 5  | 12                                    |
| Finished goods   | 116                                      | 111                                   |
| Total            | \$ 886                                   | \$ 874                                |

**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. The Company issued 59,176 shares in 2009 as consideration for directors' fees for the fourth quarter of 2008 and the first, second and third quarters of 2009. Directors' fees were accrued on the Company's financial statements for each of those quarters. 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 1,814,798 options have been granted to non-employee directors through September 30, 2010. 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.

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 time of grant pursuant to the Company's 1999 Stock Incentive Plan. Options outstanding under the 1999 Plan are generally exercisable in cumulative increments over four years commencing one year from date of grant. Awards may no longer be granted pursuant to the Company's 1999 Stock Incentive Plan.

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. The 2009 Plan, as amended on May 19, 2010, authorizes up to 4,000,000 shares of the Company's common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of September 30, 2010, options to purchase 275,000 shares of common stock were outstanding under the 2009 Plan and 1,443,968 shares of restricted stock had been granted under the 2009 Plan.

## Stock Options

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

|                          |  |
|--------------------------|--|
|                          | For the nine months<br>ended<br>September 30, 2010 |
| Expected volatility      | 65.1%  |
| Expected term (in years) | 3.2 years  |
| Risk-free rate           | 1.77%  |
| Expected dividends       | 0%   |

A summary of option activity under the 1999 Plan, the Director Plan and the 2009 Plan as of September 30, 2010 and changes during the period are presented below:

|                                      | Number of<br>Options | Weighted<br>Average<br>Exercise Price |
|--------------------------------------|----------------------|---------------------------------------|
| Outstanding as of January 1, 2010    | 2,014,177            | \$1.12                                |
| Issued                               | 105,000              | \$0.79                                |
| Exercised                            | (8,333)              | \$1.00                                |
| Forfeited                            | (771,328)            | \$1.08                                |
| Expired                              | (65,000)             | \$1.95                                |
| Outstanding as of September 30, 2010 | 1,274,516            | \$1.08                                |
| Exercisable as of September 30, 2010 | 1,036,179            | \$1.12                                |

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options outstanding at September 30, 2010 was \$0.18.

The following table summarizes information regarding options outstanding and exercisable at September 30, 2010:

**Outstanding:**

Range of Exercise Prices

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|        |        | Stock<br>Options<br>Outstanding | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual Life |
|--------|--------|---------------------------------|---------------------------------------|--|
| \$0.50 | \$1.00 | 363,500                         | \$0.71                                | 5.90   |
| \$1.01 | \$1.50 | 854,000                         | \$1.21                                | 7.01   |
| \$1.51 | \$2.00 | 57,016                          | \$1.52                                | 3.26   |
| Total  |        | 1,274,516                       | \$1.08                                | 6.53   |

**Exercisable:**

| Range of Exercise Prices |        | Stock<br>Options<br>Exercisable | Weighted<br>Average<br>Exercise Price |
|--------------------------|--------|---------------------------------|---------------------------------------|
| \$0.50                   | \$1.00 | 258,500                         | \$0.68                                |
| \$1.01                   | \$1.50 | 720,663                         | \$1.24                                |
| \$1.51                   | \$2.00 | 57,016                          | \$1.52                                |
| Total                    |        | 1,036,179                       | \$1.12                                |

As of September 30, 2010, the intrinsic value of the options outstanding was \$550,745 and the intrinsic value of the options exercisable was \$409,677. The intrinsic value of options exercised during the nine months ended September 30, 2010 was \$4,250. As of September 30, 2010, there was approximately \$64,664 of total unrecognized compensation cost that will be recognized through November 2012 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 \$261,000 and \$199,000, respectively, of compensation expense during the nine months ended September 30, 2010 and 2009 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At September 30, 2010, the Company had approximately \$620,034 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized from October 2010 through April 2013.

|  | Number of<br>Restricted<br>Stock | Weighted Average<br>Exercise Price |
|--|----------------------------------|------------------------------------|
| Non-vested balance at January 1, 2010    | 801,355                          | \$ 1.06                            |
| Changes during the period:               |                                  |                                    |
| Shares granted                           | 1,019,000                        | 0.71                               |
| Shares vested                            | (117,979)                        | 1.02                               |
| Shares forfeited                         | (650,032)                        | 1.07                               |
| Non-vested balance at September 30, 2010 | 1,052,344                        | \$ 0.72                            |

See Footnote 13 below regarding restricted stock award to Philip S. Forte, the Company's Chief Financial Officer and Charles E. Moore, CEO and President.

See Footnote 13 below regarding restricted stock and stock options for Hemanshu Pandya, the Company's former President and Chief Executive Officer, upon his resignation as of April 1, 2010.

## 6. Income Taxes

As a result of the Company's history of continuing tax losses, the Company has not paid income taxes and has recorded a full valuation allowance against its net deferred tax asset. The Company has not recorded a liability for unrecognized tax benefits at September 30, 2010 and no significant changes are expected in the next twelve months. The tax years 2007 through 2009 remain open to examination by the major taxing jurisdictions to which the Company is subject.

There was no accrued interest related to unrecognized tax benefits at September 30, 2010.

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, 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.

## **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 \$75,000 related to this agreement for each of the nine month periods ended September 30, 2010 and 2009.

## 8. Note Payable

On January 26, 2009, the Company signed the Second Amendment to Loan and Security Agreement, which amended and restated the Loan and Security Agreement, as amended, with Pinnacle Mountain Partners, LLC ( Pinnacle ). This Second Amendment to Loan and Security Agreement extended the maturity date of the \$500,000 maximum loan amount from January 31, 2009 to July 31, 2009, with interest at 8.5% (rather than prime plus 1.5%). As in the original Loan and Security Agreement, as amended, loans under this amendment were collateralized by the assets of the Company (other than real property). The Company borrowed \$500,000 under this Second Amendment to Loan and Security Agreement as of May 15, 2009 and incurred associated interest expense of \$14,065 for the period January 1, 2009 to May 15, 2009 (date of conversion).

On March 13, 2009, the Company completed the 2009 Offering as more fully described in Footnote 11 below. As a condition to the consummation of the 2009 Offering, on March 13, 2009, the Company and Pinnacle entered into the Third Amendment to Loan and Security Agreement pursuant to which the parties agreed to change the final payment date of the amounts borrowed under the agreement from July 31, 2009 to instead provide that 50% of the amount of all loans and advances made by Pinnacle under the agreement will become due and payable on July 31, 2010 and the remaining outstanding loans and advances, together with interest thereon, will become due and payable on July 31, 2011.

In addition, as a condition to the consummation of the 2009 Offering, the Company and Pinnacle entered into a note conversion agreement ( Note Conversion Agreement ) dated March 13, 2009, pursuant to which Pinnacle agreed to convert the principal amount outstanding under the Third Amended and Restated Revolving Note ( the Note Payable ) into shares of the Company s common stock at a conversion rate of \$0.41 per share of common stock (the conversion shares ) upon receipt of stockholder approval by the Company of such conversion. Upon receipt of the conversion shares, the obligations and liabilities of the Company to repay the principal amount of the Note Payable would be deemed satisfied and paid in full. At the Company s 2009 annual meeting of stockholders held on May 15, 2009, the Company s stockholders approved the Note Conversion. Immediately upon stockholder approval, the \$500,000 principal amount outstanding under the Note Payable was converted into 1,219,512 shares of the Company s common stock. For additional information relating to the 2009 Offering, see Footnote 11 below.

## 9. Related Party Transactions

For a description of the Company s Credit Agreement with Pinnacle and the Private Placement with Signet Healthcare Partners, G.P., the related parties, see Footnotes 8 above and 11 below, respectively.

## 10. Stock Warrants

In connection with the 2009 Offering (See Footnote 11 below), 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. Until stockholder approval of the 2009 Offering was obtained, this Common Stock Warrant was exercisable for no more than 88,550 shares. At the Company s 2009 annual meeting of stockholders held on May 15, 2009, the Company s stockholders approved the 2009 Offering. The fair value of the Common Stock Warrant of approximately \$102,000 was determined using the Black Scholes model. The factors used in the calculation are as follows: expected volatility of 66.8%, expected term of 3 years and risk-free interest rate

of 1.36%. Expected volatility and risk-free interest rates are based upon the expected life of the warrant. The interest rates used are the yield of a 3-year U.S. Treasury Note as of March 13, 2009. Of this amount, \$82,000 was deemed to be attributable to the issuance of debt and was capitalized as debt issuance costs. 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.

In connection with a Private Placement Memorandum dated December 10, 2007, the Company entered into a subscription agreement with Univest Management, Inc. EPSP, which granted Univest a warrant to purchase 52,500 shares of common stock at an exercise price of \$1.25 per share. This warrant expired on December 10, 2009, two years from issuance.

In connection with a Private Placement Memorandum dated December 4, 2007, the Company entered into a subscription agreement which granted a warrant to purchase 175,000 shares of common stock at an exercise price of \$1.25 per share. These warrants expired on December 4, 2009, two years from issuance.

In connection with the Private Placement transaction executed with Pharmachem, dated February 5, 2007, the Company issued a warrant to purchase 150,000 shares at \$1.00 per share to Landmark Financial Corporation as commission on the transaction. During the quarter ended June 30, 2008, Landmark Financial Corporation exercised a portion of the warrant to acquire 25,000 shares of common stock. The remainder of this warrant expired on March 7, 2009.

#### **11. Convertible Preferred Stock and Convertible Promissory Notes 2009 Offering**

On March 13, 2009, the Company completed a \$6,000,000 private placement with certain investment funds affiliated with Signet Healthcare Partners, G.P. (the 2009 Offering ). As part of the 2009 Offering, the Company issued 202.9 shares of Series B-1 Preferred Stock, \$4,782,600 in Secured Convertible Promissory Notes ( Promissory Notes ), Preferred Stock Purchase Warrants to purchase 797.1 shares of non-voting Series B-2 Preferred Stock ( Preferred Stock Warrants ), a Common Stock Purchase Warrant to purchase 350,000 shares of common stock ( Common Stock Warrant ) and amended its line of credit with Pinnacle. In connection with the 2009 Offering, the Company incurred placement and legal fees of approximately \$721,000, resulting in net proceeds of \$5,279,000. These fees were recorded as debt issuance costs in the amount of \$577,000 and paid-in capital in the amount of \$144,000.

The Series B-1 Preferred Stock has a par value of \$0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore, each share of the Series B-1 Preferred Stock is convertible into 14,634 shares of common stock for an implied common stock conversion price of \$0.41 per share, subject to certain adjustments and any accrued and unpaid dividends. At the time of issuance, the market price of the common stock into which the Series B-1 Preferred Stock is convertible was greater than the conversion price. The embedded beneficial conversion feature is being accounted for in accordance with ASC 470 relating to *Debt with Conversions and Other Options* . Accordingly, the beneficial conversion feature on the Series B-1 Preferred Stock is approximately \$505,000, which represents the amount by which the estimated fair value of the common stock issuable upon conversion exceeds the proceeds from such issuance and was treated as a deemed dividend on the date of the 2009 Offering.

The Promissory Notes had a maturity date of July 31, 2009 and an annual interest rate of 5%. On the date of issuance, the Promissory Notes had a fair value of approximately \$4,706,000, resulting in a debt discount of \$77,000. Furthermore, the Company entered into Guaranty and Security Agreements to guarantee repayment of the Promissory Notes upon maturity. The Promissory Notes were collateralized by the assets of the Company. However, upon approval by the Company's stockholders of the 2009 Offering, the Promissory Notes, unamortized discount, and any accrued interest automatically converted into Series B-1 Preferred Stock for \$6,000 per share and the Preferred Stock Warrants became null and void. The beneficial conversion feature of the Promissory Notes is approximately \$1,983,000 which is recorded as a deemed dividend from March 14, 2009 through May 15, 2009. The value of the Preferred Stock Warrants was nominal. Under applicable NYSE Amex rules, the 2009 Offering required stockholder approval, which was obtained at the Company's 2009 annual meeting of stockholders held on May 15, 2009. Immediately upon stockholder approval, the \$4,782,600 aggregate principal amount of Promissory Notes issued in the 2009 Offering, together with accrued and unpaid interest, were converted into an aggregate of 803.979 shares of the Company's Series B-1 Preferred Stock and the Preferred Stock Warrants issued in the 2009 Offering became null and void.

The Company granted its placement agent for the 2009 Offering a Common Stock Warrant to purchase 350,000 shares of common stock for \$0.41 per share, which expires on March 13, 2012, as described more fully in Footnote 10.

In connection with the 2009 Offering, the Company and Pinnacle entered into the Third Amendment to Loan and Security Agreement. Pinnacle agreed to change the terms of repayment such that 50% of the amount borrowed under the line of credit, or \$500,000 as of March 31, 2009 (see Footnote 8 above), would be payable on July 31, 2010 and the remaining balance would be payable on July 31, 2011. Furthermore, the Company and Pinnacle entered into a Note Conversion Agreement for which Pinnacle agreed to automatically convert the principal amount due under the Third Amended and Restated Revolving Note (the Note Payable ) into shares of the Company s Common Stock at a conversion rate of \$0.41 per share upon stockholder approval of the Note Conversion. The beneficial conversion feature of the Note Payable of approximately \$207,000 was recorded as a debt discount. The fair value of the Note Payable, as modified, was approximately \$460,000, resulting in a debt discount of \$40,000. At the Company s 2009 annual meeting of stockholders held on May 15, 2009, the Company s stockholders approved the Note Conversion. Immediately upon stockholder approval, the \$500,000 principal amount outstanding under the Note Payable was converted into 1,219,512 shares of the Company s common stock.

Debt discounts and debt issuance costs were amortized using the effective interest method. No amounts were outstanding at September 30, 2010 or December 31, 2009.

On August 20, 2010, all of the issued and outstanding shares of the Series B-1 Convertible Preferred Stock, par value \$0.01 per share of the Company, as well as accrued dividends of \$1,284,000 automatically converted into an aggregate of 15,692,824 shares of the Company's common stock, par value \$0.01 per share, in accordance with the terms and conditions set forth in the Certificate of Designation of the Rights and Preferences of Series B-1 Convertible Preferred Stock and Series B-2 Preferred Stock (the "Certificate of Designation").

Pursuant to the terms of the Certificate of Designation, the shares of Series B-1 Preferred Stock automatically convert into shares of the Company's Common Stock upon the date that the closing price of the Company's Common Stock shall have exceeded \$1.20 for a period of twenty-five (25) consecutive trading days immediately preceding such date. On August 19, 2010, the closing price of the Company's Common Stock was \$1.29, which was the twenty-fifth consecutive trading day for which the closing price of such Common Stock exceeded \$1.20. Accordingly, on August 20, 2010, the shares of Series B-1 Preferred Stock automatically converted into shares of the Company's Common Stock.

The total number of shares of the Company's Common Stock outstanding immediately prior to the conversion was 17,714,548 and the total number of shares of Series B-1 Preferred Stock outstanding was 1,006,879. After giving effect to the conversion, the total number of shares of the Company's Common Stock outstanding was 33,407,372 and there were no shares of Series B-1 Preferred Stock outstanding.

A copy of the Certificate of Designation is filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 19, 2009 and incorporated herein by reference. The foregoing description of the Certificate of Designation is qualified in its entirety by reference to such exhibit.

## **12. Convertible Preferred Stock - 2010 Offering**

On March 29, 2010, the Company completed a \$1,550,000 private placement with certain investors, including investment funds affiliated with Signet Healthcare Partners, G.P. and Jane E. Hager (the "Series C Offering"). As part of the Series C Offering, the Company issued 1,550 shares of Series C Convertible Preferred Stock. The Series C Convertible Preferred Stock has a par value of \$0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore each share of Series C Preferred Stock is convertible into shares of common stock equal to (i) 1,000 plus any accrued and unpaid dividends, divided by (ii) \$0.69 (the closing price of the Company's common stock on the date of issuance of the Series C Convertible Preferred Stock). Liquidation preference is the original cost plus undeclared dividends and amounted to \$1,589,493 at September 30, 2010.

## **13. Changes in Management**

On February 19, 2010, the Company announced in a Form 8-K filed with the Securities and Exchange Commission, that it had named Charles E. Moore as its Executive Vice President of Technical Operations, effective February 12, 2010. Under the terms of his employment agreement, Mr. Moore would receive an annual salary of \$250,000. Mr. Moore also received a grant of 379,000 shares of restricted stock, one-third of which will vest on January 4, 2011, one-third of which will vest on January 4, 2012 and one-third of which will vest on January 4, 2013, so long as he is employed by the Company on each such vesting date. In addition, Mr. Moore 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. Moore 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. Moore's target bonus will be equal to 20% of his base salary for the applicable fiscal year. All performance targets pursuant to such plan shall be determined by the Company's Compensation Committee. Mr. Moore is also subject to certain restrictive covenants as set forth in his employment agreement, including confidentiality, non-solicitation and non-competition. Mr. Moore's employment agreement further provides for payments upon certain types of employment termination events as further set forth in his employment agreement.

Additionally, in the Form 8-K filed on February 19, 2010, the Company announced that the Employment Agreement between Philip S. Forte and the Company dated May 18, 2009 as filed with the Securities and Exchange Commission on Form 8-K on May 29, 2009, was amended to provide Mr. Forte with one-year base salary continuation (instead of six months of salary continuation as previously provided for his Employment Agreement) in the event of his termination by the Company without cause. On February 18, 2010, the Company also (i) increased Mr. Forte's base salary to \$185,000 and (ii) granted Mr. Forte 80,000 shares of restricted stock which vest as follows: (A) one-twelfth of the shares vested as of February 12, 2010; (B) one-twelfth of the shares shall vest on each of the following dates: (x) June 30, 2010, (y) September 30, 2010 and (z) December 31, 2010; (C) one-third of the shares shall vest on February 12, 2011 and (D) one-third of the shares shall vest on February 12, 2012, so long as he is employed by the company on each such vesting date.

On March 23, 2010, the Company announced in a Form 8-K filed with the Securities and Exchange Commission that on March 19, 2010, Hemanshu Pandya, the President and Chief Executive Officer of the Company, resigned as an employee of the Company and as a member of the board of directors, effective April 1, 2010. Upon the effective date of his resignation, Mr. Pandya retained the 324,968 restricted shares of common stock that were vested and forfeited the 650,032 restricted shares of common stock that were not vested per his Restricted Stock Agreement. Additionally, Mr. Pandya had 90 days from April 1, 2010 to exercise his 176,718 vested stock options, and he forfeited 353,427 stock options that were not vested per his Option Agreement. In connection with Mr. Pandya's resignation, the Company appointed Charles E. Moore its new President and Chief Executive Officer and to fill the vacant board seat created by Mr. Pandya's resignation, each effective April 1, 2010. The Board of Directors of IGI amended Mr. Moore's February 19, 2010 employment agreement in respect to his new responsibilities with the Company as President and Chief Executive Officer. Under the amended terms of his employment agreement, Mr. Moore would receive an annual salary of \$265,000. Mr. Moore also received an additional grant of 560,000 restricted shares of common stock. These shares had a grant date of April 1, 2010 and would vest over three years, in one-third increments beginning after Mr. Moore's first year of service as the President and Chief Executive Officer. Mr. Moore's target incentive bonus was also increased to 40% of his base salary for the applicable fiscal year. Further, Mr. Moore would be entitled to payment of six months of severance plus a pro-rata portion of his bonus, if he was terminated without cause following the first anniversary of his employment start date. If terminated within the first year, he would not be entitled to a severance payment.

#### **14. Legal**

On April 22, 2010, a complaint for patent infringement was filed by Ferndale Laboratories Inc. against PruGen, Inc. and the Company in the United States District Court Eastern District of Michigan (Detroit) relating to U.S. Patent No. 5,635,497 (the '497 Patent) entitled Topical Application Compositions. Ferndale is the licensee of the '497 Patent, which is owned by Astellas Pharma Europe B.V. The Complaint alleges infringement of the '497 Patent by PruGen and the Company in the manufacturing, using, selling and offering to sell their PruVel product. The Company is identified in the Complaint as PruGen's contract-manufacturer of the PruVel product. Ferndale is seeking unspecified money damages and injunctive relief.

On June 30, 2010, discussions and negotiations among Ferndale, PruGen and the Company resulted in a Settlement Agreement between the parties and the withdrawal of the complaint by Ferndale against PruGen Inc. and the Company. Pursuant to the Settlement Agreement, IGI agreed not to manufacture any product or composition which falls within the '497 Patent. Part of the Settlement Agreement also requires PruGen and the Company to destroy any inventory of the PruVel product in their possession after June 30, 2010 and to provide evidence of destruction to Ferndale. The Company complied with the Settlement Agreement and provided supporting evidence to Ferndale to the effect that it did not have any inventory of the PruVel product and that was duly acknowledged by Ferndale. The Company received the final letter from Ferndale confirming the resolution of the claim. There were no costs to the Company related to the settlement.



## **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.

### **Overview**

We develop, manufacture, fill and package topical semi-solid and liquid products for cosmetic, cosmeceutical and pharmaceutical customers. Our products are used for cosmetic, cosmeceutical and prescription applications for the treatment of symptoms of dermatitis, acne, psoriasis and eczema. We are building upon this foundation by filing our own ANDAs and continuing to expand into the prescription pharmaceutical arena. Our 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 our licensed Novasome® technology. All of our product development and manufacturing is performed at our 25,000 sq.ft. facility in Buena, NJ.

### **Our Services and Products**

#### *Contract Services Business*

We provide contract services to marketers of topical formulations. These customers contract with us for formulation development and/or manufacturing of products which are marketed in the customer's brand. These products range from pure cosmetic formulations sold by retail to the public, to prescription formulations promoted to physicians.

We believe that contract manufacturing services will continue to be crucial to our success. The customer base for these services is pharmaceutical companies, as well as cosmetic, cosmeceutical and over-the-counter 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. We intend to continue to create niche opportunities by providing high quality, customer-oriented service.

*IGI's Pharmaceutical Business*

We are leveraging our expertise in pharmaceutical formulation and manufacturing to expand our own product offerings. We are focused on developing a portfolio of topical generic drug products via the Abbreviated New Drug Application, or ANDA, route. ANDAs are submitted to the Food and Drug Administration, or FDA, for generic drug products that are bioequivalent versions of innovator brand drug products. ANDA approval by the FDA allows for the interchangeability in the United States of the generic product with the innovator drug, meaning that the generic version may be substituted for the brand product by either a physician or pharmacist when dispensing a prescription.

In September 2010, we filed our first ANDA with the FDA in our own name. We have a number of additional product candidates in various pre-ANDA-filing stages of development. We anticipate filing 4 to 6 ANDAs per year on an ongoing basis, assuming sufficient financial resources to support these product development plans. The entire approval process can take 3-5 years before a product is approved, of which the FDA approval portion is approximate 18-24 months.

*Novasome® Technology Platform*

We have an exclusive license for use of the patented Novasome® encapsulation technology in topical formulations, from Novavax, Inc., until December 11, 2015. The technology utilizes non-phospholipid structures for enhanced absorption via topical delivery of pharmaceuticals and cosmeceuticals. The Novasome® technology is inexpensive to manufacture, and its structures are stable, biodegradable, and highly hydrophobic and hydrophilic, making them suitable for a wide range of topical applications.

Many of the *Novasome®* patents under this license have expired and more will expire before this license terminates on December 11, 2015. We have already filed our own patents based on this technology. An integral piece of this technology is manufacturing know-how which will not be lost as a result of the expiration of the license. As we continue to implement our new strategy, we believe that sales related to the Novasome® technology will constitute a smaller percentage of our sales in the future.

**Recent Capital Transactions**

On March 13, 2009, we completed a \$6,000,000 private placement, resulting in net proceeds of approximately \$5,279,000, with certain investment funds affiliated with Signet Healthcare Partners, G.P. as more fully described in Footnote 11 to our Consolidated Financial Statements.

On March 29, 2010 the Company completed a \$1,550,000 private placement with certain investors, including investment funds affiliated with Signet Healthcare Partners, G.P. and Jane E. Hager (the Series C Offering). As part of the Series C Offering, the Company issued 1,550 shares of Series C Convertible Preferred Stock. The Series C Convertible Preferred Stock has a par value of \$0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5% when and if declared by the Board of Directors. Furthermore, each share of Series C Preferred Stock is convertible into shares of common stock equal to (i) 1,000 plus any accrued and unpaid dividends, divided by \$0.69 (the closing price of the Company's Stock on the date of issuance of the Series C Convertible Preferred Stock).

*Results of Operations***Three months ended September 30, 2010 compared to September 30, 2009**

The Company had a net loss attributable to common stockholders of \$1,963,000, or \$0.08 per share, for the three months ended September 30, 2010, compared to \$918,000, or \$0.05 per share, in the comparable period for 2009, which resulted from the following:

**Revenues (in thousands):**

| <b>Components of Revenue:</b>          | <b>2010</b> | <b>2009</b> | <b>\$ Change</b> | <b>% Change</b> |
|--|-------------|-------------|------------------|-----------------|
| <b>Product sales</b>                   | \$1,531     | \$668       | \$863            | 129%            |
| <b>Research and development income</b> | 165         | 83          | 82               | 99%             |

|   |         |       |       |      |
|---|---------|-------|-------|------|
| <b>Licensing and royalty<br/>income</b> | 48      | 47    | 1     | 2%   |
| <b>Total Revenues</b>                   | \$1,744 | \$798 | \$946 | 119% |

The increase in product sales for the three months ended September 30, 2010 as compared to the same period in 2009 was primarily due to increased annual product sales reflecting the strong customer relationships established with the Company's major customers. Research and development income will not be consistent and will vary, from quarter to quarter, depending on the required timeline of each development project; however the increase in research and development income during the period ended September 30, 2010 as compared to the same period in 2009 is attributable to new customer relationships 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.

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

|  | <b>2010</b> | <b>2009</b> | <b>\$ Change</b> | <b>% Change</b> |
|--|-------------|-------------|------------------|-----------------|
| <b>Cost of sales</b>                       | \$1,286     | \$ 691      | \$595            | 86%             |
| <b>Selling, general and administrative</b> | 760         | 758         | 2                | .3%             |
| <b>Product development and research</b>    | 373         | 273         | 100              | 37%             |
| <b>Totals costs and expenditures</b>       | \$2,419     | \$1,722     | \$697            | 40%             |

Cost of sales increased for the three months ended September 30, 2010 as a result of the increased product sales. Cost of sales as a percentage of product sales was 84% for the three months ended September 30, 2010 or a 15% improvement as compared to the three months ended September 30, 2009, which resulted in a gross margin of 16% in 2010.

Selling, general and administrative expenses for the three month period ended September 30, 2010 increased as compared to the same period in 2009 due to an increase of \$52,000 in recruiting fees, an increase of \$15,800 in salaries and employer taxes, an increase of \$18,200 in travel related expenses and an increase of \$12,800 in trade shows expenses offset by a decrease of \$33,100 in consulting fees, a decrease in stock option expense of \$30,600, a decrease of \$13,400 in temporary help and a decrease of \$11,000 in bad debt expense.

Product development and research expenses for the three months ended September 30, 2010 increased as compared to the same period for 2009 due to an increase of \$29,000 in supplies and outside testing, an increase of \$107,000 in salaries and employer taxes due to the establishment of a fully staffed Quality Analytical department and an increase in expense from the issuance of stock options of \$20,000 offset by a decrease of \$47,000 in consulting fees.

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

|                         | <b>2010</b> | <b>2009</b> | <b>\$ Change</b> | <b>% Change</b> |
|-------------------------|-------------|-------------|------------------|-----------------|
| <b>Interest Expense</b> | \$ (4)      | \$ -        | \$ 4             | 100%            |
| <b>Interest Income</b>  | \$ -        | \$ 6        | \$ (6)           | (100)%          |

Interest expense increased for the three months ended September 30, 2010 as compared to the same period in 2009 due to payments on the Capital Lease Obligation in 2010. Interest income decreased for the three months ended September 30, 2010 as compared to the same period in 2009 due to lower average cash balances in 2010.

**Net loss attributable to common stockholders (in thousands, except per share numbers):**

|   | <b>2010</b> | <b>2009</b> | <b>\$ Change</b> | <b>% Change</b> |
|---|-------------|-------------|------------------|-----------------|
| <b>Net loss attributable to common stockholders</b> | \$(1,963)   | \$(918)     | \$1,045          | 114%            |

|                           |       |       |     |     |
|---------------------------|-------|-------|-----|-----|
| <b>Net loss per share</b> | (.08) | (.05) | .03 | 60% |
|---------------------------|-------|-------|-----|-----|

The increase in net loss attributable to common stockholders for the three months ended September 30, 2010 as compared to the same period in 2009 is due to the preferred stock dividends of \$1,284 offset by the increase in Revenues and the increase in Costs and expenses noted above.

**Nine months ended September 30, 2010 compared to September 30, 2009**

The Company had a net loss attributable to common stockholders of \$4,186,000, or \$0.21 per share, for the nine months ended September 30, 2010, compared to \$6,378,000, or \$0.40 per share, in the comparable period for 2009, which resulted from the following:

**Revenues (in thousands):**

| <b>Components of Revenue:</b>          | <b>2010</b> | <b>2009</b> | <b>\$ Change</b> | <b>% Change</b> |
|--|-------------|-------------|------------------|-----------------|
| <b>Product sales</b>                   | \$3,814     | \$2,172     | \$1,642          | 76%             |
| <b>Research and development income</b> | 348         | 149         | 199              | 134%            |
| <b>Licensing and royalty income</b>    | 206         | 213         | (7)              | (3)%            |
| <b>Total Revenues</b>                  | \$4,368     | \$2,534     | \$1,834          | 72%             |

The increase in product sales for the nine months ended September 30, 2010 as compared to the same period in 2009 was primarily due to increased annual product sales to the Company's major customers. Research and development income will not be consistent and will vary, from period to period, depending on the required timeline of each development project; the increase in research and development income during the period ended September 30, 2010 as compared to the same period in 2009 is attributable to new customer relationships 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.

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

|  | <b>2010</b> | <b>2009</b> | <b>\$ Change</b> | <b>% Change</b> |
|--|-------------|-------------|------------------|-----------------|
| <b>Cost of sales</b>                       | \$3,760     | \$2,220     | \$1,540          | 69%             |
| <b>Selling, general and administrative</b> | 2,482       | 2,717       | (235)            | (9)%            |
| <b>Product development and research</b>    | 1,027       | 542         | 485              | 89%             |
| <b>Totals costs and expenses</b>           | \$7,269     | \$5,479     | \$1,093          | 20%             |

Cost of sales increased for the nine months ended September 30, 2010 as a result of the increase in product sales and reserves for obsolete and expired inventory. Cost of sales as a percentage of product sales was 99% for the nine months ended September 30, 2010 as compared to 102% for the nine months ended September 30, 2009.

Selling, general and administrative expenses for the nine month period ended September 30, 2010 decreased as compared to the same period in 2009 as the prior period included a severance expense of \$341,000 for our former President and Chief Executive Officer per his 2009 separation agreement, a decrease of \$275,000 in professional and consulting fees and a decrease of \$33,900 in temporary help, offset by an increase in employees compensation payable in stock of \$62,000, an increase of \$268,000 in salaries and employer taxes and an increase of \$45,700 in travel related expenses.

Product development and research expenses for the nine months ended September 30, 2010 increased as compared to the same period for 2009 due to an increase of \$55,300 in supplies and outside testing, an increase of \$304,600 in salaries, employer taxes and benefits attributable to the establishment of a fully staffed Quality Analytical department, an increase in professional fees of \$34,000, an increase in expense from the issuance of

stock options of \$64,900 and an increase of \$12,500 in compensation payable in stock offset by a decrease of \$15,000 in consulting fees.

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

|                         | <b>2010</b> | <b>2009</b> | <b>\$ Change</b> | <b>% Change</b> |
|-------------------------|-------------|-------------|------------------|-----------------|
| <b>Interest Expense</b> | \$ (5)      | \$(957)     | \$(953)          | (99)%           |
| <b>Interest Income</b>  | \$ 2        | \$ 12       | \$ (10)          | (83)%           |

Interest expense decreased for the nine months ended September 30, 2010 as compared to the same period in 2009 due to approximately \$943,000 of accrued interest and amortization of debt discount and debt issuance costs related to the convertible notes payable issued in connection with the Offering (see Footnote 11 to the Company's Consolidated Financial Statements) that were included in interest expense in 2009. Interest income decreased for the nine months ended September 30, 2010 as compared to the same period in 2009 due to lower average cash balances in 2010.

**Net loss attributable to common stockholders (in thousands, except per share numbers):**

|   | 2010      | 2009       | \$ Change  | % Change |
|---|-----------|------------|------------|----------|
| <b>Net loss attributable to common stockholders</b> | \$(4,186) | \$ (6,378) | \$ (2,192) | (34)%    |
| <b>Net loss per share</b>                           | (.21)     | (.40)      | (.19)      | (48)%    |

The decrease in net loss attributable to common stockholders for the nine months ended September 30, 2010 as compared to the same period in 2009 is due to approximately \$943,000 of accrued interest and amortization of debt discount and debt issuance costs related to the convertible notes payable issued in connection with the 2009 Offering (see Footnote 11 to our Consolidated Financial Statements) that were included in interest expense and the dividend accreted for beneficial conversion features of \$2,488,000 for 2009, as well as the items noted above, offset by the preferred stock dividends of \$1,284 in 2010.

**Liquidity and Capital Resources**

The Company's operating activities used \$2,256,000 of cash during the nine months ended September 30, 2010 compared to \$2,369,000 used in the comparable period of 2009. The use of cash for the nine months ended September 30, 2010 and for the same period of 2009 was substantially a result of the net loss for the period offset by non-cash expense items.

The Company's investing activities used \$186,000 of cash in the nine months ended September 30, 2010 compared to \$624,000 of cash used in investing activities in the first nine months of 2009. The funds used for the period ended September 30, 2010 were for additional equipment and related services for the analytical area, and the funds used for the period ended September 30, 2009 were for additional equipment and improvements for the packaging and filling lines.

The Company's financing activities provided \$1,510,000 of cash in the nine months ended September 30, 2010 compared to \$5,307,000 provided in the nine months ended September 30, 2009. The cash provided for the nine month period ended September 30, 2010 is primarily the proceeds of the Series C Convertible Preferred Stock financing as more fully described in Footnote 12 to the Company's Consolidated Financial Statements. The cash provided for the nine month period ended September 30, 2009 is mainly from the proceeds of the Series B-1 Convertible Preferred Stock financing and the Note Payable as more fully described in Footnote 11 to the Company's Consolidated Financial Statements.

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$192,000 at September 30, 2010 and future cash from operations. The Company had working capital of \$1,029,000 at September 30, 2010.

We believe that we will need an additional capital infusion in the fourth quarter of 2010 to support our business plan. However, the trading price of our stock, our pending application to continue listing our stock on NYSE Amex, a downturn in the U.S. equity and debt markets and the negative economic trends in general could make it more difficult to obtain financing through the issuance of equity securities or otherwise. There can be no

assurance that such financing will be available on terms acceptable to the Company, or at all. In the event we do not obtain such financing, we will be required to delay or abandon certain development projects to avoid the associated costs.

### **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, 2009 for a complete list of all Critical Accounting Policies and Estimates. See also Footnote 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 September 30, 2010. Based on that evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that, as of September 30, 2010, 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

On April 22, 2010, a complaint for patent infringement was filed by Ferndale Laboratories Inc. against PruGen, Inc. and the Company in the United States District Court Eastern District of Michigan (Detroit) relating to U.S. Patent No. 5,635,497 (the '497 Patent) entitled Topical Application Compositions. Ferndale is the licensee of the '497 Patent, which is owned by Astellas Pharma Europe B.V. The Complaint alleges infringement of the '497 Patent by PruGen and the Company in the manufacturing, using, selling and offering to sell their PruVel product. The Company is identified in the Complaint as PruGen's contract-manufacturer of the PruVel product. Ferndale is seeking unspecified money damages and injunctive relief.

On June 30, 2010, discussions and negotiations among Ferndale, PruGen and the Company resulted in a Settlement Agreement between the parties and the withdrawal of the complaint by Ferndale against PruGen Inc. and the Company. Pursuant to the Settlement Agreement, IGI agreed not to manufacture any product or composition which falls within the '497 Patent.

Part of the Settlement Agreement also requires PruGen and the Company to destroy any inventory of the PruVel product in their possession after June 30, 2010 and to provide evidence of destruction to Ferndale. The Company complied with the Settlement Agreement and provided supporting evidence to Ferndale to the effect that it did not have any inventory of the PruVel product and that was duly acknowledged by Ferndale. The Company received the final letter from Ferndale confirming the resolution of the claim. There were no costs to the Company related to the settlement.

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, 2009, as amended or supplemented by our quarterly reports on Form 10-Q, 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, 2009, as amended or supplemented by our quarterly reports on Form 10-Q, have not materially changed.

### **Risks Related to our Business**

**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 seven years, and no net income has been available to common stockholders during each of these years. As of September 30, 2010, our stockholders' equity was \$4.4 million and we had an accumulated deficit of \$36 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 face intense competition in the consumer products business.**

Our business competes with large, well-financed cosmetic, pharmaceutical and consumer products companies with development and marketing groups that are experienced in the industry and possess far greater resources than those available to us. There is no assurance that we can compete successfully against our competitors or that we can develop and market products that will be favorably received in the marketplace. In addition, certain of our customers that use our Novasome® lipid vesicles in their products may decide to reduce their purchases from us or shift their business to other technologies.



**Rapidly changing technologies and developments by our competitors may make our technologies and products obsolete.**

We expect to sublicense our technologies to third parties, which would manufacture and market products incorporating these technologies. However, if our competitors develop new and improved technologies that are superior to our technologies, our technologies could be less acceptable in the marketplace and our business could be harmed.

**We will need to raise additional capital that will be required to operate and grow our business, and we may not be able to raise capital on terms acceptable to us or at all.**

Operating our business and maintaining our growth efforts will require additional cash outlays and capital expenditures. If cash on hand and cash generated from operations are not sufficient to meet our cash requirements, we will need to seek additional capital, potentially through debt or equity financings, to fund our growth. We cannot assure you that we will be able to raise needed cash on terms acceptable to us or at all. Financings may be on terms that are dilutive or potentially dilutive to our stockholders, and the prices at which new investors would be willing to purchase our securities may be lower than the current price per share of our Common Stock. The holders of new securities may also have rights, preferences or privileges which are senior to those of existing holders of Common Stock. If new sources of financing are required, but are insufficient or unavailable, we will be required to modify our growth and operating plans based on available funding, if any, which would harm our ability to grow our business or even stay in business.

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

We depend on a limited number of customers for a large portion of our revenue. For the three months ended September 30, 2010 and 2009, two of our customers accounted for 51% and three of our customers accounted for 53% of our revenue, respectively. For the nine months ended September 30, 2010 and 2009, two of our customers accounted for 50% and three of our customers accounted for 35% 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 face increased financial risk from the inaccurate pricing of our agreements.**

Since our product development agreements are often structured as fixed price agreements, we bear the financial risk if we initially under-price our agreements or otherwise over-run our cost estimates. Such under pricing or significant cost overruns could have a material adverse effect on our business, results of operations, financial condition, and cash flows. Further, the period of revenue recognition under such agreements are based upon the timing of work performed or completed.

**We rely on third parties for raw materials used in our contract manufacturing services business.**

We currently rely on several third party suppliers to provide us with the raw materials necessary to manufacture cosmetic and over-the-counter products. The loss of one or more of these suppliers, the non-performance of one or more of their materials or the lack of availability of raw materials could suspend our manufacturing process related to these products. This interruption of the manufacturing process could impair our ability to fill our customers' orders as they are placed, which could put our business at a competitive disadvantage. In addition, while we have processes intended to reduce volatility in component and material pricing, we may not be able to successfully manage price fluctuations which may have an adverse effect on our results of operations.

**We are subject to stringent regulatory requirements. Failure to adhere to such requirements could harm our business and results of operations.**

In the United States, pharmaceuticals are subject to rigorous FDA regulations. Any non-compliance with the regulatory guidelines may necessitate corrective action that may result in additional expenses and use of more of our resources.

We are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Failure to adhere to such regulations could harm our business and results of operations. In addition, our analytical department uses certain hazardous materials and chemicals in limited and controlled quantities. We have implemented safety procedures for handling and disposing of such materials, however, such procedures may not comply with the standards prescribed by federal, state and local regulations. Even if we follow such safety procedures for handling and disposing of hazardous materials and chemicals and such procedures comply with applicable law, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages and any such liability could exceed our resources.

Our operations and properties are also subject to a wide variety of increasingly complex and stringent federal, state and local environmental laws and regulations, including those governing the remediation of contaminated soil and groundwater. Such environmental laws may apply to conditions at properties and facilities presently or formerly owned or operated by us, as well as to conditions at properties at which wastes or other contamination attributable to us have been sent or otherwise come to be located. Two of our facilities are currently undergoing remediation of environmental contamination. The total estimated costs for the clean-up and remediation of such facilities are \$676,000 and \$65,000, respectively, of which \$26,000 and \$11,000 remain accrued as of September 30, 2010. Based on information provided to us from our environmental consultants and what is known to date, we believe the reserves are sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed our estimates. In addition, we can give no assurance that the future cost of compliance with existing environmental laws will not give rise to additional significant expenditures or liabilities that would be material to us. Future events, such as new information, changes in existing environmental laws or their interpretation, and more vigorous enforcement policies of federal, state or local regulatory agencies, may have a material adverse effect on our business, financial condition and results of operations.

**We are subject to extensive government regulation that increases our costs and could prevent us from marketing or selling our products.**

The manufacturing, processing, formulation, packaging, labeling, testing, storing, distributing, marketing, advertising and sale of the Company's products is subject to extensive regulation by one or more U.S agencies, including the FDA, the Federal Trade Commission, the Drug Enforcement Administration and the Consumer Products Safety Commission, as well as by several state and local agencies in localities where the Company's products are stored, distributed or sold. In addition, the Company manufactures and markets certain of its products in accordance with standards set by organizations, such as the United States Pharmacopeial Conventions (USP). The FDA regulates the testing, manufacture, labeling, marketing and sale of pharmaceutical products. Approval by the FDA is generally required before any new drug or the generic equivalent to any previously approved drug may be marketed or sold in the United States. In order to receive approval from the FDA for our product candidates that are generic versions of brand-name drugs, we intend to use the Abbreviated New Drug Application (ANDA) process and thus demonstrate to the FDA that each generic product candidate is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator, or brand-name reference drug. Bioequivalency may be demonstrated by comparing the generic product to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. However, if the FDA determines that an ANDA for a generic drug product is not adequate to support approval, it could deny our application or request additional information, including preclinical and clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.

If our product candidates receive FDA approval through the ANDA process, the labeling claims and marketing statements that we can make for our generic drugs are limited by statutes and regulations and by the claims made in the brand-name product's label. In addition, following regulatory approval, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive and ongoing regulatory requirements. As a manufacturer of pharmaceutical products distributed in the United States, we must also comply

with cGMPs, which include requirements related to production processes, quality control and assurance and recordkeeping. Our manufacturing facilities and procedures and those of our suppliers are subject to periodic inspection by the FDA and foreign regulatory agencies. Any material deviations from cGMPs or other applicable standards identified during such inspections may result in enforcement actions, including delaying or preventing new product approvals, a delay or suspension in manufacturing operations, consent decrees or civil or criminal penalties. Further, discovery of previously unknown problems with a product or manufacturer may result in restrictions or sanctions, including withdrawal of the product from the market.

**We are susceptible to product liability claims that may not be covered by insurance and could require us to pay substantial sums.**

We face the risk of loss resulting from, and adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We may not be able to avoid such claims. In addition, our product liability insurance may not be adequate to cover such claims and we may not be able to obtain adequate insurance coverage in the future at acceptable costs. A successful product liability claim that exceeds our policy limits could require us to pay substantial sums. In addition, product liability coverage for pharmaceutical companies is becoming more expensive and increasingly difficult to obtain and, as a result, we may not be able to obtain the type and amount of coverage we desire or to maintain our current coverage.

**The manufacture and storage of pharmaceutical and cosmetics products are subject to inherent risk.**

Because chemical ingredients are used in the manufacture of our products and due to the nature of the manufacturing process itself, there is a risk of incurring liability for damages caused by or during the storage or manufacture of both the chemical ingredients and the finished products. Although we have never incurred any material liability for damages of that nature, we may be subject to liability in the future. In addition, while we believe our insurance coverage is adequate, it is possible that a successful claim would exceed our coverage, requiring us to pay a substantial sum.

**The failure to obtain, maintain or protect patents, trade secrets, know-how and other intellectual property could impact our ability to compete effectively.**

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technology, products and business. We rely on a combination of patents, trade secrets, proprietary know-how and other intellectual property to protect our proprietary technology and rights. We own nine patents and through a license agreement we have obtained the use of patents relating to the Novasome® technology for specified uses. We also maintain a number trade secrets, know-how and other intellectual property.

The risks and uncertainties that we face with respect to patents and other proprietary rights include the following:

the pending patent applications we have filed or may file, or to which we have exclusive rights, may not result in issued patents, or may take longer than we expect to result in issued patents;

changes in U.S. patent laws may adversely affect our ability to obtain or maintain our patent protection;

we may be subject to interference proceedings;

the claims of any patents that are issued may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our collaborators may not provide a competitive advantage;

other companies may challenge patents licensed or issued to us or our collaborators;

other companies may independently develop similar or alternative technologies, or duplicate our technology;

other companies may design around technologies we have licensed or developed; and enforcement of patents is complex, uncertain and expensive.

If we are unable to effectively enforce our proprietary rights, or if we are found to infringe the rights of others, we may be in breach of our license agreements with our partners.

Our success also depends upon trade secrets, proprietary know-how and the skills, knowledge and experience of our personnel. As a result, we require our employees, consultants, advisors, and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We also require our employees and consultants to disclose and assign to us their ideas, developments, discoveries, and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure. If any material trade secret or proprietary know-how were to be disclosed to or independently developed by a competitor, our competitive position may be materially harmed.

**Our product offerings and our customers' products may infringe on the intellectual property rights of third parties.**

From time to time, third parties have asserted intellectual property infringement claims against us and our customers and there can be no assurance that third parties will not assert infringement claims against either us or our customers in the future. While we believe that our product offerings do not infringe in any material respect upon proprietary rights of other parties and/or that meritorious defenses would exist with respect to any assertions to the contrary, there can be no assurance that we would not be found to infringe on the proprietary rights of others. Patent applications in the U.S. and some foreign countries are generally not publicly disclosed until the patent is issued or published, and we may not be aware of currently filed patent applications that relate to our offerings or processes. If patents later issue on these applications, we may be found liable for subsequent infringement. There has been substantial litigation in the pharmaceutical and biotechnology industries with respect to the manufacture, use and sale of products and processes that are the subject of conflicting patent rights.

Any claims that our product offerings or processes infringe these rights, regardless of their merit or resolution, could be costly and may divert the efforts and attention of our management and technical personnel. We may not prevail in such proceedings given the complex technical issues and inherent uncertainties in intellectual property litigation. If such proceedings result in an adverse outcome, we could, among other things, be required to:

pay damages in the form of lost profits and/or a reasonable royalty for any infringement;

pay substantial damages (potentially treble damages in the U.S. if any such infringement is found to be willful);

pay attorney fees of a prevailing party, if the case is found to be exceptional;

cease the manufacture, use or sale of the infringing offerings or processes;

discontinue the use of the infringing technology;

expend significant resources to design around patented technology and develop non-infringing technology;  
and

license patented technology from the third party claiming infringement, which license may not be available on commercially reasonable terms, or may not be available at all.

In addition, our customers' products may be subject to claims of intellectual property infringement and such claims could materially affect our business if their products cease to be manufactured and they have to discontinue the use of the infringing technology which we may provide. Further, depending on the particular circumstances of any given claim, it may be the case that we may be responsible for indemnifying our customer for a claim of intellectual

property infringement.

If we were to assert any of our own intellectual property against third parties and the third parties were found not to infringe our intellectual property or our intellectual property was found to be invalid, and/or unenforceable, we would lose the opportunity to leverage our own intellectual property, for example, through licensing of our technology to others, collection of damages and/or royalty payments based upon successful assertion of our intellectual property rights or market exclusivity via enjoining others from practicing the technology at issue.

Any of the foregoing could affect our ability to compete or have a material adverse effect on our business, financial condition and results of operations.

**The expiration of certain patents related to the Novasome technology could negatively impact our ability to generate income from the Novasome products.**

We license certain patents related to the Novasome technology platform pursuant to a license agreement. Many of the patents under this license have expired and more will expire before this license terminates on December 11, 2015. The loss of patent protection could allow additional competition. To the extent such competition develops, it could negatively impact the income we generate from the Novasome technology platform.

**Economic conditions could severely impact us.**

Current economic conditions may cause a decline in business and consumer spending which could adversely affect our business and financial performance. Our operating results are impacted by the health of the North American economies. Our business and financial performance, including collection of our accounts receivable, realization of inventory, recoverability of assets including investments, may be adversely affected by current and future economic conditions, such as a reduction in the availability of credit, financial market volatility and recession.

**Adverse conditions in the economy and disruption of financial markets could negatively impact our customers and therefore our results of operations.**

An economic downturn in the businesses or geographic areas in which we sell our products could reduce demand for these products and result in a decrease in sales volume that could have a negative impact on our results of operations. Volatility and disruption of financial markets could limit our customers' ability to obtain adequate financing or credit to purchase and pay for our products in a timely manner, or to maintain operations, and result in a decrease in sales volume that could have a negative impact on our results of operations. Additionally, economic conditions and market turbulence may also impact our suppliers causing them to be unable to supply in a timely manner sufficient quantities of product components, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

If the U.S. economy rapidly contracts or expands, we may have difficulty quickly scaling our operations in response, which may negatively impact our business and financial position.

**We are dependent on our new management team.**

Our success depends upon a number of members of our senior management, technical and other key personnel, including our executive officers, our board of directors and key employees with expertise in the generic pharmaceutical industry. Given our new strategy, during 2009 and 2010 we hired a new management team, including our new President and Chief Executive Officer and our new Chief Financial Officer. While the members of our new management team have been actively involved in the generic pharmaceutical industry, they have not worked together in their new positions with us and may not be able to successfully implement our strategy in the current economic environment. Integration of our new management team could harm our ability to manage our business effectively. In addition, the failure of our new management team to address our business objectives and strategy could materially adversely affect our financial performance and our future operating results.

**If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.**

We will need to hire additional qualified personnel with expertise in nonclinical testing, clinical research and testing, government regulation, formulation and manufacturing, sales and marketing and finance. We compete for qualified individuals with numerous pharmaceutical and consumer products companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

**If we fail to comply with the reporting obligations of the Exchange Act and Section 404 of the Sarbanes-Oxley Act of 2002, or if we fail to achieve and maintain adequate disclosure controls and procedures and internal control over financial reporting, our business results of operations and financial condition, and investors' confidence in us, could be materially adversely affected.**

As a public company, we are required to comply with the periodic reporting obligations of the Exchange Act including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. In addition, we are required under applicable law and regulations to integrate our systems of disclosure controls and procedures and internal control over financial reporting. Our management assessed our existing disclosure controls and procedures as of December 31, 2008, and our management concluded that our disclosure controls and procedures were not effective as of December 31, 2008 due to the material weakness described in our Annual Report on Form 10-K for that year. However, our management assessed our existing disclosure controls and procedures as of December 31, 2009 and through June 30, 2010 and our management concluded that our disclosure controls and procedures were effective as of such time.

If we fail to achieve and maintain the adequacy of our disclosure controls and procedures and internal control over financial reporting, we may not be able to ensure that we can conclude that we have effective disclosure controls and procedures and internal control over financial reporting in accordance with the Sarbanes-Oxley Act of 2002. Moreover, effective disclosure controls and procedures and internal control over financial reporting is necessary for us to produce reliable financial reports and is important to help prevent fraud. As a result, our failure to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business and negatively impact the trading price of our Common Stock.

**The pharmaceutical industry in which we operate is intensely competitive. We are particularly subject to the risks of competition. For example, the competition we encounter may have a negative impact upon the prices we may charge for our products, the market share of our products and our revenue and profitability.**

The pharmaceutical industry in which we operate is intensely competitive. The competition which we encounter has an effect on our product prices, market share, revenue and profitability. Depending upon how we respond to this competition, its effect may be materially adverse to us. We compete with:

the original manufacturers of the brand-name equivalents of our generic products; and  
other generic drug manufacturers.

Most of the products that we are developing are either generic drugs or products without patent protection. These drugs and products do not benefit from patent protection and are therefore more subject to the risk of competition than patented products. In addition, because many of our competitors have substantially greater financial, production and research and development ( R&D ) resources, substantially larger sales and marketing organizations, and substantially greater name recognition than we have, we are particularly subject to the risks inherent in competing with them. For example, many of our competitors may be able to develop products and processes competitive with, or superior to, our own. Furthermore, we may not be able to successfully develop or introduce new products that are less costly or offer better performance than those of our competitors or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

**Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third-parties.**

Our ability to market generic pharmaceutical products successfully depends, in part, on the acceptance of the products by independent third-parties (including pharmacies, government formularies, managed care providers, insurance

companies and retailers), as well as patients. In addition, unanticipated side effects or unfavorable publicity concerning any of our products, or any brand-name product of which our generic product is the equivalent, could have an adverse effect on our ability to achieve acceptance by managed care providers, pharmacies and other retailers, customers and patients.

### **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, 2010, the average daily trading volume of our Common Stock on the NYSE Amex was approximately 10,000 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.

**We have not paid dividends in the past nor do we expect to pay dividends in the foreseeable future, and any return on investment may be limited to potential future appreciation on the value of our Common Stock.**

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including without limitation, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. To the extent we do not pay dividends, our stock may be less valuable because a return on investment will only occur if and to the extent our stock price appreciates, which may never occur. In addition, investors must rely on sales of their Common Stock after price appreciation as the only way to realize their investment, and if the price of our stock does not appreciate, then there will be no return on investment. Investors seeking cash dividends should not purchase our Common Stock.

**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, 2004, 2005, 2006, 2007, 2008 and 2009 fiscal years. Our stockholders' equity at June 30, 2010 was \$4.9 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, 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 will be subject to periodic review by NYSE Amex Staff during the extension period. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the extension period could result in us being delisted from the NYSE Amex.

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.

**Our principal stockholders, directors and executive officers own a significant percentage of our stock and will be able to exercise significant influence over our affairs.**

Our current principal stockholders, directors and executive officers beneficially own approximately 83% of our outstanding capital stock entitled to vote. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their Common Stock as part of a sale of our Company and might ultimately affect the market price of our Common Stock.

**Our stock price is, and we expect it to remain, volatile and subject to wide fluctuations, which may make difficult for stockholders to sell shares of Common Stock at or above the price for which they were acquired.**

Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit. During the last two fiscal years, our stock price has closed at a low of \$.48 in the fourth quarter of 2008 and a high of \$2.57 in the second quarter of 2008. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our Common Stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the U.S. and foreign countries;
- economic or other crises, especially given the recent financial deterioration in the markets in which we compete, and other external factors;
- stock market price and volume fluctuations of other publicly traded companies and, in particular, those that are in the cosmetic, pharmaceutical and consumer products industry;
- actual or anticipated sales of our Common Stock, including sales by our directors, officers or significant stockholders;
- period-to-period fluctuations in our revenues and other results of operations;
- speculation about our business in the press or the investment community;
- changes in financial estimates by us or by any securities analysts who might cover our stock; and
- sales of our Common Stock.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation, even if it does not result in liability for us, could result in substantial costs to us and divert management's attention and resources.

**If the holders of our Series A Convertible Preferred Stock, Series C Convertible Preferred Stock, options and warrants to purchase Common Stock exercise their conversion rights, our Common Stock will be diluted.**

We have outstanding shares of Series A Convertible Preferred Stock and Series C Convertible Preferred Stock, as well as outstanding options and warrants to purchase shares of our Common Stock. If all or any number of these holders of

derivative securities were to exercise their conversion rights, our Common Stock would be substantially diluted, which could negatively impact our stock price.

**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.               |
| 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.   |

**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 15, 2010

By: /s/ Charles E. Moore  
Charles E. Moore  
President and Chief Executive Officer

Date: November 15, 2010

By: /s/ Philip S. Forte  
Philip S. Forte  
Chief Financial Officer

Exhibit Index

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