IGI LABORATORIES, INC
Form S-3/A
March 28, 2011

As filed with the Securities and Exchange Commission on March 28, 2011

Registration No. 333-171446

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 3 to

FORM S-3

Registration Statement Under

the Securities Act of 1933

IGI Laboratories, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

01-0355758

(I.R.S. Employer Identification No.)

105 Lincoln Avenue

Buena, New Jersey 08310

(856) 697-1441

(Address, including zip code, and telephone number, including area code,

of Registrant s principal executive offices)

Charles Moore

President and Chief Executive Officer

IGI Laboratories, Inc.

105 Lincoln Avenue

Buena, New Jersey 08310

(856) 697-1441

(Name, address, including zip code, and telephone number, including area code,

of agent for service)

COPY TO:

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Eighteenth and Arch Streets

Philadelphia, PA 19103-2779

(215) 981-4000

As soon as practicable after this Registration Statement becomes effective

(Approximate date of commencement of proposed sale to the public)

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. [ ]

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. [ ]

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. (Check one):

Large accelerated filer [ ]	Accelerated filer [ ]	Non-accelerated filer [ ] (Do not check if a smaller reporting company)	Smaller reporting company þ

_____

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 28, 2011

PROSPECTUS

IGI LABORATORIES, INC.

2,668,584 Shares

Common Stock

This prospectus relates to the resale from time to time of up to 2,668,584 shares of our common stock, par value $0.01 per share, for resale by the selling stockholders identified in this prospectus. These shares consist of approximately (i) 2,246,381 shares of our common stock issuable upon the initial conversion of 1,550 shares of our outstanding Series C Convertible Preferred Stock, par value $0.01 per share and (ii) up to 422,203 shares of our common stock issuable upon conversion of accrued dividends on the Series C Convertible Preferred Stock from the issuance date of such shares through December 29, 2013. We issued these shares of Series C Convertible Preferred Stock in a private placement that closed on March 29, 2010.

We are not selling any shares of our common stock under this prospectus and we will not receive any of the proceeds from the sale of shares by the selling stockholders. The selling stockholders have advised us that they will sell the common stock from time to time in the open market, on the NYSE Amex or on any national securities exchange or automated interdealer quotation system on which our common stock is then listed or quoted, in privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or otherwise as described under Plan of Distribution on page 23. We will pay all expenses of registration incurred in connection with this offering, but the selling stockholders will pay all of their selling commissions, brokerage fees and related expenses.

Our common stock is listed on NYSE Amex under the symbol IG. On March 18, 2011, the last reported sales price for our common stock was $1.55 per share.

INVESTING IN OUR COMMON STOCK INVOLVES RISKS. YOU SHOULD CAREFULLY CONSIDER THE RISK FACTORS INCLUDED IN THIS PROSPECTUS BEGINNING ON PAGE 2 AND THE RISK FACTORS INCLUDED IN OUR ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2010 AND ANY SUBSEQUENTLY FILED PERIODIC REPORTS THAT ARE INCORPORATED BY REFERENCE HEREIN BEFORE YOU DECIDE TO INVEST.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____ , 2011.

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FORWARD-LOOKING STATEMENTS

This prospectus, any supplements to this prospectus and other documents that are and will be incorporated into this prospectus contain statements that involve expectations, plans or intentions (such as those relating to future business or financial results, new products or services, or management strategies). These statements are forward-looking and are subject to risks and uncertainties, so actual results may vary materially. You can identify these forward-looking statements by words such as may, should, expect, anticipate, believe, estimate, intend, plan and other similar expressions. You should consider our forward-looking statements in light of the risks discussed under the heading Risk Factors below and in documents incorporated herein by reference, including our consolidated financial statements, related notes and other financial information appearing in our other filings and documents incorporated herein by reference. Given these risks and uncertainties, we caution you not to place undue

reliance on such forward-looking statements. The forward-looking statements contained in this prospectus speak only as of the date hereof and we assume no obligation to update such statements.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus and any supplements to this prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus or any such supplements, before making an investment decision.

IGI Laboratories, Inc.

We develop, manufacture, fill and package topical semi-solid and liquid products for cosmetic, cosmeceutical and pharmaceutical customers. Our products are used for cosmetic, cosmeceutical and prescription applications for the treatment of symptoms of dermatitis, acne, psoriasis and eczema. We are building upon this foundation by filing our own Abbreviated New Drug Applications, or ANDAs, and continuing to expand into the prescription pharmaceutical arena.

Our strategy is based upon three initiatives:

- increasing our current contract services business;
- developing a portfolio of generic formulations in topical dosage forms; and
- creating unique opportunities around our licensed Novasome® technology.

All of our product development and manufacturing is performed at our 25,000 square foot facility in Buena, New Jersey.

Our head-office, product development laboratories and manufacturing facility are located at 105 Lincoln Avenue, Buena, New Jersey, our telephone number is 856-697-1441 and our website is *http://www.askigi.com*. Information contained on our website is not incorporated into this prospectus.

The Offering

On March 29, 2010, we completed a $1,550,000 private placement offering to the selling stockholders named on page 16, which we refer to as the March 2010 Private Placement, pursuant to which these selling stockholders purchased an aggregate of 1,550 shares of our Series C Convertible Preferred Stock. We issued these shares in a private placement transaction in reliance upon the exemption from registration provided for under Section 4(2) of the Securities Act of 1933, as amended, or the Securities Act, and Rule 506 of Regulation D thereunder.

We are registering an aggregate of 2,668,584 shares of common stock issuable upon conversion of outstanding shares of Series C Convertible Preferred Stock, including shares issuable upon conversion of accrued dividends on the Series C Convertible Preferred Stock from the issuance date of such shares through December 29, 2013, to satisfy the registration rights we granted to the selling stockholders in connection with the private placement. The dollar value of these securities is $1,841,323, calculated based on the 2,668,584 shares of common stock issuable upon conversion of the Series C Convertible Preferred Stock, including shares issuable upon conversion of accrued dividends on the Series C Convertible Preferred Stock from the issuance date of such shares through December 29, 2013, multiplied by $0.69, the closing price of the Company s common stock on March 29, 2010 (the date of the closing of the private placement) as quoted on NYSE Amex.

On March 13, 2009, we completed a $6,000,000 private placement with Life Sciences Opportunities Fund II, L.P. and Life Sciences Opportunities Fund (Institutional) II, L.P. (the Life Science Opportunities Funds), which we refer to as the March 2009 Private Placement, pursuant to which the Life Science Opportunities Funds were issued 202.9 shares of our Series B-1 Convertible Preferred Stock, $4,782,600 in secured convertible promissory notes, a preferred stock purchase warrant to purchase 797.1 shares of our non-voting Series B-2 Preferred Stock and a warrant to purchase 350,000 shares of our common stock. At our annual meeting of stockholders held on May 15, 2009, our stockholders approved the March 2009 Private Placement. Immediately upon stockholder approval, the $4,782,600 aggregate principal amount of secured convertible promissory notes, together with accrued and unpaid interest, were converted into an aggregate of 803.979 shares of our Series B-1 Convertible Preferred Stock and the

warrant to purchase 797.1 shares of non-voting Series B-2 Preferred Stock was cancelled. Pursuant to our Registration Statement on Form S-3 declared effective on February 9, 2010 (Reg. No. 333-163524), which we refer to as the 2010 Registration Statement, we registered 17,251,597 shares of common stock issuable upon conversion of the Series B-1 Convertible Preferred Stock issued to the Life Science Opportunities Funds in the March 2009 Private Placement (including shares of common stock issuable upon conversion of accrued dividends thereon). The dollar value of the securities we are registering on this registration statement for the benefit of the Life Science Opportunities Funds, together with the securities registered for the benefit of the Life Science Opportunities Funds on the 2010 Registration Statement is $10,807,791, calculated based on the 1,162,123 shares of common stock to be registered herein for resale on behalf of the Life Science Opportunities Funds, multiplied by $0.69, the closing price of the Company s common stock on March 29, 2010 (the date of the closing of the March 2010 Private Placement) as quoted on NYSE Amex, plus the 17,251,597 shares of common stock registered on behalf of the Life Science Opportunities Funds on the 2010 Registration Statement multiplied by $0.58, the closing price of the Company s common stock on March 13, 2009 (the date of the closing of the March 2009 Private Placement) as quoted on NYSE Amex.

We are not selling any securities under this prospectus or its supplements and will not receive any of the proceeds from the sale of shares by the selling stockholders.

RISK FACTORS

Investing in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the risks and uncertainties described below, together with all of the other information contained in or incorporated by reference in this prospectus. In particular, you should carefully consider the risks described in the sections entitled Risk Factors contained in our latest Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, which have been filed with the SEC and are incorporated herein by reference, as well as other information in this prospectus and any accompanying prospectus supplement before purchasing any of our securities. Our actual results could differ materially from those discussed herein. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this prospectus.

Risks Related to our Business

We have a history of losses and cannot assure you that we will become profitable. As a result, we may have to cease operations and liquidate our business.

Our expenses have exceeded our revenue in each of the last seven years, and no net income has been available to our common stockholders during each of these years. As of December 31, 2010, our stockholders equity was $10.4 million and we had an accumulated deficit of $37 million. Our future profitability depends on revenue exceeding expenses, but we cannot assure you that this will occur. If we do not become profitable or continue to raise external financing, we could be forced to curtail operations and sell or liquidate our business, and you could lose some or all of your investment.

We face intense competition in the consumer products business.

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

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

We expect to sublicense our technologies to third parties, which would manufacture and market products incorporating these technologies. If our competitors develop new and improved technologies that are superior to our technologies, however, 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, 2010, two of our customers accounted for 55% and for the year ended December 31, 2009, three of our customers accounted for 52% of our product sales 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 over-run our cost estimates. Such under-pricing or significant cost overruns could have a material adverse effect on our business, results of operations, financial condition, and cash flows. Further, the period of revenue recognition under such agreements are based upon the timing of work performed or completed.

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

We currently rely on several third party suppliers to provide us with the raw materials necessary to manufacture cosmetic and over-the-counter products. The loss of one or more of these suppliers, the non-performance of one or

more of their materials or the lack of availability of raw materials could suspend our manufacturing process related to these products. This interruption of the manufacturing process could impair our ability to fill our customers orders as they are placed, which could put our business at a competitive disadvantage. In addition, while we have processes intended to reduce volatility in component and material pricing, we may not be able to successfully manage price fluctuations which may have an adverse effect on our results of operations.

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

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

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

Our operations and properties are also subject to a wide variety of increasingly complex and stringent federal, state and local environmental laws and regulations, including those governing the remediation of contaminated soil and groundwater. Such environmental laws may apply to conditions at properties and facilities presently or formerly owned or operated by us, as well as to conditions at properties at which wastes or other contamination attributable to us have been sent or otherwise come to be located. Two of our facilities are currently undergoing remediation of environmental contamination. The total estimated costs for the clean-up and remediation of such facilities are $676,000 and $65,000, respectively, of which $24,000 and $10,000 remain accrued as of December 31, 2010. Based on information provided to us from our environmental consultants and what is known to date, we believe the reserves are sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed our estimates. In addition, we can give no assurance that the future cost of compliance with existing environmental laws will not give rise to additional significant expenditures or liabilities that would be material to us. Future events, such as new information, changes in existing environmental laws or their interpretation, and more vigorous enforcement policies of federal, state or local regulatory agencies, may have a material adverse effect on our business, financial condition and results of operations.

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

The manufacturing, processing, formulation, packaging, labeling, testing, storing, distributing, marketing, advertising and sale of our products is subject to extensive regulation by one or more U.S agencies, including the FDA, the Federal Trade Commission and the Consumer Products Safety Commission, as well as by several state and local agencies in localities were the Company s products are stored, distributed or sold. In addition, we manufacture and market certain of our products in accordance with standards set by organizations, such as the United States Pharmacopeial Conventions, the USP.

The FDA regulates the testing, manufacture, labeling, marketing and sale of pharmaceutical products. Approval by the FDA is generally required before any new drug or the generic equivalent to any previously approved drug may be marketed or sold in the United States. In order to receive approval from the FDA for our product candidates that are generic versions of brand-name drugs, we intend to use the Abbreviated New Drug Application, or ANDA, process and thus demonstrate to the FDA that each generic product candidate is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator, or brand-name reference drug. Bioequivalency may be demonstrated by comparing the generic product to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. However, if the FDA determines that an ANDA for a generic drug product is not adequate to support approval, it could deny our application or request additional information, including preclinical and clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.

If our product candidates receive FDA approval through the ANDA process, the labeling claims and marketing statements that we can make for our generic drugs are limited by statutes and regulations and by the claims made in

the brand-name product s label. In addition, following regulatory approval, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive and ongoing regulatory requirements. As a manufacturer of pharmaceutical products distributed in the United States, we must also comply with cGMPs, which include requirements related to production processes, quality control and assurance and recordkeeping. Our manufacturing facilities and procedures and those of our suppliers are subject to periodic inspection by the FDA and foreign regulatory agencies. Any material deviations from cGMPs or other applicable standards identified during such inspections may result in enforcement actions, including delaying or preventing new product approvals, a delay or suspension in manufacturing operations, consent decrees or civil or criminal penalties. Further, discovery of previously unknown problems with a product or manufacturer may result in restrictions or sanctions, including withdrawal of the product from the market.

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

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

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

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

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

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

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

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

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

we may be subject to interference proceedings;

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

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

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

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

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

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

enforcement of patents is complex, uncertain and expensive.

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

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

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

From time to time, third parties have asserted intellectual property infringement claims against us and our customers and there can be no assurance that third parties will not assert infringement claims against either us or our customers in the future. While we believe that our product offerings do not infringe in any material respect upon proprietary rights of other parties and/or that meritorious defenses would exist with respect to any assertions to the contrary, there can be no assurance that we would not be found to infringe on the proprietary rights of others.

Patent applications in the U.S. and some foreign countries are generally not publicly disclosed until the patent is issued or published, and we may not be aware of currently filed patent applications that relate to our offerings or processes. If patents later issue on these applications, we may be found liable for subsequent infringement. There has been substantial litigation in the pharmaceutical and biotechnology industries with respect to the manufacture, use and sale of products and processes that are the subject of conflicting patent rights.

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

- pay damages in the form of lost profits and/or a reasonable royalty for any infringement;
- pay substantial damages (potentially treble damages in the U.S. if any such infringement is found to be willful);
- pay attorney fees of a prevailing party, if the case is found to be exceptional;
- cease the manufacture, use or sale of the infringing offerings or processes;

discontinue the use of the infringing technology;

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

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

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

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

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

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

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

Economic conditions could severely impact us.

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

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

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

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

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

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

As a public company, we are required to comply with the periodic reporting obligations of the Exchange Act including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. In addition, we are required under applicable law and regulations to integrate our systems of disclosure controls and procedures and internal control over financial reporting. Our management assessed our existing disclosure controls and procedures as of December 31, 2010 and December 31, 2009, and our management concluded that our disclosure controls and procedures were effective as of such times.

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

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

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

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

other generic drug manufacturers.

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

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

Our ability to market generic pharmaceutical products successfully depends, in part, on the acceptance of the products by independent third-parties (including pharmacies, government formularies, managed care providers, insurance companies and retailers), as well as patients. In addition, unanticipated side effects or unfavorable publicity concerning any of our products, or any brand-name product of which our generic product is the equivalent, could have an adverse effect on our ability to achieve acceptance by managed care providers, pharmacies and other retailers, customers and patients.

Risks Related to Our Securities

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

For the year ended December 31, 2010, the average daily trading volume of our common stock on the NYSE Amex was approximately 9,900 shares. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

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

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

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

On May 6, 2008, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. Specifically, we are required to reflect income from continuing operations and/or net income in one of our five most recent fiscal years and a minimum of $6 million in stockholders equity to remain listed on the exchange. We had net income from continuing operations in our 2002 fiscal year, but had net losses and losses from continuing operations in each of our 2003, 2004, 2005, 2006, 2007, 2008 and 2009 fiscal years. Our stockholders equity at June 30, 2010 was $4.9 million.

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

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

On June 19, 2009, we were notified by NYSE Amex that we had resolved our continued listing deficiencies and would retain our status as a listed issuer on NYSE Amex. However, as of March 31, 2010, our stockholders equity had again fallen below the $6 million threshold.

On May 25, 2010, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. Specifically, we are required to reflect a minimum of $6 million in stockholders equity to remain listed on the exchange. On June 24, 2010, we submitted a plan to NYSE Amex for compliance with the continued listing standards, which included our plan to increase out stockholders equity through additional offerings.

On August 6, 2010, NYSE Amex notified us that it accepted our plan of compliance and granted us an extension until February 25, 2011 to regain compliance with the continued listing standards. We will be subject to periodic review by NYSE Amex staff during the extension period. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the extension period could result in us being delisted from the NYSE Amex. On December 10, 2010, NYSE Amex notified us that we had resolved our continued listing deficiencies referenced in its May 2010 letter, and that we were in compliance with the NYSE Amex alternative listing standards, which require at least a $50 million market capitalization.

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

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

Our current principal stockholders, directors and executive officers beneficially own approximately 63% of our outstanding capital stock entitled to vote. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our Company and might ultimately affect the market price of our common stock.

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

Our stock price is, and we expect it to remain, volatile, which could limit investors ability to sell stock at a profit. During the last two fiscal years, our stock price has closed at a low of $.55 in the first quarter of 2009 and a high of $1.74 in the fourth quarter of 2010. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the U.S. and foreign countries;

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

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

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

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

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

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

sales of our common stock.

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

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

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

USE OF PROCEEDS

We will not receive any proceeds from the sale or other disposition by the selling stockholders of the shares of our common stock covered hereby. In addition, we will not receive any proceeds from the conversion by the selling stockholders of their shares of Series C Convertible Preferred Stock into shares of common stock.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of these shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration fees, listing fees of NYSE Amex and fees and expenses of our counsel and our accountants.

DIVIDEND POLICY

We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

CONVERTIBLE PREFERRED STOCK TRANSACTION

Description of Private Placement. On March 29, 2010, we completed a private placement of Series C Convertible Preferred Stock to certain investors, including certain investment funds affiliated with Signet Healthcare Partners, G.P. and Jane E. Hager, for an aggregate purchase price of approximately $1,550,000. Upon completion of the private placement, we issued 1,550 shares of Series C Convertible Preferred Stock to the Investors. Each share of Series C Convertible Preferred Stock may be converted at any time at the option of the holder into 1,449.28 shares of our common stock (calculated by dividing (i) 1,000 by (ii) $0.69, or the closing price of our common stock on the date of issuance, subject to adjustments to reflect stock splits, stock dividends, reverse stock splits or similar corporate events), plus such number of shares of common stock as shall equal (x) the accrued and unpaid dividends on the Series C Preferred Stock as of the date of conversion divided by (y) $0.69. See Description of Our Capital Stock set forth on page 21 for a brief description of the terms of the Series C Convertible Preferred Stock.

The combined market price of the total number of shares underlying the Series C Convertible Preferred Stock, calculated using the market price per share on the date of sale of the Series C Convertible Preferred Stock, or March 29, 2010, and the total possible shares underlying the Series C Convertible Preferred Stock on the date of issuance, is equal to approximately $1,550,000. The shares underlying the Series C Convertible Preferred Stock were not issued at a discount to the market price on the date of sale of the Series C Convertible Preferred Stock. The conversion price of the Series C Convertible Preferred Stock is equal to the fair market value of our common stock on the date of sale of the Series C Convertible Preferred Stock. The dollar value of the securities registered on this registration statement as of March 29, 2010, the date of the closing of the private placement, was $1,841,323. See Prospectus Summary The Offering for a further discussion of the market value of the securities registered hereby.

The following table discloses the market price of the number of shares underlying the Series C Convertible Preferred Stock, calculated using the market price per share on the date of sale of the Series C Convertible Preferred Stock for each Selling Stockholder.

Selling Stockholder	Approximate Market Price of Shares Underlying Series C Convertible Preferred Stock on March 29, 2010
Life Sciences Opportunities Fund II, L.P.	$102,000
Life Sciences Opportunities Fund (Institutional) II, L.P.	$573,000
Christine Sanders	$50,000
Don Weir and Julie E. Weir, Tenants in Common	$25,000
Jane E. Hager Trust of 1990	$50,000
LEBA Investments, LP	$100,000
Michael and Patricia M. Gironta JTWROS	$75,000
Lionel G. Hest and Amy Hest JTWROS	$75,000

Howard Silverman and Phyllis Silverman JTWROS	$250,000
Robert Sablowsky	$50,000
Katherine U. Sanders	$50,000
Don A. Sanders	$75,000
Katherine U. Sanders 2003 Children s Trust	$75,000

The following table discloses, among other things, the proceeds to us as a result of the private placements after giving effect to any payments that may be required to be made by us in the year following the private placements:

	March 2010 Private Placement	Combined Private Placements (1)
Gross proceeds	$1,550,000	$7,550,000
Accrued dividends on Preferred Stock during the year following the private placement	$77,500	$338,760
Expenses incurred in connection with the private placement	$32,800	$753,800
Resulting net proceeds to the Company	$1,439,700	$6,457,440
The total possible profit that could have been realized as of the date of issuance by the selling stockholders (2)	--	$2,564,393
Percentage calculation (3)	5.38%	44.96%

(1) This column reflects information from the March 2010 Private Placement and the March 2009 Private Placement on a combined basis.

(2) Such amount was calculated by multiplying (i) the shares of common stock issuable upon conversion of the Series B-1 Convertible Preferred Stock (14,734,667) plus the shares of common stock issuable upon exercise of the warrant granted to the placement agent (350,000), and (ii) the fair market value of our common stock at the closing of the private placement ($0.58) less the conversion price of the Series B-1 Convertible Preferred Stock and the exercise price of the warrant ($0.41). Such calculation assumes that holders of Series B-1 Convertible Preferred Stock could have converted their shares into 14,734,667 shares of common stock on the date of issuance.

(3) Such amount represents the percentage of the total possible payments that may be required to be made by us in the year following the private placement plus the total possible profit that could have been realized as of the date of issuance by the selling stockholders divided by the net proceeds to us after the expenses of the offering from the private placement.

The following table discloses the net proceeds to the Company from the sale of the convertible preferred stock and the total possible payments to all selling stockholders and their affiliates in the first year following the sale of the convertible preferred stock for the March 2010 Private Placement, the March 2009 Private Placement and the two private placements combined:

	March 2010 Private	March 2009 Private	Combined Private

	Placement $ Amount	Placement $ Amount	Placements $ Amount
Net proceeds to the Company from the offering	$1,517,156	$5,279,000	$6,796,156
Cash payments to the placement agent in connection with the convertible preferred stock transaction (such amount is already reflected in net proceeds to the Company from the offering set forth above)	--	$350,000	$350,000
Accrued Dividends on the convertible preferred stock during the first year following the convertible preferred stock transaction	$77,500	$261,260	$338,760

The following is a summary of the material provisions of the agreements executed by us in connection with the private placement..

Securities Purchase Agreement. The Securities Purchase Agreements provided for the issuance and sale to the selling stockholders of an aggregate of 1,550 shares of Series C Convertible Preferred Stock for an aggregate purchase price of approximately $1,550,000.

Registration Rights Agreement. In connection with the private placement, we entered into a registration rights agreement with the selling stockholders pursuant to which we agreed to file an initial registration statement with the Securities and Exchange Commission on or prior to December 29, 2010 and to use our best efforts to have such registration statement declared effective by the Commission by March 29, 2011.

Proceeds from the Private Placement. In connection with the private placement, we incurred legal fees and related offering expenses of approximately $32,843.64, resulting in net proceeds of $1,517,156.36.

SELLING STOCKHOLDERS

The selling stockholders named in this prospectus acquired shares of our Series C Convertible Preferred Stock in our private placement completed on March 29, 2010. In connection with the private placement, we granted to the selling stockholders and their transferees, named in this prospectus, registration rights pursuant to which we agreed to file with the SEC a registration statement on Form S-3, of which this prospectus forms a part, with respect to the resale or other disposition of the shares of common stock issuable upon conversion of the Series C Convertible Preferred Stock. The shares of common stock being offered for resale by this prospectus may be sold or otherwise disposed of from time to time by the selling stockholders on NYSE Amex, in privately negotiated transactions or otherwise as further described under the Plan of Distribution set forth on page 23. We have also agreed to prepare and file amendments and supplements to the registration statement to the extent necessary to keep the registration statement effective for the period of time required under our agreement with the selling stockholders.

The table set forth below presents the following information regarding the selling stockholders and the shares of common stock that each such selling stockholder may offer and sell from time to time under this prospectus:

The Number of Shares of Common Stock Beneficially Owned Prior to the Offering represents the number of shares of common stock beneficially owned prior to the offering for each selling stockholder, which includes (i) all shares held by such selling stockholder prior to the date hereof, including the number of shares issuable upon conversion of the Series C Convertible Preferred Stock purchased by the selling stockholder (or its transferee) in the private placement, (ii) shares issuable upon conversion of accrued and unpaid dividends on the Series C Convertible Preferred Stock held by the selling stockholder from the issuance date of such shares through February 26, 2011, the date which is within 60 days of December 28, 2010, and (iii) shares issuable upon all options or other derivative securities held by the selling stockholder that are exercisable within 60 days of December 28, 2010.

The Maximum Number of Shares of Common Stock Being Offered represents all of the shares of common stock issuable upon conversion of the Series C Convertible Preferred Stock that each selling stockholder may offer under this prospectus, including all shares of common stock that may be issuable to the selling stockholder upon conversion of accrued and unpaid dividends on the Series C Convertible Preferred Stock held by the selling stockholder from the issuance date of such shares through December 29, 2013 as if such shares were issued and outstanding on the date hereof.

The Number of Shares of Common Stock Beneficially Owned After Offering assumes that the selling stockholder sells all of the shares it may offer under this prospectus.

The Percentage of Shares of Common Stock Beneficially Owned After the Offering is based on 41,288,199 shares of our common stock issued and outstanding as of December 28, 2010.

Beneficial ownership is determined in accordance with the rules of the SEC, and is based upon information provided by each respective selling stockholder, Forms 4, Schedules 13D and 13G and other public documents filed with the SEC. Unless otherwise indicated below, to our knowledge, all persons named in this table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

Except as noted in the footnotes below, none of the selling stockholders has held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years, other than as a result of the ownership of our shares or other securities.

The selling stockholders may sell some, all or none of the shares of common stock offered by this prospectus. We do not know how long the selling stockholders will hold their shares of Series C Convertible Preferred Stock before converting into common stock and selling them. We currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares of common stock being offered hereunder other than the definitive agreements pursuant to which the selling stockholders purchased their shares of Series C Convertible Preferred Stock. The shares offered by this prospectus may be offered from time to time by the selling stockholders, although the shares of our common stock underlying the Series C Convertible Preferred Stock will not be eligible to be offered pursuant to this prospectus until shares of Series C Convertible Preferred Stock are converted into shares of common stock. Accordingly, for purposes of this table, we have assumed that, after completion of the offering, the only shares that will continue to be held by the selling stockholders are those shares that do not have registration rights as a result of the private placement. The selling stockholders may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act some or all of their shares of common stock since the date on which the information in the table below is presented. Information about the selling stockholders may change over time.

The following table sets forth, to our knowledge, information about the selling stockholders as of December 28, 2010.

Name of Selling Stockholders	**Number of Shares of Common Stock Beneficially Owned Prior to the Offering**	**Maximum Number of Shares of Common Stock Being Offered**	**Number of Shares of Common Stock Beneficially Owned After Offering**	**Percentage of Shares of Common Stock Beneficially Owned After Offering**
Life Sciences Opportunities Fund II, L.P. (1)				