

IGI INC
Form 10-K
March 31, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

OR

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

For the transition period from _____ to _____.

Commission file number 001-08568

IGI Laboratories, Inc.

(Name of small business issuer in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

105 Lincoln Ave., Buena, NJ

01-0355758
(I.R.S. Employer
Identification No.)

08310

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number: (856) 697-1441

Securities registered pursuant to Section 12(b) of the Exchange Act:

| <u>Title of each class</u> | <u>Name of each exchange on which registered</u> |
|-------------------------------|--|
| Common Stock \$0.01 Par Value | NYSE Alternext US |

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes No

Indicate by check 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

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

The aggregate market value of the registrant's voting common equity held by non-affiliates of the registrant on June 30, 2008 was approximately \$ 13,461,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the NYSE Alternext US on June 30, 2008.

As of March 23, 2009, there were 14,923,407 shares of common stock outstanding.

Documents Incorporated By Reference

Certain information contained in the definitive Proxy Statement for the Company's 2009 Annual Meeting of Stockholders is incorporated by reference into Part III hereof.

PART I

ITEM 1.

DESCRIPTION OF BUSINESS

Overview

IGI Laboratories, Inc. is a Delaware corporation formed in 1977. On May 7, 2008, the stockholders of IGI, Inc. approved the name change of the Company from IGI, Inc. to IGI Laboratories, Inc. As used in this report, the terms the Registrant, the Company, IGI, Inc. and IGI refer to IGI Laboratories, Inc., unless the context requires otherwise. The Company's head-office, product development laboratories and manufacturing facility are located at 105 Lincoln Avenue, Buena, New Jersey. IGI is principally engaged in the development, manufacturing, filling and packaging of topical, semi solid and liquid products for pharmaceutical, cosmeceutical and cosmetic companies. The primary focus of the business is on the commercialization of its licensed Novasome® encapsulation technology for skin care/treatment products. Except as otherwise specified, information in this report is provided as of December 31, 2008 (the end of the Company's fiscal year).

The Company licenses the Novasome® encapsulation technology from Novavax, Inc. for applications in (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).

Manufacturing

The Company's product manufacturing is conducted in an FDA registered facility for human and veterinary pharmaceutical and cosmetic products. The manufacturing operations include compounding, filling and packaging of Novasome® based products as well as conventional dermatological, cosmeceutical and cosmetic cream and lotion products. In December 2006, the Company purchased three fully automatic filling and packaging lines to provide turnkey solutions to our customers. The lines were installed and fully operational in the second quarter of 2007. This added capability allowed the Company to fill and package more than 40% of the bulk product we manufacture into tubes, bottles and jars. The raw materials used for these products are available commercially from several suppliers. The Company has manufacturing capacity to meet its current and foreseeable needs.

Research and Product Development

The Company's product development efforts are directed toward formulating topical pharmaceutical cream, lotion and liquid products, in many products, using Novasome® encapsulation technology to improve performance and efficacy of products. In late 2006, the Company instituted a policy of charging fees for providing product development services to its customers. Besides developing products as per the Product Development Agreements with its customers, IGI also initiated the research and development of generic and branded pharmaceutical products. The Company anticipates finishing the development of these products up to the Clinical Phase I stage and then seeking partnership with other Pharmaceutical companies to further develop and commercialize these products. This process will span several years. The Company also initiated development of several Over The Counter Liquid Oral and Nasal Spray products with anticipated commercialization in the 2nd Quarter 2009.

Patents and Trademarks

Under the terms of a license agreement entered into in 1995 and renewed in 2005, the Company has an exclusive license to use the Patented Technologies licensed from Novavax in the IGI Field until December 11, 2015. Novavax holds the U.S. patents and a number of foreign patents covering the technologies licensed to IGI with various expiration dates thru 2021. The scientists in the research laboratories of IGI are constantly seeking new chemical entities capable of making different membrane structures of Novasome®. A new patent on such chemical entity was filed in January 2008 and research work on additional patents is being continued.

Government Regulation and Regulatory Proceedings

In the United States, pharmaceuticals are subject to rigorous Food and Drug Administration (FDA) regulations. The Company is required to obtain a satisfactory inspection by the FDA covering its manufacturing facilities before a product can be marketed in the United States. Any non-compliance with the regulatory guidelines may necessitate corrective action that may result in additional expenses and use of more resources. The Company was audited by the FDA in April 2007 and was found to be in compliance with the agency's regulations.

In addition to regulations enforced by the FDA, the Company is 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. The Company's analytical service group uses certain hazardous materials and chemicals in limited and controlled quantities. Although the Company believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. The Company has procedures in place to be in compliance with the standards prescribed by the regulators.

Intense Competition in the Marketplace

The Company 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 the Company. The Company faces great challenges ensuring that its products can compete successfully against its competitors and in developing new products that will be favorably received in the marketplace. Furthermore, certain of the Company's customers that use the Company's encapsulation technology in their products could decide to reduce their purchases from the Company or shift their business to other technologies.

Dependence on Major Customers

The Company has successfully broadened its customer base to fuel its revenue growth. Based on its product sales, the Company has four (4) major customers. Major customers of the Company are defined as having sales for the latest fiscal year equal to or greater than 10% of that year's total gross product sales. The loss of any of these customers would have a material adverse effect on the Company. In 2008, the Company had sales to four customers which individually accounted for more than 10% of the Company's product sales. These customers had sales of \$615,000, \$555,000, \$555,000 and \$471,000 respectively, and aggregately represented 65% of revenues from product sales. Accounts receivable related to the Company's major customers comprised 48% of all account receivables as of December 31, 2008. In 2007, the Company had sales to one customer which individually accounted for more than 10% of the Company's product sales. This customer had sales of \$1,012,000 representing 35% of revenues from product sales.

Employees

On March 23, 2009, the Company had a total of 23 employees, all of which are fulltime. The Company has no collective bargaining agreement with its employees, and believes that its employee relations are good.

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 year ended December 31, 2008 and 2007, four of our customers accounted for 54% of our revenue in 2008 and three of our customers accounted for 43% of our revenue in 2007. The loss of one or more of these customers could have a significant impact on our revenues and harm our business and results of operations.

We face increased financial risk from the inaccurate pricing of our agreements.

Since our product development agreements are often structured as fixed price agreements, we bear the financial risk if we initially under price our agreements or otherwise 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:

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

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

we may be subject to interference proceedings;

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

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

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

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

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

other companies may design around technologies we have licensed or developed; and

enforcement of patents is complex, uncertain and expensive.

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.

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

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

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

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

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 December 31, 2008, our shareholders' equity was \$3 million and we had an accumulated deficit of \$24.4 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 December 31, 2008, and our management concluded that our disclosure controls and procedures were not effective as of December 31, 2008 due to the material weakness described below in Item 9A(T). Controls and Procedures in this Annual Report on Form 10-K.

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

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 67.8% of our outstanding capital stock entitled to vote, and if stockholders approve the private placement with Signet Healthcare Partners discussed in footnote 17. below. Then such ownership will increase to 80.3% of our outstanding capital stock entitled to vote. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

Our stock price is, and we expect it to remain, volatile, 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 \$.48 in the fourth quarter of 2008 to a high of \$2.57 in the second quarter of 2008. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

publicity regarding actual or potential clinical results relating to products under development by our competitors or us;

delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;

achievement or rejection of regulatory approvals by our competitors or us;

announcements of technological innovations or new commercial products by our competitors or us;

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

regulatory developments in the United States and foreign countries;

economic or other crises, especially given the recent financial deterioration in the markets in which we compete, and other external factors;

stock market price and volume fluctuations of other publicly traded companies and, in particular, those that are in the cosmetic, pharmaceutical and consumer products industry;

actual or anticipated sales of our common stock, including sales by our directors, officers or significant stockholders;

period-to-period fluctuations in our revenues and other results of operations;

speculation about our business in the press or the investment community;

changes in financial estimates by us or by any securities analysts who might cover our stock; and

sales of our common stock.

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

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

For the year ended December 31, 2008, the average daily trading volume of our common stock on the NYSE Alternext was approximately 10,625 shares. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

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

On May 6, 2008, we were notified by NYSE Alternext that we were below certain of the NYSE Alternext continued listing standards. Specifically, we are required to reflect income from continuing operations and/or net income in one of our five most recent fiscal years and a minimum of \$6 million in stockholders' equity to remain listed on the exchange. We had net income from continuing operations in our 2002 fiscal year, but had net losses and losses from continuing operations in each of our 2003, 2004, 2005, 2006, 2007 and 2008 fiscal years. Our stockholders' equity at December 31, 2008 was \$3.0 million.

On July 15, 2008, NYSE Alternext 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 NYSE Alternext 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 NYSE Alternext.

We could be required to repay our debt obligations relating to the Promissory Notes and we may not become compliant with the NYSE Alternext listing requirements if we fail to obtain stockholder approval of our March 2009 private placement transaction, which could affect our liquidity, financial position and results of operations.

If we do not obtain stockholder approval of our March 2009 private placement transaction with affiliates of Signet Healthcare Partners, the Promissory Notes issued to certain affiliates of Signet Healthcare Partners in connection with the private placement transaction will become due and payable on July 31, 2009 and our liquidity, financial position and results of operations will be negatively affected. Further, if we do not receive stockholder approval of the private placement, we may not increase our stockholder equity to thresholds required by the NYSE Alternext listing requirements, which could result from our being delisted from the NYSE Alternext. See "If we fail to meet the continued listing standards of the NYSE Alternext US our common stock could be delisted and our stock price could suffer," above. In connection with the private placement transaction, certain holders of our capital stock, representing approximately 51.7% of the voting power of the outstanding shares of capital stock entitled to vote on the private placement transaction (or who represent approximately 44.2% of the voting power of the outstanding shares of capital stock entitled to vote in the private placement transaction if one of our interested stockholders is not able to vote with respect to such matter pursuant to the rules and regulations of the NYSE Alternext as a result of the existence of a transaction relating to the private placement), entered into a voting agreement, pursuant to which these holders agreed to vote or execute and deliver a written consent in favor of approving the private placement transaction.

If the holders of our Series A Preferred Stock, Series B-1 Convertible Preferred Stock, options and warrants to purchase common stock exercise their conversion rights, our common stock will be diluted.

We have Series A Preferred Stock outstanding, Series B-1 Convertible Preferred Stock outstanding, outstanding options and warrants to purchase common stock, and outstanding Notes, which are convertible into shares of Series B-1 Convertible Preferred Stock upon stockholder approval of the Private Placement. If all or any number of these holders of derivative securities were to exercise their conversion rights, our common stock would be substantially diluted, which could negatively impact our stock price.

ITEM 1B.

UNRESOLVED STAFF COMMENTS

None

ITEM 2.

DESCRIPTION OF PROPERTY

The Company's executive administrative offices are located in Buena, New Jersey, in a 25,000 square foot facility built on 2.8 acres of land in 1995, which the Company owns. This facility is also used for production, product development, marketing and warehousing for the Company's pharmaceutical, cosmeceutical and cosmetic products. We believe this facility is in good operating condition for adequately serving our needs. The Company also owns four acres of land adjacent to its main facility that can be used for future expansion.

ITEM 3.

LEGAL PROCEEDINGS

On April 6, 2000, officials of the New Jersey Department of Environmental Protection (DEP) inspected the Company's leased storage site in Buena, New Jersey, and issued Notices of Violation (NOVs) relating to the storage of waste materials in a number of trailers at the site. The Company established a disposal and cleanup schedule and completed the removal of materials from the site. In March 2006, the Company received a judge's decision from the Office of Administrative Law (OAL) of a fine in the amount of \$35,000 in respect to the NOVs the Company received from the DEP. Due to the criminal settlement that was reached between the Company and the DEP in 2002, the Company had a credit of \$40,000 to be used against any fines determined as a result of the civil matter, therefore, the Company did not have to pay any money to the DEP for the settlement amount. The DEP subsequently issued a final decision,

which accepted the violation findings but rejected the OAL Judge's penalty recommendation, reinstating a previously proposed penalty by the DEP of \$215,000, less the \$40,000 credit previously mentioned or \$175,000. The Company appealed this to the Superior Court of the NJ Appellate Division, which determined that the Commission's decision was reasonable thus affirming the DEP Commissioner's decision. This amount of \$175,000 was accrued for in the fourth quarter of 2007. The Company reached a settlement with DEP Commissioner and agreed to pay the above amount in six equal installments. The final installment is due on June 30, 2009.

ITEM 4.

SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of the Company's stockholders during the last quarter of 2008.

PART II

ITEM 5.

MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

The Company has never paid cash dividends on its Common Stock. (\$.01 par value) (the Common Stock) The principal market for the Company s Common Stock is the NYSE Alternext US (NYSE Alternext) (symbol: IG).

On May 6, 2008, we were notified by NYSE Alternext that we were below certain of the NYSE Alternext s continued listing standards. Specifically, we are required to reflect income from continuing operations and/or net income in one of our five most recent fiscal years and a minimum of \$6 million in stockholders equity to remain listed on the exchange. We had net income from continuing operations in our 2002 fiscal year, but had net losses and losses from continuing operations in each of our 2003, 2004, 2005, 2006, 2007 and 2008 fiscal years. Our stockholders equity at December 31, 2008 was \$3.0 million.

On July 15, 2008, NYSE Alternext 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 NYSE Alternext 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 NYSE Alternext.

On March 13, 2009, the Company completed a private placement transaction with affiliates of Signet Healthcare Partners (Investors) pursuant to which the Company issued certain securities to the Investors. The Company believes that it will be in compliance with the NYSE Alternext listing requirements upon stockholder approval of the private placement transaction. The private placement transaction with the Investors is further described in Item 7: Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following table shows the range of high and low closing sale prices on the NYSE Alternext for the periods indicated:

| | <u>High</u> | <u>Low</u> |
|---------------|-------------|------------|
| <u>2008</u> | | |
| First quarter | \$ 2.10 | \$ 1.30 |

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| | | |
|----------------|------|------|
| Second quarter | 2.57 | 1.95 |
| Third quarter | 2.34 | 1.30 |
| Fourth quarter | 1.40 | .48 |

2007

| | | |
|----------------|---------|--------|
| First quarter | \$ 1.25 | \$.84 |
| Second quarter | .94 | .62 |
| Third quarter | 1.13 | .65 |
| Fourth quarter | 1.41 | .91 |

The approximate number of holders of record of the Company's Common Stock at March 23, 2009 was 590 (not including stockholders for whom shares are held in a nominee or street name).

Recent Sales of Unregistered Securities

None.

ITEM 6.

SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 7.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

Forward-Looking Statements

This Management's Discussion and Analysis of Financial Condition and Results of Operation section and other sections of this Annual Report on Form 10-K contain forward-looking statements 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 not guarantees of future performance, and involve certain risks, uncertainties and assumptions, which are difficult to predict. (See Item 1A: Risk Factors below.) Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements. The Company undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Company Overview

Strategic Overview

IGI is engaged in the 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 gives 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:

the Company divested the metal plating business to focus on its core business of topical skin care/treatment products,

the Company acquired filling and packaging equipment that broaden and enhance product and service offerings,

the Company instituted a policy of charging a fee for its Product Development Services; and

the Company sold the marketing rights of the Miaj product line to a Cosmetic marketing company.

Metal Plating Business- The Company ceased operations of the metal plating division in November 2005. In the first quarter of 2007, the Company received a purchase order and deposit in the amount of \$130,000 toward the purchase of the plating equipment from Universal Chemical Technologies, Inc. (UCT) to re-purchase the equipment back from the Company. The Company estimated the fair value of the metal plating equipment less cost to sell at \$350,000. The sales price of the equipment was \$378,000, which consisted of \$260,000 in cash net of \$118,000 owed to UCT by the Company. The Company recorded a gain of \$5,000 on the sale of this equipment in 2007. The purchaser, UCT, paid all relocation and removal expenses relating to this equipment. This transaction was completed in the second quarter of 2007 and all equipment was removed from our facility as of June 30, 2007.

Filling and Packaging Equipment- In December 2006, the Company purchased three fully automatic filling and packaging lines to provide turnkey solutions to our customers. The lines were installed and fully operational in the second quarter of 2007. This added capability allowed the Company to fill and package more than 40% of the bulk product we manufacture. This also resulted in an increase of approximately 20% in revenues from contract filling and packaging of generic products in 2007.

Licensing Agreement / Fees for Product Development Services- In August 2007, the Company renegotiated its exclusive licensing, development and manufacturing agreement with Dermworx, Inc., which was originally signed in October 2006. The original agreement was for a series of dermatological specialty products utilizing Novasome encapsulation technology. The new agreement was narrowed down to include only one Keratolytic cream product. The first installment of \$250,000 received by the Company for the original agreement was recorded as deferred income for the year ended December 31, 2006. This payment was recognized as Product Development revenue against the new agreement in the third quarter of 2007. Subsequently, the Company signed an additional Product Development Agreement with Dermworx for a Novasome® based sprayable moisturizer product. The Company manufactured commercial quantities of the product developed under the amended agreement in December 2007 and has produced commercial quantities of the product from the additional agreement in the first quarter 2008.

Miaj Product Line- The Company launched its first in house product line under the name Miaj™ in June 2006. The marketing right of the product line was subsequently licensed in December 2007 to an established cosmetic marketing company. Since the licensor failed to meet certain conditions of the agreement and failed to cure the deficiencies on notice, the Company cancelled the agreement in December 2008. Since some of the products in the line were technologically obsolete, the Company decided to write off the entire inventory and recorded impairment charges of \$105,000 at December 31, 2008. Additionally, the Company recorded a bad debt reserve of \$63,000 related to the outstanding invoice for the purchase of the products by the marketing company.

Results of Operations

2008 Compared to 2007

The Company had a net loss attributable to common stockholders of \$1,852,000, or \$(0.12) per share, in 2008 compared to a net loss of \$412,000, or \$(0.03) per share, in 2007 which resulted from the following:

| <u>Revenues</u> | <u>For the years ended</u> | | <u>\$ change</u> | <u>% change</u> |
|---------------------------------|----------------------------|--------------------------|------------------|-----------------|
| | <u>December 31, 2008</u> | <u>December 31, 2007</u> | | |
| | <i>(in thousands)</i> | | | |
| Product Sales, net | \$ 3,376 | \$ 2,904 | \$ 472 | 16% |
| Research and Development Income | 273 | 836 | (563) | (67%) |
| Licensing and Royalty Income | 420 | 841 | (421) | (50%) |
| Total Revenues | \$ 4,069 | \$ 4,581 | \$ (512) | (11%) |

The revenues from product sales increased by 16% for the year ended December 31, 2008 (2008) compared to the same period in 2007. The increase in product sales can be attributed to the addition of three new customers whose products were successfully launched late in 2007. In addition, the Company executed three new product development agreements in 2008. The decline in research and development income can be attributed to the failure of PTHrP Gel product at clinical phase 2a and the decision by Manhattan Pharmaceuticals to cancel the agreement. The Company received \$300,000 of research and development income from Manhattan Pharmaceuticals at the initiation of Phase 2a studies in 2007.

Licensing and royalty income decreased due to the decrease in sales of Novasome based products marketed by J&J Consumer and Estee Lauder. The Company believes the loss of certain royalties is related to the normal life cycle of the products and that certain royalties of the Company may continue to decline.

| <u>Costs of Sales</u> | <u>For the years ended</u> | | <u>\$ change</u> | <u>% change</u> |
|-----------------------|----------------------------|--------------------------|------------------|-----------------|
| | <u>December 31, 2008</u> | <u>December 31, 2007</u> | | |
| | <i>(in thousands)</i> | | | |
| Costs of Sales | \$ 2,851 | \$ 2,476 | \$ 375 | 15% |

Cost of sales increased by 15% for the year ended December 31, 2008 compared to the same period in 2007 primarily from increased product sales. Cost of sales as a percentage of revenues can vary depending on the product mix. The increase in our cost of sales was primarily due to our underutilized manufacturing capacity which led to higher cost of sales due to the unabsorbed overhead expenses.

| <u>Operating Expenses</u> | <u>For the years ended</u> | | <u>\$ change</u> | <u>% change</u> |
|---|----------------------------|--------------------------|------------------|-----------------|
| | <u>December 31, 2008</u> | <u>December 31, 2007</u> | | |
| | <i>(in thousands)</i> | | | |
| Selling General and Administrative Expenses | \$ 2,777 | \$ 2,430 | \$ 347 | 14% |
| Product Development and Research Expense | \$ 502 | \$ 481 | \$ 21 | 4% |

The increase in selling, general and administrative expenses in 2008 compared to the comparable period in 2007 related to an increase in stock-based compensation expense of \$270,000 in accordance with SFAS 123(R) as discussed under Summary of Significant Accounting Policies (Footnote 1) and Stock-based Compensation (Footnote 9) and an increase in bad debt expense of \$55,000. These expenses were 68% of total revenues for 2008 compared to 53% in 2007.

| <u>Interest</u> | <u>For the years ended</u> | | <u>\$ change</u> | <u>% change</u> |
|-----------------------|----------------------------|--------------------------|------------------|-----------------|
| | <u>December 31, 2008</u> | <u>December 31, 2007</u> | | |
| | <i>(in thousands)</i> | | | |
| Interest Expense, net | \$ 15 | \$ 48 | (\$ 33) | (69%) |

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

The amounts in other income, net in 2008 were \$28,000 of miscellaneous income. The amounts in other income in 2007 were insurance proceeds received as reimbursement for the employee theft that was discovered in 2007 in the amount of \$58,000 and \$6,000 of miscellaneous income.

The tax benefit of \$196,000 in 2008 and \$453,000 in 2007 was the result of a sale of a portion of the Company's state tax operating loss carry forwards to a third party.

The gain from discontinued operations of \$5,000 in 2007 was related to the sale of the equipment for the operations that were shutdown and discontinued in 2006.

Liquidity and Capital Resources

Our business operations have been partially funded over the past four years through equity transactions. During 2007, the Company entered into three (3) equity transactions:

(i)

with Pharmachem Laboratories for 1,500,000 shares of Common Stock for gross proceeds of \$1,500,000,

(ii)

with Federico Buonanno for 50 shares of Series A Convertible Preferred Stock for gross proceeds of \$500,000, and

(iii)

with Univest Management, Inc. EPSP for 150,000 shares of Common Stock for gross proceeds of \$150,000.

Also during the first quarter of 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 stockholders of the Company, for a term of eighteen months. Jane E. Hager (Mrs. Hager), a director of the Company, is also the President of Pinnacle. Loans under the Credit Agreement bear interest at Wall Street prime (3.25% at December 31, 2008), 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 has borrowed \$500,000 against this line of credit as of December 31, 2008 and 2007.

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).

On January 26, 2009, the Company entered into an amendment of its line of credit agreement with Pinnacle. The amendment (a) revised the interest rate calculation from the Prime Rate as published by the Wall Street Journal plus 1.5% per annum to 8.5% per annum, and (b) extended the maturity date until July 31, 2009.

On March 13, 2009, the Company completed a \$6,000,000 private placement (the Offering). As part of the Offering, the Company issued 202.9 shares of Series B-1 Convertible Preferred Stock (Series B Preferred Stock), \$4,782,600 in Secured Convertible Promissory Notes (Promissory Notes), a Preferred Stock Purchase Warrant to purchase 797.1 shares of non-voting Series B-2 Preferred Stock (Preferred Stock Warrant), a Common Stock Purchase Warrant to purchase 350,000 shares of common stock (Common Stock Warrant) and amended its Credit Agreement with Pinnacle.

The Promissory Notes bear interest at an annual rate of 5% and mature on July 31, 2009. Upon approval by the Company's stockholders of the Offering or an earlier liquidation event of the Company, the Promissory Notes automatically convert into Series B-1 Preferred Stock for \$6,000 per share and the Preferred Stock Warrant becomes null and void. The board of directors anticipates submitting the Offering for approval at the Company's 2009 annual meeting of stockholders. If stockholder approval of the Offering is not obtained, the Promissory Notes will remain outstanding and the Preferred Stock Warrant will become exercisable for an aggregate of 797.1 shares of non-voting Series B-2 Preferred Stock for a term of 4 years commencing on July 31, 2009 at a price of \$6,000 per share.

The Company granted its placement agent for the Offering a Common Stock Warrant to purchase 350,000 shares of common stock for \$0.41 per share. Until stockholder approval of the Offering, the warrant may only be exercised for 88,550 shares of the Company's common stock. Following receipt of stockholder approval of the Offering, the warrant may be exercised in full.

In addition, as a condition to the consummation of the Offering, the Company and Pinnacle entered into a third amendment to the line of credit with Pinnacle pursuant to which the parties agreed to change the final payment date of the amounts borrowed under the line of credit from July 31, 2009 to instead provide that 50% of the amount of all loans and advances made by Pinnacle pursuant to the line of credit will become due and payable on July 31, 2010 and the remaining outstanding loans and advances, together with interest thereon, will become due and payable on July 31, 2011.

As a condition to the consummation of the Offering, the Company and Pinnacle entered into a note conversion agreement dated March 13, 2009, pursuant to which Pinnacle agreed to convert the principal amount under the line of credit into shares of the Company's common stock at a conversion rate of \$0.41 per share upon receipt of stockholder approval by the Company of such conversion.

In connection with the private placement transaction, certain holders of our capital stock, representing approximately 51.7% of the voting power of the outstanding shares of capital stock entitled to vote on the private placement transaction (or who represent approximately 44.2% of the voting power of the outstanding shares of capital stock entitled to vote in the private placement transaction if one of our interested stockholders is not able to vote with respect to such matter pursuant to the rules and regulations of the NYSE Alternext as a result of the existence of a transaction relating to the private placement), entered into a voting agreement, pursuant to which these holders agreed to vote or execute and deliver a written consent in favor of approving the private placement transaction.

If the Company receives stockholder approval of the Offering, the Company's capital resources will be sufficient to support our current business plan through March 2010. 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.

The Company's operating activities used \$722,000 in 2008, compared to \$668,000 used during 2007. The increase in cash used in 2008 was primarily due to the decrease in revenues and the increase in costs and expenses during 2008.

The Company's investing activities used \$119,000 of cash in 2008 compared to \$3,000 cash used in 2007. Cash used in 2008 was for capital expenditures related to additional equipment and improvements for the packaging and filling lines. Cash used in 2007 was for capital expenditures for the new filling lines offset by the proceeds of the sale of equipment of our plating division.

The Company's financing activities provided \$98,000 of cash in 2008 compared to \$966,000 provided in 2007. The cash provided in 2008 was from the proceeds of the exercise of common stock options and warrants. The cash provided in 2007 was from the proceeds from the completion of three (3) private placement transactions net of

repayment of notes payable.

Recent Pronouncements

In February 2007, the FASB issued Statement 159, *The Fair Value Option for Financial Assets and Financial Liabilities-Including an Amendment of SFAS 115* (Statement 159), which permits but does not require a Company to measure financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. We have evaluated the new statement and have determined that it does not have a significant impact on the determination or reporting of our financial results.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. We evaluated the new statement and have determined that it does not have a significant impact on the determination or reporting of our financial results.

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, financial position and cash flows.

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 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 June 2008, the FASB issued EITF 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of SFAS 133, "Accounting For Derivative Instruments and Hedging Activities" and/or EITF 00-19, "Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock". EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and early application is not permitted. The Company is currently evaluating the impact that the adoption of EITF 07-5 will have, if any, on its consolidated financial statements.

In October 2008, the FASB issued FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. This FASB Staff Position (FSP) clarifies the application of FASB Statement No. 157, *Fair Value Measurements*, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP shall be effective upon issuance, including prior periods for which financial statements have not been issued. We evaluated the new statement and have determined that it does not have a significant impact on the determination or reporting of our financial results.

Critical Accounting Policies and Estimates

The SEC defines *critical accounting policies* as those that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

Our significant accounting policies are described in Note 1 in the Notes to Consolidated Financial Statements. Not all of these significant accounting policies require management to make difficult, subjective or complex judgments or estimates. However, the following policies could be deemed to be critical within the SEC definition.

Environmental Remediation Liability

On April 6, 2000, officials of the New Jersey Department of Environmental Protection (DEP) inspected the Company s leased storage site in Buena, New Jersey, and issued Notices of Violation (NOVs) relating to the storage of waste materials in a number of trailers at the site. The Company established a disposal and cleanup schedule and completed the removal of materials from the site. In March 2006, the Company received a judge s decision from the Office of Administrative Law (OAL) of a fine in the amount of \$35,000 in respect to the NOVs the Company received from the DEP. Due to the criminal settlement that was reached between the Company and the DEP in 2002, the Company had a credit of \$40,000 to be used against any fines determined as a result of the civil matter, therefore, the Company did not have to pay any money to the DEP for the settlement amount. The DEP subsequently issued a final decision, which accepted the violation findings but rejected the OAL Judge s penalty recommendation, reinstating a previously proposed penalty by the DEP of \$215,000, less the \$40,000 credit previously mentioned or \$175,000. The Company appealed this to the Superior Court of the NJ Appellate Division, which determined that the Commission s decision was reasonable thus affirming the DEP Commissioner s decision. This amount of \$175,000 was accrued for in the fourth quarter of 2007. The Company reached a settlement with DEP Commissioner and agreed to pay the above amount in six equal installments. The final installment is due on June 30, 2009.

On March 2, 2001, the Company became aware of environmental contamination resulting from an unknown heating oil leak at its Companion Pet Products manufacturing facility. The Company immediately notified the New Jersey Department of Environmental Protection and the local authorities, and hired a contractor to assess the exposure and required clean up costs. The total estimated costs for the clean up and remediation is \$652,000, of which \$50,000 remains accrued as of December 31, 2008. Based on information provided to the Company from its environmental consultant and what is known to date, the Company believes the reserve is sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed the Company s estimates.

Long-Lived Assets

The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of the asset to future net undiscounted cash flows expected to be generated by the asset.

If the assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair value of the assets.

Deferred Tax Valuation Allowance

Deferred taxes arise due to temporary differences in the bases of assets and liabilities and from net operating losses and credit carry forwards. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in the Company's statement of operations become deductible expenses under applicable income tax laws or loss or credit carry forwards are utilized. Accordingly, realization of deferred tax assets is dependent on future taxable income against which these deductions, losses and credits can be utilized. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management considers historical operating losses, scheduled reversals of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. As a result, the Company concluded that it was more likely than not that it will be unable to realize the gross deferred tax assets in the foreseeable future and established a valuation reserve for all such deferred tax assets.

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 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 product 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. On occasions when revenue recognized exceeds the milestone or progress billed to our customer, an unbilled receivable is recorded on our Consolidated Balance Sheet.

Stock-based Compensation

SFAS No. 123(R), Share-Based Payment, defines the fair-value-based method of accounting for stock-based employee compensation plans and transactions used by the Company to account for its issuances of equity instruments to record compensation cost for stock-based employee compensation plans at fair value as well as to acquire goods or services from non-employees. Transactions in which the Company issues stock-based compensation to employees, directors and advisors and for goods or services received from non-employees are accounted for based on the fair value of the equity instruments issued. The Company utilizes pricing models in determining the fair values of options and warrants issued as stock-based compensation. These pricing models utilize the market price of the Company's common stock and the exercise price of the option or warrant, as well as time value and volatility factors underlying the positions.

Market Risk

Market risk represents the risk of loss that may impact the financial position, results of operations, or cash flow of the Company due to adverse changes in market prices and interest rates. The Company is exposed to market risk because of changes in interest rates. Changes in interest rates are not expected to have an adverse material effect on the Company's financial condition or results of operations due to the amount of indebtedness the Company carries or expects to carry on its financial statements.

The Company does not use derivative instruments.

Accounts Receivable and Allowance for Doubtful Accounts

The Company extends credit to its customers, based upon credit evaluations, in the normal course of business, primarily with 30- day terms. The Company does not require collateral from its customers. Bad debt provisions are provided for on the allowance method based on historical experience and management's evaluation of outstanding accounts receivable. The Company charges off uncollectible receivables when the likelihood of collection is remote.

ITEM 7A.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 8.

FINANCIAL STATEMENTS

The Company's consolidated financial statements and notes thereto begin on page F-1 of this report and are incorporated herein by reference.

ITEM 9.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A(T).

CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our Chief Executive Officer and Acting Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2008. Based on that evaluation, our Chief Executive Officer and Acting Principal Financial Officer concluded that, as of December 31, 2008, our disclosure controls and procedures were ineffective, due to the material weaknesses detailed below in our internal control over financial reporting that have not been fully remediated as of December 31, 2008.

Internal Control over Financial Reporting

(a) Management's Report on Internal Control over Financial Reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in rule 13a-15(f) under the Securities and Exchange Act of 1934, as amended. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Based on our evaluation under the framework in *Internal Control Integrated Framework*, management concluded that our internal control over financial reporting was ineffective as of December 31, 2008 due to material weaknesses in our internal control over financial reporting that have not been fully remediated as of December 31, 2008, as detailed below:

Our management has determined that we have a material weakness in our internal control over financial reporting related to not having a sufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve non-routine and complex accounting matters or to evaluate the impact of new and existing accounting pronouncements on our consolidated financial statements while completing the financial statement close process.

We did not maintain appropriate segregation of duties associated with the design controls and use of personnel within the organization. Currently, we do not have sufficient staffing to perform these responsibilities associated with proper segregation of duties.

Until these deficiencies in our internal control over financial reporting are remediated, there is a reasonable possibility that a material misstatement to our annual or interim consolidated financial statements could occur and not be prevented or detected by our internal controls in a timely manner.

In 2008 our efforts to remediate these material weaknesses was hampered by our limited financial resources. We are committed to appropriately addressing these matters in 2009, as follows:

We will reassess our accounting and finance staffing levels to determine and seek the appropriate accounting resources to be added to the team to handle the existing workload, provide extra technical accounting depth and further promote segregation of duties;

We will adopt formal policy and procedure guidelines related to Information Technology practices, covering systems development and change management, security authentication and related measures and operational activities;

We will expand the training and education of our accounting and finance staff members, including Sarbanes-Oxley compliance training, in an effort to improve their effectiveness.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

(b) Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during our fourth quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B.

OTHER INFORMATION

None.

PART III

ITEM 10.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

A portion of the information required by this item is contained in the Company's Proxy Statement for the Company's 2009 Annual Meeting of Stockholders (the "2009 Proxy Statement") under the captions "Proposal No. 1 Election of Directors", "Structure and Practices of the Board of Directors - Committees of the Board of Directors", "Audit Committee", "Section 16(a) Beneficial Ownership Reporting Compliance", and "Executive Compensation", which are incorporated herein by this reference. The Company expects to file the 2009 Proxy Statement no later than April 10, 2009.

The Company has adopted a written code of ethics that applies to all directors, officers and employees of the Company and its subsidiaries. The Company's code of ethics is available at its web site at www.askigi.com. Any amendments to the code of ethics or waivers from the provisions of the code of ethics for the Company's principal executive officer and principal financial and accounting officer will be disclosed on the Company's Internet website within four business days following the date of such amendment or waiver.

ITEM 11.

EXECUTIVE COMPENSATION

The information required by this item is contained in the Company's 2009 Proxy Statement under the captions "Executive Compensation", and "Structure and Practices of the Board of Directors - Director Compensation" and is incorporated herein by this reference.

ITEM 12.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

A portion of the information required by this item is contained in the Company's 2009 Proxy Statement under the caption "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by this reference.

Securities Authorized For Issuance Under Equity Compensation Plans

The following table includes information as of December 31, 2008 relating to the Company's 1989 Stock Option Plan, 1999 Stock Incentive Plan, the 1999 Director Stock Option Plan and the 1998 Director Stock Plan, which comprises all of the equity compensation plans of the Company. The table provides the number of securities to be issued upon the exercise of outstanding options under such plans, the weighted-average exercise price of such outstanding options and the number of securities remaining available for future issuance under such equity compensation plans:

| Plan category | Number of securities to be issued upon exercise of outstanding options | Weighted-average exercise price of outstanding options | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) |
|--|---|---|---|
| | (a)(1) | (b)(1) | (c)(2) |
| Equity compensation plans approved by security holders | 2,705,532 | \$ 1.43 | 1,352,298 |
| Equity compensation plans not approved by security holders | - | - | - |
| Total | 2,705,532 | \$ 1.43 | 1,352,298 |

(1)

Includes information with respect to the 1989 Stock Option Plan, 1999 Stock Incentive Plan, and the 1999 Director Stock Option Plan.

(2)

Includes information with respect to the 1989 Stock Option Plan, 1999 Stock Incentive Plan, the 1999 Director Stock Option Plan, and the 1998 Directors Stock Plan. As of December 31, 2008, we had 470,280 shares available for issuance pursuant to the 1998 Directors Stock Plan.

ITEM 13.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is contained in the Company's 2009 Proxy Statement under the captions Proposal 1 Election of Directors Independence of Directors , Structures and Practices of the Board of Directors Committees of the Board of Directors and "Certain Relationships and Related Transactions" and is incorporated herein by this reference.

ITEM 14.

PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is contained in the Company s 2009 Proxy Statement under the caption Relationship with Independent Public Accountants and is incorporated herein by this reference.

ITEM 15.

EXHIBITS

Exhibit

| Number | Description |
|---------------|---|
| (3)(a) | Amended and Restated Certificate of Incorporation of IGI Laboratories, Inc., dated May 7, 2008 (incorporated by reference to Exhibit 3.1 to the Company s Report on Form 8-K, File No. 001-08568, filed May 12, 2008). |
| (3)(b) | Amended and Restated Bylaws of IGI Laboratories, Inc., effective May 7, 2008 (incorporated by reference to Exhibit 3.1 to the Company s Report on Form 8-K, File No. 001-08568, filed May 12, 2008). |
| (3)(c) | Certificate of Designation of the Relative Rights and Preferences of the Series B-1 Convertible Preferred Stock and Series B-2 Preferred Stock of IGI Laboratories, Inc. (incorporated by reference to Exhibit 3.1 to the Company s Report on Form 8-K filed March 19, 2009 (the March 2009 8-K)). |
| (3)(d) | Certificate of Correction to Correct a Certain Error in the Certificate of Designation of the Relative Rights and Preferences of the Series B-1 Convertible Preferred Stock and Series B-2 Preferred Stock (incorporated by reference to Exhibit 3.2 to the March 2009 8-K). |
| (4.1) | Specimen stock certificate for shares of Common Stock, par value \$.01 per share (incorporated by reference to Exhibit 4 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2000, File No. 001-08568, filed March 28, 2001 (the 2000 Form 10-K)). |

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- (4.2) Form of Secured Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the March 2009 8-K).
- (4.3) Form of Preferred Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the March 2009 8-K).
- (4.4) IGI Laboratories, Inc. Common Stock Purchase Warrant in favor of Rockport Venture Securities, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 4.3 to the March 2009 8-K).
- (4.5) Third Amended and Restated Revolving Note in favor of Pinnacle Mountain Partners, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 4.4 to the March 2009 8-K).
- (10.1) IGI, Inc. 1989 Stock Option Plan (incorporated by reference to the Company's Proxy Statement for the Annual Meeting of Stockholders held May 11, 1989, File No. 001-08568, filed April 12, 1989).
- (10.2)# IGI, Inc. 1998 Directors Stock Plan (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-67565), filed March 12, 2009).
- (10.3) Common Stock Purchase Warrant No. 5 to purchase 150,000 shares of IGI, Inc. Common Stock issued to Fleet Bank, NH on March 11, 1999 (incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1998, File No. 001-08568, filed April 12, 1999 (the 1998 Form 10-K)).
- (10.4)# 1999 Director Stock Option Plan as amended approved by the Board of Directors on September 15, 1999 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8/A, File No. 333-52312, filed April 25, 2006).
- (10.5) Common Stock Purchase Warrant No. 7 to purchase 120,000 shares of IGI, Inc. Common Stock issued to Mellon Bank, N.A. on March 11, 1999 (incorporated by reference to Exhibit 10.42 to the 1998 Form 10-K).
- (10.6) Manufacturing and Supply Agreement dated as of February 14, 2001 among IGI, Inc., IGEN, Inc., Immunogenetics, Inc. and Genesis Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.59 to the 2000 Form 10-K).
- (10.7) Manufacturing and Supply Agreement dated May 31, 2002 between IGI, Inc. and IGEN, Inc. (collectively Suppliers) and Vetoquinol, USA, Inc. (Purchaser) (incorporated by reference to Exhibit 10.93 to the 2002 Form 10-K).

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- (10.8) Technological Rights Agreement dated May 31, 2002 between IGI, Inc. and IGEN, Inc. (collectively Sellers) and Vetoquinol, USA, Inc. (Purchaser) (incorporated by reference to Exhibit 10.94 to the 2002 Form 10-K).
- (10.9) Supplemental Agreement dated May 31, 2002 between IGI, Inc. (Seller) and Vetoquinol, USA, Inc. (Buyer) (incorporated by reference to Exhibit 10.95 to the 2002 Form 10-K).
- (10.10) Amendment dated March 19, 2002, to License Agreement by and among Ethicon, Inc. and IGI, Inc., IGEN, Inc. and Immunogenetics, Inc. (incorporated by reference to Exhibit 10.98 to the 2002 Form 10-K).
- (10.11) Product Development Agreement dated November 10, 2003, between Pure Energy Corporation d/b/a/ Pure Energy of America, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.99 on the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, File No. 001-08568, filed April 14, 2004 (the 2003 Form 10-K)).
- (10.12) License Agreement effective December 24, 2003, by and among Michael F. Holick, MD, PhD, A&D Bioscience, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.103 to the 2003 Form 10-K).
- (10.13) License Agreement dated February 9, 2004, between Universal Chemical Technologies, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.104 to the 2003 Form 10-K).
- (10.14) License Agreement by and between Micro-Pak, Inc. (now known as Novavax, Inc.) and IGEN, Inc. effective as of December 13, 1995 (incorporated by reference to Exhibit (10) (v) to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1995, File No. 001-08568, filed March 29, 1996).
- (10.15) Agreement for Development Services dated March 27, 2003, between Chattem, Inc. and IGI, Inc (incorporated by reference to Exhibit 10.107 to the 2003 Form 10-K).
- (10.16) Sublicense Agreement between IGI, Inc. and Tarpan Therapeutics, Inc. dated April 19, 2004 (incorporated by reference to Exhibit 10.109 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed May 14, 2004).
- (10.17) Amendment of the supply and license agreement between IGI, Inc. and Estée Lauder, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed November 24, 2004).
- (10.18) Secured Promissory Note, dated December 12, 2005 (Univest Note), in favor of Univest Management, Inc. EPSP (Univest), c/o Frank Gerardi, Trustee (incorporated by reference to Exhibit 10.1 to the Company's 8-K filed on December 16, 2005).
- (10.19) Letter Agreement dated January 30, 2006 between Univest and the Company re: Univest Note (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 3, 2006).
- (10.20) Letter Agreement dated July 21, 2006 between Univest and the Company re: Univest Note (incorporated by reference to Exhibit 99.1 to the Company's Form 8-K filed on July 27, 2006).
- (10.21) Letter Agreement dated October 4, 2006 between Univest and the Company re: Univest Note (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on October 4, 2006).
- (10.22) Letter Agreement dated December 28, 2006 between Univest and the Company re: Univest Note (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on December 29, 2006).
- (10.23) Letter Agreement dated January 31, 2007 between Univest and the Company re: Univest Note (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 2, 2007).
- (10.24) Letter Agreement dated March 1, 2007 between Univest and the Company re: Univest Note (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on March 7, 2007).
- (10.25)

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Form of Common Stock Purchase Warrants with Respect to Unit Subscription Agreement entered into on December 15, 2005 (incorporated by reference to Exhibit 4.2 to the Company's Form 8-K filed on December 21, 2005).

- (10.26) License Agreement dated October 11, 2006 between IGI, Inc. and Dermworx Inc. (incorporated by reference to Exhibit 10.51 to the Company's Form 10-KSB filed on April 2, 2007).
- (10.27) Employment Agreement dated November 7, 2006, between Rajiv Mathur and IGI, Inc. (incorporated by reference to Exhibit 10.52 to the Company's Form 10-KSB filed on April, 2007).
- (10.28) Loan and Security Agreement dated, January 29, 2007, in favor of Pinnacle Mountain Partners LLC (incorporated by reference to Exhibit 10.54 to the Company's Form 10-KSB filed on April 2, 2007).
- (10.29) Form of Common Stock Purchase Warrant issued to Landmark Financial Corporation with respect to Unit Subscription Agreement entered into February 6, 2007 (incorporated by reference to Exhibit 10.56 to the Company's Form 10-KSB filed on April 2, 2007).
- (10.30)+ Agreement dated August 21, 2007 between Pharmachem Laboratories and IGI, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form-10QSB filed on November 14, 2007).
- (10.31)+ Agreement dated August 23, 2007 between Dermworx, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Form-10QSB filed on November 14, 2007).
- (10.32)# IGI, Inc. 2008 Management Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed February 12, 2008).

- (10.33) 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).
- (10.34)# 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).
- (10.35) Form of Stock Option Award Agreement under the 1999 Stock Incentive Plan. (incorporated by reference to Exhibit 10.4 to the Company's Report on Form 10-Q filed November 14, 2008).
- (10.36) Second Amendment to Loan and Security Agreement, dated January 2, 2009, 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 January 29, 2009).
- (10.37) Second Amended and Restated Revolving Note, dated January 26, 2009, 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 January 29, 2009).
- (10.38) Securities Purchase Agreement, by and among IGI Laboratories, Inc. and the purchasers set forth on Schedule A thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.1 to the March 2009 8-K).
- (10.39) Voting Agreement by and among IGI Laboratories, Inc., Signet Healthcare Partners, G.P. and the stockholders of the Company set forth on Schedule A thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.2 to the March 2009 8-K).
- (10.40) Registration Rights Agreement by and among IGI Laboratories, Inc., the purchasers set forth on Schedule A thereto and the placement agent set forth on Schedule B thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.3 to the March 2009 8-K).
- (10.41) Guaranty Agreement by Immunogenetics, Inc. in favor of the parties listed on Schedule A thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.4 to the March 2009 8-K).
- (10.42) Security Agreement by and among IGI Laboratories, Inc., Immunogenetics, Inc. and the secured parties listed on the signature page thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.5 to the March 2009 8-K).
- (10.43) Intellectual Property Security Agreement by and among IGI Laboratories, Inc., Immunogenetics, Inc. and the secured parties listed on the signature page thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.6 to the March 2009 8-K).
- (10.44) Intercreditor Agreement by and among Life Sciences Opportunities Fund II, L.P., Life Sciences Opportunities Fund (Institutional) II, L.P., Pinnacle Mountain Partners, LLC and IGI Laboratories, Inc., dated March 13, 2009 (incorporated by reference to Exhibit 10.7 to the March 2009 8-K).
- (10.45) Third Amendment to Loan and Security Agreement by and between IGI Laboratories, Inc. and Pinnacle Mountain Partners, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 10.8 to the March 2009 8-K).
- (10.46) Note Conversion Agreement by and between IGI Laboratories, Inc. and Pinnacle Mountain Partners, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 10.9 to the March 2009 8-K).
- (10.47) Indemnification Agreement by and between IGI Laboratories, Inc. and Joyce Erony, dated March 13, 1999 (incorporated by reference to Exhibit 10.10 to the March 2009 8-K).
- (10.48) Form of Indemnification Agreement for Certain Directors (incorporated by reference to Exhibit 10.11 to the March 2009 8-K).
- (10.49)

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IGI, Inc. 1999 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-79333), filed April 25, 2006).

- (21) List of Subsidiaries (incorporated by reference to Exhibit 21 to the 1999 Form 10-K.).
- (23.1) Consent of Amper, Politziner & Mattia, LLP
- (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.

*

Filed herewith.

#

Indicates management contract or compensatory plan.

+

Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to a request for confidential treatment that has been filed with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: IGI Laboratories, Inc.
 March 31, 2009 By: /s/ Rajiv Mathur
 Rajiv Mathur
 President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacity and on the dates indicated.

| <u>Signatures</u> | <u>Title</u> | <u>Date</u> |
|--|--|----------------|
| /s/ Rajiv Mathur Rajiv Mathur | Director, President and Chief Executive Officer (Principal Executive Officer) | March 31, 2009 |
| /s/ Justine Kostka Justine Kostka | Assistant Controller (Acting Principal Financial Officer) | March 31, 2009 |
| /s/ Stephen J. Morris Stephen J. Morris | Director | March 31, 2009 |
| /s/ Terrence O Donnell Terrence O Donnell | Director | March 31, 2009 |
| /s/ Jane E. Hager Jane E. Hager | Director | March 31, 2009 |

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

IGI Laboratories, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of IGI Laboratories, Inc. and Subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, cash flows, and stockholders equity for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of their internal control over financial reporting. Our audits include consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of IGI Laboratories, Inc. and Subsidiaries as of December 31, 2008 and 2007, and the results of their operations and their cash flows for the years then ended, in conformity with U.S generally accepted accounting principles.

/s/ AMPER, POLITZINER & MATTIA, LLP

March 31, 2009

Edison, New Jersey

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IGI LABORATORIES, INC. AND SUBSIDIARIES**CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share information)

| | December 31, 2008 | December 31, 2007 |
|--|------------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 171 | \$ 914 |
| Accounts receivable, less allowance for doubtful accounts of \$75 and \$48 in 2008 and 2007, respectively | 481 | 666 |
| Licensing and royalty income receivable | 74 | 356 |
| Inventories | 562 | 376 |
| Prepaid expenses and other current assets | 82 | 93 |
| Total current assets | 1,370 | 2,405 |
| Property, plant and equipment, net | 2,280 | 2,410 |
| Restricted cash - long term | 50 | 50 |
| License fee, net | 700 | 800 |
| Other | 20 | |
| Total assets | \$ 4,420 | \$ 5,665 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Note payable - related party | \$ 500 | \$ 500 |
| Accounts payable | 559 | 282 |
| Accrued expenses | 312 | 419 |
| Deferred income, current | 56 | 219 |
| Total current liabilities | 1,427 | 1,420 |
| Deferred income, long term | 40 | 45 |
| Other long term liabilities | | 60 |
| Total liabilities | 1,467 | 1,525 |

Commitments and contingencies

Stockholders' equity:

| | | |
|--|----------|----------|
| Series A Convertible Preferred stock, \$.01 par value, 100 shares authorized; 50 shares issued as of December 31, 2008 and 2007, respectively; liquidation preference- \$500,000 | 500 | 500 |
| Common stock, \$.01 par value, 50,000,000 shares authorized; 16,873,218 and 16,795,202 shares issued as of December 31, 2008 and 2007, respectively | 168 | 168 |
| Additional paid-in capital | 28,076 | 27,411 |
| Accumulated deficit | (24,396) | (22,544) |
| Less treasury stock, 1,965,740 shares at cost | (1,395) | (1,395) |
| Total stockholders' equity | 2,953 | 4,140 |
| Total liabilities and stockholders' equity | \$ 4,420 | \$ 5,665 |

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

IGI LABORATORIES, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF OPERATIONS****for the years ended December 31, 2008 and 2007****(in thousands, except shares and per share information)**

| | 2008 | | 2007 |
|--|-------------------|-----------|--------------|
| Revenues: | | | |
| Product sales, net | \$ 3,376 | \$ | 2,904 |
| Licensing and royalty income | 420 | | 841 |
| Research and development income | 273 | | 836 |
| Total revenues | 4,069 | | 4,581 |
| Costs and Expenses: | | | |
| Cost of sales | 2,851 | | 2,476 |
| Selling, general and administrative expenses | 2,777 | | 2,430 |
| Product development and research expenses | 502 | | 481 |
| Operating (loss) | (2,061) | | (806) |
| Interest (expense), net | (15) | | (48) |
| Other income, net | 28 | | 64 |
| Loss before benefit from income taxes | (2,048) | | (790) |
| Benefit from income taxes | 196 | | 453 |
| Loss from continuing operations | (1,852) | | (337) |
| Discontinued operations: | | | |
| Gain from discontinued operations | | | 5 |
| Net loss | (1,852) | | (332) |
| Dividend accreted to preferred stock for beneficial conversion feature | | | 80 |
| Net Loss Attributable to Common Stockholders | \$ (1,852) | \$ | (412) |
| Basic and Diluted (Loss) per Common Share | | | |
| Continuing operations | \$ (.12) | \$ | (.03) |
| Discontinued operations | (.00) | | (.00) |
| | \$ (.12) | \$ | (.03) |

Weighted average shares of common stock outstanding

Basic and diluted

14,881,399

14,308,583

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

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IGI LABORATORIES, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH FLOWS****For the years ended December 31, 2008 and 2007****(in thousands)**

| | 2008 | 2007 |
|---|-------------|-------------|
| Cash flows from operating activities: | | |
| Net (loss) | \$ (1,852) | \$ (332) |
| Reconciliation of net (loss) to net cash used in operating activities: | | |
| Gain on sale of discontinued operations | | (5) |
| Depreciation | 249 | 236 |
| Bad debt expense | 72 | 16 |
| Provision for write down of inventory | 139 | (20) |
| Stock-based compensation expense | 566 | 296 |
| Directors' stock issuance | | 66 |
| Amortization of license fee | 100 | 100 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 113 | (485) |
| Licensing and royalty income receivable | 282 | (265) |
| Inventories | (325) | 129 |
| Prepaid expenses and other current assets | (9) | (48) |
| Accounts payable and accrued expenses | 111 | (161) |
| Deferred income | (168) | (195) |
| Net cash used in operating activities | (722) | (668) |
| Cash flows from investing activities: | | |
| Capital expenditures | (119) | (263) |
| Proceeds from sale of assets | | 260 |
| Net cash used in investing activities | (119) | (3) |
| Cash flows from financing activities: | | |
| Sale of Series A Convertible preferred stock and associated warrants, net of expenses | | 486 |
| Proceeds from exercise of common stock options and warrants | 98 | |
| Proceeds from private placement of common stock, net of expenses | | 1,431 |

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| | | |
|--|--------|---------|
| Borrowings from note payable-related party | 250 | 500 |
| Repayment of note payable- related party | (250) | (1,145) |
| Repayment of note payable | | (306) |
| Net cash provided by financing activities | 98 | 966 |
| Net increase (decrease) in cash and cash equivalents | (743) | 295 |
| Cash and cash equivalents at beginning of year | 914 | 619 |
| Cash and cash equivalents at end of year | \$ 171 | \$ 914 |
| Supplemental cash flow information: | | |
| Cash payments for interest | \$ 26 | \$ 186 |
| Cash (receipt) from taxes | (196) | (463) |
| Non cash transactions: | | |
| Beneficial conversion dividend | | 80 |
| Discontinued operations offset of liabilities | | 118 |

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

IGI LABORATORIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

For the years ended December 31, 2008 and 2007

(in thousands, except share information)

| | Series A | | Common Stock | | Additional | Accumulated | Treasury | Total |
|--|------------------------|---------------|---------------------|---------------|-------------------|--------------------|-----------------|---------------------|
| | Preferred Stock | | Shares | Amount | Paid-In | Deficit | Stock | Stockholders |
| | Shares | Amount | | | Capital | | | Equity |
| Balance, December 31, 2006 | - | \$ | 15,056,516 | \$ 151 | \$ 25,569 | \$ (22,132) | \$ (1,395) | \$ 2,193 |
| Issuance of preferred stock pursuant to a private placement net of associated fees of \$14 | 50 | 500 | | | (14) | | | 486 |
| Dividend attributable to preferred stock beneficial conversion feature and associated warrant amortization | | | | | 80 | (80) | | |
| Issuance of common stock pursuant to a private placement, net of fees of \$ 219 | | | 1,672,123 | 16 | 1,415 | | | 1,431 |

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| | | | | | | | | | |
|---|----|--------|------------|--------|-----------|-------------|------------|----|---------|
| Issuance of stock as Directors compensation | | | 66,563 | 1 | 65 | | | | 66 |
| Stock-based compensation expense | | | | | 296 | | | | 296 |
| Net loss | | | | | | (332) | | | (332) |
| Balance, December 31, 2007 | 50 | 500 | 16,795,202 | 168 | 27,411 | (22,544) | (1,395) | | 4,140 |
| Stock options exercised | | | 53,016 | | 74 | | | | 74 |
| Warrants exercised | | | 25,000 | | 24 | | | | 24 |
| Stock-based compensation expense | | | | | 567 | | | | 567 |
| Net loss | | | | | | (1,852) | | | (1,852) |
| Balance, December 31, 2008 | 50 | \$ 500 | 16,873,218 | \$ 168 | \$ 28,076 | \$ (24,396) | \$ (1,395) | \$ | 2,953 |

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

IGI LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Nature of the Business

IGI Laboratories, Inc. (IGI or the Company), a Delaware corporation, operating in the State of New Jersey, is primarily engaged in the production and packaging of cosmetics, skin care, and consumer products. IGI's Consumer Products business is primarily focused on the continued commercial use of the Novasome® micro encapsulation technologies for skin care applications. These efforts have been directed toward the development of high quality skin care and consumer products marketed by the Company or through collaborative arrangements with cosmetic and consumer products companies.

IGI's Metal Plating Division has been classified as discontinued operations for all periods presented. (See Footnote 15)

Principles of Consolidation

The consolidated financial statements include the accounts of IGI Laboratories, Inc. and its wholly owned and majority-owned subsidiaries. All inter-company accounts and transactions have been eliminated.

Cash Equivalents

Cash equivalents consist of short-term investments, which have original maturities of 90 days or less.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, trade receivables, accounts payable, note payable-related party, and other accrued liabilities at December 31, 2008 approximate their fair value because of the short-term maturities of these items.

Accounts Receivable and Allowance for Doubtful Accounts

The Company extends credit to its customers, based upon credit evaluations, in the normal course of business, primarily with 30-day terms. The Company does not require collateral from its customers. Bad debt provisions are provided for on the allowance method based on historical experience and management's evaluation of outstanding accounts receivable. The Company charges off uncollectible receivables when the likelihood of collection is remote.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and accounts receivable.

The Company maintains its cash in accounts with high quality financial institutions. Although we currently believe that the financial institutions with whom we do business will be able to fulfill their commitments to us, there is no assurance that those institutions will be able to continue to do so.

In 2008, the Company had sales to four customers which individually accounted for more than 10% of the Company's product sales. These customers had sales of \$615,000, \$555,000, \$555,000 and \$471,000, respectively, and aggregately represented 65% of revenues from product sales. Accounts receivable related to the Company's major customer comprised 48% of all account receivables as of December 31, 2008.

The Company received royalty revenue in 2008 from two customers, which individually accounted for more than 10% of 2008 royalty revenues. The Company received \$351,000 and \$53,000 of royalties respectively from these customers.

In 2007, the Company had sales to one customer which individually accounted for more than 10% of the Company's product sales. This customer had sales of \$1,012,000 representing 35% of revenues from product sales.

The Company received royalty revenue in 2007 from two customers, which individually accounted for more than 10% of 2007 royalty revenues. The Company received \$420,000 and \$300,000 of royalties, respectively, from these customers.

The Company operates in the United States with a concentration of our customers located in the Northeastern United States

Inventories

Inventories are valued at the lower of cost, using the first-in, first-out (FIFO) method, or market.

Property, Plant and Equipment

Depreciation of property, plant and equipment is provided for under the straight-line method over the assets estimated useful lives as follows:

| | <u>Useful Lives</u> |
|----------------------------|----------------------------|
| Buildings and improvements | 10 - 30 years |
| Machinery and equipment | 3 - 10 years |

Repair and maintenance costs are charged to operations as incurred while major improvements are capitalized. When assets are retired or disposed, the related cost and accumulated depreciation thereon are removed and any gains or losses are included in operating results.

Long-Lived Assets

In accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, the Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. In performing such review for recoverability, the Company compares expected future cash flows of assets to the carrying value of the long-lived assets and related identifiable intangibles. If the expected future cash flows (undiscounted) are less than the carrying amount of such assets, the Company recognizes an impairment loss for the difference between the carrying value of the assets and their estimated fair value, with fair values being determined using projected discounted cash flows at the lowest level of cash flows identifiable in relation to the assets being

reviewed.

Accrued Expenses

Accrued expenses represent various obligations of the Company including certain operating expenses and taxes payable. For the fiscal year ended December 31, 2008, the largest component of accrued expenses was the fine and penalties accrued payable to the Department of Environmental Protection of \$60,000 and environmental clean-up costs of \$50,000. For the fiscal year ended December 31, 2007, the largest component of accrued expenses was the fine and penalties accrued payable to the Department of Environmental Protection of \$175,000, environmental clean up costs of \$90,000, and accrued severance for our former CEO, Frank Gerardi of \$94,000.

License Fee

License fees are amortized on a straight-line basis over the life of the agreement (10 years).

Accounting for Environmental Costs

Accruals for environmental remediation are recorded when it is probable a liability has been incurred and costs are reasonably estimable. The estimated liabilities are recorded at undiscounted amounts. Environmental insurance recoveries are included in the statement of operations in the year in which the issue is resolved through settlement or other appropriate legal process.

Income Taxes

The Company records income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*, under the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for the tax consequences of temporary differences by applying enacted statutory tax rates applicable to future years to operating loss and tax credit carry forwards and differences between the financial statement carrying amounts and

the tax bases of existing assets and liabilities. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded based on a determination of the ultimate realizability of future deferred tax assets. A valuation allowance equal to 100% of the net deferred tax assets has been recognized due to uncertainty regarding the future realization of these assets.

In July 2006, the FASB issued FASB Interpretation No. (FIN) 48, Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109 , which became effective for the Company on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with SFAS No. 109, Accounting for Income Taxes , and prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As such, there are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

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. These payments are generally non-refundable and are reported as deferred until they are recognizable as revenue. If no such arrangement exists, product development fees are recognized ratably over the entire period during which the services are performed.

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

Stock-Based Compensation

Transactions in which the Company issues stock-based compensation to employees, directors and advisors and for goods or services received from non-employees are accounted for based on the fair value of the equity instruments issued. The Company utilizes pricing models in determining the fair values of options and warrants issued as stock-based compensation. These pricing models utilize the market price of the Company's common stock and the exercise price of the option or warrant, as well as time value and volatility factors underlying the positions.

Product Development and Research

The Company's research and development costs are expensed as incurred.

Advertising Costs

Advertising costs are expensed as incurred. Such expenses for the years ended December 31, 2008 and 2007 were \$21,000 and \$17,000, respectively.

Shipping and Handling Costs

Costs related to shipping and handling is comprised of outbound freight and the associated labor. These costs are recorded in costs of sales.

Net (Loss) per Common 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. Potential dilutive common stock equivalents include shares issuable upon the exercise of options and warrants. Due to the net loss for the years ended December 31, 2008 and 2007, the effect of the Company's potential dilutive common stock equivalents was anti-dilutive for each year; 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 which were excluded from the net (loss) per share calculations due to their anti-dilutive effect amounted to 2,933,032 for 2008 and 803,250 for 2007.

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 allowances, stock based compensation and accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

Effect of Recent Accounting Pronouncements

In February 2007, the FASB issued Statement 159, *The Fair Value Option for Financial Assets and Financial Liabilities-Including an Amendment of SFAS 115* (Statement 159), which permits but does not require a Company to measure financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. We have evaluated the new statement and have determined that it does not have a significant impact on the determination or reporting of our financial results.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. We evaluated the new statement and have determined that it does not have a significant impact on the determination or reporting of our financial results.

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, financial position and cash flows.

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 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 June 2008, the FASB issued EITF 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*, or EITF 07-5. EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of SFAS 133, "Accounting For Derivative Instruments and Hedging Activities" and/or EITF 00-19, "Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock". EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and early application is not permitted. The Company is currently evaluating the impact that the adoption of EITF 07-5 will have, if any, on its consolidated financial statements.

In October 2008, the FASB issued FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. This FASB Staff Position (FSP) clarifies the application of FASB Statement No. 157, *Fair Value Measurements*, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP shall be effective upon issuance, including prior periods for which financial statements have not been issued. We evaluated the new statement and have determined that it does not have a significant impact on the determination or reporting of our financial results.

2. Liquidity

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$171,000 at December 31, 2008 and cash from operations. The Company sustained net losses of \$1,852,000 and \$332,000 for the years ended December 31, 2008 and 2007, respectively, and had negative working capital of \$57,000 at December 31, 2008.

The Company's business operations have been partially funded over the past three years through the exercise of stock options by our directors and officers and through private placements of our stock. 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. There may be additional acquisition and growth opportunities that may require external financing. There

can be no assurance that such financing will be available or available on terms acceptable to the Company.

On January 29, 2009, the Pinnacle line of credit was amended and extended for a term of six months as more fully described in Footnote 7. below. The Company had an outstanding principal balance of \$500,000 as of December 31, 2008 and interest expense related to this line of credit was \$26,000 for the year ended December 31, 2008.

As a condition to the consummation of the private placement, resulting in net proceeds of approximately \$5,371,000, with Signet Healthcare Partners, on March 13, 2009, the Company and Pinnacle entered into a third amendment to the line of credit with Pinnacle pursuant to which the parties agreed to change the final payment date of the amounts borrowed under the line of credit from July 31, 2009 to instead provide that 50% of the amount of all loans and advances made by Pinnacle pursuant to the line of credit will become due and payable on July 31, 2010 and the remaining outstanding loans and advances, together with interest thereon, will become due and payable on July 31, 2011.

In addition, as a condition to the consummation of the private placement with Signet Healthcare Partners, the Company and Pinnacle entered into a note conversion agreement dated March 13, 2009, pursuant to which Pinnacle agreed to convert the principal amount under the line of credit into shares of the Company's common stock at a conversion rate of \$0.41 per share upon receipt of stockholder approval by the Company of such conversion. See Footnote 17. Subsequent Event Convertible Preferred Stock and Convertible Promissory Notes.

In connection with the private placement transaction, certain holders of our capital stock, representing approximately 51.7% of the voting power of the outstanding shares of capital stock entitled to vote on the private placement transaction (or who represent approximately 44.2% of the voting power of the outstanding shares of capital stock entitled to vote in the private placement transaction if one of our interested stockholders is not able to vote with respect to such matter pursuant to the rules and regulations of the NYSE Alternext as a result of the existence of a transaction relating to the private placement), entered into a voting agreement, pursuant to which these holders agreed to vote or execute and deliver a written consent in favor of approving the private placement transaction.

3. 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 (Micro encapsulation 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) thru 2015. This payment is being amortized ratably over the ten-year period. For the years ended, December 31, 2008 and 2007, the Company recorded a \$100,000 expense in each year related to the amortization of the license. Amortization of this license fee will amount to \$100,000 per year for 2009-2015.

4. Inventories

Inventories as of December 31, 2008 and 2007 consisted of:

| 2008 | 2007 |
|-----------------------|-----------------------|
| (in thousands) | (in thousands) |

| | | | | |
|------------------|----|-----|----|-----|
| Raw materials | \$ | 537 | \$ | 258 |
| Work in progress | | 1 | | 8 |
| Finished goods | | 24 | | 110 |
| | \$ | 562 | \$ | 376 |

Finished goods inventory related to the Miaj product line amounted to \$0 and \$106,000 at December 31, 2008 and 2007, respectively. Since the licensor of the Miaj product line failed to meet certain terms and conditions of their license agreement with the Company, and failed to cure the deficiencies on notice, the Company cancelled the agreement in December 2008. At December 31, 2008, the Company has a valuation allowance of \$157,000 or 100% of the Miaj product line.

5. Property, Plant and Equipment

Property, plant and equipment, at cost, as of December 31, 2008 and 2007 consisted of:

| | | 2008 | | 2007 |
|------------------------------------|----|----------------|----|----------------|
| | | (in thousands) | | (in thousands) |
| Land | \$ | 257 | \$ | 257 |
| Building and improvements | | 3,070 | | 3,000 |
| Machinery and equipment | | 2,116 | | 2,068 |
| | | 5,443 | | 5,325 |
| Less accumulated depreciation | | (3,163) | | (2,915) |
| Property, plant and equipment, net | \$ | 2,280 | \$ | 2,410 |

The Company recorded depreciation expense of \$249,000, and \$226,000 in 2008 and 2007, respectively.

6. Note Payable

On December 12, 2005, the Company received \$1,000,000 in the form of a short-term note payable from Univest Management, LLC, Inc., a company owned by Frank Gerardi, former CEO and Chairman of the Company. The note was collateralized by mortgage on real property owned by the Company. The Company accrued \$18,000 of interest related to this note for the year ended December 31, 2007. In March 2007, the Company paid the short-term note payable plus accrued interest with the proceeds from a private placement.

On November 27, 2006, the Company established a \$1,000,000 line of credit with Pharmachem Laboratories Inc; collateralized by the assets of the Company (other than real property) to assist the Company with needed cash flow. The Company borrowed \$300,000 against this line of credit as of December 31, 2006. The funds could be borrowed and re-borrowed from time to time at a rate of 1.5% above Wall Street Prime rate. This line of credit was cancelled and repaid in January of 2007 when Pharmachem Laboratories Inc. agreed to participate in a private placement for 1,500,000 shares for \$1,500,000. This transaction was completed in March 2007.

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, for a term of eighteen months. Loans under the Credit Agreement bear interest at Wall Street prime (7.5% at December 31, 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 as of December 31, 2007. Interest expense related to the Pinnacle credit agreement was \$43,000 for the year ended December 31, 2007.

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).

On January 26, 2009, the Company signed the Second Amended and Restated Revolving Note related to the secured line of credit with Pinnacle. This amendment provides for a revolving \$500,000 secured line of credit for a term of six months with interest at 8.5%. As in the original agreement, loans under this amendment are collateralized by the assets of the Company (other than real property). The Company has borrowed \$500,000 against this line of credit as of December 31, 2008. Interest expense related to the Pinnacle credit agreement was \$26,000 for the year ended

December 31, 2008.

As a condition to the consummation of the private placement with Signet Healthcare Partners, on March 13, 2009, the Company and Pinnacle entered into a third amendment to the line of credit with Pinnacle pursuant to which the parties agreed to change the final payment date of the amounts borrowed under the line of credit from July 31, 2009 to instead provide that 50% of the amount of all loans and advances made by Pinnacle pursuant to the line of credit will become due and payable on July 31, 2010 and the remaining outstanding loans and advances, together with interest thereon, will become due and payable on July 31, 2011.

In addition, as a condition to the consummation of the private placement with Signet Healthcare Partners, the Company and Pinnacle entered into a note conversion agreement dated March 13, 2009, pursuant to which Pinnacle agreed to convert the principal amount under the line of credit into shares of the Company's common stock at a conversion rate of \$0.41 per share upon receipt of stockholder approval by the Company of such conversion. See Footnote 17. Subsequent Event - Convertible Preferred Stock and Convertible Promissory Notes.

7. Preferred Stock

On December 5, 2007, pursuant to a subscription agreement entered into with an accredited investor, the Company sold (i) 50 shares of Series A Convertible Preferred Stock with a liquidation preference of \$10,000 per share, with each share of preferred stock, convertible into 10,000 shares of common stock of the Company, subject to customary adjustments; and (ii) a warrant to purchase 175,000 shares of common stock at an exercise price of \$1.25 per share, expiring two years from issuance, for aggregate consideration of \$500,000. A summary of significant terms is as follows:

Dividends- Series A Convertible Preferred Stock holders are not entitled to a dividend unless the Company declares and pays a cash dividend on the Common Stock. In that event, the holders of shares of Series A Preferred Stock shall be entitled to share in such dividends on a pro rata basis, as if their shares had been converted into shares of Common Stock.

Conversion- The series A preferred stock is convertible, at the option of the holders, into shares of our common stock at a conversion price of \$1.00 per share. Based on the original purchase price of \$10,000 per share of preferred, each share of series A preferred is convertible into 10,000 shares of common. The series A preferred also contains an automatic conversion wherein the shares will automatically convert into common shares when the closing price of the Company's common stock is \$2.50 for ten (10) consecutive trading days.

Liquidation preference- The liquidation preference is \$10,000 per share for a total of \$500,000.

The Company has accounted for the Series A Preferred Stock in accordance with the provisions of Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities, and EITF 98-5, Accounting for Convertible Securities with Beneficial Conversion Features of Contingently Adjustable Conversion Ratios. The Company has allocated the value received between the preferred stock and the related warrants. The allocated value for the preferred stock and the related warrants was approximately \$475,000 and \$25,000, respectively. In addition, the Company evaluated the shares and determined a beneficial conversion feature existed within this transaction, which totaled \$55,000; the preferred stock was further discounted by this amount. The beneficial conversion amount related to the value of the preferred stock and the associated warrant was then accreted back to the preferred stock in accordance with the conversion provision, which allowed for 100% to be converted immediately. The accretion was reflected as a dividend expense.

The fair value of the warrants issued in connection with the 2007 Series A Preferred Convertible stock sale was approximately \$26,000 at issue date using Black-Scholes option-pricing model with the following assumptions:

Assumptions

| | |
|-----------------------------|--------|
| Dividend yield | 0% |
| Risk free interest rate | 4.98% |
| Estimated volatility factor | 47% |
| Expected life | 1 year |

See Footnote 17. Subsequent Event Convertible Preferred Stock and Convertible Promissory Notes for 2009 preferred stock issuance.

8. Common Stock

Pursuant to a Private Placement Memorandum (Private Placement) dated February 5, 2007; the Company issued 1,500,000 shares to an accredited investor, Pharmachem Laboratories, Inc (Pharmachem) for gross proceeds of \$1,500,000. The Company granted Pharmachem the right to have its shares included in one registration (except in the case it suffers a cutback of its shares) of the company securities (piggyback registration rights) until January 1, 2010, with certain exception and subject to certain rights of the Company to cutback shares to be included in the registration. The aforementioned securities were sold in reliance upon the exemption afforded by the provisions of Regulation D, as promulgated by the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act"), and/or Section 4(2) of the Act.

In connection with this transaction the Company paid \$112,500 to Landmark Financial Corporation, issued 22,123 shares to Landmark and issued a warrant to purchase 150,000 shares at \$1.00 per share expiring February 5, 2009. The aforementioned securities were sold in reliance upon the exemption afforded by the provisions of Regulation D, as promulgated by the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act"), and/or Section 4(2) of the Act.

Pursuant to a Private Placement Memorandum dated December 10, 2007, the Company entered into a subscription agreement with Univest Management, Inc. EPSP, an entity controlled by Frank Gerardi, our former Chief Executive Officer and Chairman of the Board of Directors and a beneficial owner of over 10% of our common stock, pursuant to which we issued to Univest 150,000 shares of common stock and a warrant to purchase 52,500 shares of common stock at an exercise price of \$1.25 per share, expiring two years from issuance, for aggregate consideration of \$150,000. The closing of the transaction occurred on December 31, 2007.

9. Stock Based Compensation

Under the 1998 Directors Stock Plan, 600,000 shares of the Company's common stock are authorized under the plan and reserved for issuance to non-employee directors, in lieu of payment of directors' fees in cash. The Company issued 15,929 shares in 2009 as consideration for directors' fees for 2008. Directors' fees for 2008 were accrued on the Company's financial statements as of December 31, 2008. The Company issued 66,563 shares in 2007 as consideration for directors' fees for the years 2004-2007.

The 1999 Stock Incentive Plan (1999 Plan) replaced all previously authorized 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 2,500,000 shares of common stock. In May 2007, the Company's stockholders approved an increase in the maximum amount of shares to be granted by 700,000, for a total of 3,200,000 shares available for grant. A total of 2,392,500 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 date of grant.

The 1999 Director Stock Option 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 1,675,000 shares have been approved and authorized for issuance pursuant to this plan. In May 2007, an additional 300,000 shares were approved for issuance under this plan, bringing the total to 1,975,000 available for issue under this plan. A total of 1,589,798 options, have been granted to non-employee directors through December 31, 2008. The options granted under the 1999 Director Stock Option Plan vest in full one year after their respective grant dates and have a maximum term of ten years.

The fair value for options granted was estimated at the grant date using the Black-Scholes option-pricing model with the following assumptions for 2008 and 2007:

| <u>Assumptions</u> | <u>2008</u> | <u>2007</u> |
|-----------------------------|-------------|-------------|
| Dividend yield | 0% | 0% |
| Risk free interest rate | 2.87% | 4.59% |
| Estimated volatility factor | 69% | 74% |
| Expected life | 5.5 years | 5.5 years |

Estimated volatility was calculated using the historical volatility of the Company's stock over the expected life of the options. The expected life of the options was estimated using the safe harbor transition method and the forfeiture rates are estimated based on historical employment/directorship termination experience. The risk free interest rate is based on US Treasury yields for securities with terms approximating the terms of the grants. The assumptions used in the Black-Scholes option valuation model are highly subjective, and can materially affect the resulting valuation.

Stock option transactions in each of the past two years under the aforementioned plans in total were:

| | <u>Shares</u> | <u>Exercise Price Per Share</u> | <u>Weighted Average Exercise Price</u> |
|--------------------------|---------------|---------------------------------|--|
| January 1, 2007 shares | | | |
| Under option | 1,818,548 | \$.50-\$3.75 | \$1.56 |
| Granted | 573,750 | .81-1.17 | 1.04 |
| Exercised | | | |
| Expired | (30,000) | 3.75 | 3.75 |
| Forfeited | (87,750) | .76-3.00 | 1.06 |
| December 31, 2007 shares | | | |
| Under option | 2,274,548 | .50-3.75 | 1.42 |
| Granted | 620,000 | 1.37-1.70 | 1.64 |
| Exercised | (53,016) | .76-1.56 | 1.41 |
| Expired | (136,000) | 1.94-2.44 | 2.33 |
| Forfeited | | | |
| December 31, 2008 shares | | | |
| Under option | 2,705,532 | .50-2.75 | 1.43 |
| Exercisable options at: | | | |
| December 31, 2008 | 2,155,532 | | \$1.44 |
| December 31, 2007 | 1,700,798 | | \$1.55 |

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2008:

| | Options Outstanding | | | Options Exercisable | |
|------------------------------|----------------------------|----------------------------|---------------------|----------------------------|---------------------|
| | | Weighted | Weighted | | Weighted |
| | | Average | Average | | Average |
| Range of | Number of | Remaining | Exercise | Number of | Exercise |
| <u>Exercise Price</u> | <u>Options</u> | <u>Life (Years)</u> | <u>Price</u> | <u>Options</u> | <u>Price</u> |

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| | | | | | |
|------------------|-----------|------|--------|-----------|--------|
| \$.50 to \$1.00 | 303,250 | 5.36 | \$.73 | 303,250 | \$.73 |
| 1.01 to 2.00 | 2,095,282 | 6.31 | 1.40 | 1,545,282 | 1.42 |
| 2.01 to 3.00 | 307,000 | 4.91 | 2.26 | 307,000 | 2.26 |
| \$.50 to \$3.00 | 2,705,532 | 6.04 | \$1.43 | 2,155,532 | \$1.44 |

The Company has recorded \$566,000 and \$296,000 related to its shared-based expenses in selling, general and administrative expenses on the accompanying Statement of Operations for the year ended December 31, 2008 and 2007, respectively. 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.

The aggregate intrinsic value for options outstanding at December 31, 2008 was \$0. The aggregate intrinsic value of the options exercisable at December 31, 2008 was \$0. The total intrinsic value of the options exercised during 2008 was \$3,000; no options were exercised in 2007.

A summary of non-vested options at December 31, 2008 and changes during the year ended December 31, 2008 is presented below:

| | Options | Weighted Average Grant Date Fair Value |
|---|----------------|---|
| Non-vested option at January 1, 2008 | 573,750 | \$.81 |
| Granted | 620,000 | 1.02 |
| Vested | (643,750) | 1.30 |
| Forfeited | | |
| Non-vested options at December 31, 2008 | 550,000 | \$.81 |

As of December 31, 2008, there was \$279,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Plan. The costs will be recognized monthly through December 2009.

10. Stock Warrants

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

In connection with a Private Placement Memorandum dated December 10, 2007, the Company entered into a subscription agreement with Univest Management, Inc. EPSP (see Note 9), which granted Univest a warrant to purchase 52,500 shares of common stock at an exercise price of \$1.25 per share, expiring two years from issuance.

In connection with the Private Placement transaction executed with Pharmachem, (see Footnote 8), the Company issued a warrant to purchase 150,000 shares at \$1.00 per share to Landmark Financial which expired March 7, 2009 as 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.

11. Income Taxes

The (benefit) from income taxes attributable to loss from continuing operations before (benefit) from income taxes for the years ended December 31, 2008 and 2007 is as follows:

| | 2008 | 2007 |
|---|-----------------------|-------------|
| | (in thousands) | |
| Current tax expense (benefit): | | |
| Federal | \$ | \$ |
| State and local | (196) | (453) |
| Total current tax expense (benefit) | (196) | (453) |
| Deferred tax expense | | |
| Federal | | |
| State and local | | |
| Total deferred tax expense | | |
| Total expense (benefit) from income taxes | \$ (196) | \$ (453) |

The Company sold some of its New Jersey operating loss carry forwards in exchange for net proceeds of \$201,000 and \$463,000 in 2008 and 2007 respectively.

The (benefit) from income taxes differed from the amount of income taxes determined by applying the applicable Federal tax rate (34%) to pretax loss from continuing operations as a result of the following:

| | 2008 | | 2007 |
|--|-----------------------|-------|-------------|
| | (in thousands) | | |
| Statutory benefit | \$ | (697) | \$ (267) |
| Other non-deductible expenses | | 4 | 63 |
| State income taxes, net of valuation allowance | | (129) | (299) |
| Increase in Federal valuation allowance | | 626 | 49 |
| Other, net | | | 1 |
| | \$ | (196) | \$ (453) |

Deferred tax assets included in the Consolidated Balance Sheets as of December 31, 2008 and 2007 consisted of the following:

| | 2008 | | 2007 | |
|---------------------------------------|-----------------------|-------|-----------------------|-------|
| | (in thousands) | | (in thousands) | |
| Current Assets (Liabilities) | | | | |
| Allowance for doubtful accounts | \$ | 31 | \$ | 19 |
| Inventory reserve | | 75 | | 30 |
| Accrued severance | | | | 22 |
| Accrued environmental clean-up costs | | | | 37 |
| Other | | 22 | | |
| Total Current Assets (Liabilities) | | 128 | | 108 |
| Long Term Assets (Liabilities) | | | | |
| Property, plant and equipment | | 117 | | 94 |
| Deferred royalty payments | | 18 | | 107 |
| Tax operating loss carry forwards | | 6,516 | | 6,109 |
| Capital loss carryforwards | | 25 | | 25 |
| Tax credit carry forwards | | 674 | | 705 |
| Non-employee stock options | | 771 | | 535 |
| Other | | (7) | | |
| Total Long Term Assets (Liabilities) | | 8,114 | | 7,575 |

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| | | |
|--------------------------------------|---------|---------|
| Gross Deferred Tax Asset (Liability) | 8,242 | 7,683 |
| Less: valuation allowance | (8,242) | (7,683) |
| Deferred taxes, net | \$ | \$ |

The Company evaluates the recoverability of its deferred tax assets based on its history of operating earnings, its plan to sell the benefit of certain state net operating loss carry forwards, its expectations for the future, and the expiration dates of the net operating loss carry forwards. The Company has concluded that it is more likely than not that it will be unable to realize the gross deferred tax assets in the foreseeable future and has established a valuation allowance for all such deferred tax assets.

Operating loss and tax credit carry forwards for tax reporting purposes as of December 31, 2008 were as follows:

(in thousands)

Federal:

| | |
|--|-----------|
| Operating losses (expiring through 2028) | \$ 18,390 |
| Capital losses (expiring in the year 2010) | 74 |
| Research tax credits (expiring through 2025) | 615 |
| Alternative minimum tax credits (available without expiration) | 28 |

State:

| | |
|--|-------|
| Net operating losses - New Jersey (expiring through 2015) | 1,982 |
| Research tax credits - New Jersey (expiring through 2012) | 2 |
| Alternative minimum assessment New Jersey (available without expiration) | 29 |

Federal net operating loss carry forwards that expire through 2028 have significant components expiring in 2018 (11%), 2019 (11%), 2020 (39%), and 2025 (11%).

The Company's ability to use net operating loss carry forwards may be subject to substantial limitation in future periods under certain provisions of the Internal Revenue Code, including but not limited to Section 382 which applies to corporations that undergo an ownership change. Internal Revenue Code Section 382 rules limit the utilization of net operating losses upon a more than 50% change in ownership of a company (such change refers to a shift in value).

The Company adopted FIN 48 on January 1, 2007. FIN 48 had no effect on the Company's consolidated financial position and results of operations. Additionally, as a result of the adoption of FIN 48, the Company did not record an adjustment to the January 1, 2007 balance of retained earnings and did not record any reserve for unrecognized tax benefits in 2008 and 2007. Accordingly, there is no interest and penalties recorded on the balance sheet for such reserves. The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and the appropriate state income taxing authorities for the tax years 2005 to 2008 due to the net loss carryforwards from those years.

12. Commitments and Contingencies

The Company's commitments and contingencies consisted of operating leases for equipment of \$75,000 for 2009, \$57,000 for 2010, \$49,000 for 2011 and \$3,000 for 2012. Rent expense was \$47,300 and \$33,700 for the years ended December 31, 2008 and 2007, respectively.

13. Legal and U.S. Regulatory Proceedings

On April 6, 2000, officials of the New Jersey Department of Environmental Protection (DEP) inspected the Company's leased storage site in Buena, New Jersey, and issued Notices of Violation (NOVs) relating to the storage of waste materials in a number of trailers at the site. The Company established a disposal and cleanup schedule and completed the removal of materials from the site. In March 2006, the Company received a judge's decision from the Office of Administrative Law (OAL) of a fine in the amount of \$35,000 in respect to the NOV's the Company received from the DEP. Due to the criminal settlement that was reached between the Company and the DEP in 2002, the Company had a credit of \$40,000 to be used against any fines determined as a result of the civil matter, therefore, the Company did not have to pay any money to the DEP for the settlement amount. The DEP subsequently issued a final decision, which accepted the violation findings but rejected the OAL Judge's penalty recommendation, reinstating a previously proposed penalty by the DEP of \$215,000, less the \$40,000 credit previously mentioned or \$175,000. The Company appealed this to the Superior Court of the NJ Appellate Division who determined that the Commission's decision was

reasonable thus affirming the DEP Commissioner's decision. This amount of \$175,000 was accrued for in the fourth quarter of 2007. The Company reached a settlement with DEP Commissioner and agreed to pay the above amount in six equal installments. The final installment is due on June 30, 2009.

On March 2, 2001, the Company became aware of environmental contamination resulting from an unknown heating oil leak at its Companion Pet Products manufacturing facility. The Company immediately notified the New Jersey Department of Environmental Protection and the local authorities, and hired a contractor to assess the exposure and required clean up. The total estimated costs for the clean up and remediation is \$652,000, of which \$50,000 remains accrued as of December 31, 2008. Based on information provided to the Company from its environmental consultant and what is known to date, the Company believes the reserve is sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed the Company's estimates.

The \$50,000 of restricted cash on the Consolidated Balance Sheet as of December 31, 2008 and 2007 represents a restricted escrow account set up on the requirement of the NJ Department of Environmental Protection (DEP) for the soil remediation work. These funds will be released to the Company upon the DEP approval when the remediation is completed.

14. Employee Benefits

The Company has a 401(k) contribution plan, pursuant to which employees may elect to contribute to the plan, in whole percentages, up to 18% of compensation. Employees' contributions are subject to a minimum contribution by participants of 1% of compensation and a maximum contribution of \$15,500 for 2008 and 2007, plus a catch-up contribution of up to \$5,000 if a participant qualifies. The plan was amended on January 1, 2008. Beginning in 2008, the Company matches 100% of the first 3% of compensation contributed by participants and 50% of the next 2% of compensation contributed by participants. For 2007, the Company matched 25% of the first 5% of compensation contributed by participants and contributed, on behalf of each participant, \$4 per week of employment during the year. The Company contribution is in the form of cash, which is vested immediately. The Company has recorded charges to expense related to this plan of approximately \$36,000 and \$13,000 in 2008 and 2007, respectively.

15. Discontinued Operations

The Company ceased operations of the metal plating division in November 2005. In the first quarter of 2007, the Company received a purchase order and deposit in the amount of \$130,000 toward the purchase of the plating equipment from Universal Chemical Technologies, Inc. (UCT) to re-purchase the equipment back from the Company. The Company estimated the fair value of the metal plating equipment less cost to sell at \$350,000. The sales price of the equipment was \$378,000, which consisted of \$260,000 in cash net of \$118,000 owed to UCT by the Company. The Company recorded a gain of \$5,000 on the sale of this equipment in 2007. The purchaser, UCT, paid all relocation and removal expenses relating to this equipment. This transaction was completed in the second quarter of 2007 and all equipment was removed from our facility as of June 30, 2007.

16. Related Party Transactions

The Company has 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 year ended December 31, 2008, the Company recognized \$131,000 of research and development revenues from Pharmachem and has a \$0 accounts receivable balance at December 31, 2008. For the year ended December 31, 2007, the Company recognized \$160,000 of research and development revenues from Pharmachem and had an accounts receivable balance of \$35,000 at December 31, 2007 that was received in the normal course of business.

For a description of the Company's Credit Agreement with a related party, see Footnote 6 above.

17. Subsequent Event Convertible Preferred Stock and Convertible Promissory Notes

On March 13, 2009, the Company completed a \$6,000,000 private placement (the Offering). As part of the Offering, the Company issued 202.9 shares of Series B-1 Convertible Preferred Stock (Series B Preferred Stock), \$4,782,600 in Secured Convertible Promissory Notes (Promissory Notes), a Preferred Stock Purchase Warrant to purchase 797.1 shares of non-voting Series B-2 Preferred Stock (Preferred Stock Warrant), a Common Stock Purchase Warrant to purchase 350,000 shares of common stock (Common Stock Warrant) and amended their Note Payable with Pinnacle. The Company has incurred placement and legal fees of \$629,000, resulting in estimated net proceeds of \$5,371,000.

The Series B Preferred Stock has a par value of \$0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore, each share of the Series B Preferred Stock is convertible into 14,634 shares of common stock for an implied common stock conversion price of \$0.41 per share, subject to certain adjustments and any accrued and unpaid dividends. At the time of issuance, the market price of the common stock into which the Series B Preferred Stock is convertible into was greater than the conversion price. The embedded beneficial conversion feature will be accounted for in accordance with Emerging Issue Task Force (EITF) Issue No. 98-5 *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* (EITF 98-5) and EITF Issue No. 00-27 *Application of Issue No. 98-5 to Certain Convertible Instruments*. Accordingly, the beneficial conversion feature on the Series B Preferred Stock is approximately \$475,000 which represents the amount by which the estimated fair value of the common stock issuable upon conversion exceed the proceeds from such issuance and will be treated as a deemed dividend on the date of the Offering.

The Promissory Notes bear interest at an annual rate of 5% and mature on July 31, 2009. Furthermore, the Company has entered into Guaranty and Security Agreements to guarantee repayment of the Promissory Notes upon maturity. They are collateralized by the assets of the Company. However, upon approval by the Company's stockholders of the Offering or an earlier liquidation event of the Company, the Promissory Notes and any accrued interest automatically convert into Series

B-1 Preferred Stock for \$6,000 per share and the Preferred Stock Warrant becomes null and void. The board of directors anticipates bringing the Offering up for approval at the Company's 2009 annual meeting of stockholders to take place in May 2009. The beneficial conversion feature of the Promissory Notes is approximately \$1,866,000 and will be treated as interest expense, using the effective yield method. The Company believes the interest expense on the beneficial conversion feature will be charged to operations during the first and second quarters of 2009. If stockholder approval of the Offering is not obtained, the Promissory Notes will remain outstanding and the Preferred Stock Warrant will become exercisable for an aggregate of 797.1 shares of non-voting Series B-2 Preferred Stock for a term of 4 years commencing on July 31, 2009 at a price of \$6,000 per share.

The Company granted its placement agent for the Offering a Common Stock Warrant to purchase 350,000 shares of common stock for \$0.41 per share. Until stockholder approval of the Offering, this Common Stock Warrant shall be exercisable for no more than 88,550 shares. This warrant expires on March 13, 2012. The fair value of the warrant will be determined using the Black Scholes Method and the beneficial conversion feature of the warrant that is attributable to the Promissory Notes will be charged to interest expense using the effective yield method. The Company believes the interest expense will be charged to operations during the first and second quarters of 2009.

The Company and Pinnacle entered into a Third Amendment to the Loan and Security Agreement. Pinnacle agreed to change the terms of repayment such that 50% of the Note payable, \$500,000 as of December 31, 2008 (see Note 7) will be payable on July 31, 2010 and the remaining balance will be payable on July 31, 2011. Furthermore, the Company and Pinnacle entered into a Note Conversion Agreement for which Pinnacle agreed to automatically convert the principal amount due under the Note Payable into shares of the Company's Common Stock at a conversion rate of \$0.41 per share upon stockholder approval of the Conversion Agreement. The beneficial conversion feature of the Note Payable is approximately \$195,000 and will be treated as interest expense, using the effective yield method. The Company believes the interest expense on the beneficial conversion feature will be charged to operations during the first and second quarters of 2009.

As part of the Offering, the Company entered into an intercreditor agreement with Pinnacle and the Promissory Noteholders. As part of the intercreditor agreement, the Promissory Noteholders agreed to certain terms setting forth debt repayment, security positions and rights.