IGI LABORATORIES, INC
Form 10-Q
November 15, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2010

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TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from _____ to_____

Commission File Number 001-08568

IGI Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**01-0355758**
(State or other Jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
105 Lincoln Avenue **Buena, New Jersey**	**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 þ No [ ]

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

Yes [ ] No [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ]	Smaller reporting company	þ

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

The number of shares outstanding of the issuer's common stock is 35,373,112 shares, net of treasury stock, as of November 10, 2010.

PART I

FINANCIAL INFORMATION

ITEM 1. Financial Statements

IGI LABORATORIES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share information)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2010	**2009**	**2010**	**2009**
Revenues:				
Product sales	$ 1,531	$ 668	$ 3,814	$ 2,172
Research and development income	165	83	348	149
Licensing and royalty income	48	47	206	213
Total revenues	1,744	798	4,368	2,534
Cost and expenses:				
Cost of sales	1,286	691	3,760	2,220
Selling, general and administrative expenses	760	758	2,482	2,717
Product development and research expenses	373	273	1,027	542
Operating loss	(675)	(924)	(2,901)	(2,945)
Interest income (expense) and other income, net	(4)	6	(1)	(945)
Net loss	(679)	(918)	(2,902)	(3,890)
Preferred stock dividends	(1,284)	-	(1,284)	-
Dividend accreted for beneficial conversion features	-	-	-	(2,488)
Net Loss Attributable to Common Stockholders	$(1,963)	$(918)	$(4,186)	$(6,378)
Basic and diluted loss per share	$ (.08)	$ (.05)	$ (.21)	$ (.40)

Weighted Average of Common Stock and Common Stock Equivalents Outstanding				
Basic and diluted	24,876,399	17,243,830	20,071,518	15,916,673

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

IGI LABORATORIES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share information)

	September 30, 2010 (unaudited)	December 31, 2009*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 192	$ 1,124
Accounts receivable, less allowance for doubtful accounts of $90 in 2010 and 2009	654	741
Licensing and royalty income receivable	29	67
Inventories	886	874
Prepaid expenses and other current assets	326	212
Total current assets	2,087	3,018
Property, plant and equipment, net	2,826	2,764
Restricted cash, long term	54	54
License fee, net	525	600
Other	68	20
Total assets	$ 5,560	$ 6,456
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 700	$ 542
Accrued expenses	242	422
Deferred income, current	86	137
Capital lease obligation, current	30	-
Total current liabilities	1,058	1,101
Long term liabilities:		
Deferred income, long term	31	34
Capital lease obligation, long term	77	-
Total long term liabilities	108	34
Total liabilities	1,166	1,135
Commitments and contingencies		
Stockholders equity:	500	500
Series A Convertible Preferred stock, $.01 par value, 100 shares authorized; 50 shares		

issued and outstanding as of September 30, 2010 and December 31, 2009; liquidation preference - $500,000		
Series B-1 Convertible Preferred stock, $.01 par value, 1,030 shares authorized; 0 and 1,006.879 shares issued and outstanding as of September 30, 2010 and December 31, 2009; liquidation preference - $6,351,466	-	5,852
Series C Convertible Preferred stock, $.01 par value, 1,550 shares authorized; 1,550 and 0 shares issued and outstanding as of September 30, 2010 and December 31, 2009, respectively; liquidation preference - $1,589,493	1,517	-
Common stock, $.01 par value, 50,000,000 shares authorized; 35,373,112 and 19,302,987 shares issued 33,407,372 and 17,337,247 shares outstanding as of September 30, 2010 and December 31, 2009, respectively	353	193
Additional paid-in capital	39,409	31,975
Accumulated deficit	(35,990)	(31,804)
Less treasury stock, 1,965,740 common shares at cost	(1,395)	(1,395)
Total stockholders equity	4,394	5,321
Total liabilities and stockholders' equity	$ 5,560	$ 6,456

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

* Derived from the audited December 31, 2009 financial statements

IGI LABORATORIES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine months ended September 30,	
	2010	**2009**
Cash flows from operating activities:		
Net loss	$(2,902)	$(3,890)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation	198	183
Amortization of license fee	75	75
Bad debt expense	-	11
Stock-based compensation expense	450	327
Directors compensation payable in stock	-	48
Interest expense on convertible note payable	-	41
Amortization of discount on convertible note payable	-	33
Amortization of discount on convertible note payable related party	-	211
Amortization of debt issuance costs	-	659
Changes in operating assets and liabilities:		
Accounts receivable	87	82
Licensing and royalty income receivable	38	53
Inventories	(12)	(370)
Prepaid expenses and other assets	(125)	(78)
Accounts payable and accrued expenses	(22)	74
Deferred income	(54)	172
Net cash used in operating activities	(2,267)	(2,369)
Cash flows from investing activities:		
Capital expenditures	(138)	(624)
Deposit for capital lease	(37)	-
Net cash used in investing activities	(175)	(624)
Cash flows from financing activities:		
Sale of Series C Convertible Preferred Stock, net of expenses	1,517	-
Principal payments on capital lease obligation	(15)	-
Sale of Series B-1 Convertible Preferred Stock, net of expenses	-	1,073
Proceeds from issuance of convertible note payable, net of expenses	-	4,206
Proceeds from exercise of common stock options	8	24
Recovery from stockholder, net	-	4
Net cash provided by financing activities	1,510	5,307

Net increase (decrease) in cash and cash equivalents	(932)	2,314
Cash and cash equivalents at beginning of period	1,124	171
Cash and cash equivalents at end of period	$ 192	$ 2,485
Supplemental cash flow information:		
Cash payments for interest	$ 5	$ 14
Cash payment for taxes	-	11
Non cash transactions:		
Equipment financed	$ 122	$ -
Issuance of restricted stock	10	11
Forfeiture of restricted stock	(7)	-
Dividend accreted for beneficial conversion features	-	2,488
Issuance of stock to directors for compensation that was previously accrued	-	20
Conversion of note payable and accrued interest to Series B-1 Convertible Preferred Stock	-	4,779
Conversion of note payable related party to common stock	-	464
Conversion of Series B-1 Convertible Preferred Stock into Common Stock	7,136	-

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

IGI LABORATORIES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

For the nine months ended September 30, 2010

(in thousands, except share information)

	Series A Preferred Stock Shares	Amount	Series B-1 Convertible Preferred Stock Shares	Amount	Series C Convertible Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Treasu Stock
Balance, December 31, 2009 (Audited)	50	$ 500	1,007	$5,852	-	$ -	19,302,987	$ 193	$ 31,975	$ (31,804)	$(1,39
Issuance of preferred stock pursuant to a private placement, net of associated fees of $33					1,550	1,517					
Conversion of Series B-1 Convertible Preferred Stock and accrued dividends of $1,284 into Common Stock			(1,007)	(5,852)			15,692,824	157	6,979	(1,284)	
Stock-based compensation expense - stock options									189		
Stock-based compensation expense - restricted stock									261		
Restricted stock issuance							1,019,00	10	(10)		

Restricted stock forfeiture							(650,032)	(7)	7			
Stock options exercised							8,333	8				
Net loss	-	-	-	-	-	-	-	-	-	(2,902)		
Balance, September 30, 2010 (Unaudited)	50	$ 500	-	$ -	1,550	$1,517	35,373,112	$ 353	$ 39,409	$ (35,990)	$(1,39	

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

IGI LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2009. The condensed consolidated balance sheet as of December 31, 2009 has been derived from those audited consolidated financial statements. Operating results for the nine month period ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010.

1. Organization

IGI Laboratories, Inc. is a Delaware corporation formed in 1977. On May 7, 2008, the stockholders of IGI, Inc. approved the name change of the Company from IGI, Inc. to IGI Laboratories, Inc. As used in this report, the terms the Registrant, the Company, IGI, Inc., IGI and IGI Laboratories refer to IGI Laboratories, Inc., unl context requires otherwise. The Company s office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. IGI develops, manufactures, fills and packages topical semi-solid and liquid products for cosmetic, cosemceutical and pharmaceutical customers. The Company s products are used for cosmetic, cosmeceutical and prescription applications for the treatment of symptoms of dermatitis, acne, psoriasis and eczema. The Company is building upon this foundation by filing its own ANDAs and continuing to expand into the prescription pharmaceutical arena. The Company s strategy is based upon three initiatives: increasing the current contract services business, developing a portfolio of generic formulations in topical dosage forms and creating unique opportunities around its licensed Novasome® technology. All of its product development and manufacturing is performed at its 25,000 sq.ft. facility in Buena, NJ.

2. Liquidity

The principal sources of liquidity for IGI Laboratories, Inc. are cash and cash equivalents of approximately $192,000 at September 30, 2010 and cash from operations. The Company sustained a net loss attributable to common stockholders of approximately $4,186,000 for the nine months ended September 30, 2010 and had working capital of approximately $1,029,000 at September 30, 2010.

On March 29, 2010, the Company completed a $1,550,000 private placement with certain investors, including investment funds affiliated with Signet Healthcare Partners, G.P. and Jane E. Hager (the Series C Offering). As part of the Series C Offering, the Company issued 1,550 shares of Series C Convertible Preferred Stock. The Series C Convertible Preferred Stock has a par value of $0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore, each share of Series C Preferred Stock is convertible into shares of common stock equal to (i) 1,000 plus any accrued and unpaid dividends, divided by (ii) $0.69 (the closing price of the Company s common stock on the date of issuance of the Series C Convertible Preferred Stock).

The Company s business operations have been partially funded over the past three years through the exercise of stock options by our directors and officers, through private placements of our capital stock, the line of credit and issuance of debt. As described more fully in Footnotes 8, 10, 11 and 12, we raised an aggregate of $5,304,000 in 2009 and $1,517,000 for the nine months ended September 30, 2010 principally from private equity investors. We may continue to seek to raise additional capital through the sale of our equity. We may accomplish this via a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing.

We believe that we need an additional capital infusion in the fourth quarter of 2010 to support our business plan. However, the trading price of our common stock, our pending application to continue listing our common stock on NYSE Amex, a downturn in the U.S. equity and debt markets or the negative economic trends in general could make it more difficult to obtain financing through the issuance of equity securities or otherwise. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. In the event we do not obtain such financing, we will be required to delay or abandon certain development projects to avoid the associated costs.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowance, stock based compensation, and accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

Loss Per Share

Basic net loss per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock is computed using the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period. Due to the net loss for the nine months ended September 30, 2010 and 2009 and the three months ended September 30, 2010 and 2009, the effect of the Company s potential dilutive common stock equivalents was anti-dilutive for each period; as a result, the basic and diluted weighted average number of common shares outstanding and net loss per common share are the same. Potentially dilutive common stock equivalents include convertible preferred stock and options and warrants to purchase the Company s common stock, which were excluded from the net loss per share calculations due to their anti-dilutive effect, and amounted to 4,340,629 for 2010 and 18,073,786 for 2009.

Revenue Recognition

The Company considers revenue realized or realizable and earned when it has persuasive evidence of an arrangement, delivery has occurred or contractual services rendered, the sales price is fixed or determinable, and collection is reasonably assured in conformity with ASC 605, *Revenue Recognition*.

The Company derives its revenues from three basic types of transactions: sales of manufactured product, licensing of technology, and research and product development services performed for third parties. Due to differences in the substance of these transaction types, the transactions require, and the Company utilizes, different revenue recognition policies for each.

Product Sales: The Company recognizes revenue when title transfers to its customers, which is generally upon shipment of products. These shipments are made in accordance with sales commitments and related sales orders entered into with customers either verbally or in written form. The revenues associated with these transactions, net of appropriate cash discounts, product returns and sales reserves, are recorded upon shipment of the products.

Licensing and Royalty Income: Revenues earned under licensing or sublicensing contracts are recognized ratably over the life of the agreements. Advance payments by customers are initially recorded as deferred income on the Consolidated Balance Sheet and then recognized ratably over the life of the agreement or as

contract obligations are completed. Licensing and royalty income is not a material part of the Company s overall revenue.

Research and Development Income*:* The Company enters into agreements with its customers to perform product development services. Product development revenues are recognized in accordance with the product development agreement upon the completion of each phase of development and when we have no future performance obligations relating to such phase of development. Revenue recognition requires the Company to assess progress against contracted obligations to assure completion of each stage. Payments under these arrangements are generally non-refundable and are reported as deferred until they are recognized as revenue. If no such arrangement exists, product development fees are recognized ratably over the entire period during which the services are performed.

Major Customers

Major customers of the Company are defined as having revenue greater than 10% of total gross revenue. For the three months ended September 30, 2010 and 2009, two of our customers accounted for 51% and three of our customers accounted for 53% of our revenue, respectively. For the nine months ended September 30, 2010 and 2009, two of our customers accounted for 50% and three of our customers accounted for 35% of our revenue, respectively. Two of these customers are the same for the nine months ended September 30, 2010 and 2009. Accounts receivable related to the Company s major customers comprised 49% of all account receivables as of September 30, 2010. 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.

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board, or FASB, provided guidance under ASC 605 on defining a milestone and determining when it is appropriate to apply the milestone method of revenue recognition for research and development transactions. Vendors can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period the milestone is achieved if the milestone meets all the criteria stated in the guidance to be considered substantive and must be considered substantive in its entirety. The Company adopted this standard for the three month period ended June 30, 2010 and the adoption is not expected to have a material impact on the Company s consolidated financial statements.

Reclassification of Prior Period Balances

Certain 2010 prior quarter balances have been reclassified to conform to the current quarter financial statement presentation. This reclassification of Quality Analytical expenses from January to September of 2010 which related to the Company s work performed for ANDA filing for FDA submission has no impact on net loss or cash flows for the prior periods.

4. Inventories

Inventories are valued at the lower of cost, using the first-in, first-out (FIFO) method, or market. Inventories at September 30, 2010 and December 31, 2009 consist of:

	September 30, 2010 (Unaudited)	**December 31, 2009** (Audited)
	(amounts in thousands)	
Raw materials	$ 765	$ 751
Work in progress	5	12
Finished goods	116	111
Total	$ 886	$ 874

5. Stock-Based Compensation

Under the 1998 Directors Stock Plan, as amended, 600,000 shares of the Company s common stock are authorized under the plan and reserved for issuance to non-employee directors, in lieu of payment of directors fees in cash. The Company issued 59,176 shares in 2009 as consideration for directors fees for the fourth quarter of 2008 and the first, second and third quarters of 2009. Directors fees were accrued on the Company s financial statements for each of those quarters. In November 2009, the Company s Board of Directors approved the elimination of payment of directors fees in stock under this plan beginning in the fourth quarter of 2009.

The 1999 Director Stock Option Plan, as amended (the Director Plan), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. An aggregate of 1,975,000 shares have been approved and authorized for issuance pursuant to this

plan. A total of 1,814,798 options have been granted to non-employee directors through September 30, 2010. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years.

A total of 2,892,500 options, having a maximum term of ten years, have been granted at 100% of the fair market value of the Company's common stock at the time of grant pursuant to the Company s 1999 Stock Incentive Plan. Options outstanding under the 1999 Plan are generally exercisable in cumulative increments over four years commencing one year from date of grant. Awards may no longer be granted pursuant to the Company s 1999 Stock Incentive Plan.

On June 26, 2009, the Board of Directors adopted, and the Company s stockholders subsequently approved by partial written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the 2009 Plan). The 2009 Plan became effective on July 29, 2009. The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company s current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. The 2009 Plan, as amended on May 19, 2010, authorizes up to 4,000,000 shares of the Company s common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of September 30, 2010, options to purchase 275,000 shares of common stock were outstanding under the 2009 Plan and 1,443,968 shares of restricted stock had been granted under the 2009 Plan.

Stock Options

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

	For the nine months ended September 30, 2010
Expected volatility	65.1%
Expected term (in years)	3.2 years
Risk-free rate	1.77%
Expected dividends	0%

A summary of option activity under the 1999 Plan, the Director Plan and the 2009 Plan as of September 30, 2010 and changes during the period are presented below:

	Number of Options	Weighted Average Exercise Price
Outstanding as of January 1, 2010	2,014,177	$1.12
Issued	105,000	$0.79
Exercised	(8,333)	$1.00
Forfeited	(771,328)	$1.08
Expired	(65,000)	$1.95
Outstanding as of September 30, 2010	1,274,516	$1.08
Exercisable as of September 30, 2010	1,036,179	$1.12

Based upon application of the Black-Scholes option-pricing formula described above, the weighted-average grant-date fair value of options outstanding at September 30, 2010 was $0.18.

The following table summarizes information regarding options outstanding and exercisable at September 30, 2010:

Outstanding:

Range of Exercise Prices

		Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.50	$1.00	363,500	$0.71	5.90
$1.01	$1.50	854,000	$1.21	7.01
$1.51	$2.00	57,016	$1.52	3.26
Total		1,274,516	$1.08	6.53

Exercisable:

Range of Exercise Prices		Stock Options Exercisable	Weighted Average Exercise Price
$0.50	$1.00	258,500	$0.68
$1.01	$1.50	720,663	$1.24
$1.51	$2.00	57,016	$1.52
Total		1,036,179	$1.12

As of September 30, 2010, the intrinsic value of the options outstanding was $550,745 and the intrinsic value of the options exercisable was $409,677. The intrinsic value of options exercised during the nine months ended September 30, 2010 was $4,250. As of September 30, 2010, there was approximately $64,664 of total unrecognized compensation cost that will be recognized through November 2012 related to non-vested share-based compensation arrangements granted under the Plans.

Restricted Stock

The Company periodically grants restricted stock awards to certain officers and other employees that typically vest one to three years from their grant date. The Company recognized $261,000 and $199,000, respectively, of compensation expense during the nine months ended September 30, 2010 and 2009 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At September 30, 2010, the Company had approximately $620,034 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized from October 2010 through April 2013.

	Number of Restricted Stock	Weighted Average Exercise Price
Non-vested balance at January 1, 2010	801,355	$ 1.06
Changes during the period:		
Shares granted	1,019,000	0.71
Shares vested	(117,979)	1.02
Shares forfeited	(650,032)	1.07
Non-vested balance at September 30, 2010	1,052,344	$ 0.72

See Footnote 13 below regarding restricted stock award to Philip S. Forte, the Company s Chief Financial Officer and Charles E. Moore, CEO and President.

See Footnote 13 below regarding restricted stock and stock options for Hemanshu Pandya, the Company s former President and Chief Executive Officer, upon his resignation as of April 1, 2010.

6. Income Taxes

As a result of the Company s history of continuing tax losses, the Company has not paid income taxes and has recorded a full valuation allowance against its net deferred tax asset. The Company has not recorded a liability for unrecognized tax benefits at September 30, 2010 and no significant changes are expected in the next twelve months. The tax years 2007 through 2009 remain open to examination by the major taxing jurisdictions to which the Company is subject.

There was no accrued interest related to unrecognized tax benefits at September 30, 2010.

The Company s ability to use net operating loss carry forwards may be subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code, which limit the utilization of net operating losses upon a more than 50% change in ownership of the Company s stock that is held by 5% or greater stockholders. The Company is currently examining the application of Section 382 with respect to an ownership change that took place during 2009, as well as the possibility of such limitation having any material effect on the application of net operating loss carry forwards in the immediate future.

7. License Fee

On December 12, 2005, the Company extended its license agreement for an additional ten years with Novavax, Inc. for $1,000,000. This extension entitles the Company to exclusive use of the Novasome® lipid vesicle encapsulation and certain other technologies (each a Microencapsulation Technology , and collectively, the Technologies) in the fields of (i) animal pharmaceuticals, biologicals and other animal health products; (ii) foods, food applications, nutrients and flavorings; (iii) cosmetics, consumer products and dermatological over-the-counter and prescription products (excluding certain topically delivered hormones); (iv) fragrances; and (v) chemicals, including herbicides, insecticides, pesticides, paints and coatings, photographic chemicals and other specialty chemicals, and the processes for making the same (collectively, the IGI Field) through 2015. This payment is being amortized ratably over the ten-year period. The Company recorded amortization expense of $75,000 related to this agreement for each of the nine month periods ended September 30, 2010 and 2009.

8. Note Payable

On January 26, 2009, the Company signed the Second Amendment to Loan and Security Agreement, which amended and restated the Loan and Security Agreement, as amended, with Pinnacle Mountain Partners, LLC (Pinnacle). This Second Amendment to Loan and Security Agreement extended the maturity date of the $500,000 maximum loan amount from January 31, 2009 to July 31, 2009, with interest at 8.5% (rather than prime plus 1.5%). As in the original Loan and Security Agreement, as amended, loans under this amendment were collateralized by the assets of the Company (other than real property). The Company borrowed $500,000 under this Second Amendment to Loan and Security Agreement as of May 15, 2009 and incurred associated interest expense of $14,065 for the period January 1, 2009 to May 15, 2009 (date of conversion).

On March 13, 2009, the Company completed the 2009 Offering as more fully described in Footnote 11 below. As a condition to the consummation of the 2009 Offering, on March 13, 2009, the Company and Pinnacle entered into the Third Amendment to Loan and Security Agreement pursuant to which the parties agreed to change the final payment date of the amounts borrowed under the agreement from July 31, 2009 to instead provide that 50% of the amount of all loans and advances made by Pinnacle under the agreement will become due and payable on July 31, 2010 and the remaining outstanding loans and advances, together with interest thereon, will become due and payable on July 31, 2011.

In addition, as a condition to the consummation of the 2009 Offering, the Company and Pinnacle entered into a note conversion agreement (Note Conversion Agreement) dated March 13, 2009, pursuant to which Pinnacle agreed to convert the principal amount outstanding under the Third Amended and Restated Revolving Note (the Note Payable) into shares of the Company s common stock at a conversion rate of $0.41 per share of common stock (the conversion shares) upon receipt of stockholder approval by the Company of such conversion. Upon receipt of the conversion shares, the obligations and liabilities of the Company to repay the principal amount of the Note Payable would be deemed satisfied and paid in full. At the Company s 2009 annual meeting of stockholders held on May 15, 2009, the Company s stockholders approved the Note Conversion. Immediately upon stockholder approval, the $500,000 principal amount outstanding under the Note Payable was converted into 1,219,512 shares of the Company s common stock. For additional information relating to the 2009 Offering, see Footnote 11 below.

9. Related Party Transactions

For a description of the Company s Credit Agreement with Pinnacle and the Private Placement with Signet Healthcare Partners, G.P., the related parties, see Footnotes 8 above and 11 below, respectively.

10. Stock Warrants

In connection with the 2009 Offering (See Footnote 11 below), the Company granted its placement agent for the Offering a Common Stock Warrant to purchase 350,000 shares of common stock for $0.41 per share, which expires on March 13, 2012. Until stockholder approval of the 2009 Offering was obtained, this Common Stock Warrant was exercisable for no more than 88,550 shares. At the Company s 2009 annual meeting of stockholders held on May 15, 2009, the Company s stockholders approved the 2009 Offering. The fair value of the Common Stock Warrant of approximately $102,000 was determined using the Black Scholes model. The factors used in the calculation are as follows: expected volatility of 66.8%, expected term of 3 years and risk-free interest rate

of 1.36%. Expected volatility and risk-free interest rates are based upon the expected life of the warrant. The interest rates used are the yield of a 3-year U.S. Treasury Note as of March 13, 2009. Of this amount, $82,000 was deemed to be attributable to the issuance of debt and was capitalized as debt issuance costs. On December 2, 2009, the Common Stock Warrant was amended to include a partial transfer for 87,500 shares of common stock. On December 2, 2009, the warrant to purchase 87,500 was exercised using the Cashless Exercise provision and 51,681 shares of common stock were issued.

In connection with a Private Placement Memorandum dated December 10, 2007, the Company entered into a subscription agreement with Univest Management, Inc. EPSP, which granted Univest a warrant to purchase 52,500 shares of common stock at an exercise price of $1.25 per share. This warrant expired on December 10, 2009, two years from issuance.

In connection with a Private Placement Memorandum dated December 4, 2007, the Company entered into a subscription agreement which granted a warrant to purchase 175,000 shares of common stock at an exercise price of $1.25 per share. These warrants expired on December 4, 2009, two years from issuance.

In connection with the Private Placement transaction executed with Pharmachem, dated February 5, 2007, the Company issued a warrant to purchase 150,000 shares at $1.00 per share to Landmark Financial Corporation as commission on the transaction. During the quarter ended June 30, 2008, Landmark Financial Corporation exercised a portion of the warrant to acquire 25,000 shares of common stock. The remainder of this warrant expired on March 7, 2009.

11. Convertible Preferred Stock and Convertible Promissory Notes 2009 Offering

On March 13, 2009, the Company completed a $6,000,000 private placement with certain investment funds affiliated with Signet Healthcare Partners, G.P. (the 2009 Offering). As part of the 2009 Offering, the Company issued 202.9 shares of Series B-1 Preferred Stock, $4,782,600 in Secured Convertible Promissory Notes (Promissory Notes), Preferred Stock Purchase Warrants to purchase 797.1 shares of non-voting Series B-2 Preferred Stock (Preferred Stock Warrants), a Common Stock Purchase Warrant to purchase 350,000 shares of common stock (Common Stock Warrant) and amended its line of credit with Pinnacle. In connection with the 2009 Offering, the Company incurred placement and legal fees of approximately $721,000, resulting in net proceeds of $5,279,000. These fees were recorded as debt issuance costs in the amount of $577,000 and paid-in capital in the amount of $144,000.

The Series B-1 Preferred Stock has a par value of $0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore, each share of the Series B-1 Preferred Stock is convertible into 14,634 shares of common stock for an implied common stock conversion price of $0.41 per share, subject to certain adjustments and any accrued and unpaid dividends. At the time of issuance, the market price of the common stock into which the Series B-1 Preferred Stock is convertible was greater than the conversion price. The embedded beneficial conversion feature is being accounted for in accordance with ASC 470 relating to *Debt with Conversions and Other Options* . Accordingly, the beneficial conversion feature on the Series B-1 Preferred Stock is approximately $505,000, which represents the amount by which the estimated fair value of the common stock issuable upon conversion exceeds the proceeds from such issuance and was treated as a deemed dividend on the date of the 2009 Offering.

The Promissory Notes had a maturity date of July 31, 2009 and an annual interest rate of 5%. On the date of issuance, the Promissory Notes had a fair value of approximately $4,706,000, resulting in a debt discount of $77,000. Furthermore, the Company entered into Guaranty and Security Agreements to guarantee repayment of the Promissory Notes upon maturity. The Promissory Notes were collateralized by the assets of the Company. However, upon approval by the Company s stockholders of the 2009 Offering, the Promissory Notes, unamortized discount, and any accrued interest automatically converted into Series B-1 Preferred Stock for $6,000 per share and the Preferred Stock Warrants became null and void. The beneficial conversion feature of the Promissory Notes is approximately $1,983,000 which is recorded as a deemed dividend from March 14, 2009 through May 15, 2009. The value of the Preferred Stock Warrants was nominal. Under applicable NYSE Amex rules, the 2009 Offering required stockholder approval, which was obtained at the Company s 2009 annual meeting of stockholders held on May 15, 2009. Immediately upon stockholder approval, the $4,782,600 aggregate principal amount of Promissory Notes issued in the 2009 Offering, together with accrued and unpaid interest, were converted into an aggregate of 803.979 shares of the Company s Series B-1 Preferred Stock and the Preferred Stock Warrants issued in the 2009 Offering became null and void.

The Company granted its placement agent for the 2009 Offering a Common Stock Warrant to purchase 350,000 shares of common stock for $0.41 per share, which expires on March 13, 2012, as described more fully in Footnote 10.

In connection with the 2009 Offering, the Company and Pinnacle entered into the Third Amendment to Loan and Security Agreement. Pinnacle agreed to change the terms of repayment such that 50% of the amount borrowed under the line of credit, or $500,000 as of March 31, 2009 (see Footnote 8 above), would be payable on July 31, 2010 and the remaining balance would be payable on July 31, 2011. Furthermore, the Company and Pinnacle entered into a Note Conversion Agreement for which Pinnacle agreed to automatically convert the principal amount due under the Third Amended and Restated Revolving Note (the Note Payable) into shares of the Company s Common Stock at a conversion rate of $0.41 per share upon stockholder approval of the Note Conversion. The beneficial conversion feature of the Note Payable of approximately $207,000 was recorded as a debt discount. The fair value of the Note Payable, as modified, was approximately $460,000, resulting in a debt discount of $40,000. At the Company s 2009 annual meeting of stockholders held on May 15, 2009, the Company s stockholders approved the Note Conversion. Immediately upon stockholder approval, the $500,000 principal amount outstanding under the Note Payable was converted into 1,219,512 shares of the Company s common stock.

Debt discounts and debt issuance costs were amortized using the effective interest method. No amounts were outstanding at September 30, 2010 or December 31, 2009.

On August 20, 2010, all of the issued and outstanding shares of the Series B-1 Convertible Preferred Stock, par value $0.01 per share of the Company, as well as accrued dividends of $1,284,000 automatically converted into an aggregate of 15,692,824 shares of the Company s common stock, par value $0.01 per share, in accordance with the terms and conditions set forth in the Certificate of Designation of the Rights and Preferences of Series B-1 Convertible Preferred Stock and Series B-2 Preferred Stock (the Certificate of Designation).

Pursuant to the terms of the Certificate of Designation, the shares of Series B-1 Preferred Stock automatically convert into shares of the Company s Common Stock upon the date that the closing price of the Company s Common Stock shall have exceeded $1.20 for a period of twenty-five (25) consecutive trading days immediately preceding such date. On August 19, 2010, the closing price of the Company s Common Stock was $1.29, which was the twenty-fifth consecutive trading day for which the closing price of such Common Stock exceeded $1.20. Accordingly, on August 20, 2010, the shares of Series B-1 Preferred Stock automatically converted into shares of the Company s Common Stock.

The total number of shares of the Company s Common Stock outstanding immediately prior to the conversion was 17,714,548 and the total number of shares of Series B-1 Preferred Stock outstanding was 1,006.879. After giving effect to the conversion, the total number of shares of the Company s Common Stock outstanding was 33,407,372 and there were no shares of Series B-1 Preferred Stock outstanding.

A copy of the Certificate of Designation is filed as Exhibit 3.1 to the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 19, 2009 and incorporated herein by reference. The foregoing description of the Certificate of Designation is qualified in its entirety by reference to such exhibit.

12. Convertible Preferred Stock 2010 Offering

On March 29, 2010, the Company completed a $1,550,000 private placement with certain investors, including investment funds affiliated with Signet Healthcare Partners, G.P. and Jane E. Hager (the Series C Offering). As part of the Series C Offering, the Company issued 1,550 shares of Series C Convertible Preferred Stock. The Series C Convertible Preferred Stock has a par value of $0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore each share of Series C Preferred Stock is convertible into shares of common stock equal to (i) 1,000 plus any accrued and unpaid dividends, divided by (ii) $0.69 (the closing price of the Company s common stock on the date of issuance of the Series C Convertible Preferred Stock). Liquidation preference is the original cost plus undeclared dividends and amounted to $1,589,493 at September 30, 2010.

13. Changes in Management

On February 19, 2010, the Company announced in a Form 8-K filed with the Securities and Exchange Commission, that it had named Charles E. Moore as its Executive Vice President of Technical Operations, effective February 12, 2010. Under the terms of his employment agreement, Mr. Moore would receive an annual salary of $250,000. Mr. Moore also received a grant of 379,000 shares of restricted stock, one-third of which will vest on January 4, 2011, one-third of which will vest on January 4, 2012 and one-third of which will vest on January 4, 2013, so long as he is employed by the Company on each such vesting date. In addition, Mr. Moore will be entitled to participate in certain of the Company s benefit programs on the same terms and conditions

generally provided by the Company to its executive employees. Mr. Moore will also be eligible to receive an annual performance bonus for each calendar year during the term of his employment, which may be payable in either cash, stock options and/or restricted stock. Mr. Moore s target bonus will be equal to 20% of his base salary for the applicable fiscal year. All performance targets pursuant to such plan shall be determined by the Company s Compensation Committee. Mr. Moore is also subject to certain restrictive covenants as set forth in his employment agreement, including confidentiality, non-solicitation and non-competition. Mr. Moore s employment agreement further provides for payments upon certain types of employment termination events as further set forth in his employment agreement.

Additionally, in the Form 8-K filed on February 19, 2010, the Company announced that the Employment Agreement between Philip S. Forte and the Company dated May 18, 2009 as filed with the Securities and Exchange Commission on Form 8-K on May 29, 2009, was amended to provide Mr. Forte with one-year base salary continuation (instead of six months of salary continuation as previously provided for his Employment Agreement) in the event of his termination by the Company without cause. On February 18, 2010, the Company also (i) increased Mr. Forte s base salary to $185,000 and (ii) granted Mr. Forte 80,000 shares of restricted stock which vest as follows: (A) one-twelfth of the shares vested as of February 12, 2010; (B) one-twelfth of the shares shall vest on each of the following dates: (x) June 30, 2010, (y) September 30, 2010 and (z) December 31, 2010; (C) one-third of the shares shall vest on February 12, 2011 and (D) one-third of the shares shall vest on February 12, 2012, so long as he is employed by the company on each such vesting date.

On March 23, 2010, the Company announced in a Form 8-K filed with the Securities and Exchange Commission that on March 19, 2010, Hemanshu Pandya, the President and Chief Executive Officer of the Company, resigned as an employee of the Company and as a member of the board of directors, effective April 1, 2010. Upon the effective date of his resignation, Mr. Pandya retained the 324,968 restricted shares of common stock that were vested and forfeited the 650,032 restricted shares of common stock that were not vested per his Restricted Stock Agreement. Additionally, Mr. Pandya had 90 days from April 1, 2010 to exercise his 176,718 vested stock options, and he forfeited 353,427 stock options that were not vested per his Option Agreement. In connection with Mr. Pandya s resignation, the Company appointed Charles E. Moore its new President and Chief Executive Officer and to fill the vacant board seat created by Mr. Pandya s resignation, each effective April 1, 2010. The Board of Directors of IGI amended Mr. Moore s February 19, 2010 employment agreement in respect to his new responsibilities with the Company as President and Chief Executive Officer. Under the amended terms of his employment agreement, Mr. Moore would receive an annual salary of $265,000. Mr. Moore also received an additional grant of 560,000 restricted shares of common stock. These shares had a grant date of April 1, 2010 and would vest over three years, in one-third increments beginning after Mr. Moore s first year of service as the President and Chief Executive Officer. Mr. Moore s target incentive bonus was also increased to 40% of his base salary for the applicable fiscal year. Further, Mr. Moore would be entitled to payment of six months of severance plus a pro-rata portion of his bonus, if he was terminated without cause following the first anniversary of his employment start date. If terminated within the first year, he would not be entitled to a severance payment.

14. Legal

On April 22, 2010, a complaint for patent infringement was filed by Ferndale Laboratories Inc. against PruGen, Inc. and the Company in the United States District Court Eastern District of Michigan (Detroit) relating to U.S. Patent No. 5,635,497 (the '497 Patent) entitled Topical Application Compositions. Ferndale is the licensee of the 497 Patent, which is owned by Astrellas Pharma Europe B.V. The Complaint alleges infringement of the 497 Patent by PruGen and the Company in the manufacturing, using, selling and offering to sell their PruVel product. The Company is identified in the Complaint as PruGen s contract-manufacturer of the PruVel product. Ferndale is seeking unspecified money damages and injunctive relief.

On June 30, 2010, discussions and negotiations among Ferndale, PruGen and the Company resulted in a Settlement Agreement between the parties and the withdrawal of the complaint by Ferndale against PruGen Inc. and the Company. Pursuant to the Settlement Agreement, IGI agreed not to manufacture any product or composition which falls within the 497 Patent. Part of the Settlement Agreement also requires PruGen and the Company to destroy any inventory of the PruVel product in their possession after June 30, 2010 and to provide evidence of destruction to Ferndale. The Company complied with the Settlement Agreement and provided supporting evidence to Ferndale to the effect that it did not have any inventory of the PruVel product and that was duly acknowledged by Ferndale. The Company received the final letter from Ferndale confirming the resolution of the claim. There were no costs to the Company related to the settlement.

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

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

Overview

We develop, manufacture, fill and package topical semi-solid and liquid products for cosmetic, cosemceutical 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 ANDAs and continuing to expand into the prescription pharmaceutical arena. Our strategy is based upon three initiatives: increasing the 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 sq.ft. facility in Buena, NJ.

Our Services and Products

Contract Services Business

We provide contract services to marketers of topical formulations. These customers contract with us for formulation development and/or manufacturing of products which are marketed in the customer s brand. These products range from pure cosmetic formulations sold by retail to the public, to prescription formulations promoted to physicians.

We believe that contract manufacturing services will continue to be crucial to our success. The customer base for these services is pharmaceutical companies, as well as cosmetic, cosmeceutical and over-the-counter product marketers who require product development/manufacturing support. This is a highly-competitive market with a

number of larger, greater-resourced companies offering similar services. We intend to continue to create niche opportunities by providing high quality, customer-oriented service.

IGI s Pharmaceutical Business

We are leveraging our expertise in pharmaceutical formulation and manufacturing to expand our own product offerings. We are focused on developing a portfolio of topical generic drug products via the Abbreviated New Drug Application, or ANDA, route. ANDAs are submitted to the Food and Drug Administration, or FDA, for generic drug products that are bioequivalent versions of innovator brand drug products. ANDA approval by the FDA allows for the interchangeability in the United States of the generic product with the innovator drug, meaning that the generic version may be substituted for the brand product by either a physician or pharmacist when dispensing a prescription.

In September 2010, we filed our first ANDA with the FDA in our own name. We have a number of additional product candidates in various pre-ANDA-filing stages of development. We anticipate filing 4 to 6 ANDAs per year on an ongoing basis, assuming sufficient financial resources to support these product development plans. The entire approval process can take 3-5 years before a product is approved, of which the FDA approval portion is approximate 18-24 months.

Novasome® Technology Platform

We have an exclusive license for use of the patented Novasome® encapsulation technology in topical formulations, from Novavax, Inc., until December 11, 2015. The technology utilizes non-phospholipid structures for enhanced absorption via topical delivery of pharmaceuticals and cosmeceuticals. The Novasome® technology is inexpensive to manufacture, and its structures are stable, biodegradable, and highly hydrophobic and hydrophilic, making them suitable for a wide range of topical applications.

Many of the *Novasome*® patents under this license have expired and more will expire before this license terminates on December 11, 2015. We have already filed our own patents based on this technology. An integral piece of this technology is manufacturing know-how which will not be lost as a result of the expiration of the license. As we continue to implement our new strategy, we believe that sales related to the Novasome® technology will constitute a smaller percentage of our sales in the future.

Recent Capital Transactions

On March 13, 2009, we completed a $6,000,000 pri