

IGI INC  
Form 10-Q  
November 14, 2008

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, 2008

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

08310

, New Jersey

(Address of Principal Executive Offices)

(Zip Code)

(856)

**697-1441**

(Registrant's telephone number, including area code)

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

Yes  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

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 14,907,478 shares, net of treasury stock, as of November 5, 2008.

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PART I  
 FINANCIAL INFORMATION

ITEM 1. Financial Statements

IGI LABORATORIES, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF OPERATIONS  
 (in thousands, except share and per share information)  
 (Unaudited)

|  | Three months ended September 30, |              | Nine months ended September 30, |              |
|--|----------------------------------|--------------|---------------------------------|--------------|
|  | 2008                             | 2007         | 2008                            | 2007         |
| Revenues:                                    |                                  |              |                                 |              |
| Product sales                                | \$ 770                           | \$ 520       | \$ 2,547                        | \$ 1,865     |
| Research and development income              | 116                              | 329          | 244                             | 617          |
| Licensing and royalty income                 | 87                               | 156          | 364                             | 444          |
| <b>Total revenues</b>                        | <b>973</b>                       | <b>1,005</b> | <b>3,155</b>                    | <b>2,926</b> |
| Cost and expenses:                           |                                  |              |                                 |              |
| Cost of sales                                | 732                              | 494          | 1,976                           | 1,632        |
| Selling, general and administrative expenses | 672                              | 469          | 2,031                           | 1,651        |
| Product development and research expenses    | 136                              | 135          | 372                             | 360          |
| <b>Operating loss</b>                        | <b>(567)</b>                     | <b>(93)</b>  | <b>(1,224)</b>                  | <b>(717)</b> |
| Interest expense (net)                       | (3)                              | (12)         | (9)                             | (39)         |
| Other income                                 | 2                                | -            | 7                               | 64           |
| <b>Loss from continuing operations</b>       | <b>(568)</b>                     | <b>(105)</b> | <b>(1,226)</b>                  | <b>(692)</b> |

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|   |                 |                 |                   |                 |
|---|-----------------|-----------------|-------------------|-----------------|
| Gain from discontinued operations   | -               | -               | -                 | 5               |
| Net loss  | <u>\$ (568)</u> | <u>\$ (105)</u> | <u>\$ (1,226)</u> | <u>\$ (687)</u> |
| Basic and Diluted Loss Per Share  |                 |                 |                   |                 |
| Continuing operations net loss per share                                  | (.04)           | \$ (.01)        | \$ (.08)          | \$ (.05)        |
| Discontinued operations income per share                                  | -               | -               | -                 | \$ -            |
| Net loss per share  | <u>\$ (.04)</u> | <u>\$ (.01)</u> | <u>\$ (.08)</u>   | <u>(.05)</u>    |
| Weighted Average of Common Stock and Common Stock Equivalents Outstanding |                 |                 |                   |                 |
| Basic and diluted   | 14,907,478      | 14,612,899      | 14,872,610        | 14,210,812      |

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

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IGI LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
(in thousands, except share and per share information)

|  | September 30,<br>2008<br>(unaudited) | December 31,<br>2007*       |
|--|--------------------------------------|-----------------------------|
|  | <u>                    </u>          | <u>                    </u> |
| <b>ASSETS</b>  |                                      |                             |
| Current assets:  |                                      |                             |
| Cash and cash equivalents  | \$ 207                               | \$ 914                      |
| Accounts receivable, less allowance for doubtful accounts<br>of \$38 and \$48 in 2008 and 2007, respectively | 570                                  | 666                         |
| Licensing and royalty income receivable  | 96                                   | 356                         |
| Inventories  | 644                                  | 376                         |
| Prepaid expenses and other current assets  | 105                                  | 93                          |
|  | <u>                    </u>          | <u>                    </u> |
| Total current assets   | 1,622                                | 2,405                       |
| Property, plant and equipment, net   | 2,332                                | 2,410                       |
| Restricted cash - long term  | 50                                   | 50                          |
| Other assets - long term   | 20                                   | -                           |
| License fee, net   | 725                                  | 800                         |
|  | <u>                    </u>          | <u>                    </u> |
| Total assets   | \$ 4,749                             | \$ 5,665                    |

## LIABILITIES AND STOCKHOLDERS' EQUITY

## Current liabilities:

|                              |        |        |
|------------------------------|--------|--------|
| Note payable - related party | \$ 250 | \$ 500 |
| Accounts payable             | 511    | 282    |
| Accrued expenses             | 349    | 419    |
| Deferred income, current     | 194    | 219    |
|                              | <hr/>  | <hr/>  |
| Total current liabilities    | 1,304  | 1,420  |
| Deferred income, long term   | 41     | 45     |
| Other long term liabilities  | -      | 60     |
|                              | <hr/>  | <hr/>  |
| Total liabilities            | 1,345  | 1,525  |
|                              | <hr/>  | <hr/>  |

## Stockholders' equity:

|  |          |          |
|--|----------|----------|
| Series A Convertible Preferred stock, \$.01 par value,<br>100 shares authorized; 50 shares issued as of<br>September 30, 2008 and December 31, 2007, respectively;         | 500      | 500      |
| Liquidation preference- \$500,000  |          |          |
| Common stock, \$.01 par value, 50,000,000 shares<br>authorized; 16,873,218 and 16,795,202 shares issued<br>as of September 30, 2008 and<br>December 31, 2007, respectively | 168      | 168      |
| Additional paid-in capital   | 27,901   | 27,411   |
| Accumulated deficit  | (23,770) | (22,544) |
| Less treasury stock, 1,965,740 shares at cost  | (1,395)  | (1,395)  |
|  | <hr/>    | <hr/>    |
| Total stockholders' equity   | 3,404    | 4,140    |
|  | <hr/>    | <hr/>    |
| Total liabilities and stockholders' equity   | \$ 4,749 | \$ 5,665 |
|  | <hr/>    | <hr/>    |

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

\* Derived from the audited December 31, 2007 financial statements

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IGI LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(in thousands)  
(Unaudited)

Nine months ended September 30,

|  |       |       |
|--|-------|-------|
|  | <hr/> | <hr/> |
|  | 2008  | 2007  |
|  | <hr/> | <hr/> |

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|  |    |         |          |
|--|----|---------|----------|
| Cash flows from operating activities:                                |    |         |          |
| Net loss   | \$ | (1,226) | \$ (687) |
| Reconciliation of net loss to net cash used in operating activities: |    |         |          |
| Depreciation and amortization  |    | 185     | 172      |
| Amortization of license fee  |    | 75      | 75       |
| Bad debt expense   |    | 34      | -        |
| Provision for write down of inventory                                |    | 42      | -        |
| Stock based compensation expense                                     |    | 392     | 231      |
| Gain on sale of assets of discontinued operations                    |    | -       | (5)      |
| Recognition of deferred revenue                                      |    | -       | (378)    |
| Changes in operating assets and liabilities:                         |    |         |          |
| Accounts receivable  |    | 62      | (228)    |
| Licensing and royalty income receivable                              |    | 260     | (55)     |
| Inventories  |    | (310)   | (37)     |
| Prepaid expenses and other assets                                    |    | (33)    | (36)     |
| Accounts payable and accrued expenses                                |    | 100     | (132)    |
| Deferred income  |    | (29)    | 156      |
|  |    | <hr/>   | <hr/>    |
| Net cash used in operating activities                                |    | (448)   | (924)    |
|  |    | <hr/>   | <hr/>    |
| Cash flows from investing activities:                                |    |         |          |
| Capital expenditures   |    | (107)   | (168)    |
| Proceeds from deposit on sale of assets of discontinued operations   |    | -       | 260      |
|  |    | <hr/>   | <hr/>    |
| Net cash (used in) provided by investing activities                  |    | (107)   | 92       |
|  |    | <hr/>   | <hr/>    |
| Cash flows from financing activities:                                |    |         |          |
| Borrowing from note payable - related party                          |    | -       | 500      |
| Repayment of notes payable - related party                           |    | (250)   | (1,145)  |
| Repayment of note payable  |    | -       | (306)    |
| Proceeds from exercise of common stock options and warrant           |    | 98      | -        |
| Proceeds from private placement of common stock, net of expenses     |    | -       | 1,298    |
|  |    | <hr/>   | <hr/>    |
| Net cash (used in) provided by financing activities                  |    | (152)   | 347      |
|  |    | <hr/>   | <hr/>    |
| Net decrease in cash and equivalents                                 |    | (707)   | (485)    |
| Cash and equivalents at beginning of period                          |    | 914     | 619      |
|  |    | <hr/>   | <hr/>    |
| Cash and equivalents at end of period                                | \$ | 207     | \$ 134   |

## Supplemental cash flow information:

|                            |    |    |    |    |
|----------------------------|----|----|----|----|
| Cash payments for interest | \$ | 19 | \$ | 51 |
| Cash payment for taxes     |    | 5  |    | 5  |

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

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IGI LABORATORIES, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the 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-KSB for the year ended December 31, 2007. The condensed consolidated balance sheet as of December 31, 2007 has been derived from those audited consolidated financial statements. Operating results for the nine month period ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008.*

1. Liquidity

The Company has sustained a net loss of \$1,226,000 for the nine months ended September 30, 2008 and had working capital of \$318,000 at September 30, 2008. The Company's principal sources of liquidity are cash and cash equivalents of approximately \$207,000 at September 30, 2008, future cash from operations, and a \$250,000 unused balance on our \$500,000 line of credit from Pinnacle Mountain Partners, LLC. This line of credit will expire on January 31, 2009.

We believe that our operating cash flow along with our existing capital resources will not be sufficient to support our current business plan through November 2009. The Company will require additional funding. This funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, 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. In addition, there may be additional acquisition and growth opportunities that may require external financing. There can be no assurances that such financing will be available or available on terms acceptable to the Company.

2. Organization

On May 7, 2008, the stockholders of IGI, Inc. approved the name change of the Company from IGI, Inc. to IGI Laboratories, Inc. IGI Laboratories, Inc. ("IGI", "IGI, Inc." or the "Company"), a Delaware corporation, operating in the State of New Jersey, is primarily engaged in the development, manufacturing, filling and packaging of topical, semi-solid and liquid products for pharmaceutical, cosmeceutical and cosmetic companies primarily using its licensed Novasome® encapsulation

technology. These efforts have been directed toward the development of high quality skin care and treatment products marketed through collaborative arrangements with pharmaceutical and consumer products companies.

The Company also provides product development and analytical services to its customers in addition to its manufacturing and packaging services.

IGI's mission is to be a premier provider of topical liquid and semi-solid products to its customers using Novasome® encapsulation technology.

On May 6, 2008, the Company was notified by the American Stock Exchange ("AMEX") that it was below certain of AMEX continued listing standards. Specifically, the Company was required to reflect income from continuing operations and/or net income in one of its five most recent fiscal years and a minimum of \$6,000,000 in stockholders' equity to remain listed on the exchange. The Company had net income from continuing operations in its 2002 fiscal year, but had net losses and losses from continuing operations in each of its 2003, 2004, 2005, 2006 and 2007 fiscal years. The Company's stockholders' equity at September 30, 2008 was \$3.4 million.

On July 15, 2008, AMEX notified the Company that it accepted the Company's plan of compliance and granted the Company an extension until May 6, 2009 to regain compliance with the continued listing standards described above. The Company will be subject to periodic review by 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 the Company being delisted from AMEX.

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#### 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, 2008 and 2007, three of our customers accounted for 62% and four of our customers accounted for 71% of our revenue, respectively. For the nine months ended September 30, 2008 and 2007, four of our customers accounted for 58% and two of our customers accounted for 34% of our revenue, respectively. Accounts receivable related to the Company's major customers comprised 57% of all account receivables as of September 30, 2008. 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.

### 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.

### Earnings Per Share

Basic earnings per common share and diluted earnings per common share are presented in accordance with SFAS No. 128, *Earnings per Share*. Basic earnings per common share have been computed using the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share incorporate the incremental shares issuable upon the assumed exercise of stock options and warrants, if dilutive. Due to the net loss for the nine months ended September 30, 2008 and 2007 and for the quarters ended September 30, 2008 and 2007, 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.

### 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 SAB No. 104, *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 Revenues

: 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.

### Product Development Services

: The Company establishes agreed upon product development agreements with its customers to perform product development services. Product development revenues are recognized in accordance with the product development agreement upon the completion of the phases of development and when we have no future performance obligations relating to that phase of development. Revenue recognition requires the Company to assess progress against contracted obligations to assure completion of each stage. Payments under these arrangements are generally non-refundable

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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.



## Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141 (revised 2007), *Business Combinations* ("FAS 141R"), which replaces FASB Statement No. 141. FAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non controlling interest in the acquiree and the goodwill acquired. The Statement also establishes disclosure requirements, which will enable users to evaluate the nature and financial effects of the business combination. FAS 141R is effective as of the beginning of an entity's fiscal year that begins after December 15, 2008. FAS 141R will only have an impact on our financial position or results of operations if we enter into a business combination.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of Accounting Research Bulletin No. 51* ("FAS 160"), which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. The Statement also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. FAS 160 is effective as of the beginning of an entity's fiscal year that begins after December 15, 2008. The Company is currently evaluating the potential impact, if any, of the adoption of FAS 160 on its consolidated financial position, results of operations and cash flows but believes the adoption of FAS 160 will not have a material effect on its results of operations or financial position.

In December 2007, the Emerging Issues Task Force (EITF) issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*. EITF 07-1 provides guidance concerning: determining whether an arrangement constitutes a collaborative arrangement within the scope of the Issue; how costs incurred and revenue generated on sales to third parties should be reported in the income statement; how an entity should characterize payments on the income statement; and what participants should disclose in the notes to the financial statements about a collaborative arrangement. EITF 07-1 is effective for the Company's collaborations existing after January 1, 2009. The Company is currently evaluating the impact, if any, of adopting EITF 07-1 on its consolidated financial statements but believes the adoption will not have a material effect on its results of operations or financial position.

In March 2008, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ("SFAS 161"). SFAS No. 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. SFAS No. 161 also improves transparency about the location and amounts of derivative instruments in an entity's financial statements; how derivative instruments and related hedged items are accounted for under Statement 133; and how derivative instruments and related hedged items affect its financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company is currently evaluating the impact of the adoption of SFAS 161 on its consolidated financial statements but believes the adoption will not have a material effect on its results of operations or financial position.

In April 2008, the FASB issued FASB Staff Position (FSP) No. 142-3, "Determination of the Useful Life of Intangible Assets" (FSP 142-3), which amends the factors that should be considered in

developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets." FSP 142-3 is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. Early adoption is prohibited. The guidance in FSP 142-3 for determining the useful life of a recognized intangible asset shall be applied prospectively to intangible assets acquired after adoption, and the disclosure requirements shall be applied prospectively to all intangible assets recognized as of, and subsequent to, adoption. The Company is currently evaluating the impact of the adoption of FSP 142-3 on its consolidated financial statements but believes the adoption will not have a material effect on its results of operations or financial position.

In May 2008, the FASB issued FASB Staff Position ("FSP") No. APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (including Partial Cash Settlement)," or FSP APB 14-1, which requires separate accounting for the debt and equity components of convertible debt issuances. The requirements for separate accounting must be applied retrospectively to previously issued cash-settleable convertible instruments as well as

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prospectively to newly issued instruments, negatively affecting both net income and earnings per share for issuers of the instruments. The Staff Position is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact that the adoption of FSP APB 14-1 will have on its consolidated financial statements.

In June 2008, the FASB issued FSP EITF No. 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities." The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, "Earnings per Share." The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for fiscal years beginning after December 15, 2008; earlier application is not permitted. The Company is currently evaluating the impact that the adoption of EITF 03-6-1 will have, if any, on its consolidated financial statements.

In September 2008, the FASB issued FAS 133-1 and FIN 45-4, "Disclosures about Credit Derivatives and Certain Guarantees - An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161." The credit derivatives market has expanded significantly over the past few years. Financial statement users and others have expressed concerns that the current disclosure requirements for derivative instruments and certain guarantees do not adequately address the potential adverse effects of changes in credit risk on the financial position, financial performance, and cash flows of the sellers of credit derivatives and certain guarantees. This FSP amends FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities", to require disclosures by sellers of credit derivatives, including credit derivatives embedded in a hybrid instrument. This FSP also amends FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others ", to require an additional disclosure about the current status of the payment/performance risk of a guarantee. Further, this FSP clarifies the Board's intent about the effective date of FASB Statement No. 161, "Disclosures about Derivative Instruments and Hedging Activities". The Company is in the process of evaluating the impact of the adoption of FAS 133-1 and FIN 45-4 on its consolidated financial statements but believes the adoption will not have a material effect on its results of operations or financial position.



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

|                          | For the nine months ended<br>September 30, 2008 |
|--------------------------|---|
| Expected volatility      | 69.70%  |
| Expected term (in years) | 5.5 - 5.75 years                                |
| Risk-free rate           | 2.82 - 3.33%                                    |
| Expected dividends       | 0%  |

A summary of option activity under the Plan and the Director Plan as of September 30, 2008 and changes during the period are presented below:

|                             | Number of<br>Options | Weighted<br>Average<br>Exercise Price |
|-----------------------------|----------------------|---------------------------------------|
| Outstanding as of 1/1/2008  | 2,274,548            | \$1.42                                |
| Issued                      | 570,000              | \$1.66                                |
| Exercised                   | 53,016               | \$1.41                                |
| Forfeited                   | -                    | -                                     |
| Expired                     | 11,000               | \$2.00                                |
| Outstanding as of 9/30/2008 | 2,780,532            | \$1.47                                |
| Exercisable as of 9/30/2008 | 2,030,532            | \$1.47                                |

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options granted during the nine months ended September 30, 2008 was \$1.04.

The following table summarizes information regarding options outstanding and exercisable at September 30, 2008:

Outstanding:

| Range of Exercise<br>Prices |        | Stock Options<br>Outstanding | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life |
|-----------------------------|--------|------------------------------|--|---|
| \$0.50                      | \$1.00 | 303,250                      | \$0.73                                   | 5.61  |
| \$1.01                      | \$2.00 | 2,065,282                    | \$1.41                                   | 6.51  |

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|        |        |           |        |       |
|--------|--------|-----------|--------|-------|
| \$2.01 | \$3.00 | 412,000   | \$2.31 | 3.94  |
|        |        | <hr/>     | <hr/>  | <hr/> |
| Total  |        | 2,780,532 | \$1.47 | 6.03  |
|        |        | <hr/>     | <hr/>  | <hr/> |

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Exercisable:

| Range of Exercise Prices |        | Stock Options Exercisable | Weighted Average Exercise Price |
|--------------------------|--------|---------------------------|---------------------------------|
| <hr/>                    |        | <hr/>                     | <hr/>                           |
| \$0.50                   | \$1.00 | 303,250                   | \$0.73                          |
| \$1.01                   | \$2.00 | 1,315,282                 | \$1.37                          |
| \$2.01                   | \$3.00 | 412,000                   | \$2.31                          |
|                          |        | <hr/>                     | <hr/>                           |
| Total                    |        | 2,030,532                 | \$1.47                          |
|                          |        | <hr/>                     | <hr/>                           |

As of September 30, 2008, the intrinsic value of the options outstanding is \$400,773 and the intrinsic value of the options exercisable is \$328,273. The intrinsic value of the options exercised during the nine months ended September 30, 2008 was \$32,000. As of September 30, 2008, there was \$414,000 of total unrecognized compensation cost that will be recognized through December 2009 related to non-vested share-based compensation arrangements granted under the Plans.

As part of the Separation Agreement dated September 16, 2008 with the former Vice President of Finance, the Company extended the time period for exercising options for an additional 90 days. Because of this modification, the Company recorded incremental compensation of \$5,300.

6. Income Taxes

Effective January 1, 2007, the Company adopted Financial Interpretation ("FIN") No. 48, *Accounting for Uncertainty in Income Taxes--An Interpretation of FASB Statement No. 109*. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more than fifty percent likely of being realized upon ultimate settlement. The interpretation also provides guidance on derecognition, classification, interest and penalties, and other matters. The adoption did not have an effect on the Company's consolidated financial statements.

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 prior to adoption of FIN 48 and there was no adjustment from the implementation. There continues to be no liability related to unrecognized tax benefits at September 30, 2008 and no significant changes are expected in the next twelve months. The tax years 2003-2007 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, 2008.

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 ("Microencapsulation Technologies" or 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")

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thru 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, 2008 and 2007.

8. Note Payable

On January 31, 2007, the Company entered into a revolving \$1,000,000 secured line of credit agreement ("Credit Agreement") with Pinnacle Mountain Partners, LLC, ("Pinnacle"), a company owned by Dr. and Mrs. Hager, significant shareholders of the Company, and in the case of Mrs. Hager, a director of the Company, for a term of eighteen months. Loans under the Credit Agreement bear interest at prime (5.00% at September 30, 2008 and

7.75% at September 30, 2007), plus 1.5% and are collateralized by assets of the Company (other than real property). All accrued and unpaid interest is payable monthly in arrears on the first of each month. The Company borrowed \$500,000 against this line of credit and has repaid \$250,000 of that balance as of September 30, 2008. The interest expense related to this note payable was \$19,000 and \$51,000 for the nine months ended September 30, 2008 and 2007, respectively.

On July 29, 2008, the Company signed an extension agreement related to the secured line of credit with Pinnacle. The extension provides for a revolving \$500,000 secured line of credit for a term of six months. As in the original agreement, loans under the extension agreement bear interest at prime plus 1.5% and are collateralized by the assets of the Company (other than real property).

9. Related Party Transactions

The Company signed an agreement with Pharmachem on August 22, 2007, a significant shareholder, to develop Novasome® based products for Pharmachem to market to third party customers. The agreement was completed on August 21, 2008, and all the development work for Pharmachem has ended.

For the nine month period ended September 30, 2008, the Company recognized \$133,000 of research and development revenues from Pharmachem and had a \$4,600 accounts receivable balance at September 30, 2008 that will be received in the normal course of business. For the nine month period ended September 30, 2007, the Company recognized \$97,000 of research and development revenues from Pharmachem and had a \$51,500 account receivable balance at September 30, 2007.

For a description of the Company's Credit Agreement with a related party, see footnote 8 above.

10. Stock Warrants

In connection with the Private Placement transaction with Pharmachem dated February 5, 2007, the Company issued a warrant to purchase 150,000 common shares at \$1.00 per share to Landmark Financial which expires on March 7, 2009 as a commission on this 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.

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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 10Q contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, that are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and on management's beliefs and assumptions. In addition, other written or oral statements, which constitute forward-looking statements, may be made by or on behalf of the Company. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are based on current expectations of management and are not guarantees of future performance, and involve certain risks, uncertainties and assumptions, which are difficult to predict. These risks and uncertainties include, without limitation, competitive factors, outsourcing trends in the pharmaceutical industry, the general economic conditions in the markets in which the Company operates, levels of industry research and development spending, the Company's ability to continue to attract and retain qualified personnel, the fixed price nature of product development agreements or the loss of customers and other factors described in the Company's filings with the Securities and Exchange Commission, including the "Risk Factors" section as set forth below in this Quarterly Report on Form 10-Q. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements. The Company undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Company Overview

On May 7, 2008, the stockholders of IGI, Inc. approved the name change of the Company from IGI, Inc. to IGI Laboratories, Inc. IGI is engaged in the development, manufacturing, filling and packaging of topical, semi solid and liquid products for pharmaceutical, cosmeceutical and cosmetic companies primarily using its licensed Novasome® encapsulation technology. The Company believes that the Novasome based products developed and manufactured by it are unique in the industry and give its customers a competitive advantage in the market place.

IGI's mission is to be a premier provider of topical liquid and semi-solid products using an encapsulation technology. Over the last two fiscal years the Company has made four major changes to better pursue its mission:

- &#149 the Company divested the metal plating business to focus on its core business of topical skin care/treatment products;
- &#149 the Company acquired filling and packaging equipment that broaden and enhance product and service offerings;
- &#149

#149

the Company instituted a policy of charging a fee for its Product Development Services; and  
the Company initiated the development of several prescription skin treatment products with possible commercialization in 2011.

The Company's business plan includes the continued upgrading of its manufacturing capabilities and expanding its production services. The Company will also continue to market its other capabilities to customers, such as product development services and analytical services, all together or separately. In addition to this, the Company intends to explore ways to expand its intellectual property portfolio and increase its R&D product pipeline.

On May 6, 2008, the Company was notified by AMEX that it was below certain of the AMEX continued listing standards. Specifically, the Company was required to reflect income from continuing operations and/or net income in one of its five most recent fiscal years and a minimum of \$6 million in stockholders' equity to remain listed on the exchange. The Company had net income from continuing operations in its 2002 fiscal year, but had net losses and losses from continuing operations in each of its 2003, 2004, 2005, 2006 and 2007 fiscal years. The Company's stockholders' equity at September 30, 2008 was \$3.4 million.

On July 15, 2008, AMEX notified the Company that it accepted the Company's plan of compliance and granted the Company an extension until May 6, 2009 to regain compliance with the continued listing standards described above. The Company will be subject to periodic review by 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 the Company being delisted from AMEX.

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## Results of Operations

### Three months ended September 30, 2008 compared to September 30, 2007

The Company had a net loss attributable to common stockholders of \$568,000, or \$0.04 per share, for the three months ended September 30, 2008, compared to a net loss of \$105,000, or \$0.01 per share, in the comparable period for 2007, which resulted from the following:

#### Revenues (in thousands):

| Components of Revenue:          | 2008         | 2007           | \$ Change      | % Change    |
|---------------------------------|--------------|----------------|----------------|-------------|
| Product sales                   | \$770        | \$ 520         | \$ 250         | 48 %        |
| Research and development income | 116          | 329            | (213)          | (65)%       |
| Licensing and royalty income    | 87           | 156            | (69)           | (44)%       |
| <b>Total Revenues</b>           | <b>\$973</b> | <b>\$1,005</b> | <b>\$ (32)</b> | <b>(3)%</b> |

The increase in product sales for the three months ended September 30, 2008 is due to sales to new customers, offset by reduced sales from some of the existing 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. Licensing and royalty income decreased as a result of a decrease in sales of royalty bearing products.

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



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|                                     | 2008     | 2007     | \$ Change | % Change |
|-------------------------------------|----------|----------|-----------|----------|
| Cost of sales                       | \$ 732   | \$ 494   | \$ 238    | 48%      |
| Selling, general and administrative | 672      | 469      | 203       | 43%      |
| Product development and research    | 136      | 135      | 1         | 1%       |
| Totals costs and expenditures       | \$ 1,540 | \$ 1,098 | \$ 442    | 40%      |

Cost of sales increased for the three months ended September 30, 2008 as a result of the increase in product sales. Cost of sales as a percent of product sales and research and development income was 83% for the three month period ended September 30, 2008 compared to 58% for the comparable period in 2007. The increase in cost of sales percentage is due to a lower gross margin related to sales to a new customer in the three months ended September 30, 2008.

Selling, general and administrative expenses for the period ended September 30, 2008 increased as a result of higher stock based compensation expense of \$70,000 from the issuance of stock options to our President and Chief Executive Officer, severance of \$51,000 for our former Vice President of Finance as per her separation agreement, consulting fees of \$21,000 and higher employer match contribution in our 401k plan of \$6,000 due to a plan change.

Interest (Expense) Income (in thousands):

|                  | 2008   | 2007    | \$ Change | % Change |
|------------------|--------|---------|-----------|----------|
| Interest Expense | \$ (4) | \$ (13) | \$ 9      | 69%      |
| Interest Income  | \$ 1   | \$ 1    | \$ -      | -%       |

Interest expense decreased for the three months ended September 30, 2008 as a result of a decrease in the Company's short-term notes payable principal balance and a reduction in the Company's average interest rate on its short-term notes payable in 2008.

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

|                    | 2008     | 2007     | \$ Change | % Change |
|--------------------|----------|----------|-----------|----------|
| Net loss           | \$ (568) | \$ (105) | \$ (463)  | (441)%   |
| Net loss per share | (.04)    | (.01)    | (.03)     | (300)%   |

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Nine months ended September 30, 2008 compared to September 30, 2007

Revenues (in thousands):

| Components of Revenue:          | 2008  | 2007  | \$ Change | % Change |
|---------------------------------|-------|-------|-----------|----------|
| Product sales                   | 2,547 | 1,865 | 682       | 37 %     |
| Research and development income | 244   | 617   | (373)     | (60)%    |

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|                              |       |       |       |       |
|------------------------------|-------|-------|-------|-------|
| Licensing and royalty income | 364   | 444   | (80)  | (18)% |
|                              | <hr/> | <hr/> | <hr/> | <hr/> |
| Total Revenues               | 3,155 | 2,926 | 229   | 8 %   |
|                              | <hr/> | <hr/> | <hr/> | <hr/> |

The increase in product sales relates to the Company's ability to package and fill the products we manufacture for our customer and sales of new products developed by the Company. The higher research and development income for the nine months ended September 30, 2007, related to fees paid to the Company to develop a new product line for a customer which was launched in the first quarter of 2008. The decrease in royalty revenue was related to a decline in royalties from Johnson & Johnson and Estee Lauder in 2008.

Costs and expenses (in thousands):

|                                     | 2008  | 2007  | \$ Change | % Change |
|-------------------------------------|-------|-------|-----------|----------|
|                                     | <hr/> | <hr/> | <hr/>     | <hr/>    |
| Cost of sales                       | 1,976 | 1,632 | 344       | 21%      |
| Selling, general and administrative | 2,031 | 1,651 | 380       | 23%      |
| Product development and research    | 372   | 360   | 12        | 3%       |
|                                     | <hr/> | <hr/> | <hr/>     | <hr/>    |
| Totals costs and expenses           | 4,379 | 3,643 | 736       | 20%      |
|                                     | <hr/> | <hr/> | <hr/>     | <hr/>    |

Cost of sales increased for the nine months ended September 30, 2008 as a result of the increase in product sales. As a percentage of product sales and research and development income, cost of sales was 71% for the nine months ended September 30, 2008 and 66% for the nine months ended September 30, 2007. The higher cost of sales as a percentage of product sales and research and development income for 2008 relates to the increase in costs associated with hiring of additional staff for the product development and analytical services. For the utilization of the surplus manufacturing capacity, the Company also engaged in the manufacturing of lower margin products developed by its new customer, resulting in increased cost of sales as a percentage of product sales.

Selling, general and administrative expenses for the period ended September 30, 2008 increased as a result of higher stock based compensation expense of \$155,000 from the issuance of stock options to our President and Chief Executive Officer, severance agreement of \$51,000 for our former Vice President of Finance as per her separation agreement, bad debt expense of \$34,000, consulting fees of \$26,000, higher employer match contribution in our 401k plan of \$19,000 as a result of changing our 401k plan and higher marketing expense of \$16,000. As a percentage of total revenues, selling, general and administrative expenses were 64% and 56% of revenues for the nine months ended September 30, 2008 and 2007, respectively.

Interest (Expense) Income (in thousands):

|                  | 2008  | 2007  | \$ Change | % Change |
|------------------|-------|-------|-----------|----------|
|                  | <hr/> | <hr/> | <hr/>     | <hr/>    |
| Interest Expense | (19)  | (51)  | 32        | 63 %     |
| Interest Income  | 10    | 12    | (2)       | (17)%    |

Interest expense decreased for the nine months ended September 30, 2008 as a result of a decrease in the Company's short-term notes payable principal balance and a reduction in the Company's average interest rate on its short-term notes payable in 2008. Interest income is lower for the same period as a result of lower cash balances.

Other income (in thousands, except per share numbers):

|              | <u>2008</u> | <u>2007</u> | <u>\$ Change</u> | <u>% Change</u> |
|--------------|-------------|-------------|------------------|-----------------|
| Other income | 7           | 64          | (57)             | (89)%           |

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Included in other income for the nine months ended September 30, 2007 is \$58,000 of insurance settlement funds received by the Company as a result of the employee theft claim submitted earlier in 2007. The funds received were net of a \$25,000 deductible the Company has on its insurance policy.

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

|                    | <u>2008</u> | <u>2007</u> | <u>\$ Change</u> | <u>% Change</u> |
|--------------------|-------------|-------------|------------------|-----------------|
| Net loss           | (1,226)     | (687)       | (539)            | (78)%           |
| Net loss per share | (.08)       | (.05)       | (.03)            | (60)%           |

## Liquidity and Capital Resources

The Company's operating activities used \$448,000 of cash during the nine months ended September 30, 2008 compared to \$924,000 used in the comparable period of 2007. The use of cash for the nine months ended September 30, 2008 is substantially a result of the net loss and increase in inventory offset by the collection of royalties from Manhattan Pharmaceuticals. The use of cash in the comparable period of 2007 was for the payments of accounts payable, increase in accounts receivable due to higher sales, and the net loss.

The Company's investing activities used \$107,000 of cash in the nine months ended September 30, 2008 compared to \$92,000 of cash provided by investing activities in the first nine months of 2007. The funds used for the period ending September 30, 2008 were for additional equipment and improvements for the packaging and filling lines. The money provided for the period ending September 30, 2007 represents a deposit of \$260,000 on the metal plating equipment sold to UCT less \$168,000 in capital expenditures for equipment for the packaging and filling operations in 2007.

The Company's financing activities used \$152,000 of cash in the nine months ended September 30, 2008 compared to \$347,000 provided by financing activities in the nine months ended September 30, 2007. The cash used for the period ended September 30, 2008 represents a pay down of the note payable balance offset by proceeds from the exercise of common stock options and warrants. For the same period in 2007 cash provided represents borrowings from the note payable and proceeds from the issuance of shares pursuant to a private placement of common stock, net of repayments of notes payable.

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$207,000 at September 30, 2008, future cash from operations, and a \$250,000 unused balance on our line of credit from Pinnacle Mountain Partners, LLC; this line of credit will expire on January 31, 2009. The Company had working capital of \$318,000 at September 30, 2008.

We believe that our operating cash flow along with our existing capital resources will not be sufficient to support our current business plan through November 2009. The Company will require additional funding. This funding will depend, in part, on the timing and structure of potential business arrangements. If

necessary, 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. In addition, there may be additional acquisition and growth opportunities that may require external financing. However, the trading price of our stock, 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 or available on terms acceptable to the Company.

#### 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 consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), 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. The following discussion highlights what we believe to be the critical accounting policies and judgments made in the preparation of these consolidated financial statements.

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Please refer to the Company's 2007 10-KSB for a complete list of all Critical Accounting Policies and Estimates. See also Note 2 of the Company's unaudited financial statements for the three and nine months periods ended September 30, 2008.

#### ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

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 and recoverability of assets, may be adversely affected by current and future economic conditions, such as a reduction in the availability of credit, financial market volatility, recession.

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.

#### ITEM 4(T). Controls and Procedures

##### (a) Management's Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its reports filed or submitted pursuant to the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that information required to be disclosed by the Company is accumulated and communicated to management, including the Company's President and Chief Executive Officer and Acting Principal Financial Officer, to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of its management, including the Company's principal executive officer and acting principal financial officer, the Company carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(e) and 15d-15(e) as of September 30, 2008. Based upon that evaluation, the

Company's principal executive officer and acting principal financial officer concluded that, because of the material weaknesses in the Company's internal control over financial reporting as described below, the Company's disclosure controls and procedures were not effective as of September 30, 2008. To compensate for the material weaknesses in the Company's internal control over financial reporting described below, the Company performed additional manual procedures and analysis and other post-closing procedures in order to prepare the consolidated financial statements included in this report. As a result of these expanded procedures, the Company believes that the consolidated financial statements contained in this report fairly present, in all material respects, the Company's financial condition, results of operations and cash flows for the period covered hereby in conformity with generally accepted accounting principles.

As a result of its evaluation, the Company has identified the following material weakness in its internal control over financial reporting for the period ended September 30, 2008

The Company lacked sufficient personnel who had basic accounting and finance understanding. A lack of sufficient personnel may prevent the Company from segregating duties within its system of internal control. The inadequate segregation of duties may increase the risk that the Company would not timely detect and resolve an irregularity and report on the resultant impact to the Company's consolidated financial statements and related disclosures.

(b) Changes to Internal Control Over Financial Reporting

In September 2008, the Company announced that its then Vice President of Finance would no longer be employed by the Company as of October 3, 2008. However, in October 2008, the Company hired an additional qualified accountant to assist with various accounting and finance functions within the organization. The Company believes this new personnel reduces the risk associated with a lack of segregation of duties and thus enhances the Company's system of internal control over financial reporting.

Management believes that the actions described above, when fully implemented will be effective in remediating the specific material weaknesses discussed above.

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(c) Limitations of Effectiveness of Controls

The Company notes that, like other companies, any system of internal controls, however well designed and operated, can provide only reasonable assurance, and not absolute assurance, that the objectives of the internal control system will be met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of the limitations inherent in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

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PART II  
OTHER INFORMATION

ITEM 1. Legal Proceedings

We are involved from time to time in claims which arise in the ordinary course of business. In the opinion of management, we have made adequate provision for potential liabilities, if any, arising from any such matters. However, litigation is inherently unpredictable, and the costs and other effects of pending or future litigation, governmental investigations, legal and administrative cases and proceedings (whether civil or criminal), settlements, judgements 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

Our current business and future results may be affected by a number of risks and uncertainties, including those described below. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not currently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

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 our products can compete successfully against our competitors' products or that we can develop and market new 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, 2008 and 2007, three of our customers accounted for 62% and four of our customers accounted for 71% of our revenue, respectively. For the nine months ended September 30, 2008 and 2007, four of our customers accounted for 58% and two of our customers accounted for 34% 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.

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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 overrun 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.

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 Food and Drug Administration (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.

The failure to obtain, maintain or protect patents 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 have obtained or have the use of over 50 patents, either through

development by us or entry into license agreements with third parties, and are seeking to develop additional patents. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- &#149;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;
- &#149;changes in U.S. patent laws may adversely affect our ability to obtain or maintain our patent protection;
- &#149;we may be subject to interference proceedings;
- &#149;the claims of any patents that are issued may not provide meaningful protection;
- &#149;we may not be able to develop additional proprietary technologies that are patentable;
- &#149;the patents licensed or issued to us or our collaborators may not provide a competitive advantage;
- &#149;other companies may challenge patents licensed or issued to us or our collaborators;
- &#149;other companies may independently develop similar or alternative technologies, or duplicate our technology;
- &#149;other companies may design around technologies we have licensed or developed; and
- &#149;enforcement of patents is complex, uncertain and expensive.

We cannot be certain that patents will be issued as a result of any future pending applications, and we cannot be certain that any of our issued patents or the proprietary rights of third parties whose patents we license, will give us adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions. In the event that another party has also filed a patent application relating to an invention claimed by us, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome were favorable to us. It is also possible that others may obtain issued patents that could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so.

The cost to us of any patent litigation or other proceeding relating to our patents or applications, even if resolved in our favor, could be substantial. Our ability to enforce our patent protection could be limited by our financial resources, and may be subject to lengthy delays. 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.

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In addition to patents and patent applications, we depend upon trade secrets and proprietary know-how to protect our proprietary technology. 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 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.

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 and 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, 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.

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.

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 five years, and no net income has been available to common shareholders during each of these years. As of September 30, 2008, our shareholders' equity was \$3.4 million and we had an accumulated deficit of \$23.7 million. Our future profitability depends on revenue exceeding expenses, but we cannot assure you that this will occur. If we do not become profitable, we could be forced to curtail operations and sell or liquidate our business, and you could lose some or all of your investment.

If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934 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 September 30, 2008, and our management concluded that our disclosure controls and procedures were not effective as of September 30, 2008 due to the material weakness described above in Item 4(T) - "Controls and Procedures" in this

Quarterly Report on Form 10-Q.

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We expect to dedicate significant management, financial and other resources in 2008 in connection with complying with Section 404 of the Sarbanes-Oxley Act of 2002. We expect these efforts to include a review of our existing disclosure controls and procedures and internal control structure. As a result of this review, we may either hire or outsource additional personnel to expand and strengthen our finance function. If we fail to achieve and maintain the adequacy of our disclosure controls and procedures and internal control, 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 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.

#### Risks Related to Our Securities

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 more than 50% of our common stock. 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, which could limit investors' ability to sell stock at a profit. During the last two fiscal years, our stock price has traded at a low of \$.81 in the first quarter of 2006 to a high of \$2.71 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:

- &#149;publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- &#149;delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- &#149;achievement or rejection of regulatory approvals by our competitors or us;
- &#149;announcements of technological innovations or new commercial products by our competitors or us;
- &#149;developments concerning proprietary rights, including patents;
- &#149;developments concerning our collaborations;
- &#149;regulatory developments in the United States and foreign countries;
- &#149;economic or other crises, especially given the recent financial deterioration in the markets in which we compete, and other external factors;
- &#149;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;
- &#149;

actual or anticipated sales of our common stock, including sales by our directors, officers or significant stockholders;  
#149period-to-period fluctuations in our revenues and other results of operations;  
#149speculation about our business in the press or the investment community;  
#149changes in financial estimates by us or by any securities analysts who might cover our stock; and  
#149sales 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.

Shares of our common stock are relatively illiquid which may affect the trading price of our common stock.

For the quarterly period ended September 30, 2008, the average daily trading volume of our common stock on the American Stock Exchange was approximately 10,600 shares. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

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If we fail to meet the continued listing standards of the American Stock Exchange our common stock could be delisted and our stock price could suffer.

On May 6, 2008, we were notified by AMEX that we were below certain of the 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 its 2003, 2004, 2005, 2006 and 2007 fiscal years. Our stockholders' equity at September 30, 2008 was \$3.4 million.

On July 15, 2008, AMEX notified us that it accepted our plan of compliance and granted us an extension until May 6, 2009 to regain compliance with the continued listing standards described above. We will be subject to periodic review by 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 our being delisted from AMEX.

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

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Submission of Matters to a Vote of Security Holders

None.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

Exhibit

Number Description

10.1 First Amendment to Loan and Security Agreement, dated July 29, 2008, between IGI, Laboratories, Inc. and Pinnacle Mountain Partners LLC (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed August 1, 2008).

10.2 Amended and Restated Revolving Note, dated July 29, 2008, of IGI Laboratories, Inc., made in favor of Pinnacle Mountain Partners LLC (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K filed August 1, 2008).

10.3 Separation Agreement and Release dated September 16, 2008 between IGI Laboratories, Inc. and Carlene Lloyd (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K filed September 22, 2008).

10.4 Form of Stock Option Award Agreement under the 1999 Stock Incentive Plan.

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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 Acting Principal 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 Acting Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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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 14, 2008

By: /s/ Rajiv Mathur

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Rajiv Mathur  
President and Chief Executive Officer

Date: November 14, 2008

By: /s/ Justine Kostka

\_\_\_\_\_

Justine Kostka  
Acting Principal Financial Officer

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Exhibit Index

| Exhibit Number | Description  |
|----------------|--|
| 10.4           | Form of Stock Option Award Agreement under the 1999 Stock Incentive Plan.  |
| 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 Acting Principal 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.    |
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