IGI LABORATORIES, INC Form 10-Q May 16, 2011

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

| FORM 10-Q |
|-----------|
|-----------|

| (Mar    | ·k One)   |
|---------|---|
| þ       | QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 |
|         | For the quarterly period ended March 31, 2011                                     |
| <br>TRA | ANSITION 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)

01-0355758

Delaware

| (State or other Jurisdiction of incorporation or organization)   | (I.R.S. Employer Identification No.)        |   |  |
|--|---|---|--|
| 105 Lincoln Avenue<br>Buena, New Jersey<br>(Address of Principal Executive Offices   | 5)  | <b>08310</b> (Zip Code)                     |  |
|  | (856) 697-1441                              |   |  |
| (Registrant's tel  | ephone number, including                    | area code)                                  |  |
| Indicate by check mark whether the registrant (1 Securities Exchange Act of 1934 during the pre required to file such reports), and (2) has been su ]                          | eceding 12 months (or for                   | such shorter period that the registrant was |  |
| Indicate by check mark whether the registrant lany, every Interactive Data File required to be (§232.405 of this chapter) during the preceding to submit and post such files). | be submitted and posted                     | pursuant to Rule 405 of Regulation S-T      |  |
|  |   | Yes [ ] No [ ]                              |  |
| Indicate by check mark whether the registrant is or a smaller reporting company. See the defin reporting company" in Rule 12b-2 of the Exchan                                  | itions of "large accelerate                 |   |  |
| Large accelerated filer [ ] Non-accelerated filer [ ]  | Accelerated filer Smaller reporting company | [ ]<br>þ                                    |  |

| Indicat | te by check ma | ark whether the re | gistrant is a she | ll company (as | s defined in R | ule 12b-2 of th | e Exchange | Act). Yes |
|---------|----------------|--------------------|-------------------|----------------|----------------|-----------------|------------|-----------|
| []      | No þ           |                    |                   |                |                |                 |            |           |

The number of shares outstanding of the issuer's common stock is 41,433,836 shares, net of treasury stock, as of May 11, 2011.

## **PART I**

## FINANCIAL INFORMATION

## **ITEM 1. Financial Statements**

# IGI LABORATORIES, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except shares and per share information)

(Unaudited)

|  | Three months ended March 31 |            |
|--|-----------------------------|------------|
|  | 2011                        | 2010       |
| Revenues:  |                             |            |
| Product sales, net                                   | \$ 1,361                    | \$ 790     |
| Research and development income                      | 151                         | 23         |
| Licensing and royalty income                         | 55                          | 68         |
| Other revenue  | 7                           | -          |
| Total revenues                                       | 1,574                       | 881        |
| Costs and Expenses:                                  |                             |            |
| Cost of sales  | 1,241                       | 1,004      |
| Selling, general and administrative expenses         | 933                         | 907        |
| Product development and research expenses            | 379                         | 195        |
| Operating loss                                       | (979)                       | (1,225)    |
| Interest income (expense), net                       | (55)                        | 1          |
| Net Loss   | \$(1,034)                   | \$(1,224)  |
| Basic and diluted loss per share                     | \$ (.03)                    | \$ (.07)   |
| Weighted average shares of common stock outstanding: |                             |            |
| Basic and diluted                                    | 39,313,087                  | 17,551,447 |

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)

|   | March 31,<br>2011 | December 31,<br>2010* |
|---|-------------------|-----------------------|
| ASSETS  |                   |                       |
| Current assets:   |                   |                       |
| Cash and cash equivalents   | \$ 4,640          | \$ 5,116              |
| Accounts receivable, less allowance for doubtful accounts of \$10 in 2011and 2010 | 1,106             | 794                   |
| Licensing and royalty income receivable   | 23                | 21                    |
| Inventories   | 854               | 816                   |
| Other receivables   | 11                | 234                   |
| Prepaid expenses  | 301               | 190                   |
| Total current assets  | 6,935             | 7,171                 |
| Property, plant and equipment, net  | 2,741             | 2,769                 |
| Restricted cash, long term  | 54                | 54                    |
| License fee, net  | 475               | 500                   |
| Debt issuance costs, net  | 760               | 800                   |
| Other   | 57                | 57                    |
| Total assets  | \$ 11,022         | \$ 11,351             |
| LIABILITIES AND STOCKHOLDERS EQUITY   |                   |                       |
| Current liabilities:  |                   |                       |
| Accounts payable  | \$ 343            | \$ 341                |
| Accrued expenses  | 572               | 476                   |
| Deferred income, current  | 57                | 58                    |
| Capital lease obligation, current   | 33                | 32                    |
| Total current liabilities   | 1,005             | 907                   |
| Note payable, related party   | 500               | -                     |

| Deferred income, long term   | 28        | 29        |
|--|-----------|-----------|
| Capital lease obligation, long term  | 60        | 68        |
| Total liabilities  | 1,593     | 1,004     |
| Commitments and contingencies  |           |           |
| Stockholders equity:   |           |           |
| Series A Convertible Preferred stock, liquidation preference - \$500,000 at March 31, 2011 and December 31, 2010 | 500       | 500       |
| Series C Convertible Preferred stock, liquidation preference - \$1,609,027                                       |           |           |
| at   |           |           |
| March 31, 2011 and December 31, 2010   | 1,517     | 1,517     |
| Common stock   | 414       | 413       |
| Additional paid-in capital   | 45,938    | 45,823    |
| Accumulated deficit  | (37,545)  | (36,511)  |
| Less treasury stock, 1,965,740 common shares at cost   | (1,395)   | (1,395)   |
| Total stockholders equity  | 9,429     | 10,347    |
| Total liabilities and stockholders' equity   | \$ 11,022 | \$ 11,351 |

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

<sup>\*</sup> Derived from the audited December 31, 2010 financial statements

# IGI LABORATORIES, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

## (in thousands)

# (Unaudited)

|  | Three months ended March |           |
|--|--------------------------|-----------|
|  | 2011                     | 2010      |
| Cash flows from operating activities:                                |                          |           |
| Net loss   | \$(1,034)                | \$(1,224) |
| Reconciliation of net loss to net cash used in operating activities: |                          |           |
| Depreciation   | 77                       | 62        |
| Amortization of license fee  | 25                       | 25        |
| Stock-based compensation expense                                     | 103                      | 165       |
| Provision for write down of inventory                                | 36                       | -         |
| Amortization of debt issuance costs                                  | 40                       | -         |
| Changes in operating assets and liabilities:                         |                          |           |
| Accounts receivable  | (312)                    | 89        |
| Licensing and royalty income receivable                              | (2)                      | 29        |
| Inventories  | (74)                     | (380)     |
| Prepaid expenses and other current assets                            | 112                      | (154)     |
| Accounts payable and accrued expenses                                | 98                       | 194       |
| Deferred income  | (2)                      | 119       |
| Net cash used in operating activities                                | (933)                    | (1,075)   |
| Cash flows from investing activities:                                |                          |           |
| Capital expenditures   | (49)                     | (67)      |
| Deposits for capital expenditures                                    | -                        | (37)      |
| Net cash used in investing activities                                | (49)                     | (104)     |
| Cash flows from financing activities:                                |                          |           |
| Proceeds from note payable, related party                            | 500                      | -         |
| Sale of Series C Convertible preferred stock, net of expenses        | -                        | 1,517     |
| Principal payments on capital lease obligation                       | (7)                      | -         |
| Proceeds from exercise of common stock options                       | 13                       | -         |

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| Net cash provided by financing activities            | 506      | 1,517    |  |
|--|----------|----------|--|
| Net (decrease) increase in cash and cash equivalents | (476)    | 338      |  |
| Cash and cash equivalents at beginning of period     | 5,116    | 1,124    |  |
| Cash and cash equivalents at end of period           | \$ 4,640 | \$ 1,462 |  |
| Supplemental cash flow information:                  |          |          |  |
| Cash payments for interest                           | \$ 3     | \$ -     |  |
| Cash payment for taxes                               | 6        | 5        |  |

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

## IGI LABORATORIES, INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

## For the three months ended March 31, 2011

(in thousands, except share information)

**Series C** 

50

naudited)

\$ 500

1,550

|  | Series A<br>Preferred Stock |                |        | ertible<br>red Stock | Common Stock |         | Additional<br>Paid-In | Accumulated           | Treasury             | Total<br>Stockholde |
|--|-----------------------------|----------------|--------|----------------------|--------------|---------|-----------------------|-----------------------|----------------------|---------------------|
|  | Shares                      | Amount         | Shares | Amount               | Shares       | Amount  | Capital               | Deficit               | Stock                | Equity              |
| lance,<br>cember 31,                             | <b>T</b> 0                  | <b>4. 5</b> 00 | 4.770  | <b>.</b>             | 44.200.400   | <b></b> | <b>4.47.022</b>       | \$ (0.6 <b>T</b> .11) | \$ (4.20 <b>.</b> 7) | <b>.</b> 10.2       |
| udited)  | 50                          | \$ 500         | 1,550  | \$1,517              | 41,288,199   | \$ 413  | \$ 45,823             | \$ (36,511)           | \$(1,395)            | \$ 10,34            |
| ock based<br>mpensation<br>pense -<br>ck options |                             |                |        |                      |              |         | 47                    |                       |                      | 4                   |
| ock based<br>mpensation<br>pense -<br>tricted    |                             |                |        |                      |              |         |                       |                       |                      |                     |
| ck   |                             |                |        |                      |              |         | 56                    |                       |                      | 4                   |
| stricted<br>ck forfeited                         |                             |                |        |                      | (106,672)    | (1)     | 1                     |                       |                      |                     |
| ock options<br>ercised                           |                             |                |        |                      | 15,000       |         | 13                    |                       |                      | :                   |
| arrants<br>ercised                               |                             |                |        |                      | 200,646      | 2       | (2)                   |                       |                      |                     |
| et loss  | -                           | -              | -      | -                    | -            | -       | -                     | (1,034)               | -                    | (1,03               |
| lance,<br>arch 31,<br>11                         |                             |                |        |                      |              |         |                       |                       |                      |                     |

\$ 45,938

\$ 414

\$ (37,545)

\$(1,395)

\$1,517 41,397,173

\$ 9,42

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, 2010. The condensed consolidated balance sheet as of December 31, 2010 has been derived from those audited consolidated financial statements. Operating results for the three month period ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011.

1.

#### **Organization**

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

2.

#### Liquidity

The Company s principal sources of liquidity are cash and cash equivalents of approximately \$4,640,000 at March 31, 2011, the \$2,500,000 available on the \$3,000,000 credit facility detailed below and cash from operations. The

Company sustained a net loss of \$1,034,000 for the three months ended March 31, 2011, and had working capital of \$5,930,000 at March 31, 2011.

The Company s business operations have been primarily funded over the past two years through private placements of our capital stock. As described more fully in Notes 8, 10 and 11, we raised an aggregate of \$7,213,000 through private placements of equity with accredited investors in 2010 and \$5,304,000 in 2009 principally from private equity investors. In 2010, we also entered into a \$3,000,000 line of credit. The Company may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, the Company may continue to seek to raise additional capital through the sale of its equity. It may be accomplished via a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. We also have the ability to defer certain product development and other programs, if necessary. We believe that our existing capital resources including the recently completed line of credit and private placements detailed below will be sufficient to support our current business plan beyond May 2012.

On December 21, 2010, we entered into a Credit Agreement with Amzak Capital Management, LLC pursuant to which Amzak has agreed to extend a \$3,000,000 credit facility to the Company. As of March 31, 2011 the outstanding balance on the line of credit was \$500,000. To secure payment of the amounts financed under the Credit Agreement, the Company has granted to the Lender a security interest in and against, generally, all of its tangible and intangible assets, except intellectual property, pursuant to that certain Pledge and Security Agreement with the Lender dated December 21, 2010. In addition, the Company has pledged to the Lender its equity interests in IGEN, Inc., one of the Company s wholly-owned subsidiaries.

On December 8, 2010, we completed the sale of 5,909,087 shares of the Company s common stock, \$0.01 par value per share (the Common Stock), to several accredited investors, as defined in Rule 501 of Regulation D under the Securities Act of 1933, as amended (the Securities Act) at a price of \$1.10 per share, or an aggregate of approximately \$6,500,000. The Company paid placement agent fees of \$650,000 and issued warrants to purchase 354,546 shares of Common Stock at \$1.21 per share. The Common Stock and the Warrants were issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

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 Convertible 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).

3.

**Summary of Significant Accounting Policies** 

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowance, stock based compensation, and accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

#### Loss Per Share

Basic net (loss) per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted net (loss) per share of common stock is computed using the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period. Due to the net loss for the three months ended March 31, 2011 and 2010, the effect of the Company s potential dilutive common stock equivalents was anti-dilutive for each period; as a result, the basic and diluted weighted

average number of common shares outstanding and net (loss) per common share are the same. Potentially dilutive common stock equivalents include options and warrants to purchase the Company s common stock and the conversion of preferred stock, which were excluded from the net (loss) per share calculations due to their anti-dilutive effect amounted to 5,430,675 for 2011 and 20,423,446 for 2010.

#### 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.

<u>Product Sales</u>: The Company recognizes revenue when title transfers to its customers, which is generally upon shipment of products. The revenues associated with these transactions, net of appropriate cash discounts, product returns and sales reserves, are recorded upon shipment of the products.

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

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

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

#### **Major Customers**

Major customers of the Company are defined as having revenue greater than 10% of total gross revenue. For the three months ended March 31, 2011 and 2010, two of our customers accounted for 56% and four of our customers accounted for 70% of our revenue, respectively. Two of these customers are the same for both periods. Accounts receivable related to the Company s major customers comprised 53% of all accounts receivable as of March 31, 2011. The loss of one or more of these customers could have a significant impact on our revenues and harm our business and results of operations.

#### **Recent Accounting Pronouncements**

There were no new accounting pronouncements for the three months ended March 31, 2011 that have a material impact on the Company s consolidated financial statements.

4.

#### **Inventories**

Inventories are valued at the lower of cost, using the first-in, first-out (FIFO) method, or market. Inventories at March 31, 2011 and December 31, 2010 consist of:

|                  | March 31, 2011 | <b>December 31, 2010</b> |
|------------------|----------------|--------------------------|
|                  | (Unaudited)    | (Audited)                |
|                  | (amounts       | in thousands)            |
| Raw materials    | \$ 781         | \$ 759                   |
| Work in progress | 19             | 10                       |
| Finished goods   | 54             | 47                       |
| Total            | \$ 854         | \$ 816                   |

5.

#### **Stock-Based Compensation**

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

The 1999 Director Stock Option Plan, as amended (the Director Plan), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. An aggregate of 1,975,000 shares have been approved and authorized for issuance pursuant to this plan. A total of 1,939,798 options have been granted to non-employee directors through March 31, 2011. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years.

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

On June 26, 2009, the Board of Directors adopted, and the Company's stockholders subsequently approved by partial written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the 2009 Plan ). The 2009 Plan became effective on July 29, 2009, 20 days after the initial mailing of the Company s Information Statement on Schedule 14C to its stockholders. The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company s current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. On April 12, 2010, the Board of Directors adopted, and the Company s stockholders subsequently approved, an amendment and restatement of the 2009 Equity Incentive Plan to increase the number of shares of common stock available for grant under such plan by adding 2,000,000 shares of common stock. The 2009 Plan, as amended on May 19, 2010, authorizes up to 4,000,000 shares of the Company s common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of March 31, 2011, options to purchase 260,000 shares of common stock were outstanding under the 2009 Plan and 1,039,000 shares of restricted stock had been granted under the 2009 Plan.

#### **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 three months ended March 31, 2011

Expected volatility 61.5% - 61.9% Expected term (in years) 3.2 years Risk-free rate 1.20% Expected dividends 0%

A summary of option activity under the 1999 Plan, the Director Plan and the 2009 Plan as of March 31, 2011 and changes during the period are presented below:

|                             | Number of Options | Weighted<br>Average<br>Exercise Price |  |
|-----------------------------|-------------------|---------------------------------------|--|
| Outstanding as of 1/1/2011  | 1,298,516         | \$1.09                                |  |
| Issued                      | 145,000           | \$1.69                                |  |
| Exercised                   | (15,000)          | \$0.86                                |  |
| Forfeited                   | (93,337)          | \$1.01                                |  |
| Expired                     | -                 | -                                     |  |
| Outstanding as of 3/31/2011 | 1,335,179         | \$1.17                                |  |
| Exercisable as of 3/31/2011 | 1,165,179         | \$1.10                                |  |

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options granted during the three months ended March 31, 2011 was \$0.73.

The following table summarizes information regarding options outstanding and exercisable at March 31, 2011:

#### **Outstanding:**

|                          |        |             |                | Weighted    |
|--------------------------|--------|-------------|----------------|-------------|
|                          |        |             |                | Average     |
|                          |        | Stock       | Weighted       | Remaining   |
|                          |        | Options     | Average        | Contractual |
| Range of Exercise Prices |        | Outstanding | Exercise Price | Life        |
| \$0.50                   | \$1.00 | 352,500     | \$0.72         | 5.56        |
| \$1.01                   | \$1.50 | 750,663     | \$1.23         | 6.26        |
| \$1.51                   | \$2.25 | 232,016     | \$1.64         | 8.05        |
| Total                    |        | 1,335,179   | \$1.17         | 6.39        |

## **Exercisable:**

|             |               | Stock       | Weighted       |
|-------------|---------------|-------------|----------------|
|             |               | Options     | Average        |
| Range of Ex | ercise Prices | Exercisable | Exercise Price |
| \$0.50      | \$1.00        | 352,500     | \$0.72         |
| \$1.01      | \$1.50        | 730,663     | \$1.24         |
| \$1.51      | \$2.25        | 82,016      | \$1.59         |
| Total       |               | 1,165,179   | \$1.10         |

As of March 31, 2011, the intrinsic value of the options outstanding is \$511,300 and the intrinsic value of the options exercisable is \$501,300. The total intrinsic value of the options exercised during the three months ended March 31, 2011 was \$10,050. As of March 31, 2011, there was approximately \$86,800 of total unrecognized compensation cost that will be recognized through October 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 \$56,500 and \$98,000, respectively, of compensation expense during the three months ended March 31, 2011 and 2010 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At March 31, 2011, the Company had approximately \$427,000 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized from April 2011 through April 2013.

|  | Number of<br>Restricted<br>Stock | Weighted<br>Average<br>Exercise Price |
|--|----------------------------------|---------------------------------------|
| Non-vested balance at January 1, 2011                                    | 939,000                          | \$ 0.71                               |
| Changes during the period: Shares granted Shares vested Shares forfeited | -<br>(126,333)<br>-              | -<br>0.75<br>-                        |
| Non-vested balance at March 31, 2011                                     | 812,667                          | \$ 0.70                               |

See Note 12 below regarding restricted stock award to Philip S. Forte, the Company s Chief Financial Officer upon his resignation as of January 11, 2011.

| 4 | • |  |
|---|---|--|
|   | n |  |

#### **Income Taxes**

As a result of the Company s history of continuing tax losses, the Company does not have a current tax provision and has recorded a full valuation allowance against its net deferred tax asset. The Company has not recorded a liability for unrecognized tax benefits at March 31, 2011 and no significant changes are expected in the next twelve months. The tax years 2007-2010 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 March 31, 2011.

The Company s ability to use net operating loss carry forwards may be subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code, which limit the utilization of net operating losses upon a more than 50% change in ownership of the Company s stock that is held by 5% or greater stockholders. The Company is currently examining the application of Section 382 with respect to an ownership change that took place during 2009 and 2010, as well as the possibility of such limitation having any material effect on the application of net operating loss carry forwards in the immediate future. The Company believes that it is likely that a change in ownership took place and that the net operating loss carryforwards will be limited.

**7.** 

#### License Fee

On December 12, 2005, the Company extended its license agreement for an additional ten years with Novavax, Inc. for \$1,000,000. This extension entitles the Company to exclusive use of the Novasome® lipid vesicle encapsulation and certain other technologies (each a Microencapsulation Technology, and collectively, the Technologies) in the fields of (i) animal pharmaceuticals, biologicals and other animal health products; (ii) foods, food applications, nutrients and flavorings; (iii) cosmetics, consumer products and dermatological over-the-counter and prescription products (excluding certain topically delivered hormones); (iv) fragrances; and (v) chemicals, including herbicides,

insecticides, pesticides, paints and coatings, photographic chemicals and other specialty chemicals, and the processes for making the same (collectively, the IGI Field ) through 2015. This payment is being amortized ratably over the ten-year period. The Company recorded amortization expense of \$25,000 related to this agreement for each of the three month periods ended March 31, 2011 and 2010.

8.

**Note Payable Related Party** 

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

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

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

Upon funding of each Advance (as defined therein), the Company shall make payments of accrued interest on the unpaid Accreted Principal Amount (as defined therein) of each promissory note. The interest rate applicable to each promissory note shall be 14% per annum and interest payments are due on each March 31, June 30, September 30 and December 31 during the term of the Credit Agreement, commencing March 31, 2011. The Company may prepay any Advance in connection with the consummation of a Liquidity Event (as defined therein) or at any time subsequent to December 21, 2012.

In addition, as consideration for entering into the Credit Agreement, on December 21, 2010, the Company issued to the Lender a ten-year warrant to purchase certain shares of the Company's common stock, at an exercise price of \$0.01 per share (the *Warrant*). The Warrant is immediately exercisable for 881,331 shares of Common Stock (the *Initial Warrant Shares*) with the remaining shares of Common Stock representing 1% of the Fully Diluted Shares (as defined therein) as of the Conditional Warrant Exercise Date (as defined therein) (the *Conditional Warrant Shares*) becoming exercisable July 1, 2012 if the Company has achieved certain milestones related to the Company's product development or financial growth. The Warrant is accounted for as an equity instrument. The fair value of the Initial Warrant of \$723,541 will be recorded as debt issuance costs and amortized on a straight-line basis over the stated term of the Credit Agreement which is five years. Amortization expense of \$40,000 was recognized for the three months ended March 31, 2011. The Company anticipates amortization expense to be approximately \$160,000 for the years 2012 to 2016. On December 21, 2010, the fair value of the Conditional Warrant is not considered to be material. The fair value of the Conditional Warrant will be recognized as additional expense when and if it becomes exercisable.

In connection with the Financing, the Company entered into two registration rights agreements (the *Registration Rights Agreements*) with the Lender pursuant to which the Company granted the Lender specified registration rights relating to the Initial Warrant Shares and the Conditional Warrant Shares. The Registration Rights Agreements provide that the Company will file resale registration statements covering all of the Registrable Shares (as defined therein) within 210 days of the execution of the Registration Rights Agreement for the Initial Warrants Shares and within 210 days of the Conditional Warrant Exercise Date (as defined therein) for the Conditional Warrant Shares, subject to certain limitations. Further, the Company has agreed to pay the Lender specified cash payments as partial liquidated damages in the event the Registration Statements are not filed in a timely manner. The Registration Statement for the Initial Warrants Shares was filed on April 20, 2011, within 210 days of the execution of the Registration Rights Agreement for the Initial Warrants Shares.

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

The Lender is a shareholder of the Company and participated in the private placement described in Note 11 below and previously disclosed in a Current Report on Form 8-K filed with the Securities and Exchange Commission on December 8, 2010.

9.

**Stock Warrants** 

Stock Warrants activity for the quarters ended March 31, 2011 and 2010 consisted of:

|                        | <u>2011</u>     |                | <u>2010</u> |                |
|------------------------|-----------------|----------------|-------------|----------------|
|                        |                 | Weighted       |             | Weighted       |
|                        |                 | Average        |             | Average        |
|                        | <u>Warrants</u> | Exercise Price | Warrants    | Exercise Price |
| Beginning balance      | 1,498,377       | \$0.36         | 262,500     | \$0.41         |
| Stock warrants granted | -               | -              | -           | -              |
| Stock warrants expired |                 |                |             |                |