IGI INC
Form 10-Q
August 13, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q
QUARTERLY REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For Quarter Ended	Commission File No.
June 30, 2004	001-08568

IGI, Inc.
(Exact name of registrant as specified in its charter)

Delaware	01-0355758
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

105 Lincoln Avenue, Buena, NJ	08310
(Address of principal executive offices)	(Zip Code)

856-697-1441
Registrant's telephone number, including area code

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

Yes X No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes No X

The number of shares outstanding of the issuer's class of common stock, as of the latest practicable date:

Common Shares Outstanding at August 12, 2004 is 11,581,780.

ITEM 1. Financial Statements

PART I FINANCIAL INFORMATION

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

	Three months ended June 30,		Six months
	2004	2003 (restated)	2004
Revenues:			
Product sales, net	$ 785	$ 718	$ 1,640
Licensing and royalty income	413	126	545
Total revenues	1,198	844	$ 2,185
Cost and expenses:			
Cost of sales	336	355	685
Selling, general and administrative expenses	657	852	1,086
Product development and research expenses	1,051	157	1,263
Operating loss	(846)	(520)	(849
Interest income (expense)	6	2	15
Loss from continuing operations before provision for income taxes	(840)	(518)	(834
Provision for income taxes	2	-	4
Loss from continuing operations	(842)	(518)	(838
Discontinued operations:			
Gain on disposal of discontinued business	-	169	-
Net income (loss)	(842)	(349)	(838
Net income (loss) attributable to common stock	$ (842)	$ (349)	$ (838
Basic and Diluted Earnings (Loss) Per Common Share			
Continuing operations	$ (.07)	$ (.05)	$ (.07
Discontinued operations	-	.02	-
Net income (loss) per share	$ (.07)	$ (.03)	$ (.07
Weighted Average of Common Stock and Common Stock Equivalents Outstanding			
Basic and diluted	11,579,582	11,400,449	11,513,417

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

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

	June 30, 2004 (unaudited)	December 31, 2
ASSETS		
Current assets:		
Cash and cash equivalents	$ 600	$ 821
Restricted cash	50	50
Marketable securities	896	800
Accounts receivable, less allowance for doubtful accounts of $10 and $16 in 2004 and 2003, respectively	366	350
Licensing and royalty income receivable	-	17
Inventories	191	192
Prepaid expenses and other current assets	130	133
Total current assets	2,233	2,363
Property, plant and equipment, net	2,663	2,607
Other assets	47	54
Total assets	$ 4,943	$ 5,024
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	82	105
Accrued payroll	98	75
Other accrued expenses	358	301
Income taxes payable	7	7
Deferred income	153	165
Total current liabilities	698	653
Deferred income	138	205
Total liabilities	836	858
Stockholders' equity:		
Common stock $.01 par value, 50,000,000 shares authorized; 13,547,520 and 13,351,237 shares issued in 2004 and 2003, respectively	136	134
Accumulated other comprehensive income	8	-
Additional paid-in capital	24,471	23,702
Accumulated deficit	(19,113)	(18,275)
Less treasury stock, 1,965,740 shares at cost in 2004 and 2003	(1,395)	(1,395)

Total stockholders' equity	4,107	4,166
Total liabilities and stockholders' equity	$ 4,943	$ 5,024

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

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

	Six months ended June 30,	
	2004	2003
		(restated)
Cash flows from operating activities:		
Net income (loss)	$(838)	$ (313)
Reconciliation of net income (loss) to net cash used in operating activities:		
Gain on disposal of discontinued operations	-	(169)
Depreciation and amortization	140	128
Provision for accounts receivable and inventories	-	7
Recognition of deferred income	(79)	(67)
Stock-based compensation expense:		
Directors' stock issuance	-	26
Non-employee stock options	548	-
Changes in operating assets and liabilities:		
Accounts receivable	(10)	51
Inventories	(5)	14
Receivables under royalty agreements	17	62
Prepaid expenses and other assets	3	(7)
Accounts payable and accrued expenses	57	(70)
Income taxes payable	-	(6)
Discontinued operations - working capital changes and non-cash charges	-	(6)
Net cash used in operating activities	(167)	(350)
Cash flows from investing activities:		
Capital expenditures	(189)	(45)
Purchase of available for sale securities	(88)	-
Decrease (increase) in other assets	-	1
Net cash provided by (used in) investing activities	(277)	(44)
Cash flows from financing activities:		

Borrowings from EDA loan	-	11
Repayments of EDA loan	-	(9)
Proceeds from exercise of common stock options and purchase of common stock	223	4
Purchase of treasury shares	-	(39)
Net cash provided by (used in) financing activities	223	(33)
Net increase (decrease) in cash and equivalents	(221)	(427)
Cash and equivalents at beginning of period	821	1,999
Cash and equivalents at end of period	$ 600	$1,572

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

IGI, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation

The accompanying consolidated financial statements have been prepared by IGI, Inc. without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"), and reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the results for the interim periods presented. All such adjustments are of a normal recurring nature.

Certain information in footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the SEC, although the Company believes the disclosures are adequate to make the information presented not misleading. These consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003 (the "2003 10-K Annual Report").

Estee Lauder, a significant customer, accounted for $498,000 or 63% of revenues for the second quarter of 2004 and $397,000 or 55% of revenues for the second quarter of 2003. The Company is renegotiating its contract with Estee Lauder. Estee Lauder will be manufacturing all Novasome(R) and non Novasome(R) products in house and will pay the Company a one time payment of $100,000 plus a royalty per kilo on all Novasome(R) products manufactured by Estee Lauder, including all new products developed. The Company's contract manufacturing of Estee Lauder non-Novasome(R) products, which accounted for $221,000 of the above revenues in 2004, is scheduled to terminate on June 30, 2004, without any future royalties or other payments to be received by the Company on any non-Novasome(R) products manufactured by Estee Lauder. In addition, during the six month period from January through June 2004, the Company has agreed to provide Estee Lauder's contract manufacturing services at a reduced price of $2.00 per kilo, as compared to the prior rate of $3.03 per kilo. As of June 30, 2004, a formal agreement with Estee Lauder has not been signed by the Company, but one is anticipated to be signed within the

near future.

Prior to filing its Form 10-K for the fiscal year ended December 31, 2003, IGI, Inc, was informed by J&J that there was an error in the calculation of the 2003 royalty due to the company by J&J. The correction of the error resulted in a reduction of revenues, with a corresponding impact on net loss, of $42,000 in the second qtr of 2003 and $51,000 in the third quarter of 2003. The restated numbers have been reflected herein.

2. Marketable Securities

Marketable securities at June 30, 2004 consist of an investment in a short term bond mutual fund and investment in securities. The Company currently classifies all marketable securities as available-for-sale, in accordance with Statement of Financial Accounting Standards (SFAS) 115. Securities classified as available-for-sale are required to be reported at fair value with unrealized gains and losses, net of taxes, excluded from earnings and shown separately as a component of accumulated other comprehensive income within stockholders' equity. Realized gains and losses on the sale of securities available-for-sale are determined using the specific-identification method.

The amortized cost, gross unrealized gains and losses and fair value of the available-for-sale marketable securities as of June 30, 2004 are as follows (amounts in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
2004				
Mutual Funds	$800	$ -	$ 9	$791
Securities	87	18	-	105
Total Marketable Securities	$887	$18	$ 9	$896

There were no sales of available-for-sale marketable securities during the six months ended June 30, 2004 or 2003.

IGI, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited), Continued

3. Inventories

Inventories are valued at the lower of cost, using the first-in, first-out ("FIFO") method, or market. Inventories at June 30, 2004 and December 31, 2003 consist of:

	June 30, 2004	December 31, 2003
	(amounts in thousands)	
Finished goods	$ 48	$ 15
Raw materials	143	177
Total	$191	$192

4. Stock-Based Compensation

Compensation costs attributable to employee stock option and similar plans are recognized based on the difference, if any, between the quoted market price of the stock on the date of grant over the amount the employee is required to pay to acquire the stock (the intrinsic value method). No stock-based employee compensation cost is reflected in net income for options that have been granted, as all options granted under the plans had an exercise price equal to the market value of the underlying common stock on the date of grant. Since the Company uses the intrinsic value method, it makes pro forma disclosures of net income (loss) and net income (loss) per share as if the fair-value based method of accounting had been applied.

If compensation cost for all grants under the Company's stock option plans had been determined based on the fair value at the grant date consistent with the provisions of Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation," the Company's net income (loss) and net income (loss) per share would have changed to the pro forma amounts indicated below:

	Six months ended June 30, 2004	2003
	(in thousands, except per share information)	
Net income (loss) - as reported	$(838)	$(313)
Deduct: Total stock-based employee compensation expense determined under the fair-value based method	(91)	(15)
Net income (loss) - pro forma	$(929)	$(328)
Income (loss) per share - as reported Basic and diluted	$(.08)	$(.03)
Income (loss) per share - pro forma Basic and diluted	$(.08)	$(.03)

The Company recorded a $548,000 expense related to non employee stock based compensation for the six months ended June 30, 2004.

5. Legal and U.S. Regulatory Proceedings

Gallo Matter

As previously reported by the Company in its historical filings with the SEC, including without limitation its Form 10-K for the year ending December 31, 1999, for most of 1997 and 1998 the Company was subject to intensive government regulatory scrutiny by the U.S. Departments of Justice, Treasury and Agriculture. In June 1997, the Company was advised by the Animal and Plant Health Inspection Service ("APHIS") of the United States Department of Agriculture ("USDA") that the Company had shipped quantities of some of its poultry vaccine products without complying with certain regulatory and record keeping requirements. The USDA subsequently issued an order that the Company stop shipment of certain of its products. Shortly thereafter, in July 1997, the Company was advised that the USDA's Office of Inspector General had commenced an investigation into possible violations of the Virus Serum Toxin Act of 1914 and alleged false statements made to APHIS. In April 1998, the SEC advised the Company that it was conducting an informal inquiry and requested information and documents from the Company, which the Company voluntarily provided to the SEC.

Based upon these events, the Board of Directors caused an immediate and thorough investigation of the facts and circumstances of the alleged violations to be undertaken by independent counsel. The Company continued to refine and strengthen its regulatory programs with the adoption of a series of compliance and enforcement policies, the addition of new managers of Production and Quality Control and a new Senior Vice President and General Counsel. At the instruction of the Board of Directors, the Company's General Counsel established and oversaw a comprehensive employee training program, designated in writing a Regulatory Compliance Officer, and established a fraud detection program, as well as an employee "hotline." The Company continued to cooperate with the USDA and SEC in all aspects of their investigation and regulatory activities. On March 13, 2002, the Company reached a settlement with the staff of the SEC to resolve matters arising with respect to the investigation of the Company. Under the settlement, the Company neither admitted nor denied that the Company violated the financial reporting and record-keeping requirements of Section 13 of the Securities and Exchange Act of 1934, as amended, for the three years ended December 31, 1997. Further, the Company agreed to the entry of an order to cease and desist from any such violation in the future. No monetary penalty was assessed.

As a result of its internal investigation, in November 1997, the Company terminated the employment of John P. Gallo as President and Chief Operating Officer for willful misconduct. On April 21, 1998, the Company instituted a lawsuit against Mr. Gallo in the New Jersey Superior Court. The lawsuit alleged willful misconduct and malfeasance in office, as well as embezzlement and related claims (referred to as "the IGI Action"). On April 28, 1998, Mr. Gallo instituted a separate action against the Company and two of its Directors, Edward Hager, M.D. and Constantine Hampers, M.D., alleging that he had been wrongfully terminated from employment and further alleging wrongdoings by the two Directors (referred to as the "Gallo Action"). The Court subsequently ordered the consolidation of the IGI Action and the Gallo Action (collectively referred to as the "Consolidated Action").

In response to these allegations, the Company instituted an investigation of

the two Directors by an independent committee ("Independent Committee") of the Board assisted by the Company's General Counsel. The investigation included a series of interviews of the Directors, both of whom cooperated with the Company, and a review of certain records and documents. The Company also requested an interview with Mr. Gallo who, through his counsel, declined to cooperate. In September 1998, the Independent Committee reported to the Board that it had found no credible evidence to support Mr. Gallo's claims and allegations and recommended no further action. The Board adopted the recommendation.

The Company denied all allegations plead in the Gallo Action and asserted all claims in the Gallo Action to be without merit. The Company did not reserve any amount relating to such claims. The Company tendered the claim to its insurance carriers, but was denied insurance coverage for both defense and indemnity of the Gallo Action.

In July 1998, the Company sought to depose Mr. Gallo in connection with the Consolidated Action. Through his counsel, Mr. Gallo asserted his Fifth Amendment privilege against self-incrimination and advised that he would not participate in the discovery process until such time as a federal grand jury investigation, in which he was a target, was concluded. In January 1999, at the suggestion of the Court, the Company and Mr. Gallo agreed to a voluntary dismissal without prejudice of the Consolidated Action, with the understanding that the statute of limitations was tolled for all parties and all claims, and that the Company and Mr. Gallo were free to reinstate their suits against each other at a later date, with each party reserving all of their rights and remedies against the other.

As of the date hereof, neither the Company nor Mr. Gallo have filed suit against each other in the Superior Court of New Jersey or any other court of competent jurisdiction to reinstitute the claims, in whole or part, previously at issue in the Consolidated Action, and pursuant to the previous order of dismissal entered in the Consolidated Action, the statute of limitation on all claims and defenses continues to be tolled as to both parties. However, the Company did receive a letter dated November 21, 2003 from Mr. Gallo's attorneys seeking to reach a settlement of the claims asserted against IGI in the Gallo Action without further resort to the courts. The letter provides a general description of Mr. Gallo's claims and a calculation of damages allegedly sustained by Mr. Gallo relative thereto. The letter states that Mr. Gallo's damages are calculated to be in the range of $3,400,000 to $5,100,000. The Company denies liability for the claims and damages alleged in the letter from Mr. Gallo's counsel dated November 21, 2003, and as such, the Company did not make any formal response thereto. Mr. Gallo has contacted the Company's Chief Executive Officer and Chairman, Frank Gerardi, in a continued effort to initiate settlement discussions. As of June 30, 2004, the Company continues to deny any merit and/or liability for the claims alleged by Mr. Gallo and has not engaged in any formal settlement discussions with either Mr. Gallo or his attorneys.

On December 8, 2003, Mr. Gallo filed suit against Novavax, Inc. in the Superior Court of New Jersey, Law Division, Atlantic County, docket no. ATL-L-3388-03, asserting claims under seven counts for damages allegedly sustained as a result of the cancellation of certain Novavax stock options held by Mr. Gallo due to his termination from IGI in November 1997 for

willful misconduct (referred to as the "Novavax Action").

On March 5, 2004, Novavax filed an Answer denying the allegations asserted by Mr. Gallo in his First Amended Complaint. In addition, while denying any liability under the First Amended Complaint, Novavax also filed a Third Party Complaint in the Novavax Action against the Company for contribution and indemnification, alleging that if liability for Mr. Gallo's claims is found, the Company has primary liability for any and all such damages sustained.

IGI has been notified by its insurance carriers that coverage is not afforded under their respective policies of insurance for defense and/or indemnification of the claims alleged by the Third Party Complaint. After IGI was notified of the foregoing, but prior to IGI's filing of any responsive pleading, the Third Party Complaint against IGI was voluntarily dismissed without prejudice by Novavax on June 30, 2004. Novavax may at any time pursuant to the rules of court re-file its Third Party Complaint against IGI.

On July 8, 2004, Novavox filed a motion for summary judgment on all claims asserted under Gallo's First Amended Complaint (referred to as "the SJ Motion"). As of the filing date hereof, the SJ Motion is pending subject to filing of Gallo's opposition and any reply thereto by Novavax. The court has not yet scheduled a hearing date for the SJ Motion. In the event the court denies the SJ Motion, the Company believes that there is a substantial likelihood that Novavax will re-file its Third Party Complaint against IGI for which coverage was previously denied by its insurance carriers.

6. License Agreements

On December 24, 2003, the Company entered into a License Agreement with Dr. Holick and A&D Bioscience, Inc., a Massachusetts corporation wholly owned by Dr. Holick (collectively referred to as "Holick"), whereby Holick granted an exclusive license to the Company to all his rights to the parathyroid hormone related peptide technologies and the glycoside technologies (referred to as "PTH Technologies" and "Glycoside Technologies", respectively) that he developed for various clinical usages including treatment of psoriasis, hair loss and other skin disorders. In consideration for entering into the License Agreement, Holick received up-front a $50,000 non-refundable payment from the Company. He also received a grant of 300,000 stock options under the Company's authorized stock option plans.

On April 19, 2004, IGI signed a sublicense agreement with a third party entity, Tarpan Therapeutics, Inc., for the PTH (1-34) technology under which the third party will be obligated at its sole cost and expense to develop and bring the PTH (1-34) technology to market as timely and efficiently as possible, which includes its sole responsibility for the cost of preclinical and clinical development, research and development, manufacturing, laboratory and clinical testing and trials and marketing of products. In addition, the sublicense agreement calls for various payments to IGI throughout the term. IGI was paid a lump sum sublicense fee of $300,000, from which amount IGI paid the sum of $232,000, representing the $236,000 payment due to Dr. Holick in accordance with the terms of his License Agreement with the Company, net of $4,000 of additional legal fees. Certain subsequent royalty payments received by the Company under the sublicense agreement will be shared with Holick after the Company has recovered any payments previously made to Holick under the License Agreement and an amount equal to the value of the options received by Holick under the License Agreement. The Company is responsible for any and all costs, fees and expenses for the prosecution and oversight of any intellectual property

rights related to the licensed technologies. Subject to Holick's early termination right as provided below, the term of the License Agreement is the longer of twenty (20) years or the life of each of the patents thereunder. However, if following 90 days from the effective date of the License Agreement, the Company has not entered into a sublicense agreement for the Glycoside Technologies, Holick has the right to terminate the License Agreement as to the Glycoside Technologies only. As of August 12, 2004, Dr. Holick has not exercised his right to terminate the License Agreement as to the Glycoside Technologies. The Company is engaged in discussions with the same third party entity for a similar sublicense for the PTH (7-34) technology.

The $50,000 payment was expensed in the fourth quarter of 2003 and the $236,000 payment was expensed in the second quarter of 2004 because the PTH and Glycoside Technologies are in a preliminary development phase and do not have any readily determinable alternative future use. The other consideration called for under the License Agreement, such as amounts advanced for the prosecution and oversight of any intellectual property rights related to the licensed technologies which amounted to $27,500 and the fair value of the 300,000 stock options granted to Holick, which amounted to $520,000, was also expensed by the Company in the second quarter of 2004 (included in product development and research expenses on the consolidated statement of operations), when the sublicense agreement with Tarpan was executed and Holick could no longer terminate the license agreement as it relates to the PTH Technologies and the options became fully vested. The fair value of the stock options was calculated under SFAS 123 using Black Scholes model.

In February 2004, the Company signed a license agreement with Universal Chemical Technologies, Inc. ("UCT") to utilize their patented technology for an electroless nickel boride metal finishing process. This will be a new venture for the Company and will require an initial capital expenditures of approximately $500,000, of which $180,000 has been paid to UCT to date as a down payment to purchase property and equipment and commits the Company to purchase a minimum of $25,000 of raw materials from UCT in the first year of the license, $75,000 during the second year and $150,000 during the third and subsequent years. The Company will also be required to hire at least one new employee to oversee the facility operations at an estimated cost of $60,000 per year. The Company has an exclusive license within a 150 mile radius of its facility for commercial and military applications. Frank Gerardi, the Company's Chairman and Chief Executive Officer, as well as a major IGI shareholder, has personally invested $350,000 in UCT, which represents less than a 1% ownership interest by Mr. Gerardi in UCT.

On July 27, 2004, the Company signed an exclusive license agreement with the University of Massachusetts Medical School (University) for the patented invention entitled "The Treatment of Skin with Adenosine or Adenosine Analogs". The Company intends to encapsulate adenosine or adenosine analogs in its Novasome for use in the skin care field. As consideration of the rights granted in this agreement, the Company will be required to make nonrefundable payments of $25,000 upon the execution of this agreement and $25,000 on October 1, 2004. The agreement also calls for minimum royalty payments of $25,000 per year commencing on July 27, 2007. If the Company enters into a Sublicense agreement with a third party entity, which it will

attempt to do, the Company shall pay the University 50% of all sublicense income.

IGI, INC. AND SUBSIDIARIES

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Prior to filing its Form 10-K for the fiscal year ended December 31, 2003, IGI, Inc, was informed by J&J that there was an error in the calculation of the 2003 royalty due to the company by J&J. The correction of the error resulted in a reduction of revenues, with a corresponding impact on net loss, of $42,000 in the second qtr of 2003 and $51,000 in the third quarter of 2003. The restated numbers have been reflected herein.

The following discussion and analysis may contain forward-looking statements. Such statements are subject to certain risks and uncertainties, including those discussed below or in the Company's 2003 10-K Annual Report that could cause actual results to differ materially from the Company's expectations. See "Factors Which May Affect Future Results" below and in the 2003 10-K Annual Report. Readers are cautioned not to place undue reliance on any forward-looking statements, as they reflect management's analysis as of the date hereof. The Company undertakes no obligation to release the results of any revision to these forward-looking statements which may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated events.

Recent Events

On April 19, 2004, IGI signed a sublicense agreement with a third party entity, Tarpan Therapeutics, for the PTH (1-34) technology under which the third party will be obligated at its sole cost and expense to develop and bring the PTH (1-34) technology to market as timely and efficiently as possible, which includes its sole responsibility for the cost of preclinical and clinical development, research and development, manufacturing, laboratory and clinical testing and trials and marketing of products. In addition, the sublicense agreement calls for various payments to IGI throughout the term. IGI was paid a lump sum sublicense fee of $300,000, from which amount IGI paid the sum of $232,000, representing the $236,000 payment due to Dr. Holick in accordance with the terms of his License Agreement with the Company, net of $4,000 of additional legal fees. This amount was expensed in the second quarter of 2004, because the technologies are in a preliminary development stage and do not have any readily determinable alternative future use. Further, over the course of the sublicense, milestone payments will be made to IGI as certain stages of development are reached, and royalty payments will be paid to IGI on sales of all sublicensed products that go to market. Certain subsequent royalty payments received by the Company under the sublicense agreement will be shared with Dr. Holick after the Company has recovered any payments previously made to Dr. Holick under the License Agreement and an amount equal to the value of the options received by Dr. Holick under the License Agreement. The Company is also negotiating with the same third party for the potential sublicensing of the PTH (7-34) technology under a similar term structure. Upon the signing of this agreement, stock options granted to Dr. Holick became fully vested and an expense of $520,000 was recorded in product development and research during the second quarter of 2004. This amount represented the value of the options using the Black Sholes model on April 19, 2004.

The Company continues discussions with Estee Lauder on revising the way they will do business with them in the future. As of this time, a formal agreement has not been signed by the two entities, but it is anticipated that one will be signed within the near future. Estee Lauder will be manufacturing all Novasome(R) products and pay the Company a royalty per kilo on all Novasome(R) products manufactured by Estee Lauder in-house plus a one time payment of $100,000. In consideration of the foregoing, Estee Lauder has agreed to release the Company from its contractual exclusivity restrictions, which will now enable the Company to sell its products in department and specialty stores.

In February 2004, the Company signed a license agreement with Universal Chemical Technologies, Inc. ("UCT") to utilize their patented technology for an electroless nickel boride metal finishing process. This will be a new venture for the Company and will require an initial capital expenditures of approximately $500,000, of which $180,000 has been paid to UCT to date as a down payment to purchase property and equipment and commits the Company to purchase a minimum of $25,000 of raw materials from UCT in the first year of the license, $75,000 during the second year and $150,000 during the third and subsequent years. The Company will also be required to hire at least one new employee to oversee the facility operations at a estimated cost of $60,000 per year. The Company has an exclusive license within a 150 mile radius of its facility for commercial and military applications. Frank Gerardi, the Company's Chairman and Chief Executive Officer, as well as a major IGI shareholder, has personally invested $350,000 in UCT, which represents less than a 1% ownership interest by Mr. Gerardi in UCT.

On June 30, 2004, IGI ended the employment agreement with Domenic N. Golato, Chief Financial Officer. Mr. Golato received a severance agreement and the corresponding expense of $203,000 is reflected in selling, general and administrative expenses on the consolidated statements of operations.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations (Continued)

Results of Operations

Three months ended June 30, 2004 compared to June 30, 2003

The Company had net loss of $842,000, or ($.07) per share, for the quarter ended June 30, 2004 compared to net loss of $349,000, or ($.03) per share, for the quarter ended June 30, 2003.

Total revenues for the quarter ended June 30, 2004 were $1,198,000, compared to $844,000 for the quarter ended June 30, 2003, or a $354,000 increase. The increase is primarily due to $300,000 of royalty income from Tarpan Therapeutics, Inc. and by higher product sales to new customers.

As a percentage of product sales, cost of sales was 43% for the quarter ended June 30, 2004 and 49% for the quarter ended June 30, 2003.

Selling, general and administrative expenses decreased $195,000, or 23%, from $852,000 in the quarter ended June 30, 2003. As a percentage of revenues, these expenses were 101% of revenues in the second quarter of 2003 compared to 55% for the second quarter of 2004. Overall, expenses decreased

primarily due to lower executive salaries, travel and entertainment costs.

Product development and research expenses increased $894,000, or 569%, compared to the quarter ended June 30, 2003. The increase in expenses is a mainly a result of a non cash expense of $548,000 being recorded in the second quarter of 2004 related to the SFAS 123 value of 300,000 stock options granted to Dr. Holick under his license agreement and 25,000 stock options granted to Dr. Holick for his service on the Scientific Advisory Board, plus a cash payment made to Dr. Holick in accordance with his license agreement in the amount of $232,000. In addition, new projects are being worked on for existing and potential new customers and there are additional personnel.

Interest income increased from $2,000 in the quarter ended June 30, 2003 to $6,000 in the quarter ended June 30, 2004.

Six months ended June 30, 2003 compared to June 30, 2002

The Company had a net loss attributable to common stock of $838,000, or ($.07) per share, for the six months ended June 30, 2004 compared to net loss attributable to common stock of $313,000, or ($.03) per share, for the six months ended June 30, 2003.

Total revenues for the six months ended June 30, 2004 were $2,185,000, which represents an increase of $333,000, or 18%, from revenues of $1,852,000 for the six months ended June 30, 2003. The increase in revenues was primarily due to increase in product sales to Estee Lauder, new customers and royalty income from Tarpan Therapeutics, Inc.

Cost of sales, as a percent of product sales, decreased from 45% for the six months ended June 30, 2003 to 42% for the six months ended June 30, 2004. The decrease resulted from a change in mix of higher profit products.

Selling, general and administrative expenses decreased $266,000, or 20%, from $1,352,000 for the six months ended June 30, 2003. As a percent of revenues, these expenses were 73% of revenues for the first six months of 2003 compared to 50% for the first six months of 2004. The decrease is primarily due to a decline in salary and travel expenses from the disposition of three positions within the company during 2004.

Product development and research expenses increased $960,000, or 317%, compared to the six months ended June 30, 2003. The increase in expenses is a mainly a result of a non cash expense of $548,000 being recorded in the second quarter of 2004 related to the SFAS 123 value of 300,000 stock options granted to Dr. Holick under his license agreement and 25,000 stock options granted to Dr. Holick for his service on the Scientific Advisory Board, plus a cash payment made to Dr. Holick in accordance with his license agreement in the amount of $232,000. In addition, new projects are being worked on for existing and potential new customers and there are additional personnel.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations (Continued)

Interest income increased $7,000 compared to the six months ended June 30, 2003. The increase is due to higher interest rates on cash investments and

better return on funds invested in mutual funds.

Liquidity and Capital Resources

The Company's operating activities used $167,000 of cash during the six months ended June 30, 2004 compared to $350,000 used in the comparable period of 2003. Payments for professional fees and payments made to Dr. Holick in accordance with license agreement, offset by lower salaries were the primary uses of cash in 2004.

The Company used $276,000 of cash in the six months ended June 30, 2004 for investing activities compared to $44,000 used in investing activities in the first six months of 2003. The $180,000 represents a down payment to Universal Chemical Technologies, Inc. ("UCT") to purchase machinery and equipment related to the electroless nickel boride finishing operations that will be set up in the Company's Buena facility, while 2003's investing activities were for the purchase of computers and machinery and equipment.

The Company's financing activities provided $223,000 of cash in the six months ended June 30, 2004 compared to $33,000 utilized by financing activities in the first quarter of 2003. The cash provided in 2004 represents proceeds from the exercise of stock options. The cash utilized in 2003 is primarily the result of the purchase of Company stock as part of a stock buy-back program, offset by funding from the EDA loan.

The Company's principal sources of liquidity are cash from operations, cash and cash equivalents and marketable securities. Management believes that existing cash and cash equivalents, marketable securities and cash flows from operations will be sufficient to meet the Company's foreseeable cash needs for at least the next year. In addition, two shareholders of the Company have agreed to loan the Company up to $500,000 each, if necessary, to fund the Company's deficit through June 30, 2005. There may be acquisition and other growth opportunities, however, that require additional external financing. Management may, from time to time, seek to obtain additional funds from the public or private issuances of equity or debt securities. There can be no assurance that such financings will be available or available on terms acceptable to the Company.

There have been no material changes to the Company's contractual commitments as reflected in the 2003 10-K Annual Report other than those disclosed in this form 10Q.

Factors Which May Affect Future Results

The industry segments in which the Company competes are subject to intense competitive pressures. The following sets forth some of the risks which the Company faces.

Intense Competition in Consumer Products Business

The Company's Consumer Products business competes with large, well-financed cosmetics and consumer products companies with development and marketing groups that are experienced in the industry and possess far greater resources than those available to the Company. There is no assurance that the Company's consumer products can compete successfully against its competitors or that it can develop and market new products that will be favorably received in the marketplace. In addition, certain of the Company's customers that use the Company's Novasome(R) lipid vesicles in their products may decide to reduce their purchases from the Company or shift their business to other suppliers.

Effect of Rapidly Changing Technologies

The Company expects to sublicense its technologies to third parties, which would manufacture and market products incorporating the technologies. However, if its competitors develop new and improved technologies that are superior to the Company's technologies, its technologies could be less acceptable in the marketplace and therefore the Company's planned technology sublicensing could be materially adversely affected.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations (Continued)

Revision of Current Contract with Estee Lauder

Currently, the Company manufactures Novasome(R) products and contract manufacturing products for Estee Lauder using the raw materials supplied by Estee Lauder. The Company is currently renegotiating its agreement with Estee Lauder. The Company anticipates that the revised agreement will end all contract manufacturing. The Company also anticipates that Estee Lauder will manufacture Novasome(R) products in house and will pay the Company a one time payment of $100,000 plus royalty on the volume produced. In addition, Estee Lauder will remove the exclusivity clause which will allow the Company to sell its products in department and specialty stores. Although it is the Company's belief that this will increase business and revenue in the future, there is no guarantee that it will occur.

Licensing Agreement with Universal Chemical Technologies, Inc.

In February 2004, the Company signed a license agreement with UCT to utilize their patented technology for an electroless nickel boride metal finishing process. This will be a new venture for the Company and will require significant capital expenditures in the Company's existing manufacturing facility to set up the operations. The Company is also obligated to purchase a minimum level of raw materials from UCT during the license term. The Company has an exclusive license within a 150 mile radius of its facility for commercial and military applications. Frank Gerardi, the Company's Chairman and Chief Executive Officer, as well as a major IGI shareholder, has personally invested $350,000 in UCT, which represents less than a 1% ownership interest by Mr. Gerardi in UCT. The Company believes there is the possibility of major revenue and profit growth using this application, but there is no guarantee that it will materialize.

American Stock Exchange (AMEX) Continuing Listing Standards

On March 28, 2002, the Company was notified by AMEX that it was below certain of the Exchange's continuing listing standards. Specifically, the Company was required to reflect income from continuing operations and net income for 2002 and a minimum of $4,000,000 in stockholders' equity by December 31, 2002 in order to remain listed.

On April 25, 2002, the Company submitted a plan of compliance to AMEX. On June 12, 2002, AMEX notified the Company that it had accepted the Company's

plan of compliance and had granted the Company an extension of time to regain compliance with the continued listing standards by December 31, 2002. The Company was subject to periodic review by the AMEX staff during the extension period. Based on the Company's reported results for 2002, the Company was not in compliance with the AMEX listing standards for income from continuing operations. On April 14, 2003, the Company received formal notification from AMEX that the Company was deemed to be in compliance with all AMEX requirements for continued listing on AMEX. This determination is subject to the Company's favorable progress in satisfying the AMEX guidelines for continued listing and to AMEX's routine periodic reviews of the Company's SEC filings. Based on the Company's 2003 year-end results, the Company was not in compliance with the AMEX requirement for reporting income from continuing operations and net income for the year ended December 31, 2003.

As of the date of the filing of the Form 10-Q for the quarter ended June 30, 2004, the Company has not been contacted by AMEX concerning the Company's non-compliance with the AMEX requirements. While as of this date, the Company has not received any notification of non-compliance from AMEX, the Company has no knowledge of nor can it predict whether AMEX shall at any time hereafter issue formal notification to the Company of its non-compliance with the requirements for continued listing on AMEX, which could result in the Company's delisting from AMEX or otherwise adversely affect the Company.

Critical Accounting Policies

There have been no material changes to the Company's critical accounting policies as reflected in the 2003
10-K Annual Report.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss that may impact the financial position, results of operations, or cash flow of the Company due to adverse changes in market prices and interest rates. The Company is exposed to market risk because of changes in interest rates and changes in the fair market value of its marketable securities portfolio.

The Company does not use derivative instruments in its marketable securities portfolio. The Company classifies its investments in its marketable securities portfolio as available-for-sale and records them at fair value. The securities unrealized holding gains and losses are excluded from income and are recorded directly to stockholders' equity in accumulated other comprehensive income. Changes in interest rates are not expected to have an adverse effect on the Company's financial condition or results of operations.

ITEM 4. Controls and Procedures

Under the supervision and with the participation of certain members of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company completed an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) to the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer believe that the disclosure controls and procedures were effective as of the end of the

period covered by this report with respect to timely communicating to them and other members of management responsible for preparing periodic reports all material information required to be disclosed in this report as it relates to the Company and its consolidated subsidiaries.

The Company's management does not expect that its disclosure controls and procedures or its internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, as opposed to absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

These inherent limitations include the realities that judgments in decision-making can be faulty, and breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some person or by collusion of two or more people. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, the Company's disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of its disclosure control system are met and, as set forth above, the Company's management has concluded, based on their evaluation as of the end of the period, that the Company's disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of the disclosure control system were met.

There was no change in the Company's internal control over financial reporting during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

IGI, INC. AND SUBSIDIARIES
PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

Gallo Matter

As previously reported by the Company in its historical filings with the Securities and Exchange Commission ("SEC"), including without limitation its Form 10-K for the year ending December 31, 1999, for most of 1997 and 1998 the Company was subject to intensive government regulatory scrutiny by the U.S. Departments of Justice, Treasury and Agriculture. In June 1997, the Company was advised by the Animal and Plant Health Inspection Service ("APHIS") of the United States Department of Agriculture ("USDA") that the Company had shipped quantities of some of its poultry vaccine products without complying with certain regulatory and record keeping requirements. The USDA subsequently issued an order that the Company stop shipment of certain of its products. Shortly thereafter, in July 1997, the Company was

advised that the USDA's Office of Inspector General had commenced an investigation into possible violations of the Virus Serum Toxin Act of 1914 and alleged false statements made to APHIS. In April 1998, the SEC advised the Company that it was conducting an informal inquiry and requested information and documents from the Company, which the Company voluntarily provided to the SEC.

Based upon these events, the Board of Directors caused an immediate and thorough investigation of the facts and circumstances of the alleged violations to be undertaken by independent counsel. The Company continued to refine and strengthen its regulatory programs with the adoption of a series of compliance and enforcement policies, the addition of new managers of Production and Quality Control and a new Senior Vice President and General Counsel. At the instruction of the Board of Directors, the Company's General Counsel established and oversaw a comprehensive employee training program, designated in writing a Regulatory Compliance Officer, and established a fraud detection program, as well as an employee "hotline." The Company continued to cooperate with the USDA and SEC in all aspects of their investigation and regulatory activities. On March 13, 2002, the Company reached a settlement with the staff of the SEC to resolve matters arising with respect to the investigation of the Company. Under the settlement, the Company neither admitted nor denied that the Company violated the financial reporting and record-keeping requirements of Section 13 of the Securities and Exchange Act of 1934, as amended, for the three years ended December 31, 1997. Further, the Company agreed to the entry of an order to cease and desist from any such violation in the future. No monetary penalty was assessed.

As a result of its internal investigation, in November 1997, the Company terminated the employment of John P. Gallo as President and Chief Operating Officer for willful misconduct. On April 21, 1998, the Company instituted a lawsuit against Mr. Gallo in the New Jersey Superior Court. The lawsuit alleged willful misconduct and malfeasance in office, as well as embezzlement and related claims (referred to as "the IGI Action"). On April 28, 1998, Mr. Gallo instituted a separate action against the Company and two of its Directors, Edward Hager, M.D. and Constantine Hampers, M.D., alleging that he had been wrongfully terminated from employment and further alleging wrongdoings by the two Directors (referred to as the "Gallo Action"). The Court subsequently ordered the consolidation of the IGI Action and the Gallo Action (collectively referred to as the "Consolidated Action").

In response to these allegations, the Company instituted an investigation of the two Directors by an independent committee ("Independent Committee") of the Board assisted by the Company's General Counsel. The investigation included a series of interviews of the Directors, both of whom cooperated with the Company, and a review of certain records and documents. The Company also requested an interview with Mr. Gallo who, through his counsel, declined to cooperate. In September 1998, the Independent Committee reported to the Board that it had found no credible evidence to support Mr. Gallo's claims and allegations and recommended no further action. The Board adopted the recommendation.

The Company denied all allegations plead in the Gallo Action and asserted all claims in the Gallo Action to be without merit. The Company did not reserve any amount relating to such claims. The Company tendered the claim to its insurance carriers, but was denied insurance coverage for both defense and indemnity of the Gallo Action.

IGI, INC. AND SUBSIDIARIES
PART II OTHER INFORMATION, Continued

In July 1998, the Company sought to depose Mr. Gallo in connection with the Consolidated Action. Through his counsel, Mr. Gallo asserted his Fifth Amendment privilege against self-incrimination and advised that he would not participate in the discovery process until such time as a federal grand jury investigation, in which he was a target, was concluded. In January 1999, at the suggestion of the Court, the Company and Mr. Gallo agreed to a voluntary dismissal without prejudice of the Consolidated Action, with the understanding that the statute of limitations was tolled for all parties and all claims, and that the Company and Mr. Gallo were free to reinstate their suits against each other at a later date, with each party reserving all of their rights and remedies against the other.

As of the date hereof, neither the Company nor Mr. Gallo have filed suit against each other in the Superior Court of New Jersey or any other court of competent jurisdiction to reinstitute the claims, in whole or part, previously at issue in the Consolidated Action, and pursuant to the previous order of dismissal entered in the Consolidated Action, the statute of limitation on all claims and defenses continues to be tolled as to both parties. However, the Company did receive a letter dated November 21, 2003 from Mr. Gallo's attorneys seeking to reach a settlement of the claims asserted against IGI in the Gallo Action without further resort to the courts. The letter provides a general description of Mr. Gallo's claims and a calculation of damages allegedly sustained by Mr. Gallo relative thereto. The letter states that Mr. Gallo's damages are calculated to be in the range of $3,400,000 to $5,100,000. The Company denies liability for the claims and damages alleged in the letter from Mr. Gallo's counsel dated November 21, 2003, and as such, the Company did not make any formal response thereto. Mr. Gallo has contacted the Company's Chief Executive Officer and Chairman, Frank Gerardi, in a continued effort to initiate settlement discussions. As of the present date, the Company continues to deny any merit and/or liability for the claims alleged by Mr. Gallo and has not engaged in any formal settlement discussions with either Mr. Gallo or his attorneys.

On December 8, 2003, Mr. Gallo filed suit against Novavax, Inc. in the Superior Court of New Jersey, Law Division, Atlantic County, docket no. ATL-L-3388-03, asserting claims under seven counts for damages allegedly sustained as a result of the cancellation of certain Novavax stock options held by Mr. Gallo due to his termination from IGI in November 1997 for willful misconduct (referred to as the "Novavax Action").

On March 5, 2004, Novavax filed an Answer denying the allegations asserted by Mr. Gallo in his First Amended Complaint. In addition, while denying any liability under the First Amended Complaint, Novavax also filed a Third Party Complaint in the Novavax Action against the Company for contribution and indemnification, alleging that if liability for Mr. Gallo's claims is found, the Company has primary liability for any and all such damages sustained.

IGI has been notified by its insurance carriers that coverage is not afforded under their respective policies of insurance for defense and/or indemnification of the claims alleged by the Third Party Complaint. After IGI was notified of the foregoing, but prior to IGI's filing of any responsive pleading, the Third Party Complaint against IGI was voluntarily dismissed without prejudice by Novavax on June 30, 2004. Novavax may at any time pursuant to the rules of court re-file its Third Party Complaint against IGI.

On July 8, 2004, Novavox filed a motion for summary judgment on all claims asserted under Gallo's First Amended Complaint (referred to as "the SJ

Motion"). As of the filing date hereof, the SJ Motion is pending subject to filing of Gallo's opposition and any reply thereto by Novavax. The court has not yet scheduled a hearing date for the SJ Motion. In the event the court denies the SJ Motion, the Company believes that there is a substantial likelihood that Novavax will re-file its Third Party Complaint against IGI for which coverage was previously denied by its insurance carriers.

ITEM 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

None.

ITEM 3. Defaults Upon Senior Securities

None.

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

None.

ITEM 5. Other Information

None.

IGI, INC. AND SUBSIDIARIES
PART II OTHER INFORMATION, Continued

ITEM 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10.110 Severance agreement between IGI, Inc and Domenic N Golato, Chief Financial Officer dated June 30, 2004

10.111 Sublicense Agreement between IGI, Inc. and University of Massachusetts dated July 27, 2004.

31.1 Certification of the Chairman 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 Controller 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 Chairman and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as enacted under Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of the Controller pursuant to 18 U.S.C. Section 1350, as enacted under Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K. The following reports on Form 8-K have been filed during the quarter for which this report is filed:

Form 8-K filed May 21, 2004, on which Item 4 was completed to announce the resignation of the Company's principal independent accountants, KPMG LLP.

Form 8-K filed June 22, 2004, on which Item 4 was completed to announce the engagement of Amper, Politziner & Mattia, PC, as the Company's new principal independent accountants.

IGI, INC. AND SUBSIDIARIES

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IGI, Inc.
(Registrant)

Date: August 12, 2004 By: /s/ Frank Gerardi
Frank Gerardi
Chairman and Chief Executive Officer

Date: August 12, 2004 By: /s/ Carlene Lloyd
Carlene Lloyd
Controller