IGI LABORATORIES, INC
Form 10-K/A
February 14, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

(Mark One)

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

For the fiscal year ended December 31, 2009

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	**01-0355758**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
105 Lincoln Ave., Buena, NJ	**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:

Title of each class	**Name of each exchange on which registered**
Common Stock $0.01 Par Value	NYSE Amex

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 [X]

Indicate by check if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [ ] No [X]

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 [X] No [ ]

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

Yes [ ] No [ ]

Indicate by check 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 [ ] Non-accelerated filer [ ] Accelerated filer [ ] Smaller reporting company [X]

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

The aggregate market value of the registrant s voting common equity held by non-affiliates of the registrant on June 30, 2009 was approximately $8,038,800. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the NYSE Amex on June 30, 2009.

As of March 29, 2010, there were 17,796,247 shares of the registrant s common stock outstanding.

Documents Incorporated By Reference

Certain information contained in the definitive Proxy Statement for the Company s 2010 Annual Meeting of Stockholders is incorporated by reference into Part III hereof.

EXPLANATORY NOTE

IGI Laboratories, Inc. (which may be referred to herein as we, us or the Company) is filing this Amendment No. 1 (Amendment No. 1) to its Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (the Annual Report), originally filed with the Securities and Exchange Commission (the SEC) on March 31, 2010, to amend Items 1A and 9A(T) to definitively state that its disclosure controls and procedures were effective as of December 31, 2009. Although all of the Risk Factors originally appearing in the Annual Report are included in this Amendment No. 1, the only changes are in the risk factor entitled 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. In addition, in connection with the filing of this Amendment No. 1 and pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, the Company is including certain currently dated certifications.

Except for the foregoing, this Amendment No. 1 does not amend the Annual Report in any way and does not modify or update any disclosures contained in the Annual Report, which continues to speak as of the original date of the Annual Report. Accordingly, this Amendment No. 1 should be read in conjunction with the Annual Report and the Company s other filings filed with or furnished to the SEC subsequent to the Annual Report.

PART I

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, 2009, three of our customers accounted for 44% of our revenue, and for the year ended December 31, 2008, four of our customers accounted for 54% of our revenue. 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 FDA regulations. Any non-compliance with the regulatory guidelines may necessitate corrective action that may result in additional expenses and use of more of our resources.

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

Our operations and properties are also subject to a wide variety of increasingly complex and stringent federal, state and local environmental laws and regulations, including those governing the remediation of contaminated soil and groundwater. Such environmental laws may apply to conditions at properties and facilities presently or formerly owned or operated by us, as well as to conditions at properties at which wastes or other contamination attributable to us have been sent or otherwise come to be located. Two of our facilities are currently undergoing remediation of environmental contamination. The total estimated costs for the clean-up and remediation of such facilities are

$669,000 and $65,000, respectively, of which $54,000 and $15,000 remain accrued as of December 31, 2009. Based on information provided to us from our environmental consultants and what is known to date, we believe the reserves are sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed our estimates. In addition, we can give no assurance that the future cost of compliance with existing environmental laws will not give rise to additional significant expenditures or liabilities that would be material to us. Future events, such as new information, changes in existing environmental laws or their interpretation, and more vigorous enforcement policies of federal, state or local regulatory agencies, may have a material adverse effect on our business, financial condition and results of operations.

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.

We are dependent on our new management team.

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

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

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

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

- pay damages in the form of lost profits and/or a reasonable royalty for any infringement
- pay substantial damages (potentially treble damages in the United States if any such infringement is found to be willful);
- pay attorney fees of a prevailing party, if the case is found to be exceptional;
- cease the manufacture, use or sale of the infringing offerings or processes;
- discontinue the use of the infringing technology;
- expend significant resources to design around patented technology and develop non-infringing technology; and
- license patented technology from the third party claiming infringement, which license may not be available on commercially reasonable terms, or may not be available at all.

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

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

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

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 six years, and no net income has been available to common shareholders during each of these years. As of December 31, 2009, our shareholders equity was $5.3 million and we had an accumulated deficit of $31.8 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, 2009, and our management concluded that our disclosure controls and procedures were effective as of December 31, 2009.

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.

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

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

which may have an adverse effect on our results of operations.

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 approximately 67.8% 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 closed at a low of $.48 in the fourth quarter of 2008 and a high of $2.57 in the second quarter of 2008. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

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

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

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

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

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

regulatory developments in the 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, 2009, the average daily trading volume of our common stock on the NYSE Amex was approximately 5,700 shares. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

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

On May 6, 2008, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. Specifically, we are required to reflect income from continuing operations and/or net income in one of our five most recent fiscal years and a minimum of $6 million in stockholders equity to remain listed on the exchange. We had net income from continuing operations in our 2002 fiscal year, but had net losses and losses from continuing operations in each of our 2003, 2004, 2005, 2006, 2007, 2008 and 2009 fiscal years. Our stockholders equity at December 31, 2008 was $3.0 million.

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

On March 13, 2009, we completed a $6,000,000 private placement offering with certain investment funds affiliated with Signet Healthcare Partners, G.P., as more fully described in Note 9 to our Consolidated Financial Statements. In recognition of our efforts in connection with the offering, NYSE Amex granted us an extension from May 6, 2009 until May 31, 2009 to regain compliance with these continued listing standards.

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

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

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

We have Series A Preferred Stock outstanding, Series B-1 Convertible Preferred Stock outstanding, Series C Convertible Preferred Stock outstanding, outstanding options and outstanding warrants to purchase common stock. If all or any number of these holders of derivative securities were to exercise their conversion rights, our common stock would be substantially diluted, which could negatively impact our stock price.

PART II

ITEM 9A(T).

CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

As of the end of the period covered by this report, our management conducted an evaluation, with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act)). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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 Exchange Act. Under the supervision and with the participation of its management, including our Chief Executive Officer and Principal Financial and Accounting Officer, the Company conducted an evaluation of the effectiveness of its 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.

Management had identified the following material weaknesses during financial year 2008,

> We had 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.

Management noted that the following remedial actions were taken to enhance internal controls as of December 31st 2009.

Management added two qualified finance professionals with the appropriate level of experience and technical expertise to address non-routine and complex accounting matters or to evaluate the impact of new and existing accounting pronouncements on our Consolidated Financial Statements.

Management has introduced the process of issuing formal policy and procedures relating to finance and operations with a view to streamline processes, introduce controls as well as to communicate them to all departments concerned.

Based on the Company s processes and assessment, as described above, management has concluded that, as of December 31, 2009, the Company s internal control over financial reporting was effective. The Company s assessment included documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

In 2010, management will be focusing its attention on:

Addressing the efficiency of our computer systems in terms of hardware and software capabilities to further support management information needs required for increased levels of operation and strategic decision and further improving functions where the company does not have sufficient staffing.

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 SEC 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 ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 15.

EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

The Consolidated Financial Statements and related Notes filed as part of this Annual Report on Form 10-K are listed on the Index to Consolidated Financial Statements on page F-1.

(a) (2) Financial Statement Schedules

Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in our Consolidated Financial Statements or Notes thereto.

(a) (3) List of Exhibits

See the following list of exhibits below which exhibits are filed as part of this Annual Report on Form 10-K. We are incorporating by reference to our previous SEC filings certain exhibits filed as part of this Annual Report on Form 10-K. The location of each such exhibit in the previous filing is indicated in parentheses.

(b) Exhibits

Exhibit Number	Description
(3.1)	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, filed May 12, 2008).
(3.2)	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, filed May 12, 2008).
(3.3)	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)).
(3.4)	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).
(3.5)	Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock of IGI Laboratories, Inc. (incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K, filed March 31, 2010).
(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, filed March 28, 2001 (the 2000 Form 10-K)).
(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).
(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, as amended (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-160342), filed June 30, 2009).
(10.3)#	IGI, Inc. 1999 Director Stock Option Plan, as amended (incorporated by reference to Exhibit 4.2 to the Company s Registration Statement on Form S-8 (Registration No. 333-160342, filed June 30, 2009).
(10.4)	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).
(10.5)	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 Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2002, filed March 10, 2003 (the 2002 Form 10-K)).
(10.6)	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).
(10.7)	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).
(10.8)	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).
(10.9)	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 to the Company s

Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed April 14, 2004 (the 2003
Form 10-K)).

(10.10) 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).

(10.11) 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).

(10.12) 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, filed March 29,1996).

(10.13) 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).

(10.14) 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).

(10.15) 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).

(10.16) 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).

(10.17) 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).

(10.18) 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).

(10.19) Second Amendment to Loan and Security Agreement, dated January 26, 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).

(10.20) 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).

(10.21) 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).

(10.22) 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).

(10.23) 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).

(10.24)+ 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).

(10.25)+ 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).

(10.26)# 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).

(10.27)# Form of Stock Option Award Agreement under the 1999 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to the Company s Report on Form 10-Q filed November 14, 2008).

(10.28) 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).

(10.29) 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).

(10.30) 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).

(10.31) 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).

(10.32)

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).

(10.33) 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).

(10.34)	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).
(10.35)#	Indemnification Agreement by and between IGI Laboratories, Inc. and Joyce Erony, dated March 13, 2009 (incorporated by reference to Exhibit 10.10 to the March 2009 8-K).
(10.36)#	Form of Indemnification Agreement for Certain Directors (incorporated by reference to Exhibit 10.11 to the March 2009 8-K).
(10.37)#	IGI, Inc. 1999 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration No. 333-160342), filed June 30, 2009).
(10.38)#	Employment Agreement dated May 29, 2009 between IGI Laboratories, Inc. and Hemanshu Pandya (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed May 29, 2009).
(10.39)#	Employment Agreement dated May 18, 2009 between IGI Laboratories, Inc. and Philip S. Forte (incorporated by reference to Exhibit 10.2 to the Company s Report on Form 8-K filed May 29, 2009).
(10.40)#	Non-Qualified Stock Option Award Agreement dated May 29, 2009 between IGI Laboratories, Inc. and Philip S. Forte (incorporated by reference to Exhibit 10.3 to the Company s Report on Form 8-K filed May 29, 2009).
(10.41)#	Separation of Employment Agreement and General Release between IGI Laboratories, Inc. and Rajiv Mathur dated May 28, 2009 (incorporated by reference to Exhibit 10.4 to the Company s Report on Form 8-K filed May 29, 2009).
(10.42)#	IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed July 2, 2009).
(10.43)#	Form of Non-Qualified Stock Option Agreement under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company s Report on Form 8-K filed July 2, 2009).
(10.44)#	Form of Award Agreement for Restricted Shares under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company s Report on Form 8-K filed July 2, 2009).
(10.45)#	IGI Laboratories, Inc. Form of Award Agreement for Restricted Shares between IGI Laboratories, Inc. and Philip S. Forte (incorporated by reference to Exhibit 4.4 to the Company s Registration Statement on Form S-8 (No. 333-160341) filed June 30, 2009).
(10.46)#	IGI Laboratories, Inc. Non-Qualified Stock Option Award Agreement dated June 29, 2009 between IGI Laboratories, Inc. and Hemanshu Pandya (incorporated by reference to Exhibit 4.5 to the Company s Registration Statement on Form S-8 (No. 333-160341) filed June 30, 2009).
(10.47)#	IGI Laboratories, Inc. Form of Award Agreement for Restricted Shares between IGI Laboratories, Inc. and Hemanshu Pandya (incorporated by reference to Exhibit 4.6 to the Company s Registration Statement on Form S-8 (No. 333-160341) filed June 30, 2009).
(10.48)	Form of Securities Purchase Agreement, by and among IGI Laboratories, Inc. and the purchasers thereto, dated March 29, 2010 (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K, filed March 31, 2010).
(10.49)	Registration Rights Agreement by and among IGI Laboratories, Inc. and the purchasers set forth on Schedule A thereto, dated March 29, 2010 (incorporated by reference to Exhibit 10.2 to the Company s Report on Form 8-K, filed March 31, 2010).
(21)	List of Subsidiaries (incorporated by reference to Exhibit 21 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, filed April 14, 2000).
(23.1)	Consent of Amper, Politziner & Mattia, LLP (incorporated by reference to Exhibit 23.1 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2009, filed March 31, 2010)
(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 Principal Financial and Accounting 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 Principal Financial and Accounting 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.
February 14, 2011	By:	/s/ Charles Moore Charles Moore President and Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification of the President and Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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