

LANNETT CO INC
Form 10-Q
November 12, 2010
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2010

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

FOR THE TRANSITION PERIOD FROM TO .

Commission File No. 001-31298

LANNETT COMPANY, INC.

(Exact Name of Registrant as Specified in its Charter)

State of Delaware

23-0787699

Edgar Filing: LANNETT CO INC - Form 10-Q

(State of Incorporation)

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

9000 State Road

Philadelphia, PA 19136

(215) 333-9000

(Address of principal executive offices and telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

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 shell company (as defined in Rule 12B-12 of the Exchange Act). Yes No

Indicate the number of shares outstanding of each class of the registrant's common stock, as of the latest practical date.

Class	Outstanding as of November 4, 2010
Common stock, par value \$0.001 per share	25,298,503 shares

Table of Contents

Table of Contents

	Page No.
<u>PART I. FINANCIAL INFORMATION</u>	
<u>ITEM 1.</u>	<u>FINANCIAL STATEMENTS</u>
	1
	2
	3
	4
	5
<u>ITEM 2.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>
	27
<u>ITEM 3.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>
	39
<u>ITEM 4.</u>	<u>CONTROLS AND PROCEDURES</u>
	39
<u>PART II. OTHER INFORMATION</u>	
<u>ITEM 1.</u>	<u>LEGAL PROCEEDINGS</u>
	40
<u>ITEM 1A.</u>	<u>RISK FACTORS</u>
	41
<u>ITEM 6.</u>	<u>EXHIBITS</u>
	48
31.1	CERTIFICATION OF PRESIDENT & CHIEF EXECUTIVE OFFICER
31.2	CERTIFICATION OF CHIEF FINANCIAL OFFICER
32	CERTIFICATION PURSUANT TO SECTION 906 OF SARBANES OXLEY ACT OF 2002

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****LANNETT COMPANY, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

	(Unaudited)	
	September 30, 2010	June 30, 2010
<u>ASSETS</u>		
Current Assets		
Cash and cash equivalents	\$ 17,624,554	\$ 21,895,648
Investment securities - available for sale	212,757	604,464
Trade accounts receivable (net of allowance of \$123,192 and \$123,192 respectively)	31,189,099	38,324,258
Inventories, net	21,036,591	19,056,868
Interest receivable	9,371	9,631
Prepaid taxes	498,215	
Deferred tax assets	5,133,873	5,337,391
Other current assets	2,162,319	2,506,114
Total Current Assets	77,866,779	87,734,374
Property, plant and equipment	51,882,758	50,160,114
Less accumulated depreciation	(22,293,000)	(21,531,845)
	29,589,758	28,628,269
Construction in progress	3,680,223	2,939,898
Investment securities - available for sale	183,771	183,742
Intangible assets (product rights) - net of accumulated amortization	7,326,945	7,785,298
Deferred tax assets	12,524,544	12,544,330
Other assets	138,858	147,886
Total Assets	\$ 131,310,878	\$ 139,963,797
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
<u>LIABILITIES</u>		
Current Liabilities		
Accounts payable	\$ 15,763,468	\$ 16,280,675
Accrued expenses	2,498,862	3,464,181
Accrued payroll and payroll related	2,486,810	6,304,465
Income taxes payable		1,479,658
Current portion of long-term debt	4,826,601	4,851,278
Rebates, chargebacks and returns payable	13,359,608	15,249,412
Total Current Liabilities	38,935,349	47,629,669
Long-term debt, less current portion	2,834,973	2,868,549
Unearned grant funds	500,000	500,000
Other long-term liabilities	6,558	7,864
Total Liabilities	42,276,880	51,006,082
Commitment and Contingencies, See notes 10 and 11		

SHAREHOLDERS EQUITY

Common stock - authorized 50,000,000 shares, par value \$0.001; issued and outstanding, 24,929,131 and 24,882,123 shares, respectively	24,929	24,882
Additional paid in capital	80,410,648	79,862,940
Retained earnings	9,161,071	9,564,632
Noncontrolling interest	121,421	111,982
Accumulated other comprehensive income	52,588	44,692
	89,770,657	89,609,128
Less: Treasury stock at cost - 130,118 and 110,108 shares, respectively	(736,659)	(651,413)
TOTAL SHAREHOLDERS EQUITY	89,033,998	88,957,715
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 131,310,878	\$ 139,963,797

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

Table of Contents

LANNETT COMPANY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three months ended September 30,	
	2010	2009
Net sales	\$ 25,395,927	\$ 31,434,989
Cost of sales	18,900,048	19,012,318
Amortization of intangible assets	448,667	448,667
Product royalties	143,271	439,774
Gross profit	5,903,941	11,534,230
Research and development expenses	2,042,369	3,027,841
Selling, general, and administrative expenses	4,600,681	3,763,161
Gain on sale of investments	(12,641)	
Operating (loss) income	(726,468)	4,743,228
Other income (expense):		
Foreign currency gain	2,415	
Interest income	11,231	23,099
Interest expense	(70,844)	(70,413)
	(57,198)	(47,314)
(Loss) income before income tax (benefit) expense	(783,666)	4,695,914
Income tax (benefit) expense	(389,544)	1,827,650
Net (loss) income	(394,122)	2,868,264
Less net income attributable to noncontrolling interest	(9,439)	(10,894)
Net (loss) income attributable to Lannett Company, Inc.	\$ (403,561)	\$ 2,857,370
Basic (loss) income per common share - Lannett Company, Inc.	\$ (0.02)	\$ 0.12
Diluted (loss) income per common share - Lannett Company, Inc.	\$ (0.02)	\$ 0.11
Basic weighted average number of shares	24,899,530	24,533,562
Diluted weighted average number of shares	24,899,530	25,054,661

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

Table of Contents

LANNETT COMPANY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

(UNAUDITED)

	Common Stock		Additional	Retained	Treasury	Noncontrolling	Accum. Other	Shareholders
	Shares	Amount	Paid-in	Earnings	Stock	Interest	Comprehensive	Equity
	Issued		Capital				Income	
Balance, June 30, 2010	24,882,123	\$ 24,882	\$ 79,862,940	\$ 9,564,632	\$ (651,413)	\$ 111,982	\$ 44,692	\$ 88,957,715
Shares issued in connection with employee stock purchase plan	14,610	15	54,254					54,269
Share based compensation								
Restricted stock			174,755					174,755
Stock options			306,232					306,232
Employee stock purchase plan			12,499					12,499
Shares issued in connection with restricted stock grant	32,398	32	(32)					
Purchase of treasury stock					(85,246)			(85,246)
Other comprehensive income, net of income tax							7,896	7,896
Net (loss) income				(403,561)		9,439		(394,122)
Balance, September 30, 2010	24,929,131	\$ 24,929	\$ 80,410,648	\$ 9,161,071	\$ (736,659)	\$ 121,421	\$ 52,588	\$ 89,033,998

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

Table of Contents**LANNETT COMPANY, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(UNAUDITED)

	For the three months ended September 30,	
	2010	2009
OPERATING ACTIVITIES:		
Net (loss) income	\$ (394,122)	\$ 2,868,264
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	1,219,508	1,166,604
Deferred tax expense	227,143	388,427
Stock compensation expense	493,486	297,315
Other noncash expenses (income)	7,722	(26,391)
Gain on sale of assets	(12,641)	
Changes in assets and liabilities which provided (used) cash:		
Trade accounts receivable	7,135,159	(1,152,466)
Inventories	(1,979,723)	(814,863)
Prepaid and income taxes payable	(1,977,873)	513,590
Prepaid expenses and other assets	344,055	58,142
Accounts payable	(517,207)	(1,155,783)
Accrued expenses	(965,319)	289,880
Rebates, chargebacks and returns payable	(1,889,804)	(871,703)
Accrued payroll and payroll related	(3,817,655)	(2,195,495)
Net cash used in operating activities	(2,127,271)	(634,479)
INVESTING ACTIVITIES:		
Purchases of property, plant and equipment (including construction in progress)	(2,462,969)	(1,067,261)
Purchase of intangible asset (product rights)		(500,000)
Proceeds from sale of investment securities - available for sale	394,721	
Net cash used in investing activities	(2,068,248)	(1,567,261)
FINANCING ACTIVITIES:		
Repayments of debt	(58,253)	(136,285)
Proceeds from issuance of stock	54,269	185,943
Purchase of treasury stock	(85,246)	(69,120)
Net cash used in financing activities	(89,230)	(19,462)
Effect of foreign currency rates on cash and cash equivalents	13,655	
NET DECREASE IN CASH AND CASH EQUIVALENTS	(4,271,094)	(2,221,202)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	21,895,648	25,832,456
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 17,624,554	\$ 23,611,254
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION -		
Interest paid	\$ 100,856	\$ 41,762
Income taxes paid	\$ 1,361,186	\$ 925,633

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

Table of Contents

LANNETT COMPANY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED

Note 1. Interim Financial Information

The accompanying unaudited financial statements have been prepared in accordance with U.S. generally accepted accounting principles for presentation of interim financial statements and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the unaudited financial statements do not include all the information and footnotes necessary for a comprehensive presentation of the financial position, results of operations, and cash flows for the periods presented. In the opinion of management, the unaudited financial statements include all the normal recurring adjustments that are necessary for a fair presentation of the financial position, results of operations, and cash flows for the periods presented. Operating results for the three months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the fiscal year ending June 30, 2011. You should read these unaudited financial statements in combination with the other Notes in this section; Management's Discussion and Analysis of Financial Condition and Results of Operations appearing in Item 2; and the Financial Statements, including the Notes to the Financial Statements, included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2010.

Note 2. Summary of Significant Accounting Policies

Lannett Company, Inc., a Delaware corporation, and subsidiaries (the Company or Lannett), develop, manufacture, package, market, and distribute active pharmaceutical ingredients as well as pharmaceutical products sold under generic chemical names. The Company manufactures solid oral dosage forms, including tablets and capsules, topical and oral solutions, and is pursuing partnerships and research contracts for the development and production of other dosage forms, including ophthalmic, nasal and injectable products.

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. Actual results could differ from those estimates.

Principles of Consolidation - The consolidated financial statements include the accounts of the operating parent company, Lannett Company, Inc., and its wholly owned subsidiaries, as well as the consolidation of Cody LCI Realty, LLC, a variable interest entity. See Note 16 regarding the consolidation of this variable interest entity. All intercompany accounts and transactions have been eliminated.

Foreign Currency Translation - The local currency is the functional currency of its foreign subsidiary. Assets and liabilities of the foreign subsidiary are translated into U.S. dollars at the period-end currency exchange rate and revenues and expenses are translated at an average currency exchange rate for the period. The resulting translation adjustment is recorded in a separate component of shareholders' equity and changes to such are included in comprehensive income. Exchange adjustments resulting from transactions denominated in foreign currencies are recognized in the consolidated statements of operations.

Reclassifications - Certain prior year amounts have been reclassified to conform to the current year financial statement presentation.

Revenue Recognition - The Company recognizes revenue when its products are shipped. At this point, title and risk of loss have transferred to the customer and provisions for estimates, including rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably

Table of Contents

determinable. Accruals for these provisions are presented in the consolidated financial statements as rebates, chargebacks and returns payable and reductions to net sales. The change in the reserves for various sales adjustments may not be proportionally equal to the change in sales because of changes in both the product and the customer mix. Increased sales to wholesalers will generally require additional accruals as they are the primary recipient of chargebacks and rebates. Incentives offered to secure sales vary from product to product. Provisions for estimated rebates and promotional credits are estimated based upon contractual terms. Provisions for other customer credits, such as price adjustments, returns, and chargebacks, require management to make subjective judgments on customer mix. Unlike branded innovator drug companies, Lannett does not use information about product levels in distribution channels from third-party sources, such as IMS and Wolters Kluwer, in estimating future returns and other credits. Lannett calculates a chargeback/rebate rate based on contractual terms with its customers and applies this rate to customer sales. The only variable is customer mix, and this assumption is based on historical data and sales expectations.

Chargebacks The provision for chargebacks is the most significant and complex estimate used in the recognition of revenue. The Company sells its products directly to wholesale distributors, generic distributors, retail pharmacy chains, and mail-order pharmacies. The Company also sells its products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, and group purchasing organizations, collectively referred to as indirect customers. Lannett enters into agreements with its indirect customers to establish pricing for certain products. The indirect customers then independently select a wholesaler from which to actually purchase the products at these agreed-upon prices. Lannett will provide credit to the wholesaler for the difference between the agreed-upon price with the indirect customer and the wholesaler's invoice price if the price sold to the indirect customer is lower than the direct price to the wholesaler. This credit is called a chargeback. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to the indirect customers and estimated wholesaler inventory levels. As sales to the large wholesale customers, such as Cardinal Health, AmerisourceBergen, and McKesson increase, the reserve for chargebacks will also generally increase. However, the size of the increase depends on the product mix and the amount of those sales that end up at indirect customers with which the Company has specific chargeback agreements. The Company continually monitors the reserve for chargebacks and makes adjustments when management believes that expected chargebacks on actual sales may differ from actual chargeback reserves.

Rebates Rebates are offered to the Company's key chain drug store, distributor and wholesaler customers to promote customer loyalty and increase product sales. These rebate programs provide customers with rebate credits upon attainment of pre-established volumes or attainment of net sales milestones for a specified period. Other promotional programs are incentive programs offered to the customers. At the time of shipment, the Company estimates reserves for rebates and other promotional credit programs based on the specific terms in each agreement. The reserve for rebates increases as sales to certain wholesale and retail customers increase. However, since these rebate programs are not identical for all customers, the size of the reserve will depend on the mix of customers that are eligible to receive rebates.

Returns Consistent with industry practice, the Company has a product returns policy that allows customers to return product within a specified period prior to and subsequent to the product's lot expiration date in exchange for a credit to be applied to future purchases. The Company's policy requires that the customer obtain pre-approval from the Company for any qualifying return. The Company estimates its provision for returns based on historical experience, changes to business practices, and credit terms. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future returns. The Company continually monitors the provisions for returns and makes adjustments when management believes that actual product returns may differ from established reserves. Generally, the reserve for returns increases as net sales increase. The reserve for returns is included in the rebates, chargebacks and returns payable account on the balance sheet.

Table of Contents

Other Adjustments Other adjustments consist primarily of price adjustments, also known as shelf stock adjustments, which are credits issued to reflect decreases in the selling prices of the Company's products that customers have remaining in their inventories at the time of the price reduction. Decreases in selling prices are discretionary decisions made by management to reflect competitive market conditions. Amounts recorded for estimated shelf stock adjustments are based upon specified terms with direct customers, estimated declines in market prices, and estimates of inventory held by customers. The Company regularly monitors these and other factors and evaluates the reserve as additional information becomes available. Other adjustments are included in the rebates, chargebacks and returns payable account on the balance sheet.

The following tables identify the reserves for each major category of revenue allowance and a summary of the activity for the three months ended September 30, 2010 and 2009:

For the three months ended September 30, 2010

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2010	\$ 6,282,127	\$ 3,566,031	\$ 5,401,254	\$	\$ 15,249,412
Actual credits issued related to sales recorded in prior fiscal years	(6,112,838)	(2,558,582)	(1,151,174)		(9,822,594)
Reserves or (reversals) charged during Fiscal 2011 related to sales in prior fiscal years					
Reserves charged to net sales during Fiscal 2011 related to sales recorded in Fiscal 2011	11,960,878	3,776,169	2,987,308	1,663,371	20,387,726
Actual credits issued related to sales recorded in Fiscal 2011	(7,056,592)	(2,347,273)	(1,387,700)	(1,663,371)	(12,454,936)
Reserve Balance as of September 30, 2010	\$ 5,073,575	\$ 2,436,345	\$ 5,849,688	\$	\$ 13,359,608

For the three months ended September 30, 2009

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2009	\$ 6,089,802	\$ 2,537,746	\$ 5,106,992	\$	\$ 13,734,540
Actual credits issued related to sales recorded in prior fiscal years	(4,767,581)	(1,852,708)	(1,147,720)		(7,768,009)
Reserves or (reversals) charged during Fiscal 2010 related to sales in prior fiscal years					
Reserves charged to net sales during Fiscal 2010 related to sales recorded in Fiscal 2010	10,272,936	4,066,855	1,140,128	407,784	15,887,703
Actual credits issued related to sales recorded in Fiscal 2010	(7,000,389)	(1,789,955)		(407,784)	(9,198,128)
Reserve Balance as of September 30, 2009	\$ 4,594,768	\$ 2,961,938	\$ 5,099,400	\$	\$ 12,656,106

The total reserve for chargebacks, rebates, returns and other adjustments decreased from \$15,249,412 at June 30, 2010 to \$13,359,608 at September 30, 2010. The decrease in total reserves was due to a decrease in the rebates reserve as a result of a decrease in overall sales, and a decrease in chargeback reserves due primarily to a decrease in inventory levels at wholesaler distribution centers.

Table of Contents

The Company ships its products to the warehouses of its wholesale and retail chain customers. When the Company and a customer enter into an agreement for the supply of a product, the customer will generally continue to purchase the product, stock its warehouse(s), and resell the product to its own customers. The Company's customer will reorder the product as its warehouse is depleted. The Company generally has no minimum size orders for its customers. Additionally, most warehousing customers prefer not to stock excess inventory levels due to the additional carrying costs and inefficiencies created by holding excess inventory. As such, the Company's customers continually reorder the Company's products. It is common for the Company's customers to order the same products on a monthly basis. For generic pharmaceutical manufacturers, it is critical to ensure that customers' warehouses are adequately stocked with its products. This is important due to the fact that several generic competitors compete for the consumer demand for a given product. Availability of inventory ensures that a manufacturer's product is considered. Otherwise, retail prescriptions would be filled with competitors' products. For this reason, the Company periodically offers incentives to its customers to purchase its products. These incentives are generally up-front discounts off its standard prices at the beginning of a generic campaign launch for a newly-approved or newly-introduced product, or when a customer purchases a Lannett product for the first time. Customers generally inform the Company that such purchases represent an estimate of expected resale for a period of time. This period of time is generally up to three months. The Company records this revenue, net of any discounts offered and accepted by its customers at the time of shipment. The Company's products generally have 24 months or 36 months of shelf-life at the time of manufacture. The Company monitors its customers' purchasing trends to attempt to identify any significant lapses in purchasing activity. If the Company observes a lack of recent activity, inquiries will be made to such customer regarding the success of the customer's resale efforts. The Company attempts to minimize any potential return (or shelf life issues) by maintaining an active dialogue with the customers.

The products that the Company sells are generic versions of brand named drugs. The consumer markets for such drugs are well-established markets with many years of historically-confirmed consumer demand. Such consumer demand may be affected by several factors, including alternative treatments and costs. However, the effects of changes in such consumer demand for the Company's products, like generic products manufactured by other generic companies, are gradual in nature. Any overall decrease in consumer demand for generic products generally occurs over an extended period of time. This is because there are thousands of doctors, prescribers, third-party payers, institutional formularies and other buyers of drugs that must change prescribing habits and medicinal practices before such a decrease would affect a generic drug market. If the historical data the Company uses and the assumptions management makes to calculate its estimates of future returns, chargebacks, and other credits do not accurately approximate future activity, its net sales, gross profit, net income and earnings per share could change. However, management believes that these estimates are reasonable based upon historical experience and current conditions.

Cash and cash equivalents - The Company considers all highly liquid securities purchased with original maturities of 90 days or less to be cash equivalents. Cash equivalents are stated at cost, which approximates fair value, and consist of certificates of deposit that are readily convertible to cash. The Company maintains cash and cash equivalents with several major financial institutions. Such amounts frequently exceed Federal Deposit Insurance Corporation (FDIC) limits.

Accounts Receivable - The Company performs ongoing credit evaluations of its customers and adjusts credit limits based upon payment history and the customer's current credit worthiness, as determined by a review of current credit information. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses based upon historical experience and any specific customer collection issues that have been identified. While such credit losses have historically been within both the Company's expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same credit loss rates that it has in the past.

Fair Value of Financial Instruments - The Company's financial instruments consist primarily of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and debt obligations. The carrying values

Table of Contents

of these assets and liabilities approximate fair value based upon the short-term nature of these instruments. The Company has estimated that the fair value of long-term debt associated with the 20 year mortgage on its land and building in Cody, Wyoming approximates the discounted amount of future payments to the mortgage-holder.

Investment Securities - The Company's investment securities consist of marketable debt securities, primarily in U.S. government and agency obligations. All of the Company's marketable debt securities are classified as available-for-sale and recorded at fair value, based on quoted market prices. Unrealized holding gains and losses are recorded, net of any tax effect, as a separate component of accumulated other comprehensive income. No gains or losses on marketable debt securities are realized until they are sold or a decline in fair value is determined to be other-than-temporary. The Company reviews its marketable securities and determines whether the investments are other-than-temporarily impaired. If the investments are deemed to be other-than-temporarily impaired, the investments are written down to their then current fair market value with a new cost basis being established. There were no securities determined by management to be other-than-temporarily impaired during the three months ended September 30, 2010 or the fiscal year ended June 30, 2010.

Shipping and Handling Costs - The cost of shipping products to customers is recognized at the time the products are shipped, and is included in cost of sales.

Research and Development - Research and development expenses are charged to operations as incurred.

Intangible Assets - In March 2004, the Company entered into an agreement with Jerome Stevens Pharmaceuticals, Inc. (JSP) for the exclusive marketing and distribution rights in the United States to the current line of JSP products in exchange for four million (4,000,000) shares of the Company's common stock. As a result of the JSP agreement, the Company recorded an intangible asset for the exclusive marketing and distribution rights obtained from JSP. As of September 30, 2010 and June 30, 2010, management concluded the carrying value of the intangible asset was less than its fair value and, therefore, no impairment was required. The Company will incur annual amortization expense of approximately \$1,785,000 for the JSP intangible asset over the remaining term of the agreement.

On April 10, 2007, the Company entered into a Stock Purchase Agreement to acquire Cody by purchasing all of the remaining shares of common stock of Cody. The consideration for the April 10, 2007 acquisition was approximately \$4,438,000, which represented the fair value of the tangible net assets acquired. The agreement also required Lannett to issue to the sellers up to 120,000 shares of unregistered common stock of the Company contingent upon the receipt of a license from a regulatory agency. This license was subsequently received in July 2008 and triggered the payment of 105,000 shares (87.5% of the 120,000 shares to be issued as the Company already owned 12.5% of Cody) of Lannett stock to the former owners of Cody Labs, which was completed in October 2008. Therefore, the Company recorded an intangible asset related to the acquisition of a drug import license in the original amount of \$581,175 and recorded a corresponding deferred tax liability of approximately \$150,700 due to the non-deductibility of the amortization for tax purposes. The Company has assigned a 15 year life to this intangible asset based on average life cycles of Lannett products.

In January 2005, Lannett Holdings, Inc. entered into an agreement in which the Company purchased for \$100,000 and future royalty payments the proprietary rights to manufacture and distribute a product for which Pharmeral, Inc. owned the ANDA. In May 2008, the Company and Pharmeral waived their rights to any royalty payments on the sales of the drug by Lannett under Lannett's current ownership structure. Should Lannett undergo a change in control transaction with a third party, this royalty will be reinstated. In Fiscal 2008, the Company obtained FDA approval to use these proprietary rights. Accordingly, the Company originally capitalized these purchased product rights as an indefinite lived intangible asset and tested this asset for impairment at least on an annual basis. During the fourth quarter of fiscal 2009, it was determined that

Edgar Filing: LANNETT CO INC - Form 10-Q

this intangible asset no longer has an indefinite life. No impairment existed because the estimated fair value exceeded the carrying amount on that date. Accordingly, the \$100,000 carrying amount of this intangible asset is being amortized on a straight line basis prospectively over its 10 year remaining estimated useful life.

Table of Contents

In August 2009, the Company acquired eight new ANDAs covering three separate product lines from another generic drug manufacturer for a purchase price of \$500,000. The Company began shipping one of these product lines in October 2010 and it is expected that the Company will be able to produce the other two product lines by the second half of Fiscal 2011. Amortization will begin when the Company starts shipping these products. An intangible asset that is not subject to amortization shall be tested for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. Our discounted cash flow models are highly reliant on various assumptions which are considered level 3 inputs, including estimates of future cash flow (including long-term growth rates), discount rate, and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows. As of September 30 and June 30, 2010, no impairment existed with respect to these assets.

For the three months ended September 30, 2010 and 2009, the Company incurred amortization expense of approximately \$458,000 and \$458,000, respectively. As of September 30, 2010 and June 30, 2010, accumulated amortization totaled approximately \$9,916,000 and \$9,458,000, respectively.

Future annual amortization expense consists of the following as of September 30, 2010:

Fiscal Year Ending June 30,	Annual Amortization Expense	
2011	\$	1,375,059
2012		1,833,412
2013		1,833,412
2014		1,387,245
2015		48,745
Thereafter		349,072
	\$	6,826,945

The amounts above do not include the ANDAs purchased in August 2009 for \$500,000 as amortization will begin when the Company starts shipping these products. As noted above, the Company began shipping one of these product lines in October 2010.

Advertising Costs - The Company charges advertising costs to operations as incurred. Advertising expense for the three months ended September 30, 2010 and 2009 was approximately \$19,000 and \$10,000, respectively.

Income Taxes - The Company uses the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. Deferred tax expense/(benefit) is the result of changes in deferred tax assets and liabilities. The Company may recognize the tax benefit from an uncertain tax position claimed on a tax return only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The authoritative standards issued by the FASB also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures.

Table of Contents

Segment Information - The Company operates one business segment - generic pharmaceuticals; accordingly the Company has one reporting segment. The Company aggregates its financial information for all products and reports as one operating segment. The following table identifies the Company's approximate net product sales by medical indication for the three months ended September 30, 2010 and 2009:

Medical Indication	For the Three Months Ended	
	2010	2009
Migraine Headache	\$ 2,525,000	\$ 2,663,000
Epilepsy	521,000	611,000
Prescription Vitamin	869,000	1,489,000
Heart Failure	3,229,000	4,852,000
Thyroid Deficiency	10,336,000	13,024,000
Antibiotic	1,381,000	1,661,000
Pain Management	2,900,000	3,880,000
Other	3,635,000	3,255,000
Total	\$ 25,396,000	\$ 31,435,000

Concentration of Market and Credit Risk - Five of the Company's products, defined as generics containing the same active ingredient or combination of ingredients, accounted for approximately 41%, 13%, 10%, 4% and 3%, respectively of net sales for the three months ended September 30, 2010. Those same products accounted for 41%, 15%, 8%, 3% and 5% respectively, of net sales for the three months ended September 30, 2009.

Four of the Company's customers accounted for 23%, 13%, 9%, and 9%, respectively, of net sales for the three months ended September 30, 2010, and 25%, 12%, 8%, and 8%, respectively, of net sales for the three months ended September 30, 2009. At September 30, 2010, four customers accounted for 64% of the Company's accounts receivable balances. At June 30, 2010, four customers accounted for 69% of the Company's accounts receivable balances.

Share-based Compensation - The Company recognizes compensation cost for share-based compensation issued to or purchased by employees, net of estimated forfeitures, under share-based compensation plans using a fair value method.

At September 30, 2010, the Company had three stock-based employee compensation plans (the Old Plan, the 2003 Plan, and the 2006 Long-term Incentive Plan, or 2006 LTIP).

At September 30, 2010, there were 2,058,851 options outstanding. Of those, 1,032,925 were options issued under the 2006 LTIP, 820,693 were issued under the 2003 Plan, and 205,233 under the Old Plan. There are no further shares authorized to be issued under the Old Plan. 1,125,000 shares were authorized to be issued under the 2003 Plan, with 49,365 shares under options having already been exercised under that plan since its inception, leaving a balance of 254,942 shares in that plan for future issuances. 2,500,000 shares were authorized to be issued under the 2006 LTIP, with 94,725 shares under options having already been exercised under that plan since its inception. At September 30, 2010, there were 237,500 nonvested restricted shares outstanding which were issued under the 2006 LTIP, with 372,689 shares having already vested under that plan since its inception. At September 30, 2010, a balance of 762,161 shares is available in the 2006 LTIP for future issuances.

During the fiscal year ended June 30, 2010, the Company awarded 237,500 shares of restricted stock to management employees under the 2006 LTIP which vest in equal portions on October 29, 2010, 2011 and 2012.

Table of Contents

Stock compensation expense of \$144,787 was recognized during the three months ended September 30, 2010 related to these shares of restricted stock.

During the fiscal year ended June 30, 2008, the Company awarded 209,264 shares of restricted stock to management employees under the 2006 LTIP, of which 74,464 of these shares vested 100% on January 1, 2008, and the remainder vested in equal portions on September 18, 2008, 2009 and 2010. Stock compensation expense of \$29,968 and \$43,007 was recognized during the three months ended September 30, 2010 and 2009, respectively, related to these shares of restricted stock.

The Company measures the fair value of share-based compensation cost for options using the Black-Scholes option pricing model. The following table presents the weighted average assumptions used to estimate fair values of the stock options granted and the estimated forfeiture rates during the three months ended September 30:

	Incentive Stock Options FY 2011	Non-qualified Stock Options FY 2011	Incentive Stock Options FY 2010	Non-qualified Stock Options FY 2010
Risk-free interest rate	%	%	2.4%	%
Expected volatility	%	%	67.1%	%
Expected dividend yield	%	%	%	%
Forfeiture rate	%	%	5.0%	%
Expected term	n/a	n/a	5.0 years	n/a
Weighted average fair value at date of grant	\$	\$	\$ 4.86	\$

Expected volatility is based on the historical volatility of the price of our common shares since the date we commenced trading on the NYSE-Amex, April 2002, or a historical period equal to the expected term of the option, whichever is shorter. We use historical information to estimate expected term within the valuation model. The expected term of awards represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. Compensation cost is recognized using the straight-line method over the vesting or service period and is net of estimated forfeitures.

The forfeiture rate assumption is the estimated annual rate at which unvested awards are expected to be forfeited during the vesting period. This assumption is based on our historical forfeiture rate. Periodically, management will assess whether it is necessary to adjust the estimated rate to reflect changes in actual forfeitures or changes in expectations. For example, adjustments may be needed if forfeitures were affected by turnover that resulted from a business restructuring that is not expected to recur. The Company will incur additional expense if the actual forfeiture rate is lower than originally estimated. A recovery of prior expense will be recorded if the actual rate is higher than originally estimated.

Table of Contents

The following table presents all share-based compensation costs recognized in our statements of operations, substantially all of which is reflected in the selling, general and administrative expense line:

	Three Months Ended September 30,	
	2010	2009
Share based compensation		
Stock options	\$ 306,232	\$ 232,868
Employee stock purchase plan	12,499	21,440
Restricted stock	174,755	43,007
Tax benefit at statutory rate	31,467	27,604

Options outstanding that have vested and are expected to vest as of September 30, 2010 are as follows:

	Awards	Weighted - Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Options vested	1,306,240	\$ 7.96	\$ 330,755	5.1
Options expected to vest	694,084	\$ 6.55	\$ 106,299	9.0
Total vested and expected to vest	2,000,324	\$ 7.47	\$ 437,054	6.5

A summary of nonvested restricted stock award activity as of September 30, 2010 and changes during the three months then ended, is presented below:

	Awards	Weighted Average Grant Date Fair Value
Nonvested at July 1, 2010	269,898	\$ 1,778,814
Granted		
Vested	(32,398)	(130,564)
Forfeited		
Nonvested at September 30, 2010	237,500	\$ 1,648,250

Edgar Filing: LANNETT CO INC - Form 10-Q

Table of Contents

A summary of award activity under the Plans as of September 30, 2010 and 2009, and changes during the three months then ended, is presented below:

	Incentive Stock Options				Nonqualified Stock Options			
	Awards	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life	Awards	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Outstanding at July 1, 2010	1,309,254	\$ 6.11			749,597	\$ 9.77		
Granted		\$				\$		
Exercised		\$				\$		
Forfeited, expired or repurchased		\$				\$		
Outstanding at September 30, 2010	1,309,254	\$ 6.11	\$ 353,362	7.3	749,597	\$ 9.77	\$ 89,926	5.2
Outstanding at September 30, 2010 and not yet vested	599,953	\$ 6.45	\$ 112,533	8.9	152,658	\$ 6.99	\$	9.1
Exercisable at September 30, 2010	709,301	\$ 5.83	\$ 240,829	5.9	596,939	\$ 10.48	\$ 89,926	4.2

	Incentive Stock Options				Nonqualified Stock Options			
	Awards	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life	Awards	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Outstanding at July 1, 2009	958,909	\$ 5.60			626,772	\$ 10.52		
Granted	20,000	\$ 8.48				\$		
Exercised	(36,100)	\$ 4.23				\$		
Forfeited, expired or repurchased	(6,400)	\$ 5.38				\$		
Outstanding at September 30, 2009	936,409	\$ 5.71	\$ 2,217,739	7.2	626,772	\$ 10.52	551,242	5.3
Outstanding at September 30, 2009 and not yet vested	350,474	\$ 4.64	1,015,723	8.7	63,067	\$ 4.51	187,483	8.1
Exercisable at September 30, 2009	585,935	\$ 6.36	\$ 1,202,016	6.3	563,705	\$ 11.19	373,133	4.9

Options with a fair value of \$342,556 vested during the three months ended September 30, 2010. As of September 30, 2010, there was \$2,786,917 of total unrecognized compensation cost related to nonvested share-based compensation awards granted under the Plans. That cost is expected to be recognized over a weighted average period of 2.0 years. The Company issues new shares when stock options are exercised.

Unearned Grant Funds The Company records all grant funds received as a liability until the Company fulfills all the requirements of the grant funding program.

Table of Contents

Earnings (loss) per Common Share A dual presentation of basic and diluted earnings (loss) per share is required on the face of the Company's consolidated statement of operations as well as a reconciliation of the computation of basic earnings (loss) per share to diluted earnings per share. Basic earnings (loss) per share excludes the dilutive impact of common stock equivalents and is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding for the period. Diluted earnings per share include the effect of potential dilution from the exercise of outstanding common stock equivalents into common stock using the treasury stock method. A reconciliation of the Company's basic and diluted income (loss) per share follows:

	2010		Three Months Ended September 30, 2009	
	Net (Loss) Attributable to Lannett (Numerator)	Shares (Denominator)	Net Income Attributable to Lannett (Numerator)	Shares (Denominator)
Basic (loss) earnings per share factors	\$ (403,561)	24,899,530	\$ 2,857,370	24,533,562
Effect of potentially dilutive option and restricted stock plans				521,099
Diluted (loss) earnings per share factors	\$ (403,561)	24,899,530	\$ 2,857,370	25,054,661
Basic (loss) earnings per share	\$ (0.02)		\$ 0.12	
Diluted (loss) earnings per share	\$ (0.02)		\$ 0.11	

Dilutive shares have been excluded in the weighted average shares used for the calculation of earnings per share in periods of net loss because the effect of such securities would be anti-dilutive. The number of anti-dilutive shares that have been excluded in the computation of diluted earnings per share for the three months ended September 30, 2010 and 2009 were 2,296,351 and 352,845, respectively.

Note 3. New Accounting Standards

In June 2009, the Financial Accounting Standards Board (FASB) issued authoritative guidance for determining whether an entity is a variable interest entity and modifies the methods allowed for determining the primary beneficiary of a variable interest entity. This guidance requires an enterprise to perform an analysis to determine whether the enterprise's variable interest or interests give it a controlling financial interest in a variable interest entity. It also requires ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity. The authoritative guidance is effective for the annual reporting period that begins after November 15, 2009. We do not expect the adoption of this authoritative guidance to have a significant impact on our consolidated financial statements.

In January 2010, the FASB issued authoritative guidance which requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair-value measurements and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair-value measurements. The FASB's Accounting Standards Update (ASU) 2010-6 is effective for annual reporting periods beginning after December 15, 2009, except for

Edgar Filing: LANNETT CO INC - Form 10-Q

Level 3 reconciliation disclosures which are effective for annual periods beginning after December 15, 2010. We do not anticipate that this update will have a material impact on our consolidated financial statements.

Table of Contents**Note 4. Inventories**

The Company values its inventory at the lower of cost (determined by the first-in, first-out method) or market, regularly reviews inventory quantities on hand, and records a provision for excess and obsolete inventory based primarily on estimated forecasts of product demand. The Company's estimates of future product demand may fluctuate, in which case estimated required reserves for excess and obsolete inventory may increase or decrease. If the Company's inventory is determined to be overvalued, the Company recognizes such costs in cost of goods sold at the time of such determination. Likewise, if inventory is determined to be undervalued, the Company may have recognized excess cost of goods sold in previous periods and would recognize such additional operating income at the time of sale.

Inventories consist of the following:

	September 30, 2010		June 30, 2010
Raw materials	\$ 7,840,599	\$	5,183,735
Work-in-process	2,588,395		2,375,396
Finished goods	9,865,669		10,527,630
Packaging supplies	741,928		970,106
	\$ 21,036,591	\$	19,056,868

The preceding amounts are net of excess and obsolete inventory reserves of \$3,115,605 and \$2,481,810 at September 30, 2010 and June 30, 2010, respectively.

Recently, the FDA has increased its efforts to force companies to file and seek FDA approval for GRASE or Grandfathered products. GRASE products are those old drugs that do not require prior approval from FDA in order to be marketed because they are generally recognized as safe and effective based on published scientific literature. Similarly, Grandfathered products are those which entered the market before the passage of the 1906 act, the 1938 act or the 1962 amendments to the act. Efforts have included granting market exclusivity to approved GRASE or Grandfathered products and issuing notices to discontinue marketing certain products to companies currently producing these products. Lannett currently manufactures and markets several products that are considered GRASE or Grandfathered products, including Morphine Sulfate Oral Solution. The Company is currently litigating the issue of Grandfathered drugs with the FDA. The FDA is currently undertaking activities to force all companies who manufacture Morphine Sulfate Oral Solution to file applications and seek approval for this product or remove their product from the market. As of July 24, 2010, Lannett has stopped manufacturing and distributing Morphine Sulfate Oral Solution and as of September 30, 2010, the Company has approximately \$2.0 million of Morphine Sulfate Oral Solution finished goods inventory. Lannett has filed a 505(b)(2) New Drug Application and currently awaits FDA approval on the submission. If the Company is rejected on its current application, if the current application takes significantly longer than eleven months to be approved, or if the FDA were to prevail on the current lawsuit filed by Lannett which seeks determination that Morphine Sulfate Oral Solution is a Grandfathered product, the Company is at risk of losing some or all of the approximately \$2.0 million of Morphine Sulfate Oral Solution inventory as of September 30, 2010. Lannett also has approximately \$2.7 million of inventory value at September 30, 2010 of other Grandfathered products which would also be at risk if the FDA were to pursue enforcement actions on these products similar to their actions on Morphine Sulfate Oral Solution.

Table of Contents**Note 5. Property, Plant and Equipment**

Property, plant and equipment are stated at cost. Depreciation is provided for by the straight-line method for financial reporting purposes over the estimated useful lives of the assets. Depreciation expense for the three months ended September 30, 2010 and 2009 was approximately \$762,000 and \$708,000, respectively.

Property, plant and equipment consist of the following:

	Useful Lives	September 30, 2010	June 30, 2010
Land	-	\$ 1,375,103	\$ 1,375,103
Building and improvements	10 - 39 years	23,970,883	23,101,751
Machinery and equipment	5 - 10 years	25,436,336	24,638,754
Furniture and fixtures	5 - 7 years	1,100,436	1,044,506
		\$ 51,882,758	\$ 50,160,114
Accumulated depreciation		(22,293,000)	(21,531,845)
		\$ 29,589,758	\$ 28,628,269

Note 6. Investment Securities - Available-for-Sale

On July 1, 2008, the Company adopted the authoritative guidance which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The authoritative guidance also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Three levels of inputs were established that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities. The Company does not have any Level 1 available-for-sale securities as of September 30, 2010 or June 30, 2010.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar instruments in markets that are not active; or model-derived valuations whose inputs are observable or whose significant value drivers are observable. The Company's Level 2 assets and liabilities primarily include debt securities with quoted prices that are traded less frequently than exchange-traded instruments, corporate bonds, U.S. government and agency securities and certain mortgage-backed and asset-backed securities whose values are determined using pricing models with inputs that are observable in the market or can be derived principally from or corroborated by observable market data. The fair value of the Company's available-for-sale securities in the table below are derived solely from Level 2 inputs.

Edgar Filing: LANNETT CO INC - Form 10-Q

Level 3 Unobservable inputs that are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation. The Company does not have any Level 3 available-for-sale securities as of September 30, 2010 or June 30, 2010.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Table of Contents

The amortized cost, gross unrealized gains and losses, and fair value of the Company's available-for-sale securities are summarized as follows:

September 30, 2010

Available-for-Sale

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Government Agency	\$ 208,671	\$ 4,086	\$	\$ 212,757
Corporate Bonds	179,507	4,264		183,771
	\$ 388,178	\$ 8,350	\$	\$ 396,528

June 30, 2010

Available-for-Sale

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Government Agency	\$ 590,751	\$ 13,713	\$	\$ 604,464
Corporate Bonds	179,507	4,235		183,742
	\$ 770,258	\$ 17,948	\$	\$ 788,206

The amortized cost and fair value of the Company's current available-for-sale securities by contractual maturity at September 30, 2010 and June 30, 2010 are summarized as follows:

	September 30, 2010 Available for Sale		June 30, 2010 Available for Sale	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in one year or less	\$ 208,671	\$ 212,757	\$ 590,751	\$ 604,464
Due after one year through five years	179,507	183,771	179,507	183,742
Due after five years through ten years				
Due after ten years				
Total available-for-sale securities	388,178	396,528	770,258	788,206
Less current portion	208,671	212,757	590,751	604,464
Long term available-for-sale securities	\$ 179,507	\$ 183,771	\$ 179,507	\$ 183,742

Edgar Filing: LANNETT CO INC - Form 10-Q

The Company uses the specific identification method to determine the cost of securities sold. For the three months ended September 30, 2010, the Company had realized gains of \$12,641, whereas for the three months ended September 30, 2009, the Company had no realized gains or losses.

Table of Contents

As of September 30, 2010 and June 30, 2010, there were no securities held from a single issuer that represented more than 10% of shareholders equity. As of September 30, 2010, there were no individual securities in a continuous unrealized loss position.

Note 7. Bank Line of Credit

The Company has a \$3,000,000 line of credit from Wells Fargo, N. A., formerly Wachovia Bank, N.A. (Wells Fargo) that bears interest at the prime interest rate less 0.25% (3.00% at September 30, 2010 and June 30, 2010, respectively). As of September 30, 2010 and June 30, 2010, the Company had \$3,000,000 of availability under this line of credit. The line of credit is collateralized by substantially all of the Company's assets. The agreement contains covenants with respect to working capital, net worth and certain ratios, as well as other covenants. As of September 30, 2010, the Company was not in compliance with all financial covenants under the agreement, but received a waiver from its lending institution with respect to the failed covenant as of September 30, 2010. The noncompliance was caused by the direct use of cash to purchase and fit out Lannett's third facility during the December 2009, March 2010 and June 2010 quarters over a period where the Company experienced reduced earnings caused by the DEA withholding production quota for Morphine Sulfate Oral Solution and the FDA actions barring Lannett from shipping Morphine Sulfate Oral Solution. As a result of the expected refinancing of the \$4.5 million PIDC Regional Center, LP III loan which is due on January 1, 2011, the Company will consider renegotiation of its current covenant requirements.

The existing line of credit, which was scheduled to expire on November 30, 2010, was renewed and extended during the first quarter of Fiscal 2011 to November 30, 2011. As part of the renewal agreement last fiscal year, the Company is no longer required to maintain any minimum deposit balances with Wells Fargo, and the availability fee on the unused balance of the line of credit was reduced to 0.375%.

Note 8. Unearned Grant Funds

In July 2004, the Company received \$500,000 of grant funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development. The grant funding program requires the Company to use the funds for machinery and equipment located at their Pennsylvania locations, hire an additional 100 full-time employees by June 30, 2006, operate its Pennsylvania locations a minimum of five years and meet certain matching investment requirements. If the Company fails to comply with any of the requirements above, the Company would be liable to repay the full amount of the grant funding (\$500,000). The Company has recorded the unearned grant funds as a liability until the Company complies with all of the requirements of the grant funding program. As of September 30, 2010, the Company has had preliminary discussions with the Commonwealth of Pennsylvania to determine whether it will be required to repay any of the funds provided under the grant funding program. Based on information available at September 30, 2010, the Company has recorded the grant funding as a long-term liability under the caption of Unearned Grant Funds.

Table of Contents**Note 9. Long-Term Debt**

Long-term debt consists of the following:

	September 30, 2010	June 30, 2010
PIDC Regional Center, LP III loan	\$ 4,500,000	4,500,000
Pennsylvania Industrial Development Authority loan	914,726	933,820
Pennsylvania Department of Community & Economic Development loan	61,923	88,141
Tax-exempt bond loan (PAID)	555,000	555,000
First National Bank of Cody mortgage	1,629,925	1,642,866
Total debt	7,661,574	7,719,827
Less current portion	4,826,601	4,851,278
Long term debt	\$ 2,834,973	\$ 2,868,549

	September 30, 2010	June 30, 2010
Current Portion of Long Term Debt		
PIDC Regional Center, LP III loan	\$ 4,500,000	\$ 4,500,000
Pennsylvania Industrial Development Authority loan	77,600	77,091
Pennsylvania Department of Community & Economic Development loan	61,923	88,141
Tax-exempt bond loan (PAID)	130,000	130,000
First National Bank of Cody mortgage	57,078	56,046
Total current portion of long term debt	\$ 4,826,601	\$ 4,851,278

In December 2005, the Company financed \$4,500,000 through the Philadelphia Industrial Development Corporation (PIDC). The Company pays a bi-annual interest payment at a rate equal to two and one-half percent per annum. The outstanding principal balance is due and payable on January 1, 2011. The Company intends to refinance this loan prior to its maturity date.

The Company financed \$1,250,000 through the Pennsylvania Industrial Development Authority (PIDA). The Company is required to make equal payments each month for 180 months starting February 1, 2006 with interest of two and three-quarter percent per annum.

An additional \$500,000 was financed through the Pennsylvania Department of Community and Economic Development Machinery and Equipment Loan Fund. The Company is required to make equal payments for 60 months starting May 1, 2006 with interest of two and three quarter percent per annum.

In April 1999, the Company entered into a loan agreement (the Agreement) with a governmental authority, the Philadelphia Authority for Industrial Development (the Authority or PAID), to finance future construction and growth projects of the Company. The Authority issued \$3,700,000 in tax-exempt variable rate demand and fixed rate revenue bonds to provide the funds to finance such growth projects pursuant to a trust indenture (the Trust Indenture). A portion of the Company's proceeds from the bonds was used to pay for bond issuance costs of

Edgar Filing: LANNETT CO INC - Form 10-Q

approximately \$170,000. The Trust Indenture requires that the Company repay the Authority loan through installment payments beginning in May 2003 and continuing through May 2014, the year the bonds mature. The bonds bear interest at the floating variable rate determined by the organization responsible for selling the bonds

Table of Contents

(the remarketing agent). The interest rate fluctuates on a weekly basis. The effective interest rate at September 30, 2010 and June 30, 2010 was 0.49% and 0.52%, respectively.

The Company has executed Security Agreements with Wells Fargo, PIDA and PIDC in which the Company has agreed to pledge substantially all of its assets to collateralize the amounts due.

The Company is the primary beneficiary to a variable interest entity (VIE) called Cody LCI Realty, LLC. See Note 16, Consolidation of Variable Interest Entity for additional description. The VIE owns land and a building which is being leased to Cody. A mortgage loan with First National Bank of Cody has been consolidated in the Company's financial statements, along with the related land and building. Principal and interest payments of \$14,782, at a fixed interest rate of 7.5%, are being made on a monthly basis through June 2026. The mortgage loan is collateralized by the land and building.

Long-term debt amounts due, for the twelve month periods ending September 30 are as follows:

Twelve Month Periods	Amounts Payable to Institutions
2011	\$ 4,826,601
2012	276,284
2013	288,522
2014	305,716
2015	163,608
Thereafter	1,800,843
	\$ 7,661,574

Note 10. Contingencies

In January 2010, the Company initiated an arbitration proceeding against Olive Healthcare (Olive) for damages arising out of Olive's delivery of defective soft-gel prenatal vitamin capsules. The Company seeks damages in excess of \$3.5 million. Olive has denied liability and filed a counterclaim in February 2010 for breach of contract.

In June 2008, the Company filed a declaratory judgment suit in the Federal District Court of Delaware (Civil Action No. 08-338 (JJF)) against KV Pharmaceuticals, DrugTech Corp. and Ther-Rx Corp (collectively, KV). The complaint sought declaratory judgment for non-infringement and invalidity of certain patents owned by KV. The complaint further sought declaratory judgment of anti-trust violations and federal and state unfair competition violations for actions taken by KV in securing and enforcing these patents. After the complaint was filed, KV countered with a motion for a Temporary Restraining Order (TRO) to prevent the Company from launching its Multivitamin with Mineral Capsules (MMCs), due to alleged patent and trademark infringement issues. The TRO was heard and, ultimately, resulted in a conclusion by the court that the Company's product label on the MMCs should be modified. KV also countered with claims of infringement by the Company of KV's patents seeking the Company's profits for sales of MMCs or other monetary relief, preliminary and permanent injunctive relief, attorney's fees and a finding of willful infringement. In March 2009, the Company and KV settled the litigation. In light of the withdrawal of KV's innovator

Edgar Filing: LANNETT CO INC - Form 10-Q

prenatal product due to FDA enforcement actions, and the resulting anticipated decline in sales and declining market for written prescription, the Company decided it was pointless to continue the litigation and entered into the settlement arrangement with KV. Pursuant to the settlement, the Company received a license from KV and became an authorized generic

Table of Contents

provider. During the terms of the license, the Company is to pay KV a royalty on all future sales of its Prenatal vitamin product. Lannett will cease offering its Prenatal vitamin product if and when the brand is restored to the marketplace. In May 2010, the Company filed an action for declaratory relief in the Delaware Superior Court against KV seeking a declaration that KV breached its obligations under a settlement agreement entered into with the Company (the Binding Agreement). In June 2010, KV filed a counterclaim to the complaint and asserted claims for breach of contract, declaratory judgment, negligent misrepresentation and fraud in connection with the Binding Agreement, alleging among other things that the Company has improperly withheld royalties from KV arising out of its sales of a pre-natal vitamin product. KV filed a motion for summary judgment, which the Company opposed. The Court has not yet held a hearing on the motion or ruled on it.

Note 11. Commitments

Leases

In June 2006, Lannett signed a lease agreement on a 66,000 square foot facility located on approximately seven acres in Philadelphia. The Company purchased this building in October 2009 for approximately \$3.8 million plus the cost of fit out of approximately \$2.0 million. A significant portion of the purchase price and fit out costs are expected to be financed through a series of loans with a bank and a Pennsylvania state run development agency. These loans can not be put in place until all construction has been completed and a proper certificate of occupancy has been obtained, due to a requirement by the state run development agency. Construction was substantially complete by June 30, 2010. A certificate of occupancy was obtained by September 2010. The financing is expected to be completed and funded by the second quarter of Fiscal 2011. This new facility is being used for certain administrative functions, warehouse space, shipping and possibly additional manufacturing space in the future.

Lannett's subsidiary, Cody leases a 73,000 square foot facility in Cody, Wyoming. This location houses Cody's manufacturing and production facilities. Cody leases the facility from Cody LCI Realty, LLC, a Wyoming limited liability company which is 50% owned by Lannett. See Note 16.

Rental and lease expense for the three months ended September 30, 2010 and 2009 was approximately \$22,000 and \$82,000, respectively.

Employment Agreements

The Company has entered into employment agreements with Arthur P. Bedrosian, President and Chief Executive Officer, Keith R. Ruck, Vice President of Finance and Chief Financial Officer, Kevin Smith, Vice President of Sales and Marketing, William Schreck, Senior Vice President and General Manager, Ernest Sabo, Vice President of Regulatory Affairs and Chief Compliance Officer, and Stephen Kovary, Vice President of Operations. Each of the agreements provide for an annual base salary and eligibility to receive a bonus. The bonus amounts of these executives are determined by the Board of Directors. Additionally, these executives are eligible to receive stock options and restricted stock awards, which are granted at the discretion of the Board of Directors, and in accordance with the Company's policies regarding stock option and restricted stock grants. Under the agreements, these executive employees may be terminated at any time with or without cause, or by reason of death or disability. In certain termination situations, the Company is liable to pay severance compensation to these executives of between 18 months and three years.

During the third quarter of Fiscal Year 2009, the Company's former Vice President of Finance, Treasurer, Secretary and Chief Financial Officer resigned. As part of his separation agreement, the Company is obligated to pay to him approximately \$670,000 to settle any outstanding obligations from his employment agreement, including any salary,

Table of Contents

bonus, vacation, stock options and medical benefits. Of this amount, \$300,440 was paid in Fiscal 2009 with \$165,000 designated for the payment of pro rated bonus, and \$11,440 was designated for the payment of accrued but unused paid time off. As part of the settlement, \$124,000 was designated as the portion of the settlement related to the repurchase of his outstanding stock options. The Company therefore charged this amount to Additional Paid in Capital, as it represents the fair value of the options repurchased on the repurchase date. Additional payments totaling approximately \$369,000 for severance and benefits were paid in the first quarter of Fiscal 2011 pursuant to the separation agreement.

Fiscal 2010 Bonus

The Company accrued approximately \$4,812,000 of incentive compensation costs at June 30, 2010, of which approximately \$3,421,000 was paid in cash during the first quarter of Fiscal 2011. The remaining \$1,391,000 is expected to be paid in unrestricted shares of Company stock, and which shares are expected to vest immediately upon grant. These shares will only be granted upon the timely approval by the FDA of Lannett's 505(b)(2) New Drug Application to manufacture and distribute its Morphine Sulfate Oral Solution product. The determination of the actual payment of this portion of the bonus is at the discretion of the CEO, dependent on the timing of the approval and the financial results of the Company dictated by the events surrounding the approval.

Note 12. Comprehensive (Loss) Income

The Company's other comprehensive (loss) income is comprised of unrealized gains (losses) on investment securities classified as available-for-sale as well as foreign currency translation adjustments. There is no other comprehensive income (loss) attributable to the noncontrolling interest. The components of comprehensive (loss) income and related taxes consisted of the following:

	For the Three Months Ended September 30,	
	2010	2009
Net (Loss) Income	\$ (394,122)	\$ 2,868,264
Foreign currency translation adjustments	13,655	
Unrealized holding loss on securities	(9,598)	(3,751)
Tax effect	3,839	1,500
Total Other Comprehensive Income (Loss)	7,896	(2,251)
Total Comprehensive (Loss) Income	\$ (386,226)	\$ 2,866,013

Table of Contents

Note 13. Employee Benefit Plan

The Company has a defined contribution 401k plan (the Plan) covering substantially all employees. Pursuant to the Plan provisions, the Company is required to make matching contributions equal to 50% of each employee's contribution, but not to exceed 4% of the employee's compensation for the Plan year. Contributions to the Plan during the three months ended September 30, 2010 and 2009 were \$140,000 and \$153,000, respectively.

Note 14. Employee Stock Purchase Plan

In February 2003, the Company's shareholders approved an Employee Stock Purchase Plan (ESPP). Employees eligible to participate in the ESPP may purchase shares of the Company's stock at 85% of the lower of the fair market value of the common stock on the first day of the calendar quarter, or the last day of the calendar quarter. Under the ESPP, employees can authorize the Company to withhold up to 10% of their compensation during any quarterly offering period, subject to certain limitations. The ESPP was implemented on April 1, 2003 and is qualified under Section 423 of the Internal Revenue Code. The Board of Directors authorized an aggregate total of 1,125,000 shares of the Company's common stock for issuance under the ESPP. As of September 30, 2010, 231,803 shares have been issued under the ESPP. Compensation expense of \$12,499 and \$21,440 relating to the ESPP was recognized for the three months ended September 30, 2010 and 2009, respectively.

Note 15. Income Taxes

The Company uses the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. Deferred tax expense/(benefit) is the result of changes in deferred tax assets and liabilities.

The provision for federal, state and local income taxes for the three months ended September 30, 2010 and 2009 was tax (benefit) expense of approximately \$(390,000) and \$1,828,000, respectively, with effective tax rates of 50% and 39%, respectively. The effective tax rate for the three months ended September 30, 2010 was higher compared to the three months ended September 30, 2009 due primarily to nondeductible incentive stock option compensation expenses relative to the expected pretax income for Fiscal 2011. The Company expects its overall effective tax rate will be approximately 48% to 50% for the full year ended June 30, 2011.

The Company may recognize the tax benefit from an uncertain tax position claimed on a tax return only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The authoritative standards issued by the FASB also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures.

As of September 30, 2010 and June 30, 2010, the Company reported total unrecognized tax benefits of \$399,034. As a result of the positions taken during the period, the Company has not recorded any interest and penalties for the period ended September 30, 2010 in the statement of

Edgar Filing: LANNETT CO INC - Form 10-Q

operations and no cumulative interest and penalties have been recorded either in the Company's statement of financial position as of September 30, 2010 and June 30, 2010. The Company will recognize interest accrued on unrecognized tax benefits in interest expense and any related penalties in operating expenses. The Company does not believe that the total unrecognized tax benefits will significantly increase or decrease in the next twelve months.

Table of Contents

The Company files income tax returns in the United States federal jurisdiction, Pennsylvania, New Jersey and California. The Company's tax returns for Fiscal 2006 and prior generally are no longer subject to review as such years generally are closed. The Company believes that an unfavorable resolution for open tax years would not be material to the financial position of the Company.

Note 16. Consolidation of Variable Interest Entity

Lannett consolidates any Variable Interest Entity (VIE) of which it is the primary beneficiary. The liabilities recognized as a result of consolidating a VIE do not represent additional claims on our general assets; rather, they represent claims against the specific assets of the consolidated VIE. Conversely, assets recognized as a result of consolidating a VIE do not represent additional assets that could be used to satisfy claims against our general assets. Reflected in the September 30, 2010 and June 30, 2010 balance sheets are consolidated VIE assets of approximately \$1.9 million and \$1.9 million, which are comprised mainly of land and building. VIE liabilities consist of a mortgage on that property in the amount of approximately \$1.6 and \$1.6 million at September 30, 2010 and June 30, 2010, respectively.

Cody LCI Realty LLC (Realty) is the only VIE that is consolidated. Realty had been consolidated by Cody prior to its acquisition by Lannett. Realty is a 50/50 joint venture with a former shareholder of Cody. Its purpose was to acquire the facility used by Cody. Until the acquisition of Cody in April 2007, Lannett had not consolidated the VIE because Cody Labs had been the primary beneficiary of the VIE. The risks associated with our interests in this VIE is limited to a decline in the value of the land and building as compared to the balance of the mortgage note on that property, up to Lannett's 50% share of the venture. Realty owns the land and building, and Cody leases the building and property from Realty for \$20,000 per month effective October 2009, when the lease increased from \$15,000 per month. All intercompany rent expense is eliminated upon consolidation with Cody. The Company is not involved in any other VIE.

Note 17. Related Party Transactions

The Company had sales of approximately \$177,000 and \$213,000 during the three months ended September 30, 2010 and 2009, respectively, to a generic distributor, Auburn Pharmaceutical Company (Auburn). Jeffrey Farber (the related party), who is a current board member and the son of the Chairman of the Board of Directors and principal shareholder of the Company, is the owner of Auburn. Accounts receivable includes amounts due from the related party of approximately \$164,000 and \$161,000 at September 30, 2010 and June 30, 2010, respectively. In the Company's opinion, the terms of these transactions were not more favorable to the related party than would have been to a non-related party.

In January 2005, Lannett Holdings, Inc. entered into an agreement in which the Company purchased for \$100,000 and future royalty payments the proprietary rights to manufacture and distribute a product for which Pharmeral, Inc. (Pharmeral) owned the ANDA. In Fiscal 2008, the Company obtained FDA approval to use the proprietary rights. Accordingly, the Company originally capitalized these rights as an indefinite lived intangible asset and tested this asset for impairment at least on an annual basis. During the fourth quarter of Fiscal 2009, it was determined that this intangible asset no longer has an indefinite life. No impairment existed because the estimated fair value exceeded the carrying amount on that date. Accordingly, the \$100,000 carrying amount of this intangible asset is being amortized on a straight line basis prospectively over its 10 year remaining estimated useful life.

Arthur Bedrosian, President and Chief Executive Officer, currently owns 100% of Pharmeral. This transaction was approved by the Board of Directors of the Company and in their opinion the terms were not more favorable to the related party than they would have been to a non-related

party. In May 2008, Mr. Bedrosian and Pharmeral waived their rights to any royalty payments on the sales of the drug by Lannett under Lannett's current ownership

Table of Contents

structure. Should Lannett undergo a change in control where a third party is involved, this royalty would be reinstated. The registered trademark OB-Natal® was transferred to Lannett for one dollar from Mr. Bedrosian.

Lannett Company, Inc. paid a management consultant who is related to Mr. Bedrosian \$37,100 in fees during the three months ended September 30, 2010 and \$21,420 in fees and \$ 4,533 in reimbursable expenses during the three months ended September 30 2009. This consultant provided management, construction planning, laboratory set up and administrative services in regards to the Company's initial set up of its Bio-study laboratory in a foreign country. It is expected that this consultant will continue to be utilized into Fiscal 2011. In the Company's opinion, the fee rates paid to this consultant and the expenses reimbursed to him were not more favorable than what would have been paid to a non-related party.

Note 18. Material Contract with Supplier

Jerome Stevens Pharmaceuticals agreement:

The Company's primary finished product inventory supplier is Jerome Stevens Pharmaceuticals, Inc. (JSP), in Bohemia, New York. Purchases of finished goods inventory from JSP accounted for approximately 56% and 67% of the Company's inventory purchases during the three months ended September 30, 2010 and 2009, respectively. On March 23, 2004, the Company entered into an agreement with JSP for the exclusive distribution rights in the United States to the current line of JSP products, in exchange for four million (4,000,000) shares of the Company's common stock. The JSP products covered under the agreement included Butalbital, Aspirin, Caffeine with Codeine Phosphate capsules, Digoxin tablets and Levothyroxine Sodium tablets, sold generically and under the brand name Unithroid®. The term of the agreement is ten years, beginning on March 23, 2004 and continuing through March 22, 2014. Both Lannett and JSP have the right to terminate the contract if one of the parties does not cure a material breach of the contract within thirty (30) days of notice from the non-breaching party.

During the term of the agreement, the Company is required to use commercially reasonable efforts to purchase minimum dollar quantities of JSP's products being distributed by the Company. The minimum quantity to be purchased in the first year of the agreement was \$15 million. Thereafter, the minimum quantity to be purchased increases by \$1 million per year up to \$24 million for the last year of the ten-year contract. The Company has met the minimum purchase requirement for the first six years of the contract, but there is no guarantee that the Company will be able to continue to do so in the future. If the Company does not meet the minimum purchase requirements, JSP's sole remedy is to terminate the agreement.

Under the agreement, JSP is entitled to nominate one person to serve on the Company's Board of Directors (the Board) provided, however, that the Board shall have the right to reasonably approve any such nominee in order to fulfill its fiduciary duty by ascertaining that such person is suitable for membership on the board of a publicly traded corporation. Suitability is determined by, but not limited to, the requirements of the Securities and Exchange Commission, the American Stock Exchange, and other applicable laws, including the Sarbanes-Oxley Act of 2002. As of September 30, 2010, JSP has not exercised the nomination provision of the agreement.

The Company's financial condition, as well as its liquidity resources, are very dependent on an uninterrupted supply of product from JSP. Should there be an interruption in the supply of product from JSP for any reason, this event would have a material impact to the financial condition of Lannett.

Table of Contents

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Introduction

The following information should be read in conjunction with the consolidated financial statements and notes in Part I, Item 1 of this Quarterly Report and with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2010.

This Report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements which are not historical facts made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not promises or guarantees and investors are cautioned that all forward-looking statements involve risks and uncertainties, including but not limited to the impact of competitive products and pricing, product demand and market acceptance, new product development, the regulatory environment, including without limitation, reliance on key strategic alliances, availability of raw materials, fluctuations in operating results and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission. These statements are based on management's current expectations and are naturally subject to uncertainty and changes in circumstances. We caution you not to place undue reliance upon any such forward-looking statements which speak only as of the date made. Lannett is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities at the date of our financial statements. Actual results may differ from these estimates under different assumptions or conditions.

Critical accounting policies are defined as those that are reflective of significant judgments and uncertainties, and potentially result in materially different results under different assumptions and conditions. We believe that our critical accounting policies include those described below.

Revenue Recognition The Company recognizes revenue when its products are shipped. At this point, title and risk of loss have transferred to the customer and provisions for rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable. Accruals for these provisions are presented in the consolidated financial statements as rebates, chargebacks and returns payable and as reductions to net sales. The change in the reserves for various sales adjustments may not be proportionally equal to the change in sales because of changes in both the product and the customer mix. Increased sales to wholesalers will generally require additional accruals as they are the primary recipient of chargebacks and rebates. Incentives offered to secure sales vary from product to product. Provisions for estimated rebates and promotional credits are estimated based upon contractual terms. Provisions for other customer credits, such as price adjustments, returns, and chargebacks, require management to make subjective judgments on customer mix. Unlike branded innovator drug companies, Lannett does not use information about product levels in distribution channels from third-party sources, such as IMS and Wolters

Edgar Filing: LANNETT CO INC - Form 10-Q

Kluwer, in estimating future returns and other credits. Lannett calculates a chargeback/rebate rate based on contractual terms with its customers and applies this rate to customer sales. The only variable is customer mix, and this assumption is based on historical data and sales expectations. The chargeback/rebate reserve is reviewed on a monthly basis by management using several ratios and calculated metrics. As we continue to obtain additional information about our historical experience for chargebacks, rebates and returns, we also update our estimates of the required reserves.

Table of Contents

Chargebacks The provision for chargebacks is the most significant and complex estimate used in the recognition of revenue. The Company sells its products directly to wholesale distributors, generic distributors, retail pharmacy chains, and mail-order pharmacies. The Company also sells its products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes, and group purchasing organizations, collectively referred to as indirect customers. Lannett enters into agreements with its indirect customers to establish pricing for certain products. The indirect customers then independently select a wholesaler from which to actually purchase the products at these agreed-upon prices. Lannett will provide credit to the wholesaler for the difference between the agreed-upon price with the indirect customer and the wholesaler's invoice price if the price sold to the indirect customer is lower than the direct price to the wholesaler. This credit is called a chargeback. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to the indirect customers and estimated wholesaler inventory levels. As sales by the Company to the large wholesale customers, such as Cardinal Health, AmerisourceBergen, and McKesson, increase, the reserve for chargebacks will also generally increase. However, the size of the increase depends on the expected mix of product sales to the indirect customers. The Company continually monitors the reserve for chargebacks and makes adjustments when management believes that expected chargebacks on actual sales may differ from the amounts that were assumed in the establishment of the chargeback reserves.

Rebates Rebates are offered to the Company's key chain drug store and wholesaler customers to promote customer loyalty and increase product sales. These rebate programs provide customers with rebate credits upon attainment of pre-established volumes or attainment of net sales milestones for a specified period. Other promotional programs are incentive programs offered to the customers. At the time of shipment, the Company estimates reserves for rebates and other promotional credit programs based on the specific terms in each agreement. The reserve for rebates increases as sales to rebate-eligible customers are recognized and decreases when actual rebate payments are made. However, since rebate programs are not identical for all customers, the size of the reserve will depend on the mix of sales to customers that are eligible to receive rebates.

Returns Consistent with industry practice, the Company has a product returns policy that allows certain customers to return product within a specified period prior to and subsequent to the product's lot expiration date in exchange for a credit to be applied to future purchases. The Company's policy requires that the customer obtain pre-approval from the Company for any qualifying return. The Company estimates its provision for returns based on historical experience, adjusted for any changes in business practices or conditions that would cause management to believe that future product returns may differ from those returns assumed in the establishment of reserves. Generally, the reserve for returns increases as sales increase and decrease when credits are issued or payments are made for actual returns received. The reserve for returns is included in the rebates, chargebacks and returns payable account on the balance sheet.

Other Adjustments Other adjustments consist primarily of price adjustments, also known as shelf stock adjustments, which are credits issued to reflect decreases in the selling prices of the Company's products that customers have remaining in their inventories at the time of a price reduction. Decreases in selling prices are discretionary decisions made by management to reflect competitive market conditions. Amounts recorded for estimated shelf stock adjustments are based upon specified terms with direct customers, estimated declines in market prices, and estimates of inventory held by customers. The Company regularly monitors these and other factors and evaluates the reserve as additional information becomes available. Other adjustments are included in the rebates, chargebacks and returns payable account on the balance sheet. When competitors enter the market for existing products, shelf stock adjustments may be issued to maintain price competitiveness.

The following tables identify the reserves for each major category of revenue allowance and a summary of the activity for the nine months ended September 30, 2010 and 2009:

Table of Contents**For the three months ended September 30, 2010**

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2010	\$ 6,282,127	\$ 3,566,031	\$ 5,401,254	\$	\$ 15,249,412
Actual credits issued related to sales recorded in prior fiscal years	(6,112,838)	(2,558,582)	(1,151,174)		(9,822,594)
Reserves or (reversals) charged during Fiscal 2011 related to sales in prior fiscal years					
Reserves charged to net sales during Fiscal 2011 related to sales recorded in Fiscal 2011	11,960,878	3,776,169	2,987,308	1,663,371	20,387,726
Actual credits issued related to sales recorded in Fiscal 2011	(7,056,592)	(2,347,273)	(1,387,700)	(1,663,371)	(12,454,936)
Reserve Balance as of September 30, 2010	\$ 5,073,575	\$ 2,436,345	\$ 5,849,688	\$	\$ 13,359,608

For the three months ended September 30, 2009

Reserve Category	Chargebacks	Rebates	Returns	Other	Total
Reserve Balance as of June 30, 2009	\$ 6,089,802	\$ 2,537,746	\$ 5,106,992	\$	\$ 13,734,540
Actual credits issued related to sales recorded in prior fiscal years	(4,767,581)	(1,852,708)	(1,147,720)		(7,768,009)
Reserves or (reversals) charged during Fiscal 2010 related to sales in prior fiscal years					
Reserves charged to net sales during Fiscal 2010 related to sales recorded in Fiscal 2010	10,272,936	4,066,855	1,140,128	407,784	15,887,703
Actual credits issued related to sales recorded in Fiscal 2010	(7,000,389)	(1,789,955)		(407,784)	(9,198,128)
Reserve Balance as of September 30, 2009	\$ 4,594,768	\$ 2,961,938	\$ 5,099,400	\$	\$ 12,656,106

The total reserve for chargebacks, rebates, returns and other adjustments decreased from \$15,249,412 at June 30, 2010 to \$13,359,608 at September 30, 2010. The decrease in total reserves is due to a decrease in the rebates reserve as a result of a decrease in overall sales, and a decrease in chargeback reserves due primarily to a decrease in inventory levels at wholesaler distribution centers.

Credits issued during the quarter that relate to prior year sales are charged against the opening balance. In aggregate, additional reserves or reversals of reserves have historically offset each other. The table above shows the effects of reversals within the rebates, returns and other categories. It is the Company's intention that all reserves be charged to sales in the period that the sale is recognized, however, due to the nature of this estimate, it is possible that the Company may sometimes need to increase or decrease the reserve based on prior period sales. If that were to occur, management would disclose that information at that time. If the historical data the Company uses and the assumptions management makes to calculate its estimates of future returns, chargebacks, and other credits do not accurately approximate future activity, its net sales, gross profit, net income and earnings per share could change. However, management believes that these estimates are reasonable based upon historical experience and current conditions.

The rates of reserves will vary, as well as the category under which the credit falls. This variability comes about when the Company is working with indirect customers to compete with the pricing of other generic companies. The Company has improved its computer systems in order to improve the accuracy of tracking and processing chargebacks and rebates and will continue to look at ways for further improvements.

Improvements to automate

Table of Contents

calculation of reserves will not only reduce the potential for human error, but also will result in more in-depth analysis and improved customer interaction for resolution of open credits.

The rate of credits issued is monitored by the Company at least on a quarterly basis. The Company may change the estimate of future reserves based on the amount of credits processed, or the rate of sales made to indirect customers. The decrease of reserves to \$13,359,608 at September 30, 2010 from \$15,249,412 at June 30, 2010 is due to the timing of credits being processed by the customers and by the Company. Approximately \$9,823,000 or 64% of the reserve balance from June 30, 2010 has been processed through the first three months of Fiscal 2011. Management estimates reserves based on sales mix. A comparison to wholesaler inventory reports is performed quarterly, in order to justify the balance of unclaimed chargebacks and rebates. The Company has historically found a direct correlation between the calculation of the reserve based on sales mix, and the wholesaler inventory analysis.

Accounts Receivable The Company performs ongoing credit evaluations of its customers and adjusts credit limits based upon payment history and the customer's current credit worthiness, as determined by a review of current credit information. The Company continuously monitors collections and payments from its customers and maintains a provision for estimated credit losses based upon historical experience and any specific customer collection issues that have been identified. While such credit losses have historically been within both the Company's expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same credit loss rates that it has in the past.

The Company also regularly monitors accounts receivable (AR) balances by reviewing both net and gross days sales outstanding (DSO). Net DSO is calculated by dividing gross accounts receivable less the reserve for rebates and chargebacks by the average daily net sales for the period. Gross DSO shows the result of the same calculation without regard to rebates and chargebacks.

The Company monitors both net DSO and gross DSO as an overall check on collections and to assess the reasonableness of the reserves. Gross DSO provides management with an understanding of the frequency of customer payments, and the ability to process customer payments and deductions. The net DSO calculation provides management with an understanding of the relationship of the AR balance net of the reserve liability compared to net sales after charges to the reserves during the period. Standard payment terms offered to customers are consistent with industry practice at 60 days. Net DSO eliminates the effect of timing of processing, which is inherent in the gross DSO calculation.

The following table shows the results of these calculations as of the relevant periods:

	9/30/10	6/30/10	9/30/09
Net DSO (in days)	86	77	68
Gross DSO (in days)	63	69	62

The level of net DSO at September 30, 2010 is higher than the Company's expectation that DSO will be in the 60 to 70 day range based on 60 day payment terms for most customers. The increase is due to a higher percentage of sales being shipped at the end of the quarter.

Inventories The Company values its inventory at the lower of cost (determined by the first-in, first-out method) or market, regularly reviews inventory quantities on hand, and records a provision for excess and obsolete inventory based primarily on estimated forecasts of product demand and production requirements. The Company's estimates of future product demand may prove to be inaccurate, in which case it may have

Table of Contents

understated or overstated the provision required for excess and obsolete inventory. In the future, if the Company's inventory is determined to be overvalued, the Company would be required to recognize such costs in cost of goods sold at the time of such determination. Likewise, if inventory is determined to be undervalued, the Company may have recognized excess cost of goods sold in previous periods and would be required to recognize such additional operating income at the time of sale.

Consolidation of Variable Interest Entity The Company consolidates any Variable Interest Entity (VIE) of which we are the primary beneficiary. The liabilities recognized as a result of consolidating a VIE do not represent additional claims on our general assets; rather, they represent claims against the specific assets of the consolidated VIE. Conversely, assets recognized as a result of consolidating a VIE do not represent additional assets that could be used to satisfy claims against our general assets. Reflected in the September 30, 2010 and June 30, 2010 balance sheets are consolidated VIE assets of approximately \$1.9 million and \$1.9 million, respectively, which is comprised mainly of land and a building. VIE liabilities consist of a mortgage on that property in the amount of approximately \$1.6 and \$1.6 million at September 30, 2010 and June 30, 2010, respectively. This VIE was initially consolidated by Cody, as Cody has been the primary beneficiary. Cody has then been consolidated within Lannett's financial statements since its acquisition in April 2007.

Results of Operations - Three months ended September 30, 2010 compared with three months ended September 30, 2009

Net sales for the three months ended September 30, 2010 (Fiscal 2011) decreased 19% to \$25,396,000 from \$31,435,000 for the three months ended September 30, 2009 (Fiscal 2010). The following factors contributed to the \$6,039,000 decrease in sales:

Medical indication	Sales volume change %	Sales price change %
Heart Failure	-30%	-4%
Antibiotics	-22%	7%
Prescription Vitamins	-64%	60%
Epilepsy	16%	-27%
Thyroid Deficiency	-1%	-19%
Pain Management	-21%	-5%
Migraine Headache	4%	-8%

Sales of drugs used in the treatment of thyroid deficiency decreased by approximately \$2,688,000 primarily as a result of a competitive price reduction in order to retain one of our major customers. Included in this amount is a one-time shelf stock adjustment totaling approximately \$1,262,000. The overall decrease in sales was also affected by a decrease in sales of drugs for the treatment of congestive heart failure by approximately \$1,623,000 for the three months ended September 30, 2010 compared to September 30, 2009 mainly due to a decrease in the volume of bottles shipped, as well as a result of a competitive price reduction in order to retain one of our major customers. Included in this amount is a one-time shelf stock adjustment totaling approximately \$154,000. Sales of drugs used for pain management decreased by approximately \$980,000 for the three months ended September 30, 2010 compared to September 30, 2009. This decrease is primarily the result of \$2,800,000 of lost revenues as a result of the FDA's action to force Lannett and all but one competitor to cease manufacturing and/or distributing Morphine Sulfate Oral Solution effective July 24, 2010. Partially offsetting the lost Morphine Sulfate Oral Solution revenues were an increase in demand for other pain management products including Hydromorphone and Oxycodone which increased \$1,199,000 and \$666,000, respectively for the three months ended September 30, 2010 compared to September 30, 2009. Net sales of our prescription vitamins also decreased by approximately \$620,000 due to a lack of selling activities by the branded drug company.

Table of Contents

The Company sells its products to customers in various categories. The table below identifies the Company's approximate net sales to each category for the three months ended September 30, 2010 and 2009:

Customer Category	Three Months Ended September 30,	
	2010	2009
Wholesaler/ Distributor	\$ 12,717,000	\$ 15,169,000
Retail Chain	11,724,000	14,732,000
Mail-Order Pharmacy	955,000	1,534,000
Total	\$ 25,396,000	\$ 31,435,000

The sales to wholesaler/distributor decreased primarily as a result of the FDA's action to force all but one competitor to cease manufacturing and/or distributing Morphine Sulfate Oral Solution effective July 24, 2010 as discussed above. The sales to retail chains decreased primarily as a result of the competitive price reductions on two products in order to retain one of our major customers as discussed above.

Cost of sales for the first quarter decreased 2% to \$19,492,000 in Fiscal 2011 from \$19,901,000 in Fiscal 2010. The decrease reflected the impact of the 19% decrease in sales. The decrease in cost of sales was less than the decrease in sales due to a change in the mix of products sold.

Amortization expense primarily relates to the JSP Distribution Agreement. For the remaining term of the JSP Distribution Agreement, the Company will incur annual amortization expense of approximately \$1,785,000.

Gross profit margins for the first quarter of Fiscal 2011 and Fiscal 2010 were 23% and 37%, respectively. Gross profit percentage decreased due to the overall decline in sales described above and due to product mix. While the Company is continuously striving to keep product costs low, there can be no guarantee that profit margins will not fluctuate in future periods. Pricing pressure from competitors and costs of producing or purchasing new drugs may also fluctuate in the future. Changes in the future sales product mix may also occur. These changes may affect the gross profit percentage in future periods.

Research and development (R&D) expenses in the first quarter decreased 33% to \$2,042,000 for Fiscal 2011 from \$3,028,000 for Fiscal 2010. The decrease is primarily due to the timing of milestone achievements for costs of products in development and completed phases for several biostudies. The Company expenses all production costs as R&D until the drug is approved by the FDA. R&D expenses may fluctuate from period to period, based on R&D plans for submission to the FDA.

Selling, general and administrative expenses in the first quarter increased 22% to \$4,601,000 in Fiscal 2011 from \$3,763,000 in Fiscal 2010. The increase is primarily due to increased legal costs related to the litigation with the FDA regarding the status of Grandfathered products, including our Morphine Sulfate Oral solution. While the Company is focused on controlling costs, increases in personnel costs may have an ongoing and longer lasting impact on the administrative cost structure. Other costs are being incurred to facilitate improvements in the Company's infrastructure. These costs are expected to be temporary investments in the future of the Company and may not continue at the same level.

Edgar Filing: LANNETT CO INC - Form 10-Q

Interest expense was flat with \$71,000 recorded in the first quarter of Fiscal 2011 compared to \$70,000 in Fiscal 2010. Interest income in the first quarter decreased to \$11,000 in Fiscal 2011 from \$23,000 in Fiscal 2010 due to lower interest earned on smaller investment securities balances.

Table of Contents

The Company recorded an income tax benefit in the first quarter of 2011 of \$390,000 compared to income tax expense of \$1,828,000 in the first quarter of Fiscal 2010. The effective tax rate for the three months ended September 30, 2010 was 50%, compared to 39% for the three months ended September 30, 2009. The effective tax rate for the three months ended September 30, 2010 was higher compared to the three months ended September 30, 2009 due primarily to nondeductible incentive stock option compensation expenses relative to the expected pretax income for Fiscal 2011. The Company expects its overall effective tax rate will be approximately 48% to 50% for the full year ended June 30, 2011.

The Company reported a net loss attributable to Lannett of approximately \$404,000 in the first quarter of Fiscal 2011, or \$0.02 basic and diluted loss per share, as compared to net income attributable to Lannett of approximately \$2,857,000 in the first quarter Fiscal 2010, or \$0.12 basic and \$0.11 diluted earnings per share.

Liquidity and Capital Resources

The Company has historically financed its operations with cash flow generated from operations, supplemented with borrowings from various government agencies and financial institutions. At September 30, 2010, working capital was \$38,931,430, as compared to \$40,104,705 at June 30, 2010, a decrease of \$1,173,275.

Net cash used in operating activities of \$2,127,000 in the first three months of Fiscal 2011 reflected a net loss of \$394,000, after adjusting for non-cash items of \$1,935,000, as well as cash used by changes in operating assets and liabilities of \$3,668,000. Significant changes in operating assets and liabilities are comprised of:

- A decrease in trade accounts receivable of \$7,135,000 primarily as a result of decreased sales in the first quarter of Fiscal 2011.
- An increase in inventories of \$1,980,000 primarily due to returned Morphine Sulfate Oral Solution product as a result of the FDA's action to force all but one competitor to cease manufacturing and/or distributing this product effective July 24, 2010.
- An increase in prepaid taxes of \$498,000 from an income taxes payable balance of \$1,480,000 due to estimated tax payments made in September 2010 related to Fiscal 2010.
- A decrease in accounts payable of \$517,000 due to the timing of payments at the end of the month.
- A decrease in accrued expenses of \$965,000 primarily due to the timing of biostudy and product development milestone achievements.
- A decrease in rebates, chargebacks and returns payable of \$1,890,000 primarily due to a decrease in the rebates reserve as a result of a decrease in overall sales, and a decrease in chargeback reserves due primarily to a decrease in inventory levels at wholesaler distribution centers.
- A decrease in accrued payroll and payroll related costs of \$3,818,000 primarily related to the payment in the first quarter of Fiscal 2011 of the Fiscal 2010 accrued incentive compensation costs totaling approximately \$3,421,000.

Edgar Filing: LANNETT CO INC - Form 10-Q

Net cash used in investing activities of \$2,068,000 for the three months ended September 30, 2010 is mainly the result of purchases of property, plant and equipment of \$2,463,000, partially offset by proceeds of \$395,000 from the sale of available for sale investment securities.

Net cash used in financing activities of \$89,000 for the three months ended September 30, 2010 was primarily due to the purchase of shares of treasury stock totaling \$85,000 partially offset by proceeds from the issuance of stock of \$54,000. The Company also made scheduled debt repayments of \$58,000.

Table of Contents

Long-term debt amounts due, for the twelve month periods ended September 30 are as follows:

Twelve Month Periods	Amounts Payable to Institutions
2011	\$ 4,826,601
2012	276,284
2013	288,522
2014	305,716
2015	163,608
Thereafter	1,800,843
	\$ 7,661,574

The Company has a \$3,000,000 line of credit from Wells Fargo, N.A. (Wells Fargo) that bears interest at the prime interest rate less 0.25% (3.00% at September 30, 2010 and June 30, 2010, respectively). As of September 30, 2010 and June 30, 2010, the Company has \$3,000,000 of availability under this line of credit. The line of credit is collateralized by substantially all of the Company's assets. The agreement contains covenants with respect to working capital, net worth and certain ratios, as well as other covenants. As of September 30, 2010, the Company was not in compliance with all financial covenants under the agreement, but received a waiver from its lending institution with respect to the failed covenant as of September 30, 2010. The noncompliance was caused by the direct use of cash to purchase and fit out Lannett's third facility during the December 2009, March 2010 and June 2010 quarters over a period where the Company experienced reduced earnings caused by the DEA withholding production quota for Morphine Sulfate Oral Solution and the FDA actions barring Lannett from shipping Morphine Sulfate Oral Solution. As a result of the expected refinancing of the \$4.5 million PIDC Regional Center, LP III loan which is due on January 1, 2011, the Company will consider renegotiation of its current covenant requirements.

The existing line of credit, which was scheduled to expire on November 30, 2010, was renewed and extended during the first quarter of Fiscal 2011 to November 30, 2011. As part of the renewal agreement last fiscal year, the Company is no longer required to maintain any minimum deposit balances with Wells Fargo, and the availability fee on the unused balance of the line of credit was reduced to 0.375%.

In December 2005, the Company borrowed \$4,500,000 through the Philadelphia Industrial Development Corporation (PIDC). The Company pays a bi-annual interest payment at a rate equal to two and one-half percent per annum. The outstanding principal balance is due and payable on January 1, 2011. The Company intends to refinance this loan prior to its maturity date.

The Company borrowed \$1,250,000 through the Pennsylvania Industrial Development Authority (PIDA). The Company is required to make equal payments each month for 180 months starting February 1, 2006 with interest of two and three-quarter percent per annum. The PIDA Loan has \$914,726 outstanding as of September 30, 2010 with \$77,600 currently due.

The Company borrowed \$500,000 from the Pennsylvania Department of Community and Economic Development Machinery and Equipment Loan Fund. The Company is required to make equal payments for 60 months starting May 1, 2006 with interest of two and three quarter percent per annum. As of September 30, 2010, \$61,923 is outstanding and currently due.

Table of Contents

In April 1999, the Company entered into a loan agreement with the Philadelphia Authority for Industrial Development (the Authority or PAID), to finance future construction and growth projects of the Company. The Authority issued \$3,700,000 in tax-exempt variable rate demand and fixed rate revenue bonds to provide the funds to finance such growth projects pursuant to a trust indenture (the Trust Indenture). A portion of the Company's proceeds from the bonds was used to pay for bond issuance costs of approximately \$170,000. The Trust Indenture requires that the Company repay the Authority loan through installment payments beginning in May 2003 and continuing through May 2014, the year the bonds mature. The bonds bear interest at the floating variable rate determined by the organization responsible for selling the bonds (the remarketing agent). The interest rate fluctuates on a weekly basis. The effective interest rate at September 30, 2010 was 0.49%. At September 30, 2010, the Company has \$555,000 outstanding on the Authority loan, of which \$130,000 is classified as currently due. The remainder is classified as a long-term liability. In April 1999, an irrevocable letter of credit of \$3,770,000 was issued by Wells Fargo to secure payment of the Authority Loan and a portion of the related accrued interest. At September 30, 2010, no portion of the letter of credit has been utilized.

The Company has executed Security Agreements with Wells Fargo, PIDA and PIDC in which the Company has pledged substantially all of its assets to collateralize the amounts due.

The Company consolidates Cody LCI Realty, LLC, a variable interest entity (VIE), for which Cody Labs is the primary beneficiary. See note 16 to our Consolidated Financial Statements for Consolidation of Variable Interest Entities. A mortgage loan with First National Bank of Cody related to the purchase of land and building by the VIE has also been consolidated in the Company's consolidated balance sheets. The mortgage requires monthly principal and interest payments of \$14,782, at a fixed rate of 7.5%, to be made through June 2026. As of September 30, 2010, \$1,629,925 is outstanding under the mortgage loan, of which \$57,078 is classified as currently due. The mortgage is collateralized by the land and building.

In July 2004, the Company received \$500,000 of grant funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development. The grant funding program requires the Company to use the funds for machinery and equipment located at their Pennsylvania locations, hire an additional 100 full-time employees by June 30, 2006, operate its Pennsylvania locations a minimum of five years and meet certain matching investment requirements. If the Company fails to comply with any of the requirements above, the Company would be liable to repay the full amount of the grant funding (\$500,000). The Company has recorded the unearned grant funds as a liability until the Company complies with all of the requirements of the grant funding program. As of September 30, 2010, the Company has had preliminary discussions with the Commonwealth of Pennsylvania to determine whether it will be required to repay any of the funds provided under the grant funding program. Based on information available at September 30, 2010, the Company has recorded the grant funding as a long-term liability under the caption of Unearned Grant Funds.

Prospects for the Future

Generic pharmaceutical manufacturers and distributors are constantly faced by pricing pressure in the marketplace as competitors attempt to lure business from distributors, wholesalers and chain retailers by offering lower prices than the incumbent supplier. Lannett tries to differentiate itself in the marketplace by complementing its lower cost offerings with higher levels of customer service and quality of the products. But as Lannett enters Fiscal Year 2011, there is an increasing number of competitors on our key products that are attempting to supplant Lannett as the preferred vendor. Lannett will continue to evaluate each event as it arises, but any reductions in either volumes or pricing will have a negative impact on the gross profit margins of the Company.

Edgar Filing: LANNETT CO INC - Form 10-Q

During the First Quarter of Fiscal 2011, Lannett faced significant pricing challenges on its top two selling products. In order to keep the volume of business with the specific customer involved, Lannett chose to reduce

Table of Contents

its selling price on both of the products. This price reduction will have a significant impact to the gross profit margins and profitability of Lannett expected in the future.

The Company has several generic products under development. These products are all orally-administered, topical and parenteral products designed to be generic equivalents to brand named innovator drugs. The Company's developmental drug products are intended to treat a diverse range of indications. As one of the oldest generic drug manufacturers in the country, formed in 1942, Lannett currently owns several ANDAs for products which it does not manufacture and market. These ANDAs are dormant on the Company's records. Occasionally, the Company reviews such ANDAs to determine if the market potential for any of these older drugs has recently changed, so as to make it attractive for Lannett to reconsider manufacturing and selling it. If the Company makes the determination to introduce one of these products into the consumer marketplace, it must review the ANDA and related documentation to ensure that the approved product specifications, formulation and other factors meet current FDA requirements for the marketing of that drug. The Company would then redevelop the product and submit it to the FDA for supplemental approval. The FDA's approval process for ANDA supplements is similar to that of a new ANDA. Generally, in these situations, the Company must file a supplement to the FDA for the applicable ANDA, informing the FDA of any significant changes in the manufacturing process, the formulation, or the raw material supplier of the previously-approved ANDA. Recently, the FDA has announced that it will prioritize its review of 3,800 Chemistry Manufacturing and Control (CMC) supplements in order to make progress on reviewing a backlog of over 2,200 ANDAs. This could negatively impact the sales of existing products.

The products under development are at various stages in the development cycle—formulation, scale-up, and/or clinical testing. Depending on the complexity of the active ingredient's chemical characteristics, the cost of the raw material, the FDA-mandated requirement of bioequivalence studies, the cost of such studies and other developmental factors, the cost to develop a new generic product varies and can range from \$100,000 to \$1.7 million. Some of Lannett's developmental products will require bioequivalence studies, while others will not—depending on the FDA's Orange Book classification. Since the Company has no control over the FDA review process, management is unable to anticipate whether or when it will be able to begin producing and shipping additional products.

The Company views its April 2007 acquisition of Cody Laboratories, Inc. (Cody Labs or Cody) as an important step in becoming a vertically integrated narcotics manufacturer and distributor by allowing it to concentrate on developing and completing its dosage form manufacturing in order to reduce narcotic API costs. In July 2008, the DEA granted Cody Labs a license to directly import raw poppy straw for conversion into API and/or various pharmaceutical products. Only six other companies in the U.S. have been granted this license to date. This license allows the Company to avoid increased costs associated with buying narcotic API from other manufacturers. The Company anticipates that it can use this license to become a vertically integrated manufacturer of narcotic products, as well as a supplier of API to the pharmaceutical industry. The Company believes that the aging domestic population may result in a higher demand for pain management pharmaceutical products and that it will be well-positioned to take advantage of this increased demand.

Cody Labs' manufacturing expertise in narcotic APIs will allow Lannett to build a market with limited domestic competition. The Company anticipates that the demand for narcotics and controlled drugs will continue to grow with the Baby Boomer generation demographics and that it is well-positioned to take advantage of these opportunities by concentrating additional resources in the narcotic area. The sale of pain management products approximated 11% of Net Sales for the full year Fiscal 2010. Additionally, the API and dosage form production of these products were performed at our Cody Labs operations and, due to the increased volumes of sales on these products, allowed Cody to be profitable for the entire 2010 fiscal year. Due to the FDA's actions against Morphine Sulfate Oral Solution and a slow down in the demand for one other product that is manufactured at Cody, Lannett expects a decrease in the percentage of sales related to pain management products in the short term. At the time

Table of Contents

the FDA approves the Company's current 505(b)(2) New Drug Application for Morphine Sulfate Oral Solution, the Company expects the portion of net sales related to pain management products to increase again.

In addition to the efforts of its internal product development group, Lannett has contracted with several outside firms for the formulation and development of several new generic drug products. These outsourced R&D products are at various stages in the development cycle formulation, analytical method development and testing and manufacturing scale-up. These products are orally-administered solid dosage products, topical or parenterals intended to treat a diverse range of medical indications. We intend to ultimately transfer the formulation technology and manufacturing process for all of these R&D products to our own commercial manufacturing sites. The Company initiated these outsourced R&D efforts to complement the progress of its own internal R&D efforts.

Occasionally, the Company will work on developing a drug product that does not require FDA approval. Certain prescription drugs do not require prior FDA approval before marketing. They include, for instance, drugs listed as DESI drugs (Drug Efficacy Study Implementation) which are under evaluation by FDA, Grandfathered Drugs, and prescription multivitamin drugs. A generic manufacturer may sell products which are chemically equivalent to innovator drugs, under FDA rules by simply performing and internally documenting the normal research and development involved in bringing a new product to market. Under this scenario, a generic company can forego the time required for FDA approval.

More specifically, certain products, marketed prior to the Federal Food, Drug and Cosmetic Act may be considered GRASE (Generally Recognized As Safe and Effective) or Grandfathered. GRASE products are those old drugs that do not require prior approval from FDA in order to be marketed because they are generally recognized as safe and effective based on published scientific literature. Similarly, Grandfathered products are those which entered the market before the passage of the 1938 act or the 1962 amendments to the act. Under the grandfather clause, such a product is exempted from the effectiveness requirements [of the act] if its composition and labeling have not changed since 1962 and if, on the day before the 1962 amendments became effective, it was (1) used or sold commercially in the United States, (2) not a new drug as defined by the act at that time, and (3) not covered by an effective application. Recently, the FDA has increased its efforts to force companies to file and seek FDA approval for these GRASE products. Efforts have included granting market exclusivity to approved GRASE products and issuing notices to companies currently producing these products.

The Company has entered supply and development agreements with certain international companies, including Wintac of India, Orion Pharma of Finland, Azad Pharma AG and Swiss Caps of Switzerland, Pharma 2B (formerly Pharmaseed) of Israel and the GC Group, as well as certain domestic companies, including Jerome Stevens, Banner Pharmacaps, Cerovene, Summit Bioscience LLC and Inverness. The Company is currently in negotiations on similar agreements with other international companies, through which Lannett will market and distribute products manufactured by Lannett or by third parties. Lannett intends to use its strong customer relationships to build its market share for such products, and increase future revenues and income.

The majority of the Company's R&D projects are being developed in-house under Lannett's direct supervision and with Company personnel. Hence, the Company does not believe that its outside contracts for product development and manufacturing supply are material in nature, nor is the Company substantially dependent on the services rendered by such outside firms.

Lannett may increase its focus on certain specialty markets in the generic pharmaceutical industry. Such a focus is intended to provide Lannett customers with increased product alternatives in categories with relatively few market participants. While there is no guarantee that Lannett has the market expertise or financial resources necessary to succeed in such a market specialty, management is confident that such future focus will be well received by Lannett customers and increase shareholder value in the long run.

Table of Contents

The Company plans to enhance relationships with strategic business partners, including providers of product development research, raw materials, active pharmaceutical ingredients as well as finished goods. Management believes that mutually beneficial strategic relationships in such areas, including potential financing arrangements, partnerships, joint ventures or acquisitions, could allow for potential competitive advantages in the generic pharmaceutical market. The Company plans to continue to explore such areas for potential opportunities to enhance shareholder value.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company has debt instruments with variable interest rates. The Company has a \$3,000,000 line of credit from Wells Fargo, N.A. that bears interest at the prime interest rate less 0.25% (3.00% at September 30, 2010 and June 30, 2010, respectively). As of September 30, 2010 and June 30, 2010, the Company has \$3,000,000 of availability under this line of credit. The line of credit is collateralized by substantially all of the Company's assets. The agreement contains covenants with respect to working capital, net worth and certain ratios, as well as other covenants. The existing line of credit which was to expire on November 30, 2010, was renewed and extended to November 30, 2011.

The Company invests in U.S. government agency securities and corporate bonds which are exposed to interest rate fluctuations. The interest earned on these investments may vary based on fluctuations in the interest rate.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Form 10-Q, management performed, with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Based upon the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of the end of the period covered by this report.

Change in Internal Control Over Financial Reporting

There has been no change in the Company's internal control over financial reporting during the three months ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In January 2010, the Company initiated an arbitration proceeding against Olive Healthcare (Olive) for damages arising out of Olive's delivery of defective soft-gel prenatal vitamin capsules. The Company seeks damages in excess of \$3.5 million. Olive has denied liability and filed a counterclaim in February 2010 for breach of contract.

In June 2008, the Company filed a declaratory judgment suit in the Federal District Court of Delaware (Civil Action No. 08-338 (JJF)) against KV Pharmaceuticals, DrugTech Corp. and Ther-Rx Corp (collectively, KV). The complaint sought declaratory judgment for non-infringement and invalidity of certain patents owned by KV. The complaint further sought declaratory judgment of anti-trust violations and federal and state unfair competition violations for actions taken by KV in securing and enforcing these patents. After the complaint was filed, KV countered with a motion for a Temporary Restraining Order (TRO) to prevent the Company from launching its Multivitamin with Mineral Capsules (MMCs), due to alleged patent and trademark infringement issues. The TRO was heard and, ultimately, resulted in a conclusion by the court that the Company's product label on the MMCs should be modified. KV also countered with claims of infringement by the Company of KV's patents seeking the Company's profits for sales of MMCs or other monetary relief, preliminary and permanent injunctive relief, attorney's fees and a finding of willful infringement. In March 2009, the Company and KV settled the litigation. In light of the withdrawal of KV's innovator prenatal product due to FDA enforcement actions, and the resulting anticipated decline in sales and declining market for written prescription, the Company decided it was pointless to continue the litigation and entered into the settlement arrangement with KV. Pursuant to the settlement, the Company received a license from KV and became an authorized generic provider. During the terms of the license, the Company is to pay KV a royalty on all future sales of its Prenatal vitamin product. Lannett will cease offering its Prenatal vitamin product if and when the brand is restored to the marketplace. In May 2010, the Company filed an action for declaratory relief in the Delaware Superior Court against KV seeking a declaration that KV breached its obligations under a settlement agreement entered into with the Company (the Binding Agreement). In June 2010, KV filed a counterclaim to the complaint and asserted claims for breach of contract, declaratory judgment, negligent misrepresentation and fraud in connection with the Binding Agreement, alleging among other things that the Company has improperly withheld royalties from KV arising out of its sales of a pre-natal vitamin product. KV filed a motion for summary judgment, which the Company opposed. The Court has not yet held a hearing on the motion or ruled on it.

Regulatory Proceedings

The Company is engaged in an industry which is subject to considerable government regulation relating to the development, manufacturing and marketing of pharmaceutical products. Accordingly, incidental to its business, the Company periodically responds to inquiries or engages in administrative and judicial proceedings involving regulatory authorities, particularly the FDA and the Drug Enforcement Agency.

Table of Contents

ITEM 1A. RISK FACTORS

We materially rely on an uninterrupted supply of finished products from Jerome Stevens Pharmaceutical (JSP) for a majority of our sales. If we were to experience an interruption of that supply, our operating results would suffer.

Approximately 69% of our fiscal year 2010 sales are of distributed products, primarily manufactured by JSP. Two of these products are Levothyroxine Sodium (Levo) and Digoxin, which accounted for 41% and 17%, respectively, of our Fiscal 2010 net sales, and 40% and 22%, respectively, of our net sales for Fiscal 2009. Sales of Levo and Digoxin accounted for 40% and 13%, respectively, of our net sales for the three months ended September 30, 2010, and 41% and 15%, respectively, of our net sales for the three months ended September 30, 2009. If the supply of these products is interrupted in any way by any form of temporary or permanent business interruption to JSP, including but not limited to fire or other naturally-occurring, damaging event to their physical plant and/or equipment, breakdown and/or delayed replacement or installation of production equipment, condemnation of their facility, legislative or regulatory cease and desist declaration regarding their operations, and any interruption in their source of API for their products, our operating results could be materially adversely affected. We do not have, at this time, a second source for these products.

The generic pharmaceutical industry is highly competitive.

We face strong competition in our generic product business. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents for brand name products and related exclusivity periods expire, the first generic manufacturer to receive regulatory approval for generic equivalents of such products is generally able to achieve significant market penetration. As competing off-patent manufacturers receive regulatory approvals on similar products or as brand manufacturers launch generic versions of such products (for which no separate regulatory approval is required), market share, revenues and gross profit typically decline, in some cases dramatically. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. Consequently, we must continue to develop and introduce new products in a timely and cost-effective manner to maintain our revenues and gross margins.

During the First Quarter of Fiscal 2011, Lannett faced significant pricing challenges on its top two selling products. In order to keep the volume of business with the specific customer involved, Lannett chose to reduce its selling price on both of the products. This price reduction will have a significant impact to the gross profit margins and profitability of Lannett in the future.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

All pharmaceutical companies, including Lannett, are subject to extensive, complex, costly and evolving regulation by the federal government, including the FDA and in the case of controlled drugs, the DEA, and state government agencies. The FDCA, the CSA and other federal statutes and regulations govern or influence the development, testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products.

The process for obtaining governmental approval to manufacture and market pharmaceutical products is rigorous, time-consuming and costly, and we cannot predict the extent to which we may be affected by legislative and regulatory developments. We are dependent on receiving FDA and other governmental or third-party approvals prior to manufacturing, marketing and shipping our products. The FDA approval process for a particular product candidate can take several years and requires us to dedicate substantial resources to securing approvals, and we may not be able to obtain regulatory approval for our product candidates in a timely manner, or at all. In order to obtain approval for our generic product candidates, we must demonstrate that our drug product is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator drug. Bioequivalency may be demonstrated in vivo or in vitro by comparing the generic product candidate to the innovator drug product in dosage form, strength, route of administration, quality, dissolution performance characteristics, and intended use. The FDA may not agree that the bioequivalence studies we submit in the ANDA applications for our generic drug products are adequate to support approval. If it determines that an ANDA

Table of Contents

application is not adequate to support approval, the FDA could deny our application or request additional information, including clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.

Consequently, there is always the chance that we will not obtain FDA or other necessary approvals, or that the rate, timing and cost of such approvals, will adversely affect our product introduction plans or results of operations. We carry inventories of certain product(s) in anticipation of launch, and if such product(s) are not subsequently launched, we may be required to write-off the related inventory. Furthermore, the FDA also has the authority to revoke drug approvals previously granted and remove these products from the market for a variety of reasons, including a failure to comply with applicable regulations, the discovery of previously unknown problems with the product, or because the ingredients in the drug are no longer approved by the FDA.

Additionally, certain products, marketed prior to the Federal Food, Drug and Cosmetic Act may be considered GRASE or Grandfathered. GRASE products are those old drugs that do not require prior approval from FDA in order to be marketed because they are generally recognized as safe and effective based on published scientific literature. Similarly, Grandfathered products are those which entered the market before the passage of the 1906 act, 1938 act or the 1962 amendments to the act. Under the Grandfathered drug clause, such a product is exempted from the effectiveness requirements [of the act] if its composition and labeling have not changed since 1962 and if, on the day before the 1962 amendments became effective, it was (1) used or sold commercially in the United States, (2) not a new drug as defined by the act at that time, and (3) not covered by an effective application. Recently, the FDA has increased its efforts to force companies to file and seek FDA approval for these GRASE or Grandfathered products. Efforts have included granting market exclusivity to approved GRASE products or Grandfathered drugs and issuing enforcement actions against companies currently producing these products. Lannett currently manufactures and markets several products that are considered Grandfathered drug products, including Morphine Sulfate Oral Solution. The FDA is currently undertaking enforcement actions to force all companies who manufacture Morphine Sulfate Oral Solution to file applications and seek approval for their product or remove their product from the market. As of July 24, 2010, Lannett has stopped manufacturing and distributing Morphine Sulfate Oral Solution and as of the date of this Form 10-Q, the Company has approximately \$2.0 million of Morphine Sulfate Oral Solution finished goods inventory. Lannett has filed a 505(b)(2) New Drug Application and currently awaits FDA approval on the submission. Due to this application, Lannett has an additional \$1.4 million of prepaid assets on its balance sheet as of September 30, 2010. The Company expects a refund of at least half of this application fee and approval on this application within the next few months. If the Company is rejected on its current application, if the current application takes significantly longer than eleven months to be approved, or if the FDA were to prevail on the current lawsuit filed by Lannett which seeks determination that Morphine Sulfate Oral Solution is a Grandfathered product, the Company is at risk of losing some or all of the approximately \$2.0 million of Morphine Sulfate Oral Solution inventory and \$1.4 million prepaid asset recorded on its books as of September 30, 2010, and approximately 5% to 8% in projected future annual Net Sales. Lannett also has approximately \$2.7 million of inventory value at September 30, 2010 of other Grandfathered products which would also be at risk if the FDA were to pursue activities on these products similar to their actions on Morphine Sulfate Oral Solution.

In addition, Lannett, as well as many of our significant suppliers of distributed product and raw materials, is subject to periodic inspection of facilities, procedures and operations and/or the testing of the finished products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that pharmaceutical companies are in compliance with all applicable regulations. The FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether systems and processes are in compliance with cGMP, and other FDA regulations. Following such inspections, the FDA may issue notices on Form 483 that could cause us or our suppliers to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of a FDA inspection and lists conditions the FDA inspectors believe may violate cGMP or other FDA regulations. The DEA and comparable state-level agencies also heavily regulate the manufacturing, holding, processing, security, record-keeping, and distribution of drugs that are considered controlled substances. Some of the pain management products we manufacture contain controlled substances. The DEA periodically inspects facilities for compliance with its rules and regulations. If our manufacturing facilities or those of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us.

Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, delays in or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations,

Edgar Filing: LANNETT CO INC - Form 10-Q

injunctions, civil penalties, recall or seizure of products, total or partial suspension of sales, and/or criminal prosecution., Any of these or other regulatory actions could materially harm our operating results and

Table of Contents

financial condition. Although we have instituted internal compliance programs, if these programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business. Additionally, if the FDA were to undertake additional enforcement activities with any of Lannett's GRASE products, their actions could result in, among other things, removal of some of our products from the market, seizure of products and total or partial suspension of sales. Any of these regulatory actions could materially harm our operating results and financial condition.

Our manufacturing operations as well as our suppliers manufacturing are subject to licensing by the FDA and/or DEA. If we or our suppliers were unable to maintain the proper agency licensing arrangements, our operating results would be materially negatively impacted.

All of our manufacturing operations as well as those of our suppliers rely on maintaining active licenses to produce and develop generic drugs. Specifically, our Cody Labs operations rely on a DEA license to directly import and convert raw opium into several APIs or dosage forms. This license is granted for a one year period and must be renewed successfully each year in order for us to maintain Cody's current operations and allow the Company to continue to work towards becoming a fully integrated narcotics supplier. If the Company were unable to successfully renew its FDA and/or DEA licenses, the financial results of Lannett would be negatively impacted.

If we are unable to successfully develop or commercialize new products, our operating results will suffer.

Our future results of operations will depend to a significant extent upon our ability to successfully commercialize new generic products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;
- receiving requisite regulatory approvals for such products in a timely manner; the FDA has recently published that it now takes at least 26 months on average to review and approve ANDA applications;
- the availability, on commercially reasonable terms, of raw materials, including APIs and other key ingredients;
- developing and commercializing a new product is time consuming, costly and subject to numerous factors that may delay or prevent the successful commercialization of new products; and
- commercializing generic products may be substantially delayed by the listing with the FDA of patents that have the effect of potentially delaying approval of the off-patent product by up to 30 months, and in some cases, such patents have been issued and listed with the

FDA after the key chemical patent on the branded drug product has expired or been litigated, causing additional delays in obtaining approval.

As a result of these and other difficulties, products currently in development by Lannett may or may not receive the regulatory approvals necessary for marketing. If any of our products, when developed and approved, cannot be successfully or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

The loss of Arthur P. Bedrosian or our other key personnel could cause our business to suffer.

The success of our present and future operations will depend, to a significant extent, upon the experience, abilities and continued services of Arthur P. Bedrosian, our President and Chief Executive Officer, and our other key personnel. If we lose the services of Mr. Bedrosian or our other key personnel, or if he or they are unable to devote sufficient attention to our operations for any other reason, our business may be significantly impaired. If the employment of any of our current key personnel is terminated, we cannot assure you that we will be able to attract and replace the employee with the same caliber of key personnel. As such, we have entered into employment agreements with all of our senior executive officers to help prevent the loss of our key personnel.

Table of Contents

Our gross profit may fluctuate from period to period depending upon our product sales mix, our product pricing and our costs to manufacture or purchase products.

Our future results of operations, financial condition and cash flows depend to a significant extent upon our product sales mix. Our sales of certain products that we manufacture tend to create higher gross margins than do the products we purchase and resell. As a result, our sales mix will significantly impact our gross profit from period to period.

Factors that may cause our sales mix to vary include:

- the amount of new product introductions;
- marketing exclusivity, if any, which may be obtained on certain new products;
- the level of competition in the marketplace for certain products;
- the availability of raw materials and finished products from our suppliers; and
- the scope and outcome of governmental regulatory action that may involve us.

The profitability of our product sales is also dependent upon the prices we are able to charge for our products, the costs to purchase products from third parties, and our ability to manufacture our products in a cost effective manner.

If branded pharmaceutical companies are successful in limiting the use of generics through their legislative and regulatory efforts, our sales of generic products may suffer.

Many branded pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

Edgar Filing: LANNETT CO INC - Form 10-Q

- pursuing new patents for existing products which may be granted just before the expiration of one patent which could extend patent protection for additional years or otherwise delay the launch of generics;
- using the Citizen Petition process to request amendments to FDA standards;
- seeking changes to U.S. Pharmacopoeia, an organization which publishes industry recognized compendia of drug standards;
- attaching patent extension amendments to non-related federal legislation; and
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing.

If branded pharmaceutical companies are successful in limiting the use of generic products through these or other means, our sales may decline. If we experience a material decline in product sales, our results of operations, financial condition and cash flows will suffer.

Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. This is especially true in the case of generic products on which the patent covering the branded product is expiring, an area where infringement litigation is prevalent, and in the case of new branded products where a competitor has

Table of Contents

obtained patents for similar products. Litigation may be costly and time-consuming, and could divert the attention of our management and technical personnel. In addition, if we infringe on the rights of others, we could lose our right to develop or manufacture products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. Although the parties to patent and intellectual property disputes in the pharmaceutical industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be certain that the necessary licenses would be available to us on terms we believe to be acceptable. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling a number of our products, which could harm our business, financial condition, results of operations and cash flows.

If we are unable to obtain sufficient supplies from key suppliers that in some cases may be the only source of finished products or raw materials, our ability to deliver our products to the market may be impeded.

We are required to identify the supplier(s) of all the raw materials for our products in our applications with the FDA. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some products and raw materials are available only from a single source and, in some of our drug applications, only one supplier of products and raw materials has been identified, even in instances where multiple sources exist. To the extent any difficulties experienced by our suppliers cannot be resolved within a reasonable time, and at reasonable cost, or if raw materials for a particular product become unavailable from an approved supplier and we are required to qualify a new supplier with the FDA, our profit margins and market share for the affected product could decrease, and our development and sales and marketing efforts could be delayed.

Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce our revenues in future fiscal periods.

Based on industry practice, generic drug manufacturers have liberal return policies and have been willing to give customers post-sale inventory allowances. Under these arrangements, from time to time, we give our customers credits on our generic products that our customers hold in inventory after we have decreased the market prices of the same generic products due to competitive pricing. Therefore, if new competitors enter the marketplace and significantly lower the prices of any of their competing products, we would likely reduce the price of our product. As a result, we would be obligated to provide credits to our customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesalers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other customers. A chargeback is the difference between the price the wholesaler pays and the price that the wholesaler's end-customer pays for a product. Although we establish reserves based on our prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates.

Health care initiatives and other third-party payor cost-containment pressures could cause us to sell our products at lower prices, resulting in decreased revenues.

Some of our products are purchased or reimbursed by state and federal government authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs, and managed care organizations, or MCOs. Third-party payors increasingly challenge pharmaceutical product pricing. There also continues to be a trend toward managed health care in the United States. Pricing pressures by third-party payors and the growth of organizations such as HMOs and MCOs could result in lower prices and a reduction in demand for our products.

In addition, legislative and regulatory proposals and enactments to reform health care and government insurance programs could significantly influence the manner in which pharmaceutical products and medical devices are prescribed and purchased. We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could limit the amounts that federal and state governments will pay for health care products and services. The extent to which future legislation or regulations, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation or regulation would have on our business remains uncertain. For example, the American Recovery and Reinstatement Act of 2009, also known as the stimulus package, includes \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. If the stimulus package is approved in its current

Table of Contents

form, this funding will be used, among other things, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of products. Although Congress has indicated that this funding is intended for improvement in quality of health care, it remains unclear how the research will impact coverage, reimbursement or other third-party payor policies. Such measures or other health care system reforms that are adopted could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on development projects and affect our ultimate profitability.

We may need to change our business practices to comply with changes to fraud and abuse laws.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including the federal fraud and abuse law (sometimes referred to as the Anti-Kickback Statute) which apply to our sales and marketing practices and our relationships with physicians. At the federal level, the Anti-Kickback Statute prohibits any person or entity from knowingly and willfully soliciting, receiving, offering, or paying any remuneration, including a bribe, kickback, or rebate, directly or indirectly, in return for or to induce the referral of patients for items or services covered by federal health care programs, or the furnishing, recommending, or arranging for products or services covered by federal health care programs. Federal health care programs have been defined to include plans and programs that provide health benefits funded by the federal government, including Medicare and Medicaid, among others. The definition of remuneration has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, and waivers of payments. Several courts have interpreted the federal Anti-Kickback Statute's intent requirement to mean that if even one purpose in an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal health care programs, the statute has been violated. The federal government has issued regulations, commonly known as safe harbors that set forth certain provisions which, if fully met, will assure parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement will be illegal or that prosecution under the federal Anti-Kickback Statute will be pursued, but such transactions or arrangements face an increased risk of scrutiny by government enforcement authorities and an ongoing risk of prosecution. If our sales and marketing practices or our relationships with physicians (such as physicians serving on our Scientific Advisory Board) are considered by federal or state enforcement authorities to be knowingly and willfully soliciting, receiving, offering, or providing any remuneration in exchange for arranging for or recommending our products and services, and such activities do not fit within a safe harbor, then these arrangements could be challenged under the federal Anti-Kickback Statute. If our operations are found to be in violation of the federal Anti-Kickback Statute we may be subject to civil and criminal penalties including fines of up to \$25,000 per violation, civil monetary penalties of up to \$50,000 per violation, assessments of up to three times the amount of the prohibited remuneration, imprisonment, and exclusion from participating in the federal health care programs. In addition, HIPAA and its implementing regulations created two new federal crimes: health care fraud and false statements relating to health care matters. The HIPAA health care fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for health care benefits, items, or services. A violation of this statute is a felony and may result in fines and/or imprisonment. A number of states also have anti-fraud and anti-kickback laws similar to the federal Anti-Kickback Statute that prohibit certain direct or indirect payments if such arrangements are designed to induce or encourage the referral of patients or the furnishing of goods or services. Some states' anti-fraud and anti-kickback laws apply only to goods and services covered by Medicaid. Other states' anti-fraud and anti-kickback laws apply to all health care goods and services, regardless of whether the source of payment is governmental or private. Due to the breadth of these laws and the potential for changes in laws, regulations, or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could materially adversely affect our business.

Certain federal and state governmental agencies, including the U.S. Department of Justice and the U.S. Department of Health and Human Services, have been investigating issues surrounding pricing information reported by drug manufacturers and used in the calculation of reimbursements as well as sales and marketing practices. For example, many government and third-party payors, including Medicare and Medicaid, reimburse doctors and others for the purchase of certain pharmaceutical products based on the product's average wholesale price (AWP) reported by pharmaceutical companies. While Lannett has only used Suggested Wholesale Prices since 2000, the federal government, certain state

Table of Contents

agencies, and private payors are investigating and have begun to file court actions related to pharmaceutical companies' reporting practices with respect to AWP, alleging that the practice of reporting prices for pharmaceutical products has resulted in a false and overstated AWP, which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans, and others to health care providers who prescribed and administered those products. In addition, some of these same payors are also alleging that companies are not reporting their best price to the states under the Medicaid program. We are not currently subject to any such investigations or actions and having not used AWP pricing since 2000 would not likely become subject to these investigations.

We may become subject to federal and state false claims litigation brought by private individuals and the government.

We are subject to state and federal laws that govern the submission of claims for reimbursement. The federal False Claims Act imposes civil liability and criminal fines on individuals or entities that knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of the False Claims Act and other similar laws may result in criminal fines, imprisonment, and civil penalties for each false claim submitted and exclusion from federally funded health care programs, including Medicare and Medicaid. The False Claims Act also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the False Claims Act. These suits, known as qui tam actions, may be brought by, with only a few exceptions, any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the False Claims Act allows an individual to share in any amounts paid to the federal government in fines or settlement as a result of a successful qui tam action. If our past or present operations are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs, and/or the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results, action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Sales of our products may continue to be adversely affected by the continuing consolidation of our distribution network and the concentration of our customer base.

Our principal customers are wholesale drug distributors and major retail drug store chains. These customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will increase pricing and other competitive pressures on drug manufacturers, including Lannett.

For the fiscal year ended June 30, 2010, our three largest customers accounted for 26%, 11% and 9%, respectively, of our net sales. For the three months ended September 30, 2010, our three largest customers accounted for 23%, 13% and 9%, respectively, of our net sales. The loss of any of these customers could materially adversely affect our business, results of operations and financial condition and our cash flows. In addition, the Company has no long-term supply agreements with its customers that would require them to purchase our products.

The design, development, manufacture and sale of our products involves the risk of product liability claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain.

Edgar Filing: LANNETT CO INC - Form 10-Q

The design, development, manufacture and sale of our products involve an inherent risk of product liability claims and the associated adverse publicity. Insurance coverage is expensive and may be difficult to obtain, and may not be available in the future on acceptable terms, or at all. Although we currently maintain product liability insurance for our products in amounts we believe to be commercially reasonable, if the coverage limits of these insurance policies are not adequate, a claim brought against Lannett, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Table of Contents

Rising insurance costs, as well as the inability to obtain certain insurance coverage for risks faced by Lannett, could negatively impact profitability.

The cost of insurance, including workers compensation, product liability and general liability insurance, have risen in prior years and may increase in the future. In response, we may increase deductibles and/or decrease certain coverage to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverage, could have a negative impact on our results of operations, financial condition and cash flows.

Additionally, certain insurance coverages may not be available to Lannett for risks faced by Lannett. Sometimes the coverages obtained by Lannett for certain risks may not be adequate to fully reimburse the amount of damage that Lannett could possibly sustain. Should either of these events occur, the lack of insurance to cover the entire cost to the Company would adversely affect our results of operations and financial condition.

Significant balances of intangible assets, including product rights acquired, are subject to impairment testing and may result in impairment charges, which will adversely affect our results of operations and financial condition.

Our acquired contractual rights to market and distribute products are stated at cost, less accumulated amortization and related impairment charges identified to date. We determined the initial cost by referring to the original fair value of the assets exchanged. Future amortization periods for product rights are based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired products. Such factors include the product's position in its life cycle, the existence or absence of like products in the market, various other competitive and regulatory issues and contractual terms. Significant changes to any of these factors would require us to perform an additional impairment test on the affected asset and, if evidence of impairment exists, we would be required to take an impairment charge with respect to the asset. Such a charge would adversely affect our results of operations and financial condition.

Federal regulation of arrangements between manufacturers of branded and generic products could adversely affect our business.

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, companies are now required to file with the Federal Trade Commission (FTC) and the Department of Justice certain types of agreements entered into between brand and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs. This new requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with branded pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities. The impact of this new requirement and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers is uncertain, and could adversely affect our business.

ITEM 6. EXHIBITS

Edgar Filing: LANNETT CO INC - Form 10-Q

(a) A list of the exhibits required by Item 601 of Regulation S-K to be filed as a part of this Form 10-Q is shown on the Exhibit Index filed herewith.

Table of Contents

SIGNATURE

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LANNETT COMPANY, INC.

Dated: November 12, 2010

By: /s/ Arthur P. Bedrosian
Arthur P. Bedrosian
President and Chief Executive Officer

Dated: November 12, 2010

By: /s/ Keith R. Ruck
Keith R. Ruck
Vice President of Finance and Chief Financial Officer

Table of Contents

Exhibit Index

31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed Herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed Herewith
32	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed Herewith